



**TEXAS A&M**  
**UNIVERSITY**  
**CENTRAL TEXAS**

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# Institutional Review Board (IRB)

## Guidelines and Procedures Handbook

## Contents

<b>Mission</b> .....	<b>6</b>
<b>Institutional Official</b> .....	<b>7</b>
<b>Introduction to IRB</b> .....	<b>8</b>
<b>Texas A&amp;M University - Central Texas IRB</b> .....	<b>10</b>
<b>IRB Member Conflict of Interest</b> .....	<b>12</b>
<b>Educational Requirement</b> .....	<b>12</b>
<b>Protocol Submission and Initial Review</b> .....	<b>14</b>
Protocols not requiring an IRB Review .....	14
Exempt Review.....	14
Criteria for Protection of Human Subjects in Exempt Research .....	17
Expedited Review (Initial).....	17
Expedited Review (Continuing Review) .....	20
Expedited Review under Category 8 .....	20
Expedited Review under Category 9 .....	21
Full Board Review .....	21
<b>IRB Authorization Agreements-Ceded Review</b> .....	<b>22</b>
Designating A&M-Central Texas IRB as IRB of Record .....	23
Designation of External Institution’s IRB as IRB of Record .....	23
Collaborations with Non-Assured Institutions .....	24
Unaffiliated Investigators Working at A&M-Central Texas.....	24
<b>Protocol Approval Criteria for IRB</b> .....	<b>25</b>
<b>Length of Approval Period</b> .....	<b>26</b>
Review More Often than Annually.....	26
<b>Protocol Review and Approval Process for IRB</b> .....	<b>26</b>
Review Actions for Exempt Review .....	26
Review Actions for Expedited Review .....	27
Review Actions for Full Board Review .....	27
Process for Exempt Review.....	28
Process for Expedited Review.....	28
Process for Full Review.....	29

Set Meeting Times for the IRB.....	29
<b>Verification of No Changes since Previous IRB Review .....</b>	<b>29</b>
<b>Protocol Amendments.....</b>	<b>30</b>
<b>Continuing Review of Protocols.....</b>	<b>31</b>
Process for Continuing Exempt Review.....	32
Process for Continuing Expedited Review.....	32
Expedited Review Under Category 8.....	32
Expedited Review Under Category 9.....	33
Process for Continuing Full Review.....	33
<b>Unanticipated Problems and Reporting .....</b>	<b>33</b>
<b>Suspension or Termination of IRB Approval of Research .....</b>	<b>34</b>
<b>Closing a Protocol.....</b>	<b>35</b>
Principal Investigator Exits A&M-Central Texas (e.g., graduates, changes jobs).....	35
<b>IRB Review Considerations .....</b>	<b>36</b>
Determining Minimal Risk or Greater than Minimal Risk.....	36
Determination that the Risks Are Reasonable in Relation to Anticipated Benefits.....	36
Equitable Selection of Subjects .....	37
Informed Consent.....	38
Required Elements of Consent.....	39
Documentation of Informed Consent.....	41
Waiver of Some or All of the Required Elements of Consent .....	43
Subject Withdrawal .....	43
Subject Compensation.....	44
Guidelines for Compensating Research Subjects for Their Time and Effort.....	45
Protecting the Rights and Welfare of Vulnerable Populations .....	46
Research Involving Prisoners.....	47
Research Involving Children/Minors (e.g., less than 18 years of age or emancipated).....	48
IRB Review of Research Involving Wards.....	50
Requirement of Assent for Research Involving Children.....	52
Documentation of Assent.....	53
Research Involving Decisionally Impaired Subjects.....	53
Options for Additional Safeguards .....	56

Students and Employees as Research Subjects - Potential for Undue Influence .....	57
Principal Investigator’s Clinical Patient Population.....	58
Non-English Speaking Subjects and Subjects Who Are Not Proficient in English .....	59
Monitoring Data Collection.....	59
Protecting the Privacy of Subjects and Maintaining Confidentiality of Data .....	60
Protecting Privacy .....	60
Ensuring Confidentiality.....	61
Reportable Disclosures – Mandated Reporting .....	62
Certificates of Confidentiality .....	62
Research Using Deception or Withholding Information .....	63
Secondary Subjects and Third Parties .....	64
<b>The IRB and HIPAA .....</b>	<b>66</b>
A Covered Entity is:.....	66
Protected Health Information Individual Identifiers (PHI): .....	66
Research Use/Disclosure with Individual Authorization .....	67
Special provisions apply .....	67
De-identified Protected Health Information .....	67
<b>The IRB and FERPA – Use of Educational Records in Research .....</b>	<b>68</b>
Directory Information .....	68
<b>Video/Audio Recordings, Photographs.....</b>	<b>69</b>
Elements for Consideration.....	69
<b>Computer and Internet-Based Data Collection.....</b>	<b>70</b>
Data in Electronic Formats .....	71
Data Collection.....	71
Data Storage.....	71
Data Transmission .....	72
Control of Data Access .....	72
Destruction and Disposal of Data.....	72
Server Administration.....	73
Electronic Recruitment of Subjects .....	73
<b>Oral History Projects.....</b>	<b>73</b>
<b>Program Evaluation .....</b>	<b>75</b>



<b>Funded and Sponsored Projects .....</b>	<b>76</b>
<b>International Research .....</b>	<b>77</b>
<b>Pilot Studies .....</b>	<b>78</b>
<b>Record Retention and Storage.....</b>	<b>78</b>
Investigator Records .....	78
IRB Records Maintenance .....	79
<b>Quality Assurance - Quality Improvement (QA/QI) Auditing.....</b>	<b>79</b>
IRB Protocol Audit Process.....	80
Routine Evaluation.....	81
For-Cause Evaluation.....	81
IRB Evaluation .....	81
Documents Reviewed .....	81
Review Process.....	82
<b>Non-Compliance .....</b>	<b>82</b>



## Mission of the IRB

The Texas A&M University-Central Texas (A&M-Central Texas) Institutional Review Board (IRB) is charged with helping A&M-Central Texas faculty and student researchers in protecting human subjects in research conducted under its jurisdiction.

The IRB is committed to the principal that research at A&M-Central Texas must meet the highest standards of ethical conduct. Specifically, the IRB's obligation is to assure that research on human subjects is planned and carried out in accordance with all relevant laws, regulations, and university policies.

A&M-Central Texas recognizes that conducting ethical research and protecting human subjects in research studies represent a shared responsibility among faculty, students, department heads, deans, university officials, and researchers- as well as the IRB. Accordingly, the IRB seeks to foster among members of the university community a positive, collective atmosphere in which designing and implementing research studies are also based on internalized institutional values regarding ethical conduct.

The A&M-Central Texas IRB applies the policies and guidance in this guidebook for all research involving human subjects that is performed under the auspices of A&M-Central Texas. This means all such research that is conducted by

- any faculty, staff, or administrator of A&M-Central Texas in connection with his or her institutional responsibilities,
- any student enrolled at A&M-Central Texas, or
- any external individual requesting to conduct generalizable human subjects research at A&M-Central Texas. (Note: this does not apply to research covered by IRBs at other institutions.)

Both the membership of the IRB and any prospective researchers who intend to use human subjects in their research proposals are reminded that this document establishes the basic A&M-Central Texas IRB Handbook and the minimum of rules and procedures. It does not include every possibility for the variation in research proposals involving human subjects. The IRB encourages consultation at all stages of the research process, and specifically if there may be a question whether an activity should be classified as research or if it is research, and whether it should be exempt from further IRB review.

The IRB structure and function is based on the Department of Health and Human Services (DHHS) Regulations at Title 45 of the Code of Federal Regulations part 46 and from the Texas A&M University System Regulations related to Human Subjects Research

<http://policies.tamusc.edu/15-99-01.pdf> and Research Compliance  
<http://policies.tamusc.edu/15-99-05.pdf>.

A&M-Central Texas is committed to the ethical principles for the protection of human subjects in research set forth in the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and in state and federal law. It is the responsibility of each A&M-Central Texas faculty, staff, administrator, or student to have his/her research on human subjects reviewed by the IRB, when necessary. Administrators at A&M-Central Texas whose positions impact the IRB include the Institutional Officer (IO), the Chief Research Officer (CRO), the Research Compliance Officer (RCO), and the Director of Research Support (DRS). The IRB is accountable to the Office of the Vice President for Research and Economic Development (VPRED).

All institutional and non-institutional performance sites for the University, domestic or international, will be obligated by the University to conform to ethical principles which are at least equivalent to those of the University. All externally-requested research must be reviewed by the CRO or his/her designee.

## **Institutional Official**

The management of the membership of the IRB and oversight of member appointments, IRB-related activities, communications, and other administrative details are the responsibility of the Institutional Officer (IO). The IO provides administrative oversight to the IRB to ensure that the practices and procedures designed for the protection of the rights and welfare of human subjects are effective and are in compliance with the requirements of federal and state regulations and TAMU System Policy.

The IO also represents the University to federal and state regulatory agencies, and promotes a culture of compliance and oversees adherence to the ethical principles outlined in the Belmont Report, the Declaration of Helsinki, Federal and State regulations, and University and sponsoring agency policies and procedures instituted to protect the rights and welfare of human research subjects. The IO is the CRO as appointed by the President of A&M-Central Texas and is currently the VPRED.

## Introduction to the IRB

An IRB is empowered by federal regulation to review and approve of, to require modifications necessary to secure approval of, or to disapprove of any research activities dealing with human subjects. The IRB also requires that information given to subjects as part of an informed consent process is in accordance with all relevant regulations and it also conducts continuing reviews of research at least once per year.

### **Section 46.102 of the Code of Federal Regulations defines Research as:**

“A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.”

### **And defines Human Subject as:**

“A living individual about whom an investigator (whether professional or student) conducting research obtains

- data through intervention or interaction with the individual, or
- identifiable private information.”

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes direct communication or interpersonal contact between an investigator and a research subject or through indirect means such as through either another faculty member or a graduate student who is not an investigator on that project.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Institutional Review Boards have been implemented around the world to prevent unethical treatment of human subjects. IRBs in the United States were established as an outcome of Senate hearings (1972) and legislation passed in 1974, and are regulated by the federal government per the Federal Policy for the Protection of Human Subjects (Basic Department of Health and Human Services Policy for Protection of Human Research Subjects in the Code of Federal Regulations Title 45 Part 46). Prior to the initiation of any research efforts that involve human subjects, **IRB review is required**. Institutions found to be in non-compliance with the regulations can lose federal funding of both its research and student programs.

In its broadest sense, the purpose of the IRB is to protect the rights and safety of human subjects. In fulfilling its task, the IRB must carefully examine research proposals, following the process set forth in A&M-Central Texas SAP 15.99.01.D1.01 Assurance of Protection of Human Research Subjects, (available at [https://www.tamuct.edu/compliance/docs/sap\\_15.99.01.d1.01.pdf](https://www.tamuct.edu/compliance/docs/sap_15.99.01.d1.01.pdf)) to arrive at an independent determination that the research will meet the following ethical criteria, including but not limited to:

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits
- Selection of subjects is equitable and fair
- Unless waived by the IRB, informed consent is sought from each subject or his/her legally authorized representative.
- Informed consent is appropriately documented
- When appropriate, the research plan makes provisions for monitoring data collection
- Privacy and confidentiality of research subjects are appropriately protected
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included.

## Texas A&M University—Central Texas IRB

The University has established its IRB in accordance with the compositional requirements of Section 46.107 of the Federal regulations. The IRB shall be comprised of at least ten members from diverse backgrounds to promote complete and adequate review of research activities commonly conducted at the University. These members are appointed by the IO to serve a three-year term and may be reappointed. Additionally, for each IRB there must be at least one member whose primary concerns are in scientific areas, at least one member whose primary concerns are in nonscientific areas, and at least one member who is not otherwise affiliated with the University and who is not part of the immediate family of a person affiliated with the University.

The regulations call for diversity of culture, education, and experience of the IRB members. Such diversity helps to promote complete and adequate reviews of the types of research activities commonly reviewed by the IRB. The IRB membership must include:

- (a) Nonaffiliated member(s): The nonaffiliated member(s), who can be either scientific or nonscientific reviewers, should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to recruiting individuals who speak for the communities from which the University will draw its research subjects. The nonaffiliated member(s) should not be vulnerable to intimidation by the professionals on the IRB, and their services should be fully utilized by the IRB. Due to the University's close ties with Fort Hood and the military, one member of the IRB is suggested to have military experience or be very knowledgeable about military culture and service.
- (b) Scientific members: Most IRBs include Ph.D./Ed.D. level scientists. Such members satisfy the requirement for at least one scientist. When an IRB encounters studies involving science beyond the expertise of the members, the IRB may use a consultant to assist in the review, as provided by §46.107.
- (c) Nonscientific member: The intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Therefore, nonscientific members are individuals whose education, work, or interests are not solely in medical or scientific areas.
- (d) Representatives of Special Groups of Subjects: When certain types of research are reviewed, members or consultants who are knowledgeable about the concerns of certain groups may be required. For example, if an IRB reviews research involving prisoners, a member who can represent this group, either an ex-prisoner or an individual with specialized knowledge about this group must be included on the IRB.

- (e) Chair and Vice-Chair: The IRB will have a Chair and may have a Vice- Chair. The IO will appoint the Chair from the membership of the IRB; he or she must be knowledgeable in human subject research, including the regulations, University and agency policies, and ethics relevant to such research. The Chair generally will serve for three years and may be reappointed to Chair duties. The Chair should provide for a consistent, high quality, and timely review process, and provide verification of the actions of the IRB. The duties of the Chair include but are not limited to: serving as convener for the IRB, delegating appropriate tasks to IRB members, serving as a liaison between the IRB and the University community, and monitoring changes in federal regulations and institutional policy for the protection of human subjects in research. The Chair reports to the IO/CRO and makes official changes to the Federalwide Assurance. If the IRB decides it wants a Vice-Chair, he or she will be selected by the IO and will execute the duties of the Chair in the case of absence, illness, inability to carry out duties, or conflict of interest in connection to a protocol.
- (f) The IRB may have alternate members. Such alternate members will have the same qualifications and experience as regular members. Alternate members may be called upon to serve where regular members will be absent from a meeting and there will be less than a quorum at an upcoming meeting. Alternate members will have voting rights and be counted in a quorum only when they replace the respective regular member.
- (g) Membership is chosen based on the unique expertise that each member brings to an IRB. If a member cannot make a meeting, he/she should provide enough advance notice to the IRB so that an alternate can be secured. Because members serve at the pleasure A&M-Central Texas's IO, failing to regularly attend meetings or failing to demonstrate diligence in performing duties may result in removal of a member from an IRB by the IO.
- (h) Authority from the Institution. The IRB has the responsibility to review and the authority to approve, require amendments of or disapprove research involving human subjects conducted by the University's faculty, students, or staff, or such research involving the use of the University's facilities, in accordance with administrative policies and procedures established for this purpose. The IRB shall monitor and conduct continuing review of such research at intervals of at least once per year.
- (i) The IRB has the authority to inspect research facilities and to obtain records and other relevant information relating to projects it has approved and to observe, or have a third party observe the consent process and research. The IRB affords protections to subjects, and may suspend or terminate approval of protocols it has approved and take actions that it judges necessary to ensure compliance with regulations and internal policies. Review and approval must be obtained from the

IRB prior to a research project being initiated or amended.

- (j) **Reliance on IRBs of Other Institutions.** The IRB at the University may elect to rely on the IRB of other institutions for review and approval of a study. This is generally used when a study involves collaborative research between A&M-Central Texas and an external institution. In such an event, the IRB of the other institution, referred to as the IRB of Record, holds the same rights, authority and responsibility as the IRB of A&M-Central Texas.
- (k) **Authority of Institutional Official.** The IO may not approve a project that has been disapproved by the IRB. The IO may require additional review of research and has the authority to disapprove, suspend or terminate research previously approved by the IRB.
- (l) **IRB Committees:** The IRB may create permanent and ad hoc committees as needed and approved by the IO.

## **IRB Member Conflict of Interest**

There will be no selection of IRB members by investigators on any specific protocol. All IRB Members are required to sign a Confidentiality/Financial Conflict of Interest Statement and a Protocol Conflict of Interest Statement.

Neither the sponsor, nor the investigator, nor any individual involved in the conduct of the research activity under review will participate in the Board review or conclusions except to provide information. No member may participate in the Board's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the Board. Members having a conflict of interest shall announce the conflict and recuse themselves from participation during review of that research project except to provide information on request. Persons identified in this section shall leave the meeting during the discussion and the vote on any motion to approve or disapprove the research in question. When a person with a conflict of interest leaves the room he/she cannot be counted towards a quorum. If the quorum is lost, any protocol that has not already been approved will be tabled.

## **Educational Requirement**

In accordance with Federal regulations, Texas A&M University-Central Texas requires the Principal Investigator and all other key personnel on any research protocol (exempt, expedited or full/convened Board review) to satisfactorily complete required education related to the protection of human subjects before engaging in research or review of research involving human subjects.

The educational requirement is satisfied by completing the Collaborative Institutional Training Initiative (CITI) Basic training program for Social, Behavioral, or Educational Research; in rare cases, another, human subjects training program may be designated, provided, and/or approved by the IRB. If the investigator is a student, both the student and the student's faculty advisor for the protocol must complete the required training. The required CITI training is valid for a period of three (3) years from date of completion or so long as an approved protocol is active. This qualification must be maintained in order for investigators to continue research activities and the training completion certificate must be submitted with each protocol submitted by an investigator. If an investigator has completed CITI training with another university, institution, organization, etc. within the past 3 years, then a completion certificate from that other institution must accompany any submitted protocol.

The Principal Investigator (PI) is the person who is directing and/or conducting the research project. The PI may be any of the following: A&M-Central Texas faculty or staff, an A&M-Central Texas student, or an external individual approved to do research by the CRO or designee.

*"Key personnel" are persons responsible for one or more of the following:*

- Day-to-day protocol decision-making related to the study conduct;
- Subject recruitment, selection and determination of eligibility;
- Clarification of the complexities of the protocol to the subject and others, including ensuring completion of consent forms or other consent methods;
- Collecting subject information and entering data using procedures to maintain privacy and confidentiality; and
- Ensuring that the rights and welfare of subjects are monitored throughout the study.

It is the responsibility of the Principal Investigator to determine who should be considered Key Personnel based on the above criteria for each study. The IRB does not make a judgment on the level of engagement of said individual beyond what is reported on the IRB application. Key personnel shall be categorized as either PI, coPI, or Research Associate/ Investigator. Only one person can be considered the PI.

The CITI course is available at <https://www.citiprogram.org> and is the preferred training for research compliance. If you are unsure of which course you should be taking, please take the course entitled "Social, Behavioral, and Educational Research - Basic " within 3 years of the protocol submission date, and to submit documentation (i.e., a copy of the certificate of completion), to the IRB with their protocol. IRB members should select their

appropriate role under question 1 (i.e., member or chair) and complete the course every 3 years or as required by Board procedures. Protocols will not be processed or reviewed until this requirement has been fulfilled. IRB members should take the appropriate training course matching their board member duties (i.e., board member or chair).

## **Protocol Submission and Initial Review**

The review of applications that involve human subjects in research is a multi-step process. The process begins with the submission of a research protocol to the IRB Chair. It is date stamped and logged into the database. The IRB Chair reviews and screens the initial protocol packet and contacts the investigator if clarification is needed on any part of the protocol. If required documentation is not submitted or if requested clarification is not provided within 10 business days, the protocol will be returned to the investigator with an explanation.

After the protocol has passed the initial intake review, the protocol review category is determined. If a PI believes his/her research protocol to be exempt, he/she must designate that on the Protocol Submission form. As with protocols that are considered expedited or full board review, a Protocol Submission form must be submitted with all of the necessary accompanying documentation. The final determination is made by the IRB according to the Federal regulations and University policy. There are three review levels as provided by the regulations: Exempt review, Expedited review, and Full Board review, although some protocols may not require an IRB review. Depending upon the date of submission, investigators should allow a minimum of 4 weeks for Exempt reviews, 6 weeks for Expedited reviews, and 8 weeks for Full Board reviews, but may be completed more quickly on a case-by-case basis.

## **Protocols not requiring an IRB Review**

Any study conducted by Institutional Research for accreditation purposes is not considered research when the results are used solely by the institution. Any study conducted in a classroom as part of regular coursework and not being submitted for publication would not be considered research. In both cases noted above, there is no requirement for IRB review. It is recommended that protocols be submitted to the IRB Chair to determine if a review is required and, if so, what level of review.

## **Exempt Review**

Certain broad categories of research projects that involve human subjects that meet the

definition under the regulations are “exempt” from Full Board IRB review. Federal regulations permit the principal investigator to make an initial judgment as to whether the project is exempt; however only the IRB may determine that Exempt status is appropriate. Research activities in which the only involvement of human subjects will be in one or more of the following categories are considered exempt:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (1) research on regular and special education instructional strategies, or (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (No age limitations on Subjects.)
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (1) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (2) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. (Note: Subjects must be adults – legal age of adulthood)
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the paragraph, above, if: (1) the human subjects are elected or appointed public officials or candidates for public office; or (2) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained.
- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the provider in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (1) Public benefit or service programs; (2) procedures for obtaining benefits or services under those programs; (3) possible changes in or alternatives to those programs or procedures; or (4) possible changes in methods or levels of payment for benefits or services under those programs.
- Taste and food quality evaluation and consumer acceptance studies, (1) if wholesome foods without additives are consumed or (2) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental

Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

To qualify as an exempt study, the research must fall within one of the above-specified regulatory categories and must be reviewed by the IRB Chair. Only the IRB may determine when research is exempt or requires a full or expedited review. Therefore, researchers must submit a protocol (All forms are found on the IRB Forms page of the Research webpage <https://www.tamuct.edu/research/forms.html>), requesting exempt status so the IRB can ensure that the research meets the criteria for an exemption.

The following **CANNOT** be considered Exempt:

- research involving vulnerable populations, including prisoners, children, adults who cannot give informed consent, and pregnant women (pregnant women are not considered a vulnerable population when the research study is not related to pregnancy and has minimal risks or no risks).
- data obtained from adults through administration of educational tests, survey procedures, interview procedures, or by observation of public behavior IF BOTH:
  - the information is recorded in such a way that the identity of individuals can be identified either directly or through identifiers linked to the individuals

**AND**

  - disclosure of subjects' responses could reasonably place them at risk of criminal or civil liability or be damaging to an individual's financial standing, employability, or reputation; or
  - observation of behavior that takes place in settings in which subjects have a reasonable expectation of privacy; or
  - research techniques which are classified as greater than minimal risk or involve enough deception of subjects that the deception must be later explained during a debriefing.

A research project that is determined, by the IRB, to meet the criteria for Exempt status is exempt from annual continuing review by the IRB. The PI, however, is required to report to the IRB any expected revisions in the research activity that will cause the research to change from Exempt to Expedited or Full review status. The PI is also required to report to the IRB any unexpected or adverse events that occur or new information obtained that may cause the research activity to change from exempt to Expedited or Full review status. When the research project is completed, the PI is required to notify the IRB. The Exempt status expires when the research project is completed (closed) or when the review category changes as described above.

## Criteria for Protection of Human Subjects in Exempt Research

A research project that has received an Exempt designation is not exempt from protection of the human subjects. The following criteria to protect human subjects must be met:

- The PI assures that all those persons listed on the protocol as being involved in conducting the research have completed the IRB human subjects training requirements
- The PI assures that human subjects will voluntarily consent to participate in the research (e.g. surveys, interviews, interactions with subjects) and will provide subjects with pertinent information (e.g. the activity involves research, a description of procedures, that participation is voluntary, risks and benefits, contact information for PI and Research Compliance Officer (RCO))
- The PI assures that human subjects will be selected equitably, so that risks and benefits of the research are justly distributed
- The PI assures that the IRB will be immediately informed of any information, unexpected or adverse events that would increase the risk to the human subjects and cause the category of review to be upgraded to Expedited or Full review
- The PI assures that the IRB will be immediately informed of any complaints from subjects regarding their risks and benefits; and
- The PI assures that confidentiality and privacy of the subjects and the research data will be maintained appropriately to ensure minimal risk to subjects, and there are adequate provisions to maintain the confidentiality of the data.

These criteria are required if the protocol is approved as Exempt, and the PI's signature acknowledges that she or he understands and accepts these conditions.

### Expedited Review (Initial)

Research may be reviewed by the IRB under Expedited status if all research activities present no more than minimal risk to human subjects and involve procedures listed in one or more of the following expedited review categories of the regulations (as authorized by 45CFR46.110).

As defined by 45CFR46.102(2)(i) "*Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

The following 9 categories of research are permitted to receive expedited review. Most

behavioral research falls under Category 7.

Category 1: Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

- (a) Research on drugs for which an investigational new drug application 21 CFR Part 312 is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
- (b) Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- (a) blood draws will be conducted by a licensed medical practitioner; and
- (b) will be conducted within the appropriate FDA guidelines.

Category 3: Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

- (a) hair and nail clippings in a non-disfiguring manner;
- (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- (c) permanent teeth if routine patient care indicates a need for extraction;
- (d) excreta and external secretions (including sweat);
- (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- (f) placenta removed at delivery;
- (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- (h) supra- and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- (j) sputum collected after saline mist nebulization.

Category 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures

involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.). Examples:

- (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
- (b) weighing or testing sensory acuity;
- (c) magnetic resonance imaging
- (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;
- (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Category 5: Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes, such as medical treatment or diagnosis. (NOTE: Some research in this category may be exempt, see Exempt Research. This listing refers only to research that is not exempt).

Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt, see Exempt Research. This listing refers only to research that is not exempt.)

Category 8: Continuing review of research that is greater than minimal risk and has been initially reviewed and approved by the convened full-board IRB as follows:

- (a) The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
- (b) No subjects have been enrolled and no additional risks have been identified; or
- (c) The remaining research activities are limited to data analysis.

Category 9: Continuing review of research, not conducted under an investigational new

drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

**The following cannot be considered Expedited and must undergo a Full Board review:**

- research in which identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability, or
- be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing
- Classified research involving human subjects, such as for the Department of Defense
- Research that involves more than minimal risk to human subjects (i.e. the probability and magnitude of harm or discomfort anticipated in the research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)
- Research with prisoners and other vulnerable populations (see p. 47).

**Expedited Review (Continuing Review)**

Per federal regulations, an IRB must conduct continuing review of previously approved research at intervals appropriate to the degree of risk, but not less than once per year. Depending on the type of research, continuing review may be performed by expedited review or by full IRB review.

As a rule, if research did not qualify for expedited review at the time of initial review, it will not qualify for expedited review at the time of continuing review, except in limited circumstances described by expedited review categories (8) and (9). It is also possible that research that previously qualified for expedited review has changed, such that expedited IRB review would no longer be permitted for continuing review.

**Expedited Review under Category 8**

Under Category 8, an expedited review procedure may be used for the continuing review of research previously approved by a Full Board review as follows:

- The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
- No subjects have been enrolled and no additional risks have been identified; or

- The remaining research activities are limited to data analysis.

NOTE: Category 8 identifies three situations in which research that is greater than minimal risk and has been initially reviewed by a convened IRB may undergo subsequent continuing review by the expedited review procedure.

### **Expedited Review under Category 9**

Under Category 9, an expedited review procedure may be used for continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories 2 through 8 do not apply. The IRB must have determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Expedited review of research involving human subjects is done by the IRB Chair, or his/her designee in accordance with the requirements set forth in 45CFR46.110.

In reviewing the research, the IRB Chair or his/her designee may exercise all of the authorities of the IRB except that they may not disapprove the research. Disapproval requires action by a Full Board review or the CRO/IO.

### **Full Board Review**

All protocols that are determined not to qualify as Exempt or Expedited will be reviewed by the Full IRB Board. New submissions and “Greater than Minimal” risk renewals are individually presented, discussed, and voted on at a convened meeting.

Full Board reviews of protocols will take place only when a quorum (i.e., one more than 50% of the full committee) of the IRB Committee members are present, including at least one member whose primary concerns are in nonscientific areas and one community member. No official actions will be taken at a meeting where a majority of the members, including a non-scientist and a community member, are not present. A member can be considered present if attending by telephone.

Telephone conference call: Official actions may be taken at a meeting in which all members participate via telephone when each participating IRB member has a) received all pertinent material prior to the meeting, and b) can actively and equally participate in the discussion of all protocols (e.g., each member can hear and be heard by all other participating members). Satisfaction of these two conditions in addition to the standard regulatory

requirements will be documented in the meeting minutes.

**Speakerphone or Virtual Media with Audio (e.g., Skype):** If a member is not able to be physically present during a convened meeting but is available by telephone, the meeting can be convened using speakerphone. The member who is not physically present will be connected to the rest of the members via speakerphone so that all members will be able to discuss the protocol. Members participating by speakerphone may vote provided they have had an opportunity to review all of the materials the other members have reviewed.

All Committee members' votes will be deemed equal and no proxy votes (written or by telephone) will be accepted. Alternate members may vote when the regular member is not available.

The IRB will review all new and continuing protocols to determine the appropriateness of the research. Review and approval will be based on detailed applicable information provided in the IRB submission forms (e.g. subject population, subject selection, benefits to subjects, mechanisms for protecting privacy, method for minimizing the possibility of coercion).

The protocol is reviewed, discussed, and voted on by the members. The PI (and faculty/staff advisor, if applicable) can be invited to attend the meeting of the IRB to discuss the protocol. The PI may not be present, however, for the IRB's deliberation or vote. All research involving human subjects that is subject to the applicable government regulations requires Full Board review unless it meets the criteria for the exceptions as outlined above.

## **IRB Authorization Agreements-Ceded Review**

The A&M-Central Texas IRB supports the idea of IRBs from collaborating institutions ceding review of a human subjects research protocol to just one of the collaborating institution's IRB. This eliminates redundancies in the review of a study and may provide a more efficient process.

An IRB Authorization Agreement form (available from the RCO) may be used when an external organization engages in human subjects research in collaboration with an A&M-Central Texas investigator and

- the external organization/institution is not one with whom A&M-Central Texas currently has a cooperative review arrangement, and
- both A&M-Central Texas IRB and the external organization/institution IRB decide

together which institution's IRB will serve as the IRB of record, to avoid dual review.

In general, an institution is considered engaged in non-exempt human subject research projects when its employees or agents for the purposes of the research project obtain

- data about the subjects of the research through intervention or interaction with them;
- identifiable private information about the subjects of the research; or
- the informed consent of human subjects for the research.

When an IRB protocol is submitted that involves collaboration with an external organization or non-affiliated Investigator, the A&M-Central Texas Investigator should indicate this and ask if ceded review is appropriate for the protocol.

### **Designating A&M-Central Texas IRB as IRB of Record**

In certain circumstances the A&M-Central Texas IRB may agree to be designated as the IRB of record for another institution (referred to hereafter as Institution B). When this occurs the IRB assumes responsibility for the review and continuing oversight of research on behalf of Institution B.

This type of agreement would be documented by way of an executed IRB Authorization Agreement signed by the IO or signatory officials designated in A&M-Central Texas' and Institution B's Federalwide Assurance.

The agreement may be limited to a specific research project(s) or may be broader in scope. The Authorization Agreement will specify the scope of the agreement.

The A&M-Central Texas IRB will report its findings and actions to Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the A&M-Central Texas IRB's determinations and with the Terms of its Federalwide Assurances. The Authorization agreement will be kept on file by both parties and will be provided to OHRP upon request.

### **Designation of External Institution's IRB as IRB of Record**

Alternatively, in other certain circumstances the A&M-Central Texas IRB may ask Institution B to agree to be designated as the IRB of record. When this occurs, Institution B's IRB assumes responsibility for the review and continuing oversight of research on behalf of A&M-Central Texas.

Again, the agreement may be documented in an executed IRB Authorization Agreement signed by the IO or signatory officials designated in A&M-Central Texas' and Institution B's Federalwide Assurance, when required.

The agreement may be limited to a specific research project(s) or may be broader in scope. The Authorization Agreement will specify the scope of the agreement.

Institution B's IRB will report its findings and actions to A&M-Central Texas' IRB. Relevant minutes of IRB meetings will be made available to A&M-Central Texas upon request. A&M-Central Texas remains responsible for ensuring compliance with Institution B's determinations and with the Terms of its Federalwide Assurance. The Authorization agreement will be kept on file by both parties and will be provided to OHRP upon request.

### **Collaborations with Non-Assured Institutions**

A&M-Central Texas may also agree to extend the terms of its Federalwide Assurance to an external, non-assured institution when that non-assured institution is involved in collaborative research with A&M-Central Texas. Typically, this is owing to the fact that the other institution does not routinely conduct human subjects research.

In this instance, the other institution will be required to

- apply for a Federalwide Assurance, complying with all of the requirements, and
- designate the A&M-Central Texas IRB as the IRB of record for the research once the FWA has been received.

When this occurs the A&M-Central Texas IRB assumes responsibility for the review and continuing oversight of the specified research on behalf of Institution B; appropriate arrangements must be made for the A&M-Central Texas IRB to have convenient access to the IRB records for that review.

### **Unaffiliated Investigators Working at A&M-Central Texas**

A&M-Central Texas may also extend its Federalwide Assurance to investigators not affiliated with but collaborating with A&M-Central Texas, if the unaffiliated investigator is not affiliated with an assured institution. Both institutional and independent investigators must meet the conditions for extending a Federalwide Assurance.

The extension of A&M-Central Texas' Federalwide Assurance is documented by way of signed completed protocol submitted by the non-assured institution designee or

independent investigator and the IO or signatory official designated in A&M-Central Texas' Federalwide Assurance. The agreement may be limited to specific research projects or may be broader in scope. The protocol will specify the scope of the project. When A&M-Central Texas extends its Federalwide Assurance to another institution or individual the A&M-Central Texas IRB becomes the designated "IRB of Record" for the non-assured institution or independent investigator with respect to the research project(s) covered by the protocol.

For any unaffiliated individual (as opposed to an institution) who is key personnel on a protocol (i.e., engaged in collaborative research with an A&M-Central Texas Investigator), the standard investigator paperwork must be submitted to the IRB with the protocol. The A&M-Central Texas Investigator should assist the unaffiliated individual investigator in completing all relevant paperwork as delineated on the A&M-Central Texas IRB webpage.

The PI will submit the protocol document, signed by the unaffiliated individual investigator, to the IRB. After the document has been signed by the A&M-Central Texas IRB Institutional Official (or designee), a copy of the document will be provided to the A&M-Central Texas Principal Investigator and to the Unaffiliated Individual Investigator.

If the unaffiliated investigator is conducting research under their own institution's FWA and that institution has designated A&M-Central Texas as the IRB of record, a valid IRB Authorization Agreement must also be in place between the two institutions.

## **Protocol Approval Criteria for IRB**

In any review the IRB must determine that the following criteria are met. These findings must be documented regardless of the review category or procedure used:

- Risks to subjects are minimized
- Risks are justified in view of anticipated benefits, if any, to the subjects
- Selection of subjects is equitable
- Informed consent, and if relevant, assent, is sought from each prospective subject or legally authorized representative
- Informed consent is appropriately documented (when applicable.)
- Adequate provisions are made for monitoring data collection to ensure safety of subjects (when appropriate)
- Adequate provisions are made to protect the privacy of subjects and to maintain confidentiality of data (when appropriate)
- Adequate provisions are made to protect the rights and welfare of subjects who are vulnerable to undue influence or coercion (children, pregnant women, mentally

disabled persons, economically or educationally disadvantaged, when appropriate).

## **Length of Approval Period**

At the time of initial review and at continuing review, the IRB will make a determination regarding the frequency of review of the research protocols. All protocols will be reviewed by the IRB at intervals appropriate to the degree of risk but no less than once per year. In some circumstances, a shorter review interval, e.g. biannually, may be required. The meeting minutes will reflect the IRB's determination regarding review frequency.

## **Review More Often than Annually**

The IRB may require certain protocols be reviewed more than once a year. The following factors will be considered when determining which studies require review more frequently than on an annual basis:

- Probability and magnitude of anticipated risks to subjects
- A history of non-compliance on the part of the PI
- Overall qualifications and specific experience of the PI and the research team
- Any other factors that the IRB requests closer monitoring.

## **Protocol Review and Approval Process for IRB**

During the review process, the protocol and the supporting documentation is examined to ensure that the Principal Investigator has addressed the risks and benefits posed to potential subjects participating in the research, the subject selection is equitable, and that the consent process will provide adequate information to prospective subjects so that subjects can make informed decisions regarding their participation in the research activity (when applicable).

Once the protocol materials have been reviewed and the investigator has adequately addressed the concerns of the reviewer, a decision/an action will be made regarding the protocol.

## **Review Actions for Exempt Review**

The IRB Chair or designee of the IRB Chair will review the exempt submissions for Exempt studies. If the submission aligns to the criteria for Protection of Human Subjects in Exempt Research, the IRB Chair, or the designee of the IRB Chair, may designate the study to be reviewed as exempt. The designation will be recorded by the IRB Chair. The Chair will

notify the institution and the PI of the designation.

### **Review Actions for Expedited Review**

When a study is reviewed using the expedited procedure of the IRB, there are three possible actions that can be taken.

- Final approval - There are no changes needed in the study and the investigator can proceed with the research without further delay;
- Conditional approval - There are minor revisions that the Board member stipulates. After the stipulated revisions/clarifications are completed the Chair or designee will grant final approval.
- Referred for Full Review - The Reviewer conducting an expedited review does not have the authority to disapprove an application. Disapproval is an action that may be taken only at a convened meeting. Instead, the submission will be referred for full review at a convened meeting.

NOTE: A reviewer may refer research protocols to the full Committee whenever he/she believes that full Committee review is warranted.

### **Review Actions for Full Board Review**

Review actions for studies reviewed at Full Board meetings of the IRB must be determined by a majority vote of the quorum. A unanimous vote is not required. A member may vote FOR or AGAINST approval of a protocol. A member may also ABSTAIN from the vote entirely. An abstention is not considered in the FOR or AGAINST count, but is considered to obtain quorum.

When a study is reviewed and voted on at a full meeting of the IRB Board, there are four possible actions.

- Final approval - There are no changes needed in the study, and the investigator can proceed with the research without further delay;
- Conditional Approval – The IRB has voted to approve this protocol; however, the PI may not begin the activity until he/she has made minor revisions and/or clarifications that the IRB stipulates. After the revisions are completed, the IRB Chair or designee may grant the protocol final approval;

- Tabled -- There are major problems or concerns with the study that impact the protection of the human subjects. The study will require review again by the IRB at a subsequent meeting after the investigator has addressed all of IRB's questions or requests for clarification;
- Disapproved – The protocol will require resubmission. Although it is rare, the IRB will disapprove research protocols involving excess risk to the human subjects. In most cases, the IRB tries to work with the researcher to modify his/her protocol in a way that provides appropriate levels of protection for the subjects. Specific reasons for disapproving research will be communicated to the PI. The study may not be resubmitted unless completely revised. The IO may disapprove an IRB approved protocol.

### **Process for Exempt Review**

Under the exempt procedure, the PI shall submit a protocol and supporting documents to the IRB Chair. The IRB Chair, or a designee of the IRB Chair, will review the request to confirm it meets the criteria set forth under the exempt status. If it does meet the exempt status, the request will be designated exempt, and the Chair will notify the PI and the IRB.

If the request does not meet the criteria for an exempt request, it will be returned by the IRB Chair to the PI with instructions to reclassify and resubmit.

### **Process for Expedited Review**

Under the expedited review procedure, the researcher shall submit an IRB Protocol form with appropriate supporting documents to the IRB Chair. The Chair will review the proposal to determine accuracy of designation as expedited research and to insure the appropriate paperwork is complete. Expedited review of research involving human subjects may be done by the IRB Chair, or his or her designee.

In reviewing the research, the Chair or designee may act in all ways that an IRB board could act except for disapproval of the research. Disapproval requires action by Full Board Review.

The Chair shall forward to the PI and the full board the decision to approve the proposed research activity, or modifications required to secure approval, or a recommendation for full IRB review.

### **Process for Full Review**

Investigators are required to submit protocols to the IRB Chair, using the Protocol form, at least 5 working days (or fewer at the discretion of the IRB Chair) in advance of a set meeting in order to provide time for prior review by IRB members. The Chair will review the proposal. If the Chair finds that the research falls under the guidelines for Full Board review and all of the paperwork is complete, the Chair will submit the proposals to all committee members for review. The members will convene at the appointed meeting time to discuss and rule on the application. The committee may approve the research as proposed; it may approve the research pending specified modifications; or it may reject the research proposal. If the IRB gives approval pending specified modifications, the principal investigator is required to submit the modifications and the protocol must be submitted to the IRB Chair before final approval is granted.

The Chair shall forward to the PI and the full IRB board the decision to approve the proposed research activity, or modifications required to secure final approval, or a recommendation for full IRB review.

### **Meeting Times for the IRB**

The IRB will have a minimum of one monthly scheduled meeting during both the fall and spring semesters. A calendar of meeting times will be posted to the IRB's section of the Office of Research webpage each semester. If the IRB Chair has no protocols for full-board review or committee business to conduct, the IRB meeting may be cancelled.

### **Verification of No Changes since Previous IRB Review**

The IRB recognizes that protecting the rights and welfare of subjects sometimes requires that the IRB verify independently, utilizing sources other than the investigator that no material changes occurred during the IRB-designated approval period.

The IRB will determine the need for verification from outside sources on a case-by-case basis and according to the following criteria:

- History or concerns regarding investigator compliance
- Protocols where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources
- Protocols randomly selected for internal evaluation
- Whenever the IRB deems verification from outside sources is relevant.

In making determinations about independent verification, the IRB may prospectively require that such verification take place at predetermined intervals during the approval period, or may retrospectively require such verification at the time of continuing review, review of amendments or modifications.

If any material changes have occurred with IRB review and approval, the IRB will decide the corrective action to be taken.

## **Protocol Amendments**

All modifications to approved research must be reviewed and approved prior to implementation, except when necessary to eliminate apparent immediate hazards to the subject. Investigators submit their requests for modifications to the IRB using an Amendment form and include, as appropriate, the revised protocol, consent form, and recruitment materials.

A minor modification is defined as a change that would not materially affect an assessment of the risks and benefits of the study, or does not substantially change the specific aims or design of the study. Minor changes that do not increase the risk to research subjects may receive an expedited review.

Examples of minor modifications include:

- An increase or decrease in proposed human research subject enrollment
- Changes to improve the clarity of statements or to correct typographical errors provided that such changes do not alter the content or intent of the statement, and
- The addition or the deletion of study sites.

A major modification is defined as:

- A change in the PI
- The addition to or deletion of qualified investigators or
- Any change that materially affects an assessment of the risks and benefits of the study

**OR**

- Substantially changes the specific aims or design of the study.

NOTE: Major modifications to approved protocols that may increase the risk to subjects beyond minimal risk require a full board review. An Amendment form must be submitted to the IRB Chair to request major modifications. For minor modifications, the PI must inform the IRB Chair.

The IRB may only approve modifications submitted during a current approval year to the end of that period. For example, if the new or annual review takes place on January 2, 2017, the protocol will have an expiration date of January 1, 2018. If a modification is approved during this time, the protocol's expiration date still remains January 1, 2018. All modifications, amendments, and, when applicable, informed consent forms should be incorporated into the renewal application for IRB consideration during the annual review.

## **Continuing Review of Protocols**

Protocol approval automatically expires at the end of the approval period. If a researcher would like to continue research activities past the approval period, the researcher must request continuing review using the Continuing Review Application form. As a courtesy, the Office of Research will send out reminder memos to investigators prior to the IRB approval expiration date. Investigators must submit a brief summary of the research activities including number of subjects enrolled in the study to date, and any unexpected events to the IRB. Federal Regulations require review of research at least annually. Consequently the date of approval always begins on the date of approval and extends to the maximum one year from this date.

Research that includes protected categories of subjects and is greater than minimal risk will need to provide verification from sources other than the investigators that no material changes have occurred since the IRB Review. Other sources may include a designee of the IRB physically viewing the research process and procedures.

## **Process for Continuing Exempt Review**

A research project that is found to meet the criteria for Exempt status is exempt from annual continuing review by the IRB. The PI, however, is required to report to the IRB any expected revisions in the research activity that will cause the research to change from exempt to Expedited or Full Board review status. The PI is also required to report to the IRB any unexpected or adverse events that occur (using the Adverse Event form) or to report new information obtained that may cause the research activity to change from exempt to Expedited or Full review status. When the research project is completed, the PI is required to notify the IRB using the Completion Report form. The Exempt status expires when the research project is completed (closed) or when the review category changes as described above.

## **Process for Continuing Expedited Review**

Per federal regulations, an IRB must conduct continuing review of previously approved research at intervals appropriate to the degree of risk, but not less than once per year. Depending on the type of research, continuing review may be performed by expedited review or by full IRB review. Because the Expedited Review may be no greater than minimal risk, these protocols may be reviewed during the year. At the six month point of the research, the PI will be sent a letter by the Office of Research requesting an updated status. At this point, examination of procedures or of location may occur.

As a rule, if research did not qualify for expedited review at the time of initial review, it will not qualify for expedited review at the time of continuing review, except in limited circumstances described by expedited review categories (8) and (9). It is also possible that research that previously qualified for expedited review has changed, such that expedited IRB review would no longer be permitted for continuing review.

## **Expedited Review under Category 8**

Under Category 8, an expedited review procedure may be used for the continuing review of research previously approved by the convened IRB as follows:

- The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
- No subjects have been enrolled and no additional risks have been identified; or
- The remaining research activities are limited to data analysis.

NOTE: Category 8 identifies three situations in which research that is greater than minimal

risk and has been initially reviewed by a convened IRB may undergo subsequent continuing review by the expedited review procedure.

### **Expedited Review under Category 9**

Under Category 9, an expedited review procedure may be used for continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

### **Process for Continuing Full Board Review**

Per federal regulations, an IRB must conduct continuing review of previously approved research at intervals appropriate to the degree of risk, but not less than once per year. Depending on the type of research, continuing review may be performed by expedited review or by full IRB review. At the research midyear point, a letter will be sent to the PI by the Office of Research requesting updated research status. At this point, examination of data, procedures or of location may occur. For protocols that are greater than minimal risk, a letter will be sent to the PI, at three month intervals, requesting updated status. At this point, examination of data, procedures or of location may occur.

### **Unanticipated Problems and Reporting**

Investigators are required to report any unanticipated problem that occurs during the protocol approval period. Unanticipated problems involving risks (such as a breach of confidentiality, subject complaints, or protocol deviations) can occur in all types of human subject research - both behavioral and biomedical. The Adverse Event form must be sent to the IRB Chair to report these types of problems.

An unanticipated problem is defined as any incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document, and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the drugs, devices or procedures involved in the research); and

- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

All reports to the IRB of unanticipated problems should explain clearly why the event is "unanticipated" and clearly explain why the event represents a "problem involving risks to human subjects or others."

Reports to the IRB of unanticipated problems must include a corrective action plan to address the issue, or written justification for why none is provided.

Based upon such information, the IRB may reconsider its approval of the study, require modifications to the protocol and/or consent process, or revise the continuing review timetable. At any time the IRB may suspend or terminate a protocol.

## **Suspension or Termination of IRB Approval of Research**

The IRB has the responsibility and the authority to suspend or terminate approval of any study that has an unanticipated problem involving risks to human subjects, serious or continuing noncompliance with any federal regulation or serious or continuing noncompliance with the requirements or determinations of the IRB. Such actions will be determined at a convened meeting of the full board with a quorum present and will be incorporated into the minutes of the meeting.

The IRB may suspend or terminate approval of human subject research that:

- is not being conducted in accordance with the IRB's requirements and federal regulations
- is not being conducted in accordance with applicable rules and regulations or the IRB's requirements
- has been associated with unexpected serious harm to subjects
- creates a potential threat to the safety and welfare of research subjects, the research community and/or others
- initiates data collection prior to IRB approval.

Any suspension, termination of approval, or other responses to noncompliance or misconduct will include a statement of the reasons for the IRB's action and is reported promptly to the Principal Investigator, other investigators involved in the research, department chairs, the IO, the System RCO if necessary, and OHRP and funding sources if necessary. The IO may step in on a case-by-case basis to support the process.

Additionally, if applicable, current subjects will be notified, and their rights and welfare will be taken into consideration. If subject follow-up, for safety reasons, is permitted or required by the IRB, subjects will be informed that any adverse or unanticipated problems should be reported to the IRB and the sponsor, where applicable.

## **Closing a Protocol**

Protocol approval automatically expires at the end of the approval period, generally one year from the date of final IRB approval. Investigators will be notified by the Office of Research to submit a Continuing Review Application form or a Completion Report at least annually following the initial approval of the research.

Principal investigators have the responsibility of informing the IRB when a study has been completed. An IRB protocol may be closed once:

- all subject recruitment and enrollment is complete,
- all data, records, specimens have been obtained (no further data collection will be performed),
- no additional contact with subjects will occur (research interventions and data collection are completed) , and
- analyses of subject identifiable data are complete (use and/or access to identifiable data of subjects is no longer necessary).

In order to close an IRB protocol officially, the submission of a Completion Report by the Principal Investigator is required.

### **Principal Investigator Exits A&M-Central Texas (e.g., graduates, changes jobs)**

A&M-Central Texas approves protocols of research by its IRB and is limited to research done under its own auspices, except on a case-by-case basis for collaborative research or research by an unaffiliated investigator. Thus, when a principal investigator terminates employment or other association with A&M-Central Texas, approval must be sought to change the PI or for the original PI to serve as an unaffiliated investigator. If neither is done prior to the departure of the initial PI from A&M-Central Texas, all research must be halted and protocols must be closed by the PI.

To request to transfer the protocol to another principal investigator at A&M-Central Texas, the initial PI must submit a protocol Amendment form.

Notice of study closure or request to transfer to another principal investigator should be

submitted to the IRB 30 days in advance of the closure or transfer of the study.

## **IRB Review Considerations**

### **Determining Minimal Risk or Greater than Minimal Risk**

The concept of risk is generally understood to refer to the combination of the probability and magnitude of some future harm. According to this understanding, risks are considered "high" or "low" depending on whether they are more (or less) likely to occur, and whether the harm is more (or less) serious. In research involving human subjects, risk is a central organizing principle, a filter through which protocols must pass; research evaluated by IRBs that presents greater risks to potential research subjects will be expected to include greater or more comprehensive protections designed to reduce the possibility of harm occurring.

The purpose of having multiple categories of risk is to trigger different requirements from IRBs, just as the "minimal" and "greater than minimal" risk categories trigger different types of minimal protections in the regulations.

According to federal regulations, a study presents minimal risk if “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” Most people are subject to a variety of risks in their daily lives. Human subject research with a minimal risk should not increase that baseline level of risk.

When a research protocol is found to involve minimal risk, IRBs have the latitude to waive some consent requirements (see informed consent process section of A&M-Central Texas IRB protocol form). Moreover, IRBs may expedite the review of research protocols that involve minimal risk —relying on a review by the IRB Chair and a subset of members.

### **Determination that the Risks Are Reasonable in Relation to Anticipated Benefits**

Evaluation of the risk/benefit ratio is the major ethical judgment that IRBs must make in reviewing research proposals. The risk/benefit assessment is not a technical one valid under all circumstances; rather, it is a judgment that often depends upon prevailing community standards and subjective determinations of risk and benefit. Consequently, different IRBs may arrive at different assessments of a particular risk/benefit ratio. Specific ethical theories support determination of risk in IRB discussions. Training on these theories of ethics may assist IRB members for protocol approval.

Determining whether the risks are reasonable in relation to the benefits depends on a number of factors, and each case must be reviewed individually. An IRB's decision depends not only on currently available information about the risks and benefits of the interventions involved in the research, but also on the degree of confidence about this knowledge.

The benefits of research fall into two major categories: benefits to subjects and benefits to society. Some research leads to both types of benefits. Research on cognitive strategies for memory enhancement may help subjects develop better memory skills and may lead to new techniques for memory enhancement. Research on medications for attentional problems may benefit the individual subject who can be helped by that medication when it is made available, even if it does not work for everyone with those issues. Research on educational practices may lead to better teaching overall, but may not benefit the specific students in the class where the research was done if they were the control group. The IRB should assure that the anticipated benefits to research subjects and the knowledge researchers expect to gain are clearly identified.

Direct payments or other forms of remuneration offered to potential subjects as an incentive or reward for participation should not be considered a benefit to be gained by the research subject. Although participation in research may be a personally rewarding activity or a humanitarian contribution, these subjective benefits should not enter into the IRB's analysis of benefits and risks.

### **Equitable Selection of Subjects**

The requirement for an equitable selection of subjects helps ensure that the burdens and benefits of research will be fairly distributed. In the 19th and early 20th centuries, the burdens of research fell largely upon poor patients in hospital wards, while the benefits flowed primarily to private patients. This inequity was starkly revealed in the Tuskegee syphilis study, in which disadvantaged blacks in the rural south were recruited for studies of the untreated course of a disease that was by no means confined to that population. The IRB must scrutinize the investigator's selection of subjects to determine whether some groups of potential subjects (e.g., welfare recipients, members of racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the research problem being studied. In addition, the IRB must determine whether some groups of potential subjects are being systematically excluded due to vulnerable status alone (e.g. adults not proficient in the researcher's language or pregnant women). Inclusion of these groups in research may be

critical to understanding how the research topic relates to them, so they must be included whenever feasible and the risks to them must be minimized.

## **Informed Consent**

Informed consent is one of the primary ethical requirements and foundation of research with human subjects.

Informed consent assures that prospective human subjects understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate and make such a decision with autonomy.

It is essential that IRB members think of informed consent not as a form that must be signed, but as an educational process that takes place between the investigator and the prospective subject.

No one can guarantee that another person has understood the information presented; one can only inform prospective subjects as clearly and completely as possible. This is why those not proficient in the researcher's language need special consideration on the protocol form, although they are not specifically discussed in much of the IRB literature. No one can guarantee that another's choice is voluntary; one can only attempt to remove obvious impediments to free choice by being alert to coercive aspects of the consent procedure. Students in a researcher's classes must be clearly told that their participation will not affect their grades in the researcher's course or the student's progress in their academic program, even when the protocol involves anonymous surveys.

In cases where there is reason for special concern about pressure (e.g., when patients are invited to participate in research conducted by their physician, or when students, employees, are asked to participate in research conducted by their instructors or supervisors), the IRB may require some form of monitoring (such as the presence of an impartial observer).

If the research presents significant risk, or if subjects are likely to have difficulty understanding the information to be provided, the IRB may suggest that investigators employ devices such as audiovisual aids, tests of the information presented, or consent advisors.

Because obtaining informed consent is an educational process, the IRB should do what it can to enhance the prospective subject's comprehension of the information presented. It

should consider the nature of the proposed subject population, the type of information to be conveyed, and the circumstances under which the consent process will take place (e.g., manner, timing, place, personnel involved).

Consent is not a single event; rather, it is a process. Since subjects always retain the right to withdraw from a research project, their continuing consent is important. IRBs should be aware that subjects often seem to forget they are involved in research or have difficulty distinguishing research interventions from diagnostic and therapeutic interventions. When a research proposal is first approved, the IRB should determine whether consent should be renegotiated as a formal matter during the course of the research. If renegotiation is required, the frequency and/or events that will trigger this process should be decided upon and made clear to the investigators.

### **Required Elements of Consent**

1. Study Title
2. Investigator(s) are listed, and affiliation with A&M-Central Texas is described
3. Purpose of this Research Project (does the consent document include):
  - (a) A clear statement that the study involves research
  - (b) Nature of the study
  - (c) Purpose for conducting the research
4. Procedures
  - (a) Step-by-step explanation of what will be expected from study subjects
  - (b) Length and frequency of each study procedure and total time commitment for the subject
  - (c) Location of the research
  - (d) The instruments/documents that will be used and conditions involved (include an explanation of the instruments in appropriate language)
5. Risks
  - (a) All potential risks described (mental, social, financial, legal, dignity, or physical).  
[Note the use of survey questions of a sensitive nature may pose emotional distress caused by remembering unpleasant experiences]
  - (b) Safeguards that are to be employed to reduce or minimize risks
6. Benefits
  - (a) All direct or indirect benefits
  - (b) If no benefits accrue to the subjects, the larger societal benefits
  - (c) Note, Compensation is not included/described in this section
7. Extent of Anonymity and Confidentiality
  - (a) Extent to which subjects will be identifiable
  - (b) Explanation of how the study will provide the utmost confidentiality or

- anonymity [confidentiality = individual can be identified directly or through identifiers, but the researchers promise not to divulge that information; anonymity = individuals cannot be identified by anyone, including researchers]
- (c) Explanation of the use of study ID/codes, if applicable
  - (d) Explanation of who will have access to the data
  - (e) Statement, “It is possible that the Institutional Review Board (IRB) may view this study’s collected data for auditing purposes
  - (f) The IRB is responsible for the oversight of the protection of human subjects involved in research”
  - (g) Description of when data will be destroyed.
8. Compensation
- (a) Subjects informed whether compensated or not
  - (b) Amount of compensation (including extra credit, if applicable)
  - (c) If extra credit is offered, what comparable alternative means of obtaining extra credit will be offered to those who decline to participate in the study
9. Freedom to Withdraw
- (a) Statement that subjects are free to withdraw from the study at any time without penalty
  - (b) If study involves compensation, statement that subjects will be compensated for the portion of their time spent in the study (if applicable) or fully compensated if they choose to withdraw
  - (c) Statement that subjects are free not to answer any questions or respond to experimental situations that they choose without penalty
  - (d) Optional: Statement describing that there may be circumstances under which the investigator may determine that a subject should not continue as a subject. The subject must be compensated for the portion of the project completed
10. Subject’s Responsibilities (When applicable)
- (a) Statement, “I voluntarily agree to participate in this study. I have the following responsibilities:”
  - (b) List of subject’s responsibilities
11. Subject’s Permission
- (a) Statement, “I have read the Consent Form and conditions of this project. I have had all my questions answered. I hereby acknowledge the above and give my voluntary consent.”
  - (b) Signature line for subject
  - (c) Optional: Signature line for witness (when applicable)
12. Contact information of Investigator(s). List the name and email address or telephone number of the Principal Investigator on the consent form.
13. Contact Information and Human Rights Statement. Include the following required

text as a separate paragraph after the investigator contact information paragraph. Required text: "If you have any questions concerning your rights as a research subject that have not been answered by the investigator or if you wish to report any concerns about the study, you may contact the A&M-Central Texas Research Compliance Officer (Walter Murphy) [at \(254\) 519-5761](tel:(254)519-5761) or [murphyw@tamuct.edu](mailto:murphyw@tamuct.edu)."

#### 14. Format and Structure of Consent Document

- (a) Language of the consent form is directed toward the individual signing the form (avoiding use of jargon, scientific terms, and concepts not readily comprehended by the non-scientist public)
- (b) The text and readability of consent form is appropriate for the age, mental capacity and maturity of the individual signing the form
- (c) The consent form does not contain any exculpatory language through which the subject or the representative is made to waive or appear to waive any of his legal rights or release the investigator, the sponsor, the institution or its agents from liability for negligence
- (d) The final draft of the consent document has been reviewed for grammatical and typographical errors.

### **Documentation of Informed Consent**

In most cases the regulations require that informed consent be documented but they also provide for some important exceptions.

Documentation usually involves the use of a written consent information form containing all the information to be disclosed and signed by the subject or the subject's legal representative.

However, please keep in mind that these documents are not substitutes for discussion. The consenting of subjects is a process, not merely a form. The process should be seen as a conversation and communication between the PI and the subject.

For signed documentation of consent, the person who signs the consent form must be given a copy as a reference and reminder of the information conveyed. A "short form" may sometimes be used. The use of a short form means that the information is presented without benefit of a written version of the consent document.

**NOTE on Waiver of Signed Consent:** If the investigators are not collecting a signature from subjects indicating they consent to participation, they must ask for a waiver of signed consent. Informed consent must always be gained from subjects, but an actual signed form

can be waived in situations like an online survey (in which the consent section includes a statement of consent with separate buttons for the subject to Accept or Decline participation in the project) or when collecting identifying information for subjects increases some type of risk to the subject.

**NOTE on Risk Mitigation when requesting a waiver of signed informed consent:** In cases where questions or procedures have some risk for increasing anxiety or address sensitive issues, a general statement reminding subjects that if they feel at risk of hurting themselves or someone else they should seek appropriate care by calling 911 or reporting to an Emergency Room. Subjects may also be given contact information for local mental health care providers.

The IRB may decide that, in some cases, subjects should be provided written copies of the information conveyed despite the fact that they are not asked to sign a consent form.

1. That the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

**OR**

2. That the research presents no more than minimal risk of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

## Waiver of Some or All of the Required Elements of Consent

The regulations permit the IRB to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
  - Public benefit or service programs
  - Procedures for obtaining benefits or services under those programs
  - Possible changes in or alternatives to those programs or procedures
  - Possible changes in methods or levels of payment for benefits or services under those programs

**OR**

- The IRB may approve a waiver of some or all of the consent requirements provided that:
  - The research involves no more than minimal risk to subjects
  - The waiver or alteration will not adversely affect the rights and welfare of the subjects
  - The research could not practicably be carried out without the waiver or alteration, and
  - Whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study
  - The research is not FDA regulated.

## Subject Withdrawal

Federal and system regulations state that, if applicable, the consent form shall include the consequences of a subject's decision to withdraw from the research, and the procedures for orderly termination of participation by the subject.

The consent form must include information regarding what the PI will do with the information that he or she has gathered from that subject if the subject chooses to withdraw from the study, although that is not required. The regulations do not require that the investigator return the data to the subject or destroy what has been already collected.

*Suggested statements to include:*

“If you withdraw from this study, your data will be returned to you or destroyed. Likewise, the Researcher may terminate your participation in the study at any time.”

**OR**

“If you withdraw from this study before data collection is completed, your data will be returned to you or destroyed. Likewise, the Researcher may terminate your participation in the study at any time.”

**OR**

“If you withdraw from this study for any reason, the data collected may be used by the Researcher.”

*Protocols and Consent Documents Must Address Incentives and either:*

- Describe the plan for pro-rated distribution of incentives to subjects if they choose to withdraw voluntarily from the protocol or if, upon the suggestion of investigator, early withdrawal is necessary, or
- Provide justification(s) to why prorated distribution of incentives is not being offered to the subjects.
- Incentives may include monetary payments or course credit/extra credit, but must be clearly stated in the consent form

## **Subject Compensation**

Federal regulations governing research with human subjects contain no specific guidance for IRB review of payment practices. One of the primary responsibilities of IRBs, however, is to ensure that a subject's decision to participate in research will be truly voluntary, and that consent will be sought "only under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence."

Direct payments or other forms of remuneration offered to potential subjects as an incentive or reward for participation are not considered a "benefit" to be gained from research. Although participation in research may be a personally rewarding activity or a humanitarian contribution, these subjective benefits should not enter into the IRB's analysis of benefits and risks.

Any credit for payment should accrue as the study progresses and not be contingent only upon the subject's completing the entire study. Unless it creates undue inconvenience or a coercive practice, payments to subjects who withdraw from the study may be made at the

time they would have completed the study (or completed a phase of the study) had they not withdrawn.

While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable provided that such incentive is not coercive. The amount paid as a bonus for completion must be reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn.

All projects that promise to provide incentives to subjects must include details regarding how the incentives will be provided within the protocol and consent form. The reasonableness of the amount offered will depend on the degree of discomfort the subjects experience, the invasiveness of the procedure or investigation, the character of the research, the population likely to be attracted by the protocol, the method in which the protocol will be advertised, the amount of time a subject is expected to devote to the protocol, and related considerations.

### **Guidelines for Compensating Research Subjects for Their Time and Effort**

Investigators are responsible of informing the IRB of payments to research subjects in the IRB Application for Initial Review. Investigators are responsible for disclosing to research subjects any payment being offered for their participation in the research study in the informed consent form.

- The IRB and subject should be informed how payment will be prorated or provided in total
- The subject should be informed when/how payment will be disbursed
- The IRB reviews all payment arrangements to subjects for the following criteria:
  - Payments to subjects cannot be of such a nature to affect the equitable selection of subjects
  - The amount of payment and the proposed method and timing of disbursement must be neither coercive nor present undue influence
  - Credit for payment must accrue as the study progresses, and not be contingent upon the subject completing the entire study
  - Describe the plan for pro-rated distribution of incentives to subjects if they choose to withdraw voluntarily from the protocol or if, upon the suggestion of investigator, early withdrawal is necessary, or
  - Provide justification(s) to why prorated distribution of incentives is not being offered to the subjects
  - The entire payment may not be contingent upon completion of the entire study

- Any amount paid as a bonus for completion must be reasonable and not so large as to unduly induce subjects to stay in the study when they otherwise would have withdrawn.

## **Protecting the Rights and Welfare of Vulnerable Populations**

The federal regulations require that IRBs give special consideration to protecting the welfare of particularly vulnerable subjects, such as children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons. However, groups of potential subjects should not be excluded from research, especially that with minimal risk, solely because they are from vulnerable populations. It is important that diverse population groups be included in studies when possible in order to expand the knowledge about each group in particular research scenarios.

There are federal and system regulations that set forth specific provisions on research involving:

- fetuses,
- pregnant women, when the research increases the risk to either the mother or the developing fetus,
- human in vitro fertilization,
- prisoners, and
- children.

In general, these special regulations allow IRBs to approve research that is of MINIMAL RISK or that will benefit the subjects directly.

When research involving these subjects presents significantly greater than minimal risk without direct benefit to them, in many cases, it must be reviewed and approved by the Secretary of Health and Human Services, in consultation with appropriate experts.

Research involving prisoners, fetuses, or human in vitro fertilization is not eligible for administrative or exempt review. For research including pregnant women as subjects, any study involving medications, treatments, or procedures that might adversely affect the pregnancy is not eligible for administrative or exempt review. Research that is expected to have no effect on pregnancy, such as surveys of topics not related to pregnancy, is eligible for administrative or exempt review.

Also, exemptions for research involving survey or interview procedures, or observation of public behavior, does not apply to research involving children except for research involving

observations of public behavior when the investigator does not participate in the activities being observed.

## Research Involving Prisoners

"Prisoner" is defined by the regulations as "any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing." "Penal" means relating to the punishment of offenders under the legal system; subject to punishment by law.

When reviewing research involving prisoners, the IRB must also meet the following requirements:

- A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB
- At least one member of the IRB shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.

In addition to all other responsibilities for IRBs the IRB shall review research involving prisoners and approve such research only if it finds that:

- The research falls into one of the following permitted categories (45CFR46.306)
  - study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects
  - study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects
  - research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject in cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only with the approval of the Secretary of the Department of Health and Human Services.
- any possible advantages accruing to the prisoner through his or her participation in

the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired

- the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers
- procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners; unless the PI provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for the particular research project
- the information is presented in language which is understandable to the subject population
- adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole, and
- where there may be a need for follow-up examination or care of subjects after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing subjects of this fact.

Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) requires approval by the Secretary of the Department of Health and Human Services.

### **Research Involving Children/Minors (e.g., less than 18 years of age or emancipated)**

**All research involving minors as subjects must be reviewed by University's Institutional Review Board.** The IRB tries to be as flexible as possible and reviews each project as a separate case rather than imposing rigid requirements. A primary role of the IRB is educational and, consultation with the IRB at all stages of the research and review process is encouraged.

### **Children/Minors – Not Greater Than Minimal Risk Research**

Research in which there is no direct intervention with children generally does not usually

require parental consent or child assent. However, permission of the school (superintendent or principal) and compliance with the provisions of FERPA (Family Education Rights and Privacy Act or “the Buckley Amendment”) are required.

Examples of Research That Does Not Involve Direct Intervention with Children Include:

- anonymous, non-interactive, non-participating observation of public behavior
- secondary analysis of existing data
- education research that does not modify or disrupt regular classroom activity; e.g., testing of curricula or teaching methods, or observation of classroom activity
- research involving the use of educational tests if information taken from these sources is recorded in such a manner that subjects cannot be identified.

Projects that involve direct intervention with children require permission from the school district and parental consent. In addition, assent from the child is required when appropriate. Compliance with the Buckley Amendment is also required.

Examples of Research That Involves Direct Intervention with Children Include:

- research on individual or group behavior of children
- interviews and surveys
- education research that modifies or disrupts regular classroom activity; e.g., introduces unusual activities or tests, or takes children individually or in groups out of the classroom
- the use of identifiable test information.

### **Children/Minors - Greater Than Minimal Risk Research**

Research involving greater than minimal risk to children should only be conducted when absolutely essential to the investigation. Such research raises important ethical questions which must be given serious consideration by both researchers and the IRB. Federal regulations distinguish between two types of research involving greater than minimal risk to children:

Research presenting the prospect of direct benefit to the individual subjects. Federal regulations state that an IRB can approve such research only if it finds that:

- the risk is justified by the anticipated benefit to the subjects
- the relation of the anticipated benefit to the risk is at least as favorable to the

- subjects as that presented by available alternative approaches, and
- adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

Research presenting no prospect of direct benefit to individual subjects but likely to yield generalizable knowledge about the subject's disorder or condition. Federal regulations state that an IRB can approve such research only if it finds that:

- the risk presents a minor increase over minimal risk
- the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations
- the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding of the subject's disorder or condition, and
- adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

In order to ensure that the interests of the children are being adequately protected, the IRB, when reviewing research in this category, shall have, as a member, an individual who shall serve as a "child advocate." This individual should be one whose professional responsibility is primarily concerned with the welfare of children. When appropriate, the IRB may require that the "child advocate" monitor the consent process.

Since approval of research in this category involves evaluating the potential benefits of the research, the IRB shall solicit recommendations from individuals with sufficient professional expertise to evaluate these benefits. These individuals shall not be associated with the research project.

### **IRB Review of Research Involving Wards**

Regulations allow children who are wards of the State or any other agency, institution, or entity to be included in research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition or in research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

Federal regulations define a "ward" as "a child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or

local law.”

A “ward” includes foster children, children residing at a Texas Youth Commission facility, and children who are otherwise in the care and control of the state or a state agency. For research involving no greater than minimal risk to subjects, or in which the research has greater than minimal risk but presents the prospect of direct benefit to the individual subject, there are no additional protections in addition to the standard rules for consent as covered in the sections below for foster children and children in the custody of the Texas Youth Commission apply.

For research involving greater than minimal risk with no prospect of direct benefit to individual subjects, and for research not otherwise approvable but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children, a child who is a ward can only be included if the research is:

- Related to their status as wards;
- OR**
- Conducted in schools, camps, hospitals, institutions or similar settings in which the majority of children involved as subjects are not Wards.

If children who are Wards are to be included in any research study, the investigator must provide the IRB with detailed information about the proposed permission/assent process as well as the identity and authority of the individuals who will provide permission for the Ward Subjects.

The federal regulations require IRBs to appoint an advocate for each ward in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate should be an individual who has the background and experience to act in the best interest of the child for the duration of the child’s participation in the study and who is not associated in any other way with the research, the investigator or the guardian organization.

### **Children Categorized as PINS (Person In Need of Supervision)**

Under Texas State law, Persons in Need of Supervision (PINS) are juveniles less than 18 years of age (minors) for whom complaints were filed with local probation departments because of non-criminal misconduct, such as truancy from school, incorrigibility, ungovernability or habitual disobedience. Complainants in these cases are generally parents or school officials who are seeking the formal intervention of the family court to control a juvenile's misconduct. PINS cases are recorded in the county in which a PINS

complaint is filed.

A PINS placement is not considered a criminal adjudication or a sentence. Accordingly, these children would be considered wards and not prisoners.

### **Requirement of Assent for Research Involving Children**

When children or minors are involved in research the regulations require the assent/consent of the child and the permission of the parent(s).

The requirement for parental permission may be inappropriate in some cases. Examples include research involving older adolescents who, under applicable law, may consent on their own behalf for selected treatments (e.g., treatment for sexually-transmitted diseases, drug abuse, or emotional disorders).

Permission is not necessary when the research involves the observations of public behavior when the investigator(s) do not participate in the activities being observed.

Given that children have not reached their full intellectual and emotional capacities, involving children in research requires the permission of their parents or legally authorized representatives (unless parents and representatives are designated to be legally incompetent). The IRB must determine whether the permission of both parents is necessary, and the conditions under which one parent may be considered "not reasonably available."

While children may be legally incapable of giving informed consent, they nevertheless may possess the ability to assent/consent to or dissent from participation. Out of respect for children as developing persons, children should be asked whether or not they wish to participate in the research, particularly if the research: (1) does not involve interventions likely to be of benefit to the subjects; and (2) the children can comprehend and appreciate what it means to be a volunteer for the benefit of others. Thus, adequate provisions should be made for soliciting the assent/consent of the children when, in the judgment of the IRB, the children are capable of providing such assent/consent.

## Documentation of Assent

The IRB determines if assent is required. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented. That is, the regulations go to the extent of giving the IRB the authority to waive the requirement for assent in certain circumstances. That level of regulatory oversight suggests that failure to solicit assent is considered to be a serious ethical violation; that in turn suggests that there should be a mechanism for knowing whether such a violation has occurred.

The IRB expects investigators to describe what they are doing about assent of minors in research and how they are documenting it. The use of a written assent form provides the following benefits:

- It is a symbolic indication that the child's right to involvement in this process is real
- The form, if well designed, is a useful tool in explaining the study to a child, and serves as a reference source for that child
- Requiring the investigator to think through a study well enough to be able to write a clear and simple assent form may help the researcher understand the study better and create a better adult consent form,
- Use of the A&M-Central Texas Assent Form satisfies the need for documentation.

An oral assent process with less detailed documentation may be acceptable, especially in studies of very low risk. Researchers may propose this option if they can provide sufficient support for why documentation is not required.

## Research Involving Decisionally-Impaired Subjects

The IRB recognizes that the ability of adult populations to give voluntary informed consent may be compromised by circumstances. Such circumstances can include economic or educational disadvantages, and physical handicap. The IRB will review the potential risks and benefits of each proposed study on a case-by-case basis to assure rights and welfare are protected, coercion is minimized, and the study is conducted with the utmost regards for ethical standards.

Individuals in a wide variety of situations may have impaired decision-making capacity. For example, impairment may occur at times of great stress. Impaired capacity is not limited to individuals with neurologic, psychiatric, or substance abuse problems; conversely, individuals with neurologic, psychiatric, or substance abuse problems should not be presumed to be decisionally-impaired. Some research questions may only be answered by research that involves persons with impaired decision making capacity; precluding this

research would contribute to needless suffering. The most severely impaired individuals have the greatest need for the benefits of research and treatment. While this area is controversial, limiting research to the least impaired individuals would hamper research on the underlying causes and potential therapies of many disorders. Not all research will directly benefit the individual subject but may offer future benefits to others who have or will develop the condition or disorder.

As a general rule, all adults, regardless of their diagnosis or condition, should be presumed competent to consent unless there is evidence of serious mental disability that would impair reasoning or judgment. Even those who do have a diagnosed mental disorder may be perfectly able to understand the matter of being a research volunteer, and quite capable of consenting to or refusing participation. Mental disability alone should not disqualify a person from consenting to participate in research; rather, there should be specific evidence of individuals' incapacity to understand and to make a choice before they are deemed unable to consent.

Persons formally adjudged incompetent have a court-appointed guardian who must be consulted and consent on their behalf. Officials of the institution in which incompetent individuals reside (even if they are the individual's legal guardians) are not generally considered appropriate, since their supervisory duties may give rise to conflicting interests and loyalties. Family members or others financially responsible for the individual may also be subject to conflicting interests because of financial pressures, emotional distancing, or other ambivalent feelings common in such circumstances. IRBs should bear this in mind when determining appropriate consent procedures for cognitively impaired subjects.

It is now generally accepted that research involving persons whose autonomy is compromised by disability or restraints on their personal freedom should bear some direct relationship to their condition or circumstances. Persons who are institutionalized, particularly if disabled, should not be chosen for studies that bear no relation to their situation just because it would be convenient for the researcher. An institutional setting can be advantageous to the conduct of research - the population is easily accessible, close supervision to prevent extraneous influences is possible, and medical monitoring and emergency services are available. Some not uncommon characteristics of the institutional setting, however, create circumstances that may compromise the voluntary nature of participation in research. For example, institutionalized individuals may have become emotionally dependent on their caretakers and may acquiesce too readily to requests for their "cooperation." Persons who are totally dependent on an institution may be vulnerable to perceived or actual pressures to conform to institutional wishes for fear of being denied services or privileges. If medical care, staff attention, or living conditions are inadequate, an

invitation to move into a special unit or research ward may be appealing. Finally, with little or no opportunity to make decisions regarding their daily living, the ability of institutionalized subjects to make choices may be further diminished.

Nevertheless, IRBs should not make assumptions as to the effect of an institutional setting on voluntariness or competence. People do not automatically become incapable of competent and voluntary consent the moment they enter a mental institution. On the other hand, institutionalized individuals have been used as convenient research subjects in drug tests totally unrelated to their disorders or institutionalization. This exploitation of the vulnerable and the "voiceless" led the National Commission to recommend that, even in research on mental disabilities, subjects should be recruited from among non-institutionalized populations whenever possible.

Some individuals may be incompetent and have no legal guardian. One such example would be mentally deficient or cognitively impaired adults whose parents "voluntarily" institutionalized them as children and have never subsequently gone through formal proceedings to determine incompetence and have a guardian appointed. Another example would be geriatric patients with progressive cognitive disorders (e.g., Senile Dementia of the Alzheimer type). Typically, a spouse or adult child of such patients' consents to their medical care, but no one is a "legally authorized representative." The extent to which family members may legally consent to the involvement of such patients in research (especially if no benefit to the subjects is anticipated) is not clear. According to a position paper published by the American College of Physicians (1989), surrogates of cognitively impaired persons should not consent to research that holds out no expected benefit if such research presents more than minimal risk of harm or discomfort. It is imperative to obtain Patient Advocate (ombudsman) approval for cognitively impaired individuals, and the type of Patient Advocate is assessed on a case-by-case basis.

Because no generally accepted criteria for determining competence to consent to research (for persons whose mental status is uncertain or fluctuating) exist, the role of the IRB in assessing the criteria proposed by the investigator is of major importance. The selection of an appropriate representative to consent on behalf of those unable to consent for themselves must be accomplished without clear guidance from statutes, case law, or regulations. Within the boundaries of existing legal precedents, IRBs can be creative in helping investigators formulate appropriate procedures in these uncertain areas. In the case of cognitively impaired subjects there must be an ombudsman to act as the informed consent representative. The ombudsman is usually a member of a national organization representing the cognitively impaired, or a family or friend acting as a power of attorney; along with a review by an ethics panel (i.e., a standing ethics committee).

## Options for Additional Safeguards

- A sliding scale involving assessment of risks, benefits, and capacity to consent should guide the IRB's decisions regarding additional safeguards. Many strategies are available as options for investigators as they develop their research protocols and for IRB members as they evaluate them. In considering increasing levels of risk and/or impairment, investigators should be creative in choosing appropriate protections, and seeking strategies used successfully in other situations
- Use of an Independent Monitor. When reviewing greater than minimal risk research involving individuals with questionable capacity to consent, IRBs should discuss and document the potential value of an independent monitor. A monitor should be an expert in decisional or cognitive impairment and should be present when investigators invite individuals with impaired decision-making capacity to participate in a research study. The consent process should be visible throughout, and IRBs have a right to observe recruitment, assessment, the informed consent process, and debriefing of research subjects (and/or their family/surrogates)
- Use of a Surrogate. Where permitted by law, individuals with impaired capacity may have a family member or other legally authorized representative serve as a surrogate for research decisions, with this role documented during the consent process. Surrogates should be informed of the risks, benefits, and alternatives to the research when they are providing permission for an individual to participate. Whenever possible, surrogates should make research decisions based on substituted judgment, reflecting the views of the individual expressed while decisionally capable. Best interest standards should be used if the values of the individual are not known. It is important that surrogates receive some education about their own role, the cognitive and health status of the research subject, as well as about the study in which the subject may be involved
- Use of Assent in Addition to Surrogate Permission. The autonomy of individuals with impaired decision making capacity should be respected. Their assent to participation in research should be obtained whenever possible and their decision to withdraw from a study at any time should be honored
- Use of Informational/Educational Techniques. Because informed consent is an ongoing process throughout the course of the protocol, assessing and enhancing comprehension at each stage is essential. Single sheet summaries of important information about key elements of a study may be useful when provided on a regular basis. Questions from potential subjects and family members should be encouraged, and handouts of frequently asked questions and answers regarding specific human subject protections can be prepared. Model consent forms and procedures can be developed. Communication between members of the research

team and subjects and their families is key to successful research participation

- Use of Waiting Periods. Individuals who are decisionally-impaired may need more time to consider the information they are given about a research protocol. Information should be provided incrementally to facilitate understanding. Planning built-in waiting periods within the consent process also may be useful to allow potential subjects time to consult with family members about whether or not to participate.

In all human research, varied degrees of research risk and decisional impairment call for varied levels of scrutiny and safeguards; additional protections (e.g., involvement of family surrogates where State or other applicable law permits and independent monitoring) may be highly advisable in certain circumstances. But treating all individuals who have cognitive deficits as incapable of understanding research is inaccurate and disrespectful of their autonomy. Many individuals, adequately informed, may be willing to undertake certain risks so that they, or others, may benefit in the future. Researchers and IRBs must strive for a balance that maximizes potential benefits and opportunities, recognizes and extends individual autonomy, and minimizes risks associated with scientific inquiry.

### **Students and Employees as Research Subjects - Potential for Undue Influence**

Justification of the intention to enroll a Principal Investigator's own students must be provided in the protocol. The actions to prevent coercion or undue influence must also be detailed in the protocol. Anyone with an employment or academic relationship to A&M-Central Texas or (if applicable) the collaborating institution or research site, must be informed that their participation in a study or refusal to do so, will in no way influence their grades, employment, or subsequent recommendations. Employees must never be made to feel that their job, promotion, salary, or status in any way depends on participation in research studies. Additionally, investigators must be aware that research involving the collection of data on sensitive subjects such as mental health, sexual activity, or the use of illicit drugs or alcohol presents risks to subjects of which they should be made aware and from which they should be protected, to the greatest extent possible. The close environment of a school/university/workplace amplifies this problem.

The Principal Investigator or any other co-investigator **MUST NOT** be responsible for directly recruiting and/or obtaining informed consent from any person that is his/her current student or is under his/her direct supervision.

One of the challenges presented with student participation in research conducted in schools is the possibility that their agreement to participate will not be freely given.

Students may volunteer to participate out of a belief that doing so will place them in good favor with their teacher (e.g., that participating will result in receiving better grades, recommendations, employment, or the like), or that failure to participate will negatively affect their relationship with the investigator or teacher generally (e.g., by seeming "uncooperative").

To avoid any potential for undue influence, the Principal Investigator **MUST** formally delegate this responsibility to someone who does not have the teacher/student or employer/employee relationship to the potential subject, and the person delegated should receive appropriate training before performing the informed consent process or, if applicable, the recruitment process. ANY Principal Investigator who is the instructor for a group of students **MUST** not collect himself or herself from those students.

The IRB will pay special attention to the potential for coercion or undue influence. The IRB should ensure that investigators consider ways in which the possibility of exploitation can be reduced or eliminated.

The involvement of students, staff or employees in such studies requires a statement in the consent form acknowledging that refusal to participate will have no influence on grades, recommendations or job status and this should be clarified in person during the request for consent.

### **Principal Investigator's Clinical Patient Population**

Many research protocols may involve recruitment from one's own clinical pool of patients. To avoid any potential for undue influence that may result from the physician/provider-patient/client relationship, the informed consent process and/or recruitment process should not be conducted solely by the physician/provider who has a clinical relationship to the patient that will be enrolled. The Principal Investigator **MUST** formally delegate this responsibility to someone who does not have the clinical relationship to the potential subject, and the person delegated should receive appropriate training, to perform the informed consent process and, if applicable, the recruitment process.

## **Non-English Speaking Subjects and Subjects Who Are Not Proficient in English**

An investigator who intends to include non-English speaker individuals must provide sufficient detail in the research protocol regarding the plan for inclusion, including the plan for obtaining informed consent and additional provisions made during the conduct of the study.

If an investigator intends to enroll subjects who do not speak English, a translated version of the informed consent form must be submitted to the IRB for approval prior to use. A person who is fluent in both English and the subject's language may participate in the informed consent process or, if deemed necessary by the Principal Investigator or the IRB, all research forms must be translated into the subjects' own language.

If the person authorized to obtain informed consent in the research protocol is not fluent in the subject's language, an interpreter should be obtained. Family members and friends of the potential subject may not act as the sole translation/interpretation source for enrollment and participation in a research protocol, as they are not familiar with research terminology, may withhold information during the translation process, or may change the meaning of what is said by the potential subject or research staff.

All other study related documents that will be filled out by the subject (e.g., surveys, data collection forms, self-assessment tools, etc.) must also be translated into the subject's native language. If the study involves more than one study visit, a plan must be developed to ensure that an appropriate party is available to conduct all study visits in the subject's native language.

### **Monitoring Data Collection**

For an IRB to approve proposed research, the protocol must, when appropriate, include plans for monitoring the data collected to ensure the safety of subjects. Investigators sometimes misinterpret this requirement as calling for annual reports to the IRB so that the IRB can monitor the project.

In fact, however, researchers must provide the IRB with a description of their plans for analyzing the data during the collection process. Concurrent collection and analysis enables the researcher to identify flaws in the study design early in the project. At this point, researchers are to re-evaluate the risks to human subjects to assure that they are no greater than initially predicted.

Like other considerations, the level of monitoring in the research plan should be related to the degree of risk posed by the research. Furthermore, where the research will be performed at foreign sites, the domestic IRB may want to require different monitoring and/or more frequent reporting than that required by the foreign institution.

### **Protecting the Privacy of Subjects and Maintaining Confidentiality of Data**

A significant risk of certain types of identifiable information is that its disclosure may have adverse consequences for the individual, such as the loss of employment or health insurance. If data are properly protected, the potential that such harms may occur is significantly reduced or eliminated. Protecting the confidentiality of data about identifiable individuals, whether they are human subjects or third parties, is a key responsibility of investigators and IRBs.

Risk to either the human subject or the third party from information disclosure is a function of data security and policy. Investigators must secure identifying data at all stages of research– from the time information is collected through the completion of analyses and publication of results, and for as long as the data are stored. The specific measures used to protect the data should take into account the sensitivity of the information collected and the risks associated with a breach of confidentiality. Unauthorized individuals must not be able to access individually identifiable research data or learn the identity of research subjects or third parties during or after the completion of the study.

Privacy concerns the right of individuals to control information about their person and their behavior. An invasion of privacy occurs when someone accesses this information without consent. Confidentiality concerns the ways in which information disclosed voluntarily by subjects is protected from disclosure by the researcher. The term *privacy* is about persons; the term *confidentiality* is about information.

### **Protecting Privacy**

Person's ability to control access to their personal information and to their persons is determined by a variety of factors, including socioeconomic status, age, and circumstance. For example, information about welfare rolls is public information; information about personal stock portfolios is not, unless you are a government official. Minors have fewer rights to privacy than adults. Institutionalized persons may have significant limitations on their ability to control personal information.

Assuming that respect for privacy is a critical component of ethical research, the IRB will have to determine whether or not particular activities constitute invasions of privacy. Such

determinations are complicated because differentiating between public and private behavior is not always easy and because concepts of privacy vary from culture to culture.

An individual's right to privacy from research inquiry is generally protected by the right to refuse to participate in research. Privacy issues arise when investigators wish to use personally identifiable records without obtaining consent or conduct covert observation or subject observation. Rules dictated by the Family Educational Rights Privacy Act and the Health Insurance Portability and Accountability Act MUST be observed and followed (see the relevant sections below).

### **Ensuring Confidentiality**

Confidentiality refers to agreements made with subjects, through the consent process, about if and how information provided by the subjects will be protected. These agreements may include descriptions about whether or not identifiers will be retained, who will have access to identifiable data, and what methods will be to safeguard data, such as encrypted storage or locked files.

The need for confidentiality exists in virtually all studies in which identifiable information is collected about subjects, unless the information is entirely innocuous.

Confidentiality is particularly important when subjects are selected because of a sensitive, stigmatizing, or illegal characteristic. In these cases, a breach of confidentiality may pose a serious risk to study subjects.

During the informed consent process, subjects should be made aware of confidentiality issues. That is, subjects should be informed about who will have access to the research data and for how long; what further disclosure or data sharing is anticipated; what data security measures will be employed and what, if anything, will be disclosed to others, by whom, and under what conditions. subjects should also be advised about whether or not study results will be made available to them; approximately when they will be available; and whether they can opt to know or not know the results and under what circumstances. In cases where it may not be possible to protect the confidentiality of data about subjects or third parties (e.g., reporting of child abuse and certain infectious diseases), research subjects should be informed of confidentiality limitations during the informed consent process.

If confidentiality is promised, identifying information should not be stored with research data. Every effort should be made to protect identifying information through the use of passwords, locked computers, and double-locked storage containers. Appropriate

procedures for mitigating the likelihood of failure of confidentiality must be stipulated in the IRB protocol form.

### **Reportable Disclosures – Mandated Reporting**

Current law in many states requires that professionals such as teachers, physicians, nurses, or child daycare workers must make a verbal report within 48 hours. In addition, Texas law mandates that any person who suspects abuse of children and older people is required to report it. Investigators should consult the IRB for guidance and assistance for determination regarding mandatory reporting requirements. There is more information on mandatory reporting available on the Texas Department of Family and Protective Services website at: [https://www.dfps.state.tx.us/contact\\_us/report\\_abuse.asp](https://www.dfps.state.tx.us/contact_us/report_abuse.asp).

### **Certificates of Confidentiality**

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect the privacy of research subjects enrolled in biomedical, behavioral, clinical and other forms of sensitive research. Certificates protect investigators and institutions against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research subject in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

Identifying information is broadly defined as any item or combination of items in the research data that could lead directly or indirectly to the identification of a research subject.

Sensitive information about subjects that can be protected with a Certificate of Confidentiality includes (but is not limited to):

- information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products
- information pertaining to illegal conduct
- information that, if released, might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination
- information pertaining to an individual's psychological well-being or mental health
- genetic information or tissue samples and
- their involvement in litigation related to exposures under study (e.g., breast implants, environmental or occupational exposures).

Generally, an application for a Certificate of Confidentiality is submitted after the IRB approves the research project (because IRB approval or approval conditioned upon issuance of a Certificate of Confidentiality is a prerequisite for issuance of a Certificate). Since the informed consent form should include language describing the Certificate and any voluntary disclosures specified by the investigator, the investigator should tell the IRB that they are applying for a Certificate of Confidentiality and have included appropriate language in the informed consent form.

Certificates of Confidentiality are generally effective on the date of issuance or upon commencement of the research project if that occurs after the date of issuance. The expiration date should correspond to the completion of the study.

The Certificate will state the date upon which it becomes effective and the date upon which it expires. A Certificate of Confidentiality protects all information identifiable to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect.

However, the protection afforded by the Certificate is permanent. All personally identifiable information obtained about subjects in the project during the effective period of the Certificate is protected in perpetuity.

### **Research Using Deception or Withholding Information**

Deception in research involves research in which the subject is not told, or is misled, about the true purpose of the research, such as in certain studies of group processes, contextual influences on cognition. Special considerations are required when deception or incomplete disclosure is an integral part of the research. The requirements for complete informed consent strongly favor comprehensive, honest, and understandable disclosure of all elements of the subject's participation in research.

There are times, however, when investigators plan to withhold information about the real purpose of the study or purposely give subjects false information about some aspect of the research. As a result, subjects cannot prospectively give fully informed consent. Minor deception, such as withholding specific points of interest in an attempt to prevent a bias in the results can be acceptable, provided the subject is fully debriefed after participation, or when appropriate during the study.

Deception can only be permitted where the IRB determines and documents that waiver of the required elements of informed consent is justified.

Where deception is involved, the IRB needs to be satisfied that the deception is necessary and that the subjects will be debriefed. If the Principal Investigator believes that debriefing may be inappropriate, for example, when the debriefing itself would present an unreasonable risk of harm without a countervailing benefit, such as in an experiment like Milgram's obedience study,, then the IRB must determine what procedures must be taken to ensure full subject knowledge about the study.

The IRB will ensure that the proposed subject population is suitable for the research proposed.

Investigators are responsible for sufficiently informing the IRB and justifying the use of deception in proposed research and for providing a de-briefing at the end of the research (unless the IRB determines that such disclosure would create harm or increase risk to the subjects.)

Deception can only be permitted where the IRB documents that waiver of the required elements of informed consent is justified. Specifically, the IRB must find and document that all four of the following criteria have been satisfied:

- The research presents no more than minimal risk to subjects.
- The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- The research could not practicably be carried out without the waiver or alteration.
- Where appropriate, the subjects will be provided with additional pertinent information after participation.

## **Secondary Subjects and Third Parties**

In the course of participating in a research study, a human subject may provide information to investigators about other persons, such as a spouse, relative, friend, or social acquaintance. These other persons are referred to as "secondary subjects" or "third parties."

Secondary subjects would meet the regulatory definition of human subjects if, in the course of research, individually identifiable private information about them is collected. Therefore, a third party does not become a human subject unless and until the investigator obtains information about the third party that is both private and individually identifiable.

"Readily" identifiable is the criterion used in the regulations, and it should be distinguished from "possibly" or "potentially" identifiable information, which is significantly different in

degree.

While it may be possible to ascertain the identity of a third party (e.g., the father of the subject) by piecing together bits of information (e.g., familial relationship, name, address, date, and place of birth), making those linkages often requires time and special effort unless the third party's full name or other identifying information is also collected. Information that requires such effort should generally not be considered readily ascertainable.

Federal regulations describe "private" information as including "information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)." Although many types of health information are generally treated as private information, there are many exceptions. Information such as age, body build, and ethnic or cultural background that may have a bearing on health is generally not considered private. Information about family relationships and structure, marital status, social networks, and occupation is also generally not considered private.

In most cases, a researcher will ask a research subject (or the research subject will offer) information about a third party that is necessary to understand the health, life experiences, or behavior of the subject and which is relevant to the research question being addressed. Drawing on his or her own observations and experience, the subject reports his or her knowledge, perceptions or beliefs about the third party. Information about a third party that is obtained from the research subject as background information about the subject is not generally considered "private." Information of this type is deemed "contextual" since it is usually unverified information and is used to provide background information important to the condition and/or circumstances of the subject. Therefore, such information is generally not deemed "private."

Investigators and IRBs should evaluate carefully the relevance of the information obtained from the subject to the research study. If verification of the knowledge, perceptions, or beliefs of the subject about the third party is necessary, then the third party should be recruited into the study as a research subject. Informed consent must be obtained or may be waived for those third parties, following the criteria outlined in the regulations.

## The IRB and HIPAA

The privacy rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) will make obtaining protected health information (PHI) more difficult for A&M-Central Texas researchers. To access PHI, a researcher must either obtain valid patient permission or meet three waiver criteria:

- Disclosure of PHI is of minimal risk to the privacy of patients
- The research could not practicably be conducted without the waiver
- The research could not practicably be done without access to and use of PHI.

Authorization forms that assure research is HIPAA compliant are available from the covered entities where the study is conducted. The original authorization must be maintained with the data by the researchers and a copy of the form must be on file with the A&M-Central Texas IRB. The privacy rule does not override the federal regulations for human subjects research.

### A Covered Entity is:

- a health plan
- a healthcare clearinghouse, or
- a healthcare provider that transmits any health information in electronic form in connection with healthcare transactions.

### Protected Health Information Individual Identifiers (PHI):

- 1) Names that are associated with specific health records
- 2) Geographic subdivisions smaller than State (e.g., cities, streets, counties)
- 3) All elements of dates (except year) for dates directly related to an individual, e.g., birthday, date of death, date of hospitalization (Note: All ages over 89 must be aggregated into a single category called "age 90 or older")
- 4) Telephone numbers
- 5) Fax numbers
- 6) Electronic mail addresses
- 7) Social security numbers
- 8) Medical record numbers
- 9) Health plan beneficiary numbers
- 10) Account numbers
- 11) Certificate/license numbers
- 12) Vehicle identifiers and serial numbers, including license plate numbers
- 13) Device identifiers and serial numbers

- 14) Web Universal Resource Locators (URLs)
- 15) Internet Protocol (IP) address numbers
- 16) Biometric identifiers, including finger and voice prints
- 17) Full face photographic images and any comparable images; and
- 18) Any other unique identifying number, characteristic, or code, except as permitted by the provision for re-identification.

### **Research Use/Disclosure with Individual Authorization**

The Privacy Rule permits covered entities to use or disclose protected health information for research purposes when a research subject authorizes the use or disclosure of information about him or herself.

To use or disclose protected health information with authorization by the research subject, the researcher must obtain an authorization with a form on a case-by-case basis (e.g., a clinic form where the subject is a client). The Privacy Rule has a general set of authorization requirements that apply to all uses and disclosures, including those for research purposes.

### **Special Provisions Apply:**

- Unlike other authorizations, an authorization for a research purpose may state that the authorization does not expire, that there is no expiration date or event, or that the authorization continues until the “end of the research study;” and
- An authorization for the use or disclosure of protected health information for research may be combined with a consent to participate in the research, or with any other legal permission related to the research study.

### **De-identified Protected Health Information**

Health information that is effectively de-identified is not considered protected health information. While this might be helpful with some research, the Privacy Rule states that identifiers must be removed before information is considered de-identified.

The Privacy Rule states that in order for data to be truly de-identified, all of the above Protected Health Information identifiers must be removed. The source providing de-identified data must verify this and provide a statement that there is statistically less than a “very small” risk an individual’s identity can be detected. A certification of de-identification must accompany the IRB application upon submission for review.

Data that do not contain both health information and identifiers, such as de-identified data,

which used and stored by a covered entity may be used without authorization or disclosure.

## **The IRB and FERPA – Use of Educational Records in Research**

The Family Educational Rights and Privacy Act of 1979 (FERPA or the Buckley Amendment) is a federal law which states that “An educational agency or institution shall obtain the written consent of the parent of a student, or the eligible students before disclosing personally identifiable information from educational records of a student, other than directory information.” Thus, for any research which involves obtaining identifiable information from student records, the investigator must obtain written permission from the parents. Blanket permission giving access to any information in the records is not acceptable.

Although this is not a human subjects issue, per se, the IRB cannot approve a research project unless the procedures for complying with FERPA are acceptable. This is true regardless of the willingness of the school district or University (school) to release the information without permission. Although this is a school responsibility, the University (and the investigator) would also be liable for any violation of this law.

A school must have a student's consent (or a parent's if the student is under 18 years of age) and the student's assent if part of a research study prior to the disclosure of identifiable education records. The consent must be signed and dated and state the purpose of the disclosure.

The only information that a school may disclose without permission from parents or students is student directory information. (However, if desired, the parent/student can request that such information not be disclosed.)

### **Directory Information**

- K-12 Students
  - Name of student in attendance or no longer in attendance; address; date and place of birth; telephone listing; dates of attendance; participation in officially recognized activities and sports; height and weight, if member of athletic team; awards and honors received; and other similar information.
- College Students
  - Names, student Universal Identification Numbers (UINs), addresses (including email), and telephone numbers; Dates of attendance (including term units carried and full-time/part-time status); Classification (e.g. sophomore, senior,

graduate student): Major/minor/degree program; Degrees conferred (including dates/anticipated dates); Previous institution(s) attended; Awards and academic honors; and Participation in officially recognized sports and activities.

In order to access data other than directory information, the school must obtain Permission to Disclose to Third Party.

- Consent to disclose educational records for those under the age of 18 must be given by parent(s), legal guardian(s), or other designated person(s)
- For students over 18, only the student can consent to such disclosure. Such information includes course schedules, reports of concern, grades, disciplinary records, and student account information.

Except as provided by law, no outside agencies or individuals may have access to a student's record without written consent.

## **Video/Audio Recordings, Photographs**

Recording the voice and/or image of an individual creates a type of record that requires unique handling and storage, particularly if the content may be considered sensitive. As with all research procedures, the dignity of human subjects should be respected. Therefore, only what is necessary for the purpose of the study should be recorded.

Research subjects must be informed, prior to testing (e.g., in the consent form), that recording will occur and be provided with information about the storage, confidentiality, and future use of the resulting recording.

If a research protocol involves the recording of research subjects, the investigator must include the following elements for consideration in his/her protocol and, if relevant, informed consent form for submission to and review by the IRB:

### **Elements for consideration when recording:**

- Type of recording that will be utilized
- Specific identifiers that will be recorded, e.g., partial facial features, full facial features, subject's name
- People who will have access to the recording(s)/image(s)
- Mechanisms in place to protect the confidentiality of the person(s) being recorded;
- Clear indication of when the recording(s)/image(s) will be destroyed or that recording(s)/image(s) will be kept indefinitely or for a limited time
- Use(s) of the recording(s)/image(s), including educational or commercial purposes,

- analysis by the research team; or future unspecified use
- Compensation, if any, to subjects for allowing themselves to be taped/photographed.

If the taping/recording/photographing is an integral part of the research and not an optional procedure, a separate informed consent document is not required. However, documentation of the considerations listed above must be included within the body of the informed consent document for the overall study or as an addendum, on a case-by-case basis. It is important that this information be clearly indicated, preferably preceded by a heading, so that it is clear to the subject that a recording will be made.

If the recording is not required as part of the research procedures, then the consent document must include a specific statement indicating that participation in the research study is not contingent upon agreeing to be recorded. A separate consent signature for permission to record will be necessary. This permission can be in the form of a consent addendum, which includes the considerations listed above, or a separate signature line on the informed consent document labeled specifically for permission to tape or photograph. If a separate signature line is used, the considerations listed above must be included within the body of the informed consent document. For an assent form, elements must be disclosed prior to obtaining subject approval, as indicated in the relevant assent form.

The consent and assent addendums must be reviewed and approved by the IRB as part of the initial protocol review prior to implementation.

## **Computer and Internet-Based Data Collection**

Computer and internet-based methods of collecting, storing, utilizing, and transmitting data in research involving human subjects are developing at a rapid rate. As these new methods become more widespread in research in the social and behavioral sciences, they present new challenges to the protection of research subjects.

Internet-based research protocols must address the same risks as other protocols involving human subjects (e.g., violation of privacy, legal risks, and psychosocial stress) and must provide the same level of protection. All studies, including those using computer and internet technologies, must (a) ensure that the procedures fulfill the principles of voluntary participation and informed consent, (b) maintain the confidentiality of information obtained from or about human subjects, and (c) adequately address possible risks to subjects including psychosocial stress and related risks.

## **Data in Electronic Formats**

Information in electronic formats presents specific challenges to researchers when planning for methods of collecting, storing, transmitting, controlling access to, and disposing of information that adequately preserves the confidentiality, integrity, and availability of the data.

Electronic records can be quickly and readily replicated and circulated without any obvious indications that this has happened. Electronic records can also be easily modified, so it's important to consider controls that help to maintain their integrity.

The following recommendations are intended to address the key concepts of data confidentiality, integrity, and availability.

For projects that are minimal risk, if these data security safeguards cannot be put in place, then language in the consent information should be added indicating that complete confidentiality cannot be guaranteed and/or that encryption of responses is not provided.

## **Data Collection**

It is strongly recommended that any data collected from subjects over computer networks be transmitted in encrypted format. This helps insure that any data intercepted during transmission cannot be decoded and modified, and that individual responses cannot be traced back to an individual respondent.

It is recommended that the highest level of data encryption be used, within the limits of availability and feasibility. This may require that the subjects be encouraged or required to use a specific type or version of browser software.

Researchers are cautioned that encryption standards vary from country to country and that there are legal restrictions regarding the export of certain encryption software outside of US boundaries.

## **Data Storage**

Depending on the sensitivity of the data, and specific sponsor restrictions, the data should be stored in a secure location or manner that assures only authorized access to the data, and no unauthorized changes can be made to the data. Where feasible, consideration

should be given to backups in the event of loss or damage to the primary data collection.

The physical storage location should be reasonably secured against theft and loss due to fire, flood, electrical surges, and other forms of physical damage.

Personally identifying information (e.g., IP addresses) should be kept separate from the data or removed later from data records if they are integrated into them.

### **Data Transmission**

Many of the same concerns identified in Collection apply to the transmission of electronic records. Care must be taken to assure that data are not tampered with or viewed by unauthorized parties. Public/Private Key encryption successfully addresses these concerns.

### **Control of Data Access**

Password protection is the most common form of access control. Password protection can be implemented at various levels (e.g., the computer, folder, file, or database). When access control is combined with encryption, it assures that even if the media are inappropriately accessed, the data cannot be retrieved.

Other forms of access control include two-factor authentication, smart cards, and digital-certificate-based authentication. Access control is the responsibility of the Principal Investigator at all times and PIs should ensure that the most current access control technology is used when needed.

Physical access controls should not be overlooked when planning for adequate access controls. Physical controls (such as locks) when combined with technical controls (such as passwords or smartcards) provide for defense in depth. A double lock access is suggested for data to protect against a breach of security.

### **Destruction and Disposal of Electronic Data**

Depending on the nature of the research and the requirements of the sponsor, termination of the project may require destruction of the data. This should be accomplished by physical destruction of the media containing the data, or by using Department of Defense-approved methods and tools for purging magnetic drives (e.g., DBAN, SecureErase).

## Server Administration

It is recommended that for online data collection a professionally administered survey server be used or,

- The server is administered by a professionally trained person with expertise in computer and internet security
- Access to the server is limited to key project personnel and is configured with firewalls to minimize the possibility of external access to the server data
- There are frequent, regularly scheduled security audits of the server, and
- The server is subject to the periodic security scans.

## Electronic Recruitment of Subjects

Computer and internet-based procedures for advertising and recruiting potential study subjects (e.g., internet advertising, e-mail solicitation, banner ads) must follow the IRB guidelines for recruitment that apply to any traditional media, such as newspapers and bulletin boards.

Unsolicited e-mail messages to multiple users are prohibited unless explicitly approved by the appropriate authority. All messages must show accurately from where and from whom the message originated, except in the rare, specific cases where anonymous messages are invited. Researchers who want to recruit by email from all A&M-Central Texas faculty and staff members must have an email sent out from the Office of Research by the VPRED; the email must be approved by the Office of Research. Researchers who want to recruit by email from all A&M-Central Texas students must have an email sent out from the Office of Student Affairs by the Dean of Students; the email must be approved by the Dean of Students. The office sending the email will work with the PI to develop an appropriate email message.

Authentication (proper qualification and/or identification of respondents) is a major challenge in computer- and internet-based research and one that threatens the integrity of research samples and the validity of research results. Researchers are advised to take steps to authenticate respondents. For example, investigators can provide each study subject (in person or by U.S. Postal Service mail) with a Personal Identification Number (PIN) to be used for authentication in subsequent computer- and internet- based data collection.

## Oral History Projects and Case Studies

The policy of the University is for all oral history projects be submitted to the IRB for

evaluation to determine whether IRB review is required, unless the oral history study is conducted for classroom or course work use only.

Most oral history interviewing projects are not subject to the requirements of the regulations and can be excluded from IRB oversight because they do not involve research as defined by the regulations. The Oral History Association defines oral history as "a method of gathering and preserving historical information through recorded interviews with subjects in past events and ways of life."

It is primarily on the grounds that oral history interviews, in general, are not designed to contribute to "generalizable knowledge" that they are not subject to the requirements of the regulations and, therefore, can be excluded from IRB review. Although the HHS regulations do not define "generalizable knowledge," it is reasonable to assume that the term means more than just knowledge that lends itself to generalizations, which characterizes every form of scholarly inquiry and human communication. While historians reach for meaning that goes beyond the specific subject of their inquiry, unlike researchers in the biomedical and behavioral sciences they do not reach for generalizable principles of historical or social development, nor do they seek underlying principles or laws of nature that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes. Historians explain a particular past; they do not create general explanations about all that has happened in the past, nor do they predict the future.

Moreover, oral history narrators are not anonymous individuals, selected as part of a random sample for the purposes of a survey. Nor are they asked to respond to a standard questionnaire administered to a broad swath of the population. Those interviewed are specific individuals selected because of their often unique relationship to the topic at hand. Open-ended questions are tailored to the experiences of the individual narrator. Although interviews are guided by professional protocols, the way any individual interview unfolds simply cannot be predicted. An interview gives a unique perspective on the topic at hand; a series of interviews offer up no similar "generalizable" information but a variety of particular perspectives on the topic.

However, while most oral history projects fall outside the purview of the IRB, there are still those that fall within the category of "research" and contribute to generalizable knowledge. Therefore, the current A&M-Central Texas protocol submission requirement includes oral history studies except when the oral history project is completed within a classroom setting.

While they have some similarities to oral history projects, many case studies, especially

clinical cases, are designed to be published and are thus considered research. It is therefore the policy of the A&M-Central Texas IRB to require that case studies be submitted for review by the IRB.

## **Program Evaluation**

The policy of the University is that all external program evaluations or internal program evaluations considered to be generalizable must be submitted to the IRB for assessment to determine whether IRB review is required. IRB review is not required for program evaluations done for accreditation or to fulfill State of Federal agency reporting requirements (e.g., Texas Higher Education Coordinating Board (THECB)).

Some Program Evaluation projects may not be subject to the requirements of the Human Subjects research regulations and can be excluded from IRB oversight because they do not involve research as defined by the regulations.

When considering whether a program evaluation project needs IRB review the researcher should determine whether the project meets the definition of research as defined in the human subject protection regulations? That is, is it a systematic investigation, including research development, testing and evaluation designed to contribute to generalizable knowledge?

Program evaluation activities might not be considered human subjects research when:

- They do not involve experimental or non-standard interventions
- Their intent is only to provide information for and about the setting in which they are conducted
- The results will be used for internal (to the organization being evaluated) purposes only (e.g., efficacy, quality improvement, etc.)
- They are conducted as part of the standard operating procedures of the setting; and
- They are (usually) not subject to peer review.

### **Questions used in determining if a program evaluation project requires IRB review:**

- Is the goal of the program evaluation to test a hypothesis or answer a research question? If not, the activity is probably not research
- Will the activity benefit people or communities or entities other than those from whom the data are collected? If not, the activity is probably not research
- Is the activity a routine operation in the setting? If yes, it is probably not research
- Do the data gatherers have regular and routine contact with the data or the subjects? If yes, the activity is probably not research

- Does the activity alter the timing or frequency of standard procedures? If not, the activity is probably not research
- Is the entity in which the activity is taking place paying for it? If yes, the activity is probably not research
- Is the activity part of a research project? If yes, the activity is research.

If program evaluators are unsure whether their project is considered research, they should submit a protocol to the IRB for review.

## **Funded and Sponsored Projects**

Federal regulations require that each application or proposal for HHS-supported human subject research be reviewed and approved by the IRB. It is the University's rule to provide review for all human subject research regardless of the specific federal sponsor or even if a study receives no funding.

Therefore, for any grant/contract-funded project, investigators are required to submit a copy of the grant proposal for the related protocol. If a grant is linked to multiple IRB protocols then the IRB needs to know which protocols are related to that grant so that they can all be reviewed together.

The grant proposal must include information related to the protection of human subjects. Examples include information about:

- the number and qualifications of collaborating investigators and other members of the research team
- cooperating institutions or performance sites that may require separate or additional
- IRB review or an Assurance of Compliance
- characteristics of proposed research facilities that may affect subject safety or the confidentiality of data
- the feasibility of financial commitments made to subjects; and
- the cost of proposed subject protection measures, such as consent monitors or translators.

The IRB protocol must be also consistent with the grant proposal. Any discrepancies will require the investigator to either amend the current protocol or to submit a new protocol that is consistent with the grant application.

Grant-related IRB protocols are usually reviewed after the grant is funded, to avoid

reviewing studies that will not be done. However, if a grant sponsor requires that an IRB protocol be approved prior to submission, the IRB will review that protocol before submission. It is critical for grant submitters who must have prior IRB approval to submit their protocol early enough to give the IRB time for review, given the timelines for the review indicated in the section of this Handbook titled “Protocol Submission and Initial Review”.

## International Research

International research often requires additional safeguards to protect the rights and welfare of subjects. These include everything from the use of a translator if the person(s) seeking consent and/or collecting data is not fluent in the subject's language to waiving the requirement to obtain written consent based on local custom or risks subjects may encounter due to social or political conditions. Investigators who will be conducting research internationally should provide the IRB with at least the following information:

- Information about where the research will be conducted (both the geographic location and the performance site, where applicable) as well as any of the following that are available:
  - A copy of local IRB or equivalent ethics committee approval, where possible.
    - If there is no equivalent of the IRB for the research site, the sponsoring institution, or the country, the responsibility for Human Subject research accountability is weighted more heavily on the PI than in the United States. He or she must carefully monitor the research to maintain an ethical research environment.
  - A letter of support and contact information written to the researcher by someone familiar with conducting research in the proposed country. The IRB may contact this person if it has additional or follow-up questions.
  - A letter of approval from a local university department sponsoring the research, a local institutional oversight committee, or an indigenous council. In areas where government-issued research visas are required, a copy of the visa should be submitted.
- Information about the investigator's knowledge of the local research context, including information about the current social, economic, and political conditions. This should include a detailed description of the investigator's personal experience conducting research (or studying or residing) in the region
- Information about whether there are any additional risks subjects might face as a result of the population being studied and/or the local research context
- The language(s) in which consent will be sought from subjects and the research will be conducted, as well as whether the investigator fluent in this language, or whether

a translator will be used. If a translator will be used, it should be clear what risks, if any, this might pose for subjects, as well as how those will be minimized

- Copies of the translated informed consent documents and instruments, including verification of the accuracy of the translation(s)
- If the research is federally funded, information about the status of the assurance for the performance site, where applicable
- When composing an IRB protocol for an international research project, researchers should clearly demonstrate that the proposed procedures are appropriate given the culture, norms, and mores of local communities. Whenever practical, researchers should include local community representatives in the design of the research and consent processes to ensure that local concerns about research practices, goals, or uses of collective cultural or intellectual property are considered. Community collaboration in research design demonstrates concern for the ethical principles of justice (by articulating the equitable distribution of research risks and benefits in relation to community needs) and respect for persons (by recognizing the right of individuals to form groups with corporate agency).

**NOTE: Researchers conducting international research external to the U.S. must contact the RCO for a review of Export Control and Intellectual Property research procedures.**

## Pilot Studies

Investigators sometimes conduct pilot studies designed to develop or refine research procedures and instruments. Although data collected through pilot studies may not be used in research reports and publications, pilot studies represent part of the research process that leads to the development of or contribution to generalizable knowledge. As such, pilot studies require IRB review and approval. Experts reviewing draft research procedures or instruments are not considered human subjects, and IRB approval is not required for this.

In making determinations on pilot studies, the IRB recognizes that standards of scientific merit appropriate for a full-scale study (e.g., sample size and composition) may not be appropriate to impose.

## Record Retention and Storage

### Investigator Records

Record (e.g., consent forms, study-related correspondence, treatment records) retention requirements vary depending upon the nature of a research study, but the general rules are

as follows:

- Records must be kept for at least three years after the completion of the study, or longer if stipulated by the sponsoring agency
- records must be maintained in a secured place (e.g., double-locked storage) with access limited to relevant members of the research team, to maintain the confidentiality that has been promised to the subjects, as well as to the sponsors
- Before transferring custody of the records or destroying study records, PIs must contact the sponsor of the study if applicable.

**NOTE: Some HIPPA or FERPA studies may have different data retention requirements and must follow those requirements.**

## **IRB Records Maintenance**

The IRB maintains a file for each study, containing the following information:

- protocol application forms
- consent documents
- research protocol(s) (all versions of the protocol are retained)
- any other approval documents from other committees or agencies
- texts of advertisements for subject recruitment
- notifications of IRB decisions
- records of protocol extension activities
- reports on amendments and adverse events
- correspondence between IRB and investigators of the project, and
- agendas and minutes of the IRB meetings.

The IRB documents above must be retained for every protocol it reviews for at least three years after completion of/closure of that protocol. All IRB records are stored in a double-locked location, and it is recommended that a backup of all currently-stored records be maintained until the time for records disposal. IRB records are subject to periodic audits by the TAMU system Office of Research Compliance. In addition, the IRB shall submit approved copies of minutes for each IRB meeting to the RCO/Office of Research to be submitted to the TAMU system Office of Research Compliance. Minutes must follow the format agreed upon with that office.

## **Quality Assurance - Quality Improvement (QA/QI) Auditing**

The IO's mission is to ensure that the practices and procedures designed for the protection of the rights and welfare of human subjects at A&M-Central Texas are effective and are in compliance with relevant ethical principles, federal and state law and institutional policies

for the protection of research subjects. To accomplish this objective, IO will request periodic routine audits or evaluations to verify that research was reviewed and conducted in compliance with federal regulations and the IRB approved protocol.

The IRB has the responsibility and authority to directly observe or have a third party observe ongoing research projects and the consent process, as well as conduct continuing review of the project, including audits of research records. The IRB will audit research records randomly, for cause, and based on the compliance records of the investigators. Full cooperation by the Investigator and other members of the research team is expected. The IO will also request the audit of the IRB for quality improvement purposes.

The purpose of the audit is to ensure protection of the human subjects of research. The information gathered during the audit is for the IRB to use and monitor the implementation of approved protocols, identify areas that need improvement, and to gather information for continuous improvement of the audit tool or the audit process.

An audit may also occur as the result of a complaint regarding research. The complaint will result in a review if found necessary by the IO.

If information is discovered at the time of the audit that indicates that research subjects may be at risk, or that their rights are not being adequately protected, then the IRB has the authority to:

- Stop recruitment of subjects and/or restrict activities
- Suspend approval of the protocol
- Notify officials who will take appropriate action (e.g., notify sponsors, etc.)

The IRB and the IO will determine what actions to take, in consultation with the Research Compliance Officer. Results of all quality assurance reviews are reported in writing to the IO, Principal Investigator with copies to the IRB Chair, and other relevant personnel (e.g., sponsors or the TAMU system Office of Research Compliance), as appropriate.

If possible non-compliance is discovered during the audit, the non-compliance policies and procedures will be followed by the IO.

### **IRB Protocol Audit Process**

There are three main components of the Quality Assurance/Quality Improvement Program:

- Routine Evaluation of Protocol
- For-Cause Evaluation of Protocol, and

- IRB Evaluation.

### **Routine Evaluation**

The IRB will conduct an annual evaluation of randomly selected protocols. These protocols will be identified at random by performing queries of the IRB database using established criteria which includes but is not limited to degree of risk. The purpose of the routine evaluation is to determine if the rights and welfare of research subjects used in studies have been properly protected in accordance with all applicable regulations, laws, and policies.

### **For-Cause Evaluation**

For cause evaluations may be initiated by the IRB as a result of known or suspected problems in the conduct of human subject research. These for-cause evaluations will be performed to ensure the highest degree of research standards are being maintained in regards to the safety of human subject research.

### **IRB Evaluation**

The IO may request an evaluation of the IRB, its operations, and records annually, but no less than every two years. The evaluation will be conducted through random selection of documentation. The purpose of the Internal Evaluation is to determine the alignment of IRB records and forms to applicable federal regulations, law, and policies governing human research and to provide ongoing assessment of IRB operations for continuous quality improvement.

### **Selection of protocols for auditing may also be done in the following ways:**

- At the direction of the IO
- Both as random routine selection and as identified for-cause selection
- As a follow-up to corrective actions resulting from routine or for-cause audits
- At investigator request prior to sponsor auditing
- For other reasons not specified here but as requested by outside agencies (e.g. sponsors, journal editors).

### **Documents Reviewed**

The following are examples of documents that may be reviewed during the audit process:

- All IRB submissions and correspondence

- Documents essential for complying with any relevant rules and regulations
- Sponsor documents and correspondence
- Study protocol documents
- Recruitment and consent documents
- Research subject files
- Unanticipated Problems reports
- Protocol deviations
- Staff training records

Other documents may be reviewed, as necessary, specific to situations and types of audits being conducted.

### **Review Process**

The IO or RCO will contact the IRB Chair and then the principal investigator by telephone, e-mail or letter to provide notification of the anticipated audit, and schedule a date and time for the review. An explanation of the scope, rationale of the review, what material/documents will be required for review, and the duration of the audit process will be provided.

In the case of for cause audits, no prior notification is necessary.

### **Non-Compliance**

The IRB has as its primary concern the protection of the rights and welfare of human subjects involved in research and is responsible for the review and approval of all investigations involving human subjects. No study involving human subjects research may be undertaken at the University or by faculty/staff/students of the University either at the university or at other sites without prior approval of the IRB.

Non-compliance means significant failure by an investigator to abide by University rules and relevant government regulations for protecting human subjects in research. Instances of non-compliance would include, but are not limited to beginning research before securing Institutional Review Board approval, misuse or non-use of approved consent forms, failure to secure IRB approval before introducing changes in an on-going protocol, and continuing to gather study data from subjects after IRB approval expires. Noncompliance is typically due to poor procedural control, but if it is found to be willful or malicious, it will be considered scientific misconduct and reported to the RCO, the IO, and the system Office of Research Compliance, as well as to relevant federal agencies or sponsors.

Non-compliance with IRB guidelines is a violation of A&M-Central Texas rules and federal regulations for the protection of human subjects. Incidents of non-compliance must be reported both to ensure the protection of the rights of human subjects and to uphold the university's Federalwide Assurance. Non-compliance presents a serious challenge to the IRB. Regardless of investigator intent, unapproved research involving human subjects places those subjects at unacceptable risk. Any incident of non-compliance with IRB guidelines must be reported immediately to the IO, RCO, and IRB Chair.

If, after deliberation, the IRB, IO, or RCO determines that non-compliance has occurred, appropriate action will be taken to protect the rights and welfare of human subjects. In the case of serious or continuing non-compliance, the University will address the question of the investigators' fitness to conduct human subject research it will be deemed as misconduct and the IO will take remedial action, as necessary, in regard to the welfare of the research subjects and the research data gathered in noncompliance. Further, the institution will carry out the procedures as provided in the University's Policy and Procedures on Ethics in Research, Scholarship and Creative Work.

### **Reporting Noncompliance**

Investigators and study teams are encouraged to report any observed or suspected noncompliance with human subjects research. The following procedures should be used.

Contact the chair of the IRB, the Research Compliance Officer, or the IO

Submit an anonymous report via Ethics Point at the website below:  
(<https://secure.ethicspoint.com/domain/media/en/gui/25200/index.html>)

When reporting noncompliance, it is important to provide as much information as you know including:

The name of the PI

The title of the research study

IRB protocol number

Detailed information regarding the potential noncompliance (i.e., When did the noncompliance occur? Who was involved? What happened? Who witnessed the event?)

Notification of research subjects or re-consent of current research subjects

Modifications to the protocol or informed consent document

Modifications to the continuing review schedule

Periodic monitoring of other human subjects research involving the researcher(s) by the RCO or IRB

Prior suspension or termination of research

In order to demonstrate appropriate oversight of research activities and to comply with federal and state statutes, regulations, policies, and guidelines, IRB will investigate all allegations of noncompliance, seeking guidance from the IO or RCO. The IRB will strive to achieve informal resolution of noncompliance issues with the cooperation of the Investigator, when appropriate.

Two types of more problematic noncompliance are defined below:

### **Serious Noncompliance**

Any noncompliance that creates an increase in risks to subjects, adversely affects the rights, welfare and safety of the research subjects, or adversely affects the scientific integrity of the study

Willful violation of policies, state and local laws, and/or federal regulations may also constitute serious noncompliance

A single instance of noncompliance may be deemed as serious noncompliance upon consideration of the facts by the IRB.

### **Continuing Noncompliance**

A pattern of noncompliance that if unaddressed is likely to increase risk to subjects, adversely affect the rights, welfare and safety of research subjects, or adversely affect the scientific integrity of the study

The pattern may occur regardless of whether the noncompliance is a consequence of a lack

of knowledge on the part of the investigator or a willful lack of commitment by the investigator and study team to human subjects protection

**Possible sanctions by the IRB or IO include, but are not limited to:**

- Requiring more frequent review of an Investigator's research activities
- Requiring addition of a Faculty Sponsor to an Investigator's protocol(s)
- Suspending research activities until compliance is achieved
- Terminating committee approval for research activities

The IRB may also recommend additional sanctions to the IO.

Possible additional sanction recommendations include:

- Research privilege probation
- Suspension of research privileges
- Termination of research privileges
- Embargo of publications