Institutional Review Board Manual

University of the Incarnate Word

Office of Research and Graduate Studies
Fall 2018

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Short Guide to the UIW IRB Manual

The purpose of the UIW Institutional Review Board (IRB) is to **assure protection of human subjects involved in research** conducted by members of the UIW Community and others who want to conduct research within our community.

IRB Membership

IRB Members are elected to the Board for a three-year term (see **IRB Membership**, page 3). There is one member from the community-at-large and one prisoner representative who are nominated by the Board and appointed by the Associate Provost for Research and Graduate Education.

Human Subjects Research Reviews by the IRB *Table 1*

Review Level	Risk Level	Review Process
Exempt Review	Minimal or no personal risk of physical, psychological, or social harm	Reviewed by the Office of Research and Sponsored Projects Operations
Expedited Review	No more than minimal risk	Reviewed by the College/School IRB Representative and IRB Chair or Chair's designee
Full Board Review	More than minimal risk	Reviewed by the Full Board at a convened meeting

Who Must Apply for IRB Review?

- All UIW faculty and other employees conducting research with human subjects
- UIW graduate students doing masters theses or doctoral dissertations that involve research with human subjects
- UIW students conducting research with human subjects that does not fulfill requirements of a course

The Application for IRB Review

All applications must be submitted online via the UIW Ethical Review Manager system located at https://uiw.forms.ethicalreviewmanager.com/. The following materials must be submitted as part of the IRB Application. Incomplete applications will be returned to the investigator without review.

IRB Application Documents and Accepted Formats *Table 2*

Application Document	**Accepted Formats**
Application Form	Online form
Faculty Supervisor Agreement (if PI is a student)	Online form
Research Protocol	Online form
Informed Consent Documents	Word
Instruments Used for Data Collection (may include): • Surveys • Interview Questions • Forms on which data is recorded	Word, Excel, PDF
Appendices (may include): • Recruitment materials • Site access letters • Informational materials • Excerpts of relevant grant applications with additional information	Word, Excel, PDF

Non-UIW Researchers

Non-UIW researchers wishing to conduct research involving human subjects at UIW institutions must submit the following to the Office of Research and Sponsored Projects Operations to initiate a site access request:

1. Documentation of IRB approval from their home institution
2. Approved IRB protocol from their home institution (including any instruments, consent forms, marketing materials)

IRB Approval Process

1. The Office of Research and Sponsored Projects Operations will review submissions for completion and assign an internal tracking number for each protocol received.
2. A copy of the complete IRB application is sent for the appropriate review.
3. The review process may involve communication between the applicant and reviewers. This may include requests for revision or clarification of submitted materials and protocol language.
4. Upon approval, the application is assigned an approval number, and a letter of approval is issued.

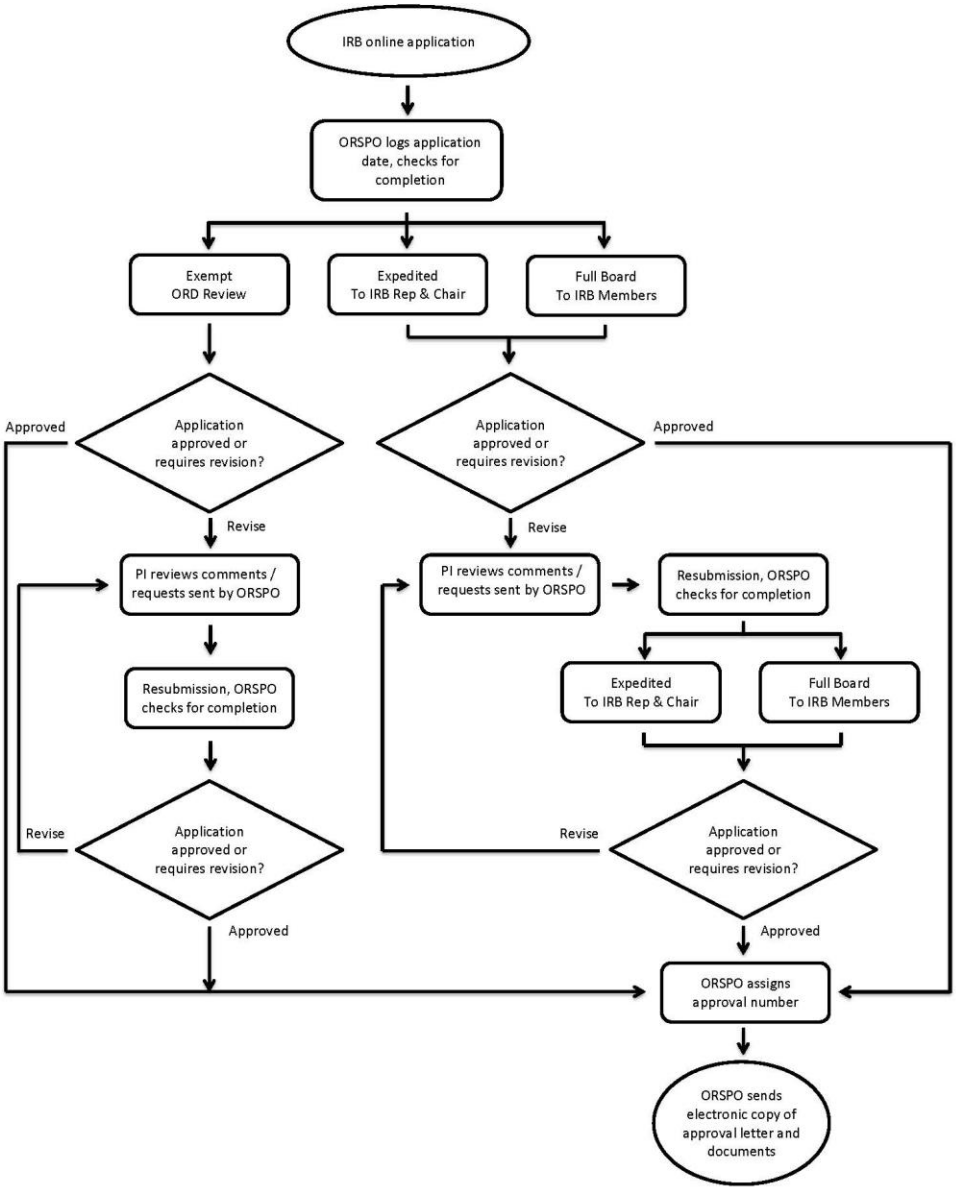
5. **Research cannot begin until the investigator has received IRB approval to conduct the protocol activities.**

Researcher Responsibilities

The final letter of approval sent to the principal investigator outlines the continuing responsibilities that the investigator has to the IRB while the research is being conducted. These responsibilities include:

1. Conducting the study only according to the protocol approved by the IRB.
2. Submitting any change(s) to the protocol and/or consent document(s) to the IRB for review and approval prior to the implementation of the change(s).
3. Ensuring that only persons formally approved by the IRB enroll subjects.
4. Reporting immediately to the IRB any severe adverse reaction or serious problem, whether anticipated or unanticipated.
5. Reporting immediately to the IRB the death of a subject, regardless of cause.
6. Reporting promptly to the IRB any significant findings that become known in the course of the research that might affect the willingness of subjects to participate in the study or, once enrolled, to continue to take part.
7. Timely submission of an annual status report at intervals designated by the IRB (but no less than once a year).
8. Completion and maintenance of an active (non-expired) CITI human subjects training certificate.
9. Timely notification of a project's completion.

IRB Submission Process



Introduction

The University of the Incarnate Word (UIW) Institutional Review Board (IRB) reviews all human subjects research conducted by UIW faculty, staff, and students, regardless of the location of the research activity or source of funding.

Federal regulation PL 93-348, National Research Service Award Act of 1974, requires that the UIW IRB assure protection of human subjects involved in all research conducted by faculty, students, and others employed at UIW.

The IRB process is consistent with the UIW Mission to hold the dignity and well-being of all persons in the highest regard. This ethical stance as regards the IRB process is founded on three key principles: respect for persons, beneficence, and justice.

The intent of this institutional policy is to foster high standards in the conduct of research and to assure uniform criteria are applied to protect the human subjects who take part in research.

The IRB reviews research in accordance with current Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations. The purpose of the IRB is to protect the rights and welfare of human subjects who take part in research. More specifically, the IRB assures that:

1. Risks to subjects are minimized. For example, the IRB evaluates whether procedures to be performed on subjects are consistent with sound research design and do not unnecessarily expose subjects to risk.
2. Risks to subjects are reasonable in relation to any benefits that might be expected from taking part in a research study and to the importance of the knowledge that may result.
3. Selection of subjects is fair and equitable. For example, the IRB seeks to determine that no eligible individuals are denied the opportunity to take part in any study, particularly those from which they may benefit, based on an arbitrary criterion such as gender or because they do not speak English.
4. Participation is voluntary and informed consent is obtained from each prospective subject or where appropriate, from the subject's legally authorized representative.
5. The research plan provides for monitoring the data collected to ensure the safety of subjects.
6. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
7. Safeguards are included to protect the rights of vulnerable subjects.

The IRB's Authority

Granted by Federal Law, the IRB holds the following authority relative to human subjects research conducted by faculty, staff, and students, regardless of the location of the research activity or source of funding, for the protection of human subjects:

1. To approve, require modifications to secure approval, or disapprove all research activities overseen and conducted by the faculty, staff, and students of UIW involving human subjects based on its consideration of the risks and potential benefits of the research and whether the rights and welfare of the subjects are adequately protected;

2. To require reports for protocol continuing review;

3. To continuously monitor the conduct of research with human subjects;

4. To suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected serious risk to subjects;

5. To place restrictions on a study, if necessary to protect human research subjects;

6. To observe, or have a third party observe, the consent process;

7. To observe, or have a third party observe, the conduct of the research;

8. To report acts of non-compliance to supervising faculty (student non-compliance), university officials, federal regulatory bodies, funding agencies, and research sites as needed.

No official within the organization may approve a protocol for human subjects research activity that has not been approved by the IRB.

IRB Membership

Appointment of Members

IRB Members are nominated by faculty within their respective College/Schools. Prior to nominations, the IRB may communicate particular areas of expertise to be filled to ensure the board includes sufficient representation of backgrounds and experience. Nominations are forwarded to the Office of Research and Graduate Studies for review to ensure the composition of the IRB complies with federal regulations. Reviewed nominations are then forwarded to the Faculty Senate to be included in the elections. The IRB Committee selects its own chair and non-affiliated member, approved by the Associate Provost for Research and Graduate Education.

Appointment of memberships to the IRB is conducted in a manner to ensure that the committee:

1. Is sufficiently qualified through experience and/or expertise (i.e. preferably composed of members with experience conducting independent research beyond the dissertation or terminal degree project) to safeguard the rights and welfare of human research subjects
2. Possesses the professional competence necessary to review research activity
3. Is able to ascertain the acceptability of proposed research in terms of institutional commitments and policy, federal regulations, and standards of professional conduct and practice
4. Has sufficient diversity of backgrounds and sensitivity to community attitudes as needed to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects

The roster of members is communicated online.

Member Terms of Service

IRB Members are appointed for three-year terms and serve Fall to Summer. IRB Members are expected to continue their service throughout the summer. IRB Member service will break for UIW holidays, including Christmas break.

Committee Composition

The IRB will consist of the following voting, active and ad-hoc members:

1. One voting member from each College/School whose expertise provides the competence necessary to review the research activity of their school (at least one of which must be scientific and at least one nonscientific)
2. One voting member from the community-at-large who is not otherwise affiliated with UIW and who is not part of the immediate family of a person who is affiliated with the institution
3. One or more (ad-hoc) individuals who are knowledgeable about and experienced in working with vulnerable categories of subjects
4. The Associate Provost for Research and Graduate Education will serve as an ex officio (non-voting) member

Member Responsibilities

Responsibility to Research Subjects
The IRB Member's responsibility to research subjects is paramount and foremost of all duties. Federal, local, and University policy are all formed and enforced for the ultimate purpose of human subjects protection. IRB Members, particularly the Community Member, have a responsibility to preserve the rights and welfare of research participants.

Federal Responsibility
The IRB is charged with review of proposed research protocols in order to ensure the rights of human subjects are protected and risk of harm to subjects is minimized. IRB Members must perform their duties within the framework of Federal requirements.

Responsibility to the University of the Incarnate Word
The IRB is an institutional committee and as such, IRB Members serve the institution as a whole, rather than a particular school or department. Members must not allow personal or departmental interests to supersede their duty to protect the rights, safety, and welfare of research subjects.

General Member Responsibilities
The commitment of IRB Members to research subjects, regulatory requirements, and the University is carried out through the following functional responsibilities:

1. Act as primary or secondary reviewer for assigned protocols, ensuring:
    a. Risks to subjects are minimized through sound research design and study hypothesis
    b. Risks to subjects are reasonable in relation to anticipated benefits
    c. Selection of subjects is equitable
    d. Informed consent is obtained (or waived, as appropriate) and documented effectively
    e. The protocol includes data and safety monitoring, if needed
    f. Subject's privacy and confidentiality are protected
    g. Additional safeguards are incorporated for vulnerable subjects
2. Attend scheduled IRB meetings – provide advanced notice the Office of Research and Sponsored Projects Operations of planned or emergency absences
3. Advise the IRB when additional, external expertise is required to adequately review protection of the rights, safety, and welfare of subjects or to comment on the acceptability of practices outside the IRB Members' fields
4. Serve as a resource for UIW researchers seeking assistance in designing human subjects protections during protocol development
5. Maintain current IRB Member CITI training
6. Adhere to the IRB Member Confidentiality Policy (page 5)
7. Adhere to the IRB Member Conflict of Interest Policy (page 6)

IRB Confidentiality Policy

During the process of initial, continuing review, or amendment of an activity, material provided to the IRB and Office of Research and Sponsored Projects Operations shall be considered privileged information. The IRB assures the confidentiality of the concepts, methodology, and data contained within materials submitted to the IRB for any type of review. It is the responsibility of the UIW IRB Members to maintain confidentiality regarding communications between the Board and any member of the UIW faculty, staff, and student body. All IRB Members and staff annually confirm their adherence to confidentiality of the privileged information contained within communications to the Board.

The following represent a limited set of circumstances under which protocol content or investigator information may be extended to the additional parties listed therein.

Consulting with External Subject Matter Experts
At times, the IRB may invite individuals with competence or necessary expertise to determine the scientific soundness of a research protocol or make an accurate determination of the risk to subjects. When required, the IRB Chair, or the primary reviewer after consultation with the IRB Chair, may request the assistance of an external subject matter expert to perform an in-depth review of the study.

External subject matter experts are not considered to be members of the IRB, are utilized only for expert review, have no voting rights, must disclose any conflict of interest with the protocol, and must sign a confidentiality agreement spanning the contents of the reviewed protocol(s).

External subject matter experts will be given a copy of all protocol materials and requested to submit a risk assessment of the protocol activities. The risk assessment and any recommendations will be disseminated to the IRB members reviewing the protocol.

Communicating Student Research Concerns
Should an IRB representative become concerned with the quality or content of a student's IRB protocol, the faculty supervisor will be contacted in an attempt to assist the student. If an issue persists, the IRB representative will notify the IRB Chair. The IRB Chair may consult other IRB Members to assist in developing human subjects protection education. If the issue regards academic integrity, UIW policy for academic integrity will prevail. If the issue remains unresolved, additional assistance may be sought.

Resolving Disputes between a Faculty Investigator and an IRB Representative
If a conflict arises between an IRB representative and a faculty investigator, the IRB representative will notify the IRB Chair, and the dispute will be arbitrated by the IRB Chair and Associate Provost for Research and Graduate Education. If the conflict remains unresolved, additional arbitration may be sought.

Reporting Non-Compliance
As a regulatory body operating under federal guidelines, the IRB is required to report non-compliance on the part of any researcher to: the supervising faculty (in the case of student non-compliance); university officials, to include academic dean or provost; federal regulatory bodies; any associated funding agencies; and any sites where research is conducted.

IRB Member Conflict of Interest Policy

In accordance with federal regulations, no IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB (45 CFR 46.107(d), 21 CFR 56.107(e)).

In order to prevent actual or perceived conflict of interest, potential for coercion, or the appearance of any conflict of interest or coercion, the following conflict of interest policies are outlined and must be adhered to:

1. An IRB Member may not review any application in which they serve as investigator, faculty supervisor, or other project personnel.

2. An IRB Member may not review any application from an investigator, faculty supervisor, or other project personnel with whom they are in direct competition.

3. An IRB Member may not review any application in which their department chair, academic dean, or program director serves as investigator, faculty supervisor, or other project personnel.

4. An IRB Member may not review any application in which a financial conflict of interest or perceived financial conflict of interest is present. This may include, but is not limited to:

    a. Applications which include funding from organizations in which an IRB Member or an IRB Member's immediate family holds employment, consultation positions, board appointments, or equity interest

    b. Applications which are presented with direct or indirect implication of financial benefit to the reviewer, their college/school, or the University in exchange for a positive review

If an IRB Member recognizes a conflict of interest in reviewing any application, they must report it immediately to the Chair and Office of Research and Sponsored Projects Operations so the application may be assigned to another reviewer. During Full Board reviews, an abstention may be recorded when an IRB Member has any concern that their impartiality may be compromised.

If any person associated with the IRB experiences undue influence or coercion, either directly or indirectly, to make a favorable decision for a specific application or investigator, the person is asked to document the issues related to the case and report it to the IRB Chair, the Associate Provost for Research and Graduate Education, and the Office of Research and Sponsored Projects Operations.

Institutional Review Board Office

The Office of Research and Graduate Studies, Office of Research and Sponsored Projects Operations provides administrative support for the IRB and serves as the liaison or communication center between the IRB and the investigators submitting their research for review.

The Office of Research and Sponsored Projects Operations has administrative responsibility for documenting that all human research activities approved by the Board are in compliance with federal regulations and guidelines and with institutional policy. The IRB Manual, online forms, and other policy information can be found on the IRB website.

Investigators should address all initial questions regarding use of human subjects or IRB actions to the Office of Research and Sponsored Projects Operations.

Mailing Address

Office of Research and Sponsored Projects Operations
4301 Broadway CPO 1216
San Antonio, Texas 78209

Campus Location

Suite 1A, Administration Building

Phone and Fax

Phone: 210-805-3036
Fax: 210-805-3559

What Needs IRB Review – Determination of Human Subjects Research

Human Subjects Research Activities Requiring IRB Review

Any UIW employee or agent who engages in human subjects research under a UIW appointment or affiliation is required to follow the UIW policies governing human subjects research included in this manual. This includes obtaining UIW IRB approval or exemption prior to beginning any research activities involving human subjects unless the UIW IRB cedes IRB oversight to another institution. For the purposes of this policy, the following definitions apply:

Agent: any individual performing institutionally designated activities (including students) or exercising institutionally designated authority or responsibility. See the HHS guidance on engagement of institutions in human subjects research.

Engagement: an institution is considered engaged in human subjects research when its employees or agents for the purpose of research obtain: (1) data about the subjects of research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. See the HHS guidance on engagement of institutions in human subjects research.

Human Subject (DHHS): a living individual about whom an investigator (whether professional or student) conducting research obtains:

(i) Data through intervention or interaction with the individual; or
(ii) Identifiable private information. [45 CFR 46.102(e)]

Intervention: Includes both physical procedures by which information are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction: Includes communication or interpersonal contact between investigator and subject.

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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information: private information for which the identity of the subject is or may be readily ascertained by the investigator or associated with the information.

Human Subject (FDA): an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient [21 CFR 56.102(e)]. In addition, a human subject includes an individual on whose specimen an investigational device or control is used, even if the specimen is anonymous [21 CFR 812.3(p)].

Research: a systematic investigation designed to develop or contribute to generalizable knowledge [45 CFR 46.102(l)]. Includes clinical investigations that support applications for research or marketing permits for products regulated by the FDA, including food and color additives, drugs, medical devices, biological products, or electronic products for human use (i.e., test articles). [21 CFR 56.102]

Note: The terms "systematic investigation" and "generalizable knowledge" are not defined in the federal regulations, but for the purposes of determining whether an activity is considered to be human subjects research at UIW, the following definitions apply:

Systematic investigation: an inquiry that is characterized by a predetermined and organized method of data collection and analysis to study a specific topic, answer a specific question, test a hypothesis, or develop a theory.

Generalizable knowledge: includes one or more of the following – information that will expand the knowledge base of a scientific discipline or other scholarly field of study; knowledge from which conclusions may be drawn that can be applied to a larger population beyond the site of data collection or the population studied; results that can be replicated in other settings.

Only those activities that meet the definitions of *research* with *human subjects* under the DHHS or FDA regulations require prior review and approval by the UIW IRB or one of the IRBs relied upon by UIW. Examples of *human subjects research* include, but are not limited to:

- Research studies that collect data *about* individuals through intervention or interaction with individuals. Interaction may include surveys, focus groups, and interviews. Intervention may include physical procedures (e.g., drawing blood), or manipulation of a subject's environment.
- Clinical studies that utilize test subjects or their specimens to investigate new devices, products, drugs, or materials.
- Research studies using private information or biological specimens where the investigators can readily ascertain the identity of the individual to whom the information or specimens pertain.
- Pilot or feasibility projects that will be used to develop or evaluate research procedures for a research project that will involve human subjects.

Activities Deemed Not Regulated Research (NRR)

When an activity does not meet both definitions of research and human subjects, no IRB review and approval is required. Examples of *not regulated research* include, but are not limited to:

- Observational studies of public behavior **ONLY** where there: is **no intervention or interaction with the subjects**, the **behavior is not private**, and there is **no manipulation of the environment** in order to stimulate certain types of behavior.

- Data collected for internal departmental, school, or other University administrative purposes, such as teaching evaluations and customer service surveys.

- Information gathering interviews or surveys where questions focus on things, products, or policies rather than on individuals or their personal thoughts, perceptions, or feelings. Examples include surveying university administrators about institutional admission policies, or interviews with company managers about how a product is made.

- Course-related activities designed specifically for educational or teaching purposes, where data are collected as part of a class exercise or course requirement, and are not intended to contribute to generalizable knowledge. See IRB Guidance on Student Class Projects.

- Quality assurance or improvement projects and program evaluations, unless the project is designed to contribute to generalizable knowledge. See IRB Guidance on QI/QA projects.

- Medical case histories or case studies if the case is limited to a description of the specific features/outcome of the case and do not contribute to generalizable knowledge.

- Research involving publicly available de-identified datasets or information, such as the U.S. Census, National Center for Health Statistics, or National Center for Educational Statistics.

- Research involving only retrospective secondary analysis of data or biological specimens that are not individually identifiable and were not collected for the current research project. See IRB Guidance on Secondary Data Analysis.

Authorization to Make NRR Determinations

It is the responsibility of investigators to make appropriate determinations based on UIW IRB policy. Each activity undertaken by UIW employees or agents must be evaluated by the individual most familiar with the planning of the activity. When an individual makes a self-determination that an activity does not constitute regulated research, the UIW IRB recommends that the individual documents in writing how the determination was made and retain this with the project records for at least three years after the conclusion of the project. The IRB has the authority to overrule an investigator's self-determination or the determination of other institutions. If a determination cannot be made, the investigator must submit the activity/project to the Office of Research and Sponsored Projects Operations for a determination. Investigators may also request a formal determination letter from the Office of Research and Sponsored Projects Operations by submitting the online Human Subjects Research Determination Questionnaire. The request should describe the activity in sufficient detail and provide adequate documentation for the ORSPO to make a determination.

Additional Guidance for NRR Activities

Regardless of whether a project is determined to be NRR or human subjects research requiring IRB review and approval, all UIW faculty, staff, and students are expected to follow adequate, discipline-specific guidelines to assure that projects are being conducted in a responsible, professional, and ethical manner. In addition, there may be other federal, state, local, or institutional laws and policies (e.g., HIPAA, FERPA) that may need to be considered even if federal regulations for human research protections do not apply. If a project is not regulated research, and the investigator intends to utilize a consent form or to publish/present the results, no references to IRB oversight should be included. When funding agencies, publishers, or external collaborators require documentation that the activity is not regulated research, the investigator should submit a request using the Human Subjects Research Determination Questionnaire for formal documentation.

In the following sections, more specific guidance is provided for the following activities that commonly lead to questions about whether the activities meet the definitions of research:

- Student Class Projects
- Quality Improvement/Quality Assurance Projects
- Secondary Data Analysis

IRB Guidance for Student Class Projects

Projects conducted by students enrolled in an official course (for credit or not for credit), as well as activities in fulfillment of class assignments involving data collection from individuals other than the members of the class, may be considered student class projects. These assignments are typically initiated and completed within the timeframe for a course. Faculty members may design assignments that require students to interact with individuals, or use data about individuals, to teach research methods or to help students understand concepts covered by the course.

Most student class projects do not require IRB review or oversight beyond faculty supervision, because their goal is educational and not the development of generalizable knowledge. Student class projects or assignments involving human subjects that are conducted for education, to teach research methods, and solely to fulfill a course requirement usually do not require IRB approval as long as they are not also designed and intended to contribute to generalizable knowledge.

Class projects involving human subjects that meet ALL of the conditions stated below may be conducted under the supervision of the faculty member without submitting a protocol to the IRB. Projects that do not meet all of these conditions must be submitted to the IRB for review.

The class project must:

- be a normal part of the student's coursework
- be supervised by a faculty member
- have as its primary purpose the development of the student's research skills
- NOT have as a primary purpose the intent to contribute to generalizable knowledge

The above refers to student class projects only. Independent research projects such as honors projects, theses, dissertations, and independent study projects that collect data through interactions with individuals or access to private information DO require IRB approval, IF they are designed to contribute to generalizable knowledge. For further guidance, see section on What Needs IRB Review – Determination of Human Subjects Research.

Faculty Instructor Responsibilities

It is the responsibility of the Faculty instructor to determine whether a class project involving human participants requires the approval of the IRB, and to contact the Office of Research and Sponsored Projects Operations if assistance in making this determination is needed.

As with any instructional activity, the Faculty instructor is responsible for the conduct and oversight of class projects or activities involving human participants. It is expected that adequate, discipline-specific guidelines are followed to assure that projects are being conducted in a responsible, professional, and ethical manner. This includes:

- Discussing the principles of ethical research with human participants with the class prior to the beginning of the project. This can be supplemented by the completion of online CITI human subjects training.
- Reviewing student projects and monitoring project activities to ensure that human participants are protected.

- Making sure students conducting projects inform participants of the voluntary nature of participation and employ measures to protect privacy and confidentiality, if applicable.
- If projects will be conducted outside of UIW, ensuring that there are appropriate permissions or authorizations from the external sites for the conduct of the project.

Disclosure to Participants

Students conducting class projects with human participants that do not require IRB approval should nonetheless disclose important information to the participants. The disclosure should not state that the project has been approved by the UIW IRB. If an informed consent document or cover letter is used, the following should be included:

- The student identifies him/herself as a UIW student who is performing the activity to fulfill a course requirement, and the course is identified.
- The name and contact information for the course instructor is provided, to contact for questions.
- The persons who will have access to the data are specified.
- Participants are informed that their participation is completely voluntary and that they can stop participating at any time.

Future Use of Data

The results of student class projects are typically not distributed through professional scholarly venues or presented as new knowledge that contributes to a scholarly or scientific discipline. However, students may present findings on or off campus if the purpose is to educate the student about the academic process and not to contribute to generalizable knowledge. If the possibility exists that either the faculty instructor or the student plans to disseminate the data as new, generalizable knowledge, then an application must be submitted to the IRB for review. It is very important that careful consideration be given to the possibility of any use of collected data for future research studies, since the IRB cannot retroactively approve data that was collected prior to IRB approval if the original project meets the federal definition of human subjects research.

IRB Guidance for Quality Improvement/Quality Assurance Projects

Quality Improvement (QI) Definition

Quality Improvement (QI) is defined as systematic, data-guided activities designed to bring about immediate improvements in health care delivery in particular settings. QI is an essential part of normal health care operations.

Human Subjects Research (HSR) Definition

Research is defined by the DHHS as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Research requires the oversight and approval of an Institutional Review Board when it involves human subjects. Human Subjects are defined as living individuals about whom a research investigator (either professional or a student) obtains data through intervention or interaction with the individual or from individually identifiable information.

Distinctions between QI and Research

Most (but not all) QI activities do not meet the federal definition of human subjects research requiring the review and oversight of an Institutional Review Board. However, since patient populations are frequently the target of QI activities, the distinction between QI and research is not always clear. To

further the confusion, attributes such as systematic data collection and publication/presentation of findings can be features of both research and non-research activities alike. Additionally, activities that start out as QI may lead to regulated human subjects research when a decision is made to use previously collected QI data for a research purpose. The chart below outlines some of the major distinctions between QI and research.

Distinctions between QI and Research *Table 3*

	Research	**QI**
Terminology	Referred to as a "study"	Referred to as a "project"
Purpose	To establish new knowledge that is generalizable or to reinforce existing knowledge for which inconclusive evidence exists	To assess or improve a process, program, or system or to improve performance as judged by established/accepted standards of care
Control Groups	Participants may be divided into control groups to test a hypothesis or intervention	May or may not involve group assignment but rigor of randomization does not exist
Benefits	Knowledge sought may or may not benefit current subjects, but may benefit future patients	Knowledge sought directly benefits a process/program/system, and may or may not directly benefit patients
Risks/Burdens	May put subjects at risk	Does not increase risk to patients beyond the risk of normal process of care, with the exception of possible privacy/confidentiality concerns
Informed Consent	Usually required	Not required, as it is part of the normal process of care
Methods	Rigorous systematic data collection	Systematic data collection, but not necessarily controlled or rigorous
Analysis	Statistically proves or disproves hypothesis; Data typically analyzed after a set end point	Compare a program/process/system to an established set of standards, or to establish internal benchmarks; Data may be continually monitored over time, and adjustments to the project may be made in response to the data
Results	Answers a research question	Improves or creates a program/process/system that results in greater safety, efficiency, or satisfaction
Dissemination	Scholarly, peer-reviewed publications and presentations	Publications and presentations to describe lessons learned;

		may be published in peer-reviewed journals that accept QI/QA projects

Quality Improvement IRB Checklist

This checklist is intended to provide a tool to help determine which QI projects meet the federal definition of human subjects research thus requiring IRB review and approval. Please answer both sets of questions below.

Quality Improvement IRB Checklist *Table 4*

Part 1: Is this QI? If you answer **NO** to any of the questions in Part 1, then IRB approval is required. If you are uncertain, please consult with your School's IRB Representative, the IRB Chair, or the Office of Research and Sponsored Projects Operations for further guidance.	**Yes**	**No**
Will the project benefit patients and/or improve a process/program/system?	☐	☐
Will all groups in the project receive, at minimum, the usual care at the institution/organization?	☐	☐
Is the purpose to measure the performance of or to determine the effect of a process change intended to improve health care delivery?	☐	☐
Will the results be used to inform and implement improvements in patient care at the institution/organization?	☐	☐
Part 2: Is this regulated human subjects research? If you answer **YES** to any question in Part 2, then IRB approval is required. If you are uncertain, please consult with your School's IRB Representative, the IRB Chair, or the Office of Research and Sponsored Projects Operations for further guidance.	**Yes**	**No**
Is the intent of the project either to establish new knowledge that is generalizable OR to reinforce existing knowledge for which inconclusive evidence exists?	☐	☐
Will patients or personnel be exposed to additional risks beyond those of usual care at the institution OR beyond what is ordinarily expected when practice changes are implemented within a health care environment?	☐	☐
Does the project involve withholding any aspect of usual care?	☐	☐
Does the project involve a drug or device used outside of usual medical practice, including non-FDA-approved agents, or off-label uses of FDA-approved drugs or devices?	☐	☐
Will the safety and/or effectiveness of a drug or regulated device be evaluated or compared to that of another?	☐	☐
Will the project be described as research in publications or presentations? (Note: QI findings may be published, but should not be described as research. The following statement may be used "*This project was conducted as a Quality Improvement initiative, and as such was not formally supervised by an Institutional Review Board";* a formal determination letter from the IRB may also be provided upon request.)	☐	☐

Ethical Conduct of QI Activities

Regardless of whether a project is defined as QI or research requiring IRB review and approval, all UIW students, faculty, and staff are expected to follow adequate, discipline-appropriate guidelines to assure that projects are being conducted in a responsible, professional, and ethical manner. In addition, there

may be other federal, state, local, or institutional laws and policies (e.g., HIPAA) that may need to be considered even if federal regulations for human research protections do not apply. If a project is not human subjects research, and the investigator intends to utilize a consent form or to publish/present the results, no references to IRB oversight should be included. When publishers require documentation that the activity is not human subjects research, the investigator should submit a request for a formal determination letter through the Human Subjects Research Determination Questionnaire. If at any point, the purpose and design of the project changes such that it could meet the federal definition of human subjects research, another request must be submitted to determine if the project will require IRB review and approval BEFORE the changes are implemented.

The ethical practice of QI activities in particular should be incorporated into the professional supervision of clinical practice. For further guidance on this matter please see the Hastings Center report "The ethics of using quality improvement methods in health care" available online at http://www.thehastingscenter.org/publications-resources/special-reports-2/the-ethics-of-using-qi-methods-to-improve-health-care-quality-safety/

IRB Guidance for Secondary Data Analysis

Secondary data analysis involves the use of existing data that was originally collected for different purposes in order to answer a research question. Some projects involving existing data sets do not meet the definition of human subjects research requiring IRB review. Other types of secondary data analyses do meet the definition of human subjects research and must be submitted to the IRB for either an Exempt determination, or IRB review (either Expedited or Full Board). Secondary data analysis requires IRB review when the data is identifiable. When IRB review is required, the level of review depends on how identifiable data is managed and how much risk is involved.

Secondary Data Analysis that is Not Regulated Research (NRR)
Secondary data analysis involving the use of existing data about living individuals does not meet the federal definition of human subjects research when the information in the data set is **not individually identifiable** (i.e., the identity of the subject is not and may not be readily be ascertained by the investigator or associated with the information). In other words, secondary data analysis does not require IRB review if the dataset is **completely de-identified** when the investigator accesses it for research purposes, and there is **no way of linking the data back to the subjects** (either through a key to a coding system or other means).

Secondary Data Analysis that is Eligible for Exempt Status
The federal regulations identify specific types of research that are considered Exempt from IRB review. It is important to understand that the Exempt research must still be submitted to the UIW IRB to confirm its Exempt status – per UIW policy, investigators may not make this determination themselves.

Secondary research use of **existing data, documents, records, pathological specimens, or diagnostic specimens** is eligible for exempt determination if:

- These sources are **publicly available**, or
- the information is **recorded by the investigator** in such a manner that **subjects cannot be identified**, directly or through identifiers linked to the subjects.

Investigators conducting research that meets one of the conditions listed above must submit an application to the UIW IRB and identify the research as “Exempt” on the application form. The Research Protocol must specifically describe how the research meets the criteria for Exempt status described in this manual.

Secondary Data Analysis that is Eligible for Expedited Review

If secondary data analysis of data about human subjects does not qualify for Exempt status, the project may be eligible for Expedited IRB review. More specifically, nonexempt 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), is eligible for Expedited review **IF** it presents **no more than minimal risk** to the subjects. The regulatory definition of minimal risk is: the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. If the research presents more than minimal risk to subjects, Full Board review is required.

Types of IRB Review

The IRB provides three types of review of proposed studies: exempt status review, expedited review, and full Board review. The type of review a study receives depends upon the risks to the potential subjects posed by the research and categories of research defined by federal regulations. Research qualifies for **exempt status** only if it involves no more than *minimal risk* or no risk to participants and falls within one or more of the exemption categories listed in 45 CFR 46.101(b)(1-6) Research qualifies for **expedited review** only if it involves no more than minimal risk to subjects and falls within one or more of the minimally invasive procedures approved by the DHHS. In all other cases, **full Board review** at an IRB convened meeting is required.

Federal regulations define minimal risk as risk that is no greater in probability and severity than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy adult is no greater than the risk of doing so as part of a routine physical examination. This definition of minimal risk serves as the benchmark to determine whether proposed studies are eligible for an expedited review or require the review of the full Board.

Human Subjects Research Reviews by the IRB *Table 1*

Review Level	Risk Level	Review Process
Exempt Review	Minimal or no personal risk of physical, psychological, or social harm	Reviewed by the Office of Research and Sponsored Projects Operations
Expedited Review	No more than minimal risk	Reviewed by the College/School IRB Representative and IRB Chair or Chair's designee
Full Board Review	More than minimal risk	Reviewed by the full Board at a convened meeting

The sections that follow outline the specific criteria to be used to determine whether a study is eligible for exempt or expedited review.

Exempt Status Review

To assure protection of human research subjects, institutional policy requires that all protocols believed by the investigator to be exempt must be reviewed by the Office of Research and Sponsored Projects Operations to certify whether the research in fact qualifies for exempt status. While most research activities in this category do not undergo IRB review, the ORSPO requires review to confirm exempt status and to determine that the research meets the ethical standards of UIW.

Exempt Review Categories

Research activities which involve no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories are considered exempt according to 45 CFR 46.101(b)(1-6):

Category 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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.

This exemption DOES NOT apply to research involving minors, except for research involving only educational tests or the observation of public behavior when the investigator does not participate in the activities being observed.

Category 3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section if (i) the human subjects are elected or appointed public officials or candidates for public office or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Category 4: 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 investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Category 5: 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: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures, or (iv) possible changes in methods or levels of payment of benefits or services under those programs.

Category 6: Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) 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.

These exemptions do not apply to research involving prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

Expedited Review

The following are situations where Expedited Review is allowable:

1. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories listed below, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The

activities listed below should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

2. The categories in this list apply regardless of the age of subjects, except as noted.

3. The expedited review procedure may not be used where 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, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

4. The expedited review procedure may not be used for classified research involving human subjects.

5. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or full--utilized by the IRB.

6. Categories one (1) through five (5) pertain to both initial and continuing IRB review.

Expedited Review Categories

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) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) 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, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children [NOTE: Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a)], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

Category 3: Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring 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 subgingival 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.

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 subjects' 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).

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.

Full Board Review

Research which is not eligible for administrative review under the above criteria as exempt or expedited or which involves deception with greater than minimal risk requires full IRB review.

Informed Consent

No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representatives (legal guardian or durable power of attorney for health care). Exceptions must be approved by the IRB.

In most cases, informed consent must be documented by use of a written informed consent form, to be signed by the subject or the subject's legally authorized representative. Electronic signatures may be used, but a written copy must always be given to the person signing the informed consent form.[1] The IRB must approve all consent documents to be used, and approve all study personnel who will obtain consent. Approval must also be obtained from the IRB for each modification made in the form thereafter, before instituting the change. The version of the consent document being used should match exactly with the version given final IRB approval in the protocol file. The IRB office will issue the approved version of the consent form stamped with "University of the Incarnate Word IRB Approved," the application number, and date of approval. Electronic surveys not requiring written informed consent must have the IRB approval number inserted into the survey before they are used.

The consent document is a legal document containing sufficient information to allow the prospective research subject to make an informed decision about whether or not to participate in the research. It is not intended to be a protection for the investigator and does not constitute any waiver of liability. The signed consent document provides documentation of a subject's consent to participate in a study.

Process of Obtaining of Consent

The process of obtaining informed consent must comply with the requirements of 45 CFR 46.116. The federal regulations mandate the following features be included in the informed consent process:

- The prospective subject or the legally authorized representative must be provided with sufficient opportunity to discuss or consider whether or not to participate. The possibility of coercion or undue influence must be minimized.
- The prospective subject or legally authorized representative must be provided with information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
- The informed consent document must present information in sufficient detail, but worded in a manner that can be readily understood by the potential subjects.
- No informed consent document may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Required Elements of Informed Consent

Each of the following points must be covered in the consent document, except in cases where the point is irrelevant to the research (45 CFR 46.116[b]):

[1] For more guidance on electronic informed consent, see https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/index.html

1. At the beginning of the consent document: a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.
2. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are non-standard and/or developed specifically for this research.

3. A description of any reasonably foreseeable risks or discomforts to the subject, their frequency and severity. These include, but are not limited to hazards of procedures, withholding methods of proven value, financial risk, and loss of privacy. Describe what will be done to minimize risks.

4. A description of any benefits to the subject or to others which may reasonably be expected from participation along with a disclaimer that the investigator cannot guarantee there will be any benefit derived from taking part in the study.

5. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

6. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

7. For research involving more than minimal risk, an explanation as to whether there will be any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

8. Identification including the full name(s) and 24-hour phone number(s) of the investigator(s) the subject may contact for answers to questions about the research. Also include the contact information for the Institutional Review Board should subjects have any questions regarding their participation, rights and/or research procedures, and whom to contact in the event of a research-related injury to the subject.

9. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

10. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

    a. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

b. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional Elements of Informed Consent

The following additional elements of informed consent should be included when appropriate (45 CFR 46.116[c]):

1. A statement that the particular treatment or procedures may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

2. Anticipated circumstances under which the subject's taking part may be terminated by the investigator.

3. Any additional costs to the subject that may result from participation in the research.

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue to take part will be provided to the subject.

6. The approximate number of subjects involved in the study.

7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing.

Distribution and Storage of Signed Consent Documents

Both the subject and the investigator will sign two copies of the consent form. A complete, signed copy of the consent document must be given to each subject. A copy with original signatures must be retained in the investigator's file for a minimum of five years after completion of the study.

Waiver of Consent

The IRB may waive the requirement to obtain informed consent in some circumstances. Such a waiver may be given when the following conditions exist:

1. The research involves no more than minimal risk to the subjects;

2. The research could not practicably be carried out without the requested waiver;

3. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

4. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Waiver of Requirement for Signed Consent

The IRB may waive the requirement of signed consent in some circumstances, and may require instead that a written statement describing the research be given to the subject. Such a waiver may be given when **one** of the following conditions exists:

1. The only record linking the subject and the research would be the consent document and the principal risk would be resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

2. 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; or

Screening Studies to identify Eligible Subjects

If a procedure is to be performed solely for the purpose of identifying a population of research subjects, consent for the screening test and/or process is required. Often, it is appropriate for the screening to be presented in a separate consent document describing the screening procedure and stating that its purpose is to determine eligibility for participation in further studies. A separate consent document for the actual study would then be signed by individuals found to be eligible. In such situations, at the time the subject is enrolled for the screening procedures, the prospective subjects should be shown the document they will be asked to sign if they meet the criteria for further study.

Non-English Speaking Subjects

If the research subject does not understand English sufficiently to be able to give informed consent, consent should be obtained in the language readily understood by the subject. Translations of consent documents should be available at the outset of a study if it is anticipated that non-English speaking subjects will be enrolled.

Format of the Informed Consent Document

Templates for adequately detailed, stylistically acceptable consent documents are available on the IRB's website. The templates include the required and recommended elements of consent, with additional elements recommended by the UIW IRB and suggested language for each section. It is strongly recommended that UIW investigators use the templates to develop informed consent documents, modifying them as appropriate for their specific studies.

Language

The informed consent form should be written in the second person, which addresses the prospective subject directly and emphasizes his/her voluntary decision making. It must be written in language that is simple enough to be readily understood by the least educated of the subjects to be utilized (normally this

should be simple enough for an eighth grade student). Scientific terms should be avoided when possible. If scientific terms must be included, the lay definition should be provided.

Unnecessary mixing or repetition of the informational content should be avoided whenever possible. This helps the prospective subject focus on each individual element of consent thereby enhancing the comprehension of the information presented.

Two or More Consent Documents
It sometimes is necessary to use two or more consent documents when procedures are to be performed on subgroups of subjects or when reasons for subject selection differ. The most common example of this situation is studies which involve a treatment and a control population. If there is more than one consent document, place a label after the title indicating the subject population to which each is addressed.

Technical Elements
At the top of the first page, the consent document should bear the title of the study, e.g., "Subject Consent to Take Part in a Study of...(give title of study)," and the name(s) of the institution(s) at which it is to be conducted. Pages should be numbered "1 of 4," "2 of 4," etc. At the end of the consent document there should be statements that the subject will be given a signed copy of the form to keep and that his/her signature means he or she has read the document and been given the chance to discuss it and ask questions.

Spaces should be provided for: (a) the signature of the subject who consents to take part; or in the case of a minor, of the parent or guardian who consents on behalf of the subject and a line for the assent of the subject if age 7 or older; (b) the signature of the investigator or other approved person who enrolls the subject; and (c) the date consent is obtained.

Guardian Consent

Unless he/she is also a court appointed guardian or has durable power of attorney to consent for medical treatment, a "next-of-kin" usually cannot give consent for research on an adult subject. Consent for a child to take part in research must be obtained from a parent or legal guardian. Generally, age 7 is accepted as the age at which assent is sought. Emancipated minors (those under 18 years of age and married, or those for whom minority status has been court-removed) may consent on their own to take part in research. Although some minors may consent to certain types of medical treatment, there is no legal precedent that they, by themselves, may consent to take part in research.

Regarding enrollment of subjects who are incompetent, incapacitated, or otherwise cognitively impaired, Texas state law permits the adult next-of-kin to consent to medical treatment, including that given in the context of a research proposal. This is only permitted if the IRB finds that it is appropriate and that sufficient safeguards have been incorporated into the protocol to protect the subject.

Generally, the IRB must consider: (i) whether there is a compelling reason to include incompetent individuals in the research (i.e. the research could not otherwise be completed due to inadequate numbers of eligible competent subjects; generally surrogate consent is reserved for evaluation of life saving measures which could not otherwise be tested); (ii) whether there is a favorable risk/benefit ratio (the research must be intended to benefit the individual subject and the probability of benefit is greater than the probability of harm); (iii) that under no circumstance will subjects be forced or coerced to participate; and (iv) that the subject's representatives will be well informed about the nature of the study and that their obligation is to try to determine what the subject would do if competent or if the subject's

wishes cannot be determined, what they think is in the incompetent person's best interests. Information that would allow the Board to evaluate these criteria must be provided.

In addition, for those studies approved by the IRB to enroll subjects by surrogate consent, there should be provisions for informing the subject immediately if he/she becomes competent and for obtaining the subject's signature to indicate he/she was informed about having been enrolled in the study. If the subject becomes competent and there are study activities to continue (such as follow-up visits), the subject should also be asked whether or not he/she consents to continue in the study.

Assent

Adequate provisions must be made for soliciting the assent of children, when the children are capable of providing assent. The ages, maturity, and psychological state of the children involved should be taken into account. Generally, age 7 is accepted as the age children should give assent. If the procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, assent of the children is not a necessary condition for proceeding with the research. Regarding the involvement of adults who are mentally disabled, in addition to the consent of a legally authorized representative or guardian, the feelings and expressed wishes of the incompetent person should still be respected. Investigators should both inform the subject and solicit his/her assent to take part in the study. (45 CFR 46.408)

Deception

The IRB recognizes that in some cases, informing the subject of the hypothesis being tested may result in a biased response. Under these circumstances, the nature of some studies requires that the full purpose not be revealed to a subject until the study has been completed. The deception to be employed must be: (a) explained and justified in the protocol (b) explained in a debriefing statement required in the protocol which describes the true intent of the study and which must be read to the participant at the close of the study. Studies which use deception but impose no more than minimal risk to participants qualify for expedited review provided they adhere to the requirements described herein.

Guidelines for Subject Consent in Exempt Survey Research

Survey research involving the use of self-administered questionnaires and telephone and face-to-face interviews generally places subjects (respondents) at minimal risk. Minimal risk could involve possible invasion of privacy and disruption of normal routine. Further risks could include possible legal risks, possible inconvenience, embarrassment, and other kinds of psychological discomfort. Such risks may become more than minimal when sensitive information (such as sexually transmitted diseases, AIDS, alcohol and drug abuse) is requested. Survey or interview-based research involving minimal or no risk is usually categorized as Exempt from federal regulations, including requirements for informed consent. However, information about the research and the voluntary nature of the study should still be provided. Guidelines for such cases are provided below.

Self-Administered Questionnaires in Exempt Research

A cover letter or introductory statement containing the following information should accompany a self-administered questionnaire:

1. An explanation of the purpose of the questionnaire.

2. An explanation of how and/or why the subject was asked to participate.
3. A statement of the amount of time the questionnaire will require.
4. A description of any stresses associated with sensitive information elicited.
5. A description of any benefits reasonably to be expected.
6. An offer to answer any inquiries concerning the questionnaire.
7. An instruction that the subject is free to refuse to fill out the questionnaire.
8. An assurance of confidentiality, including how confidentiality will be provided and maintained.

In the instance that there will be no way of tracing respondents, return of the questionnaire to the investigator will be considered to be adequate informed consent provided the cover letter including the above information accompanied the questionnaire.

Surveys or Interviews in Exempt Research: Telephone, Face-To-Face, or Electronic
Whenever possible, a letter should precede an interview to inform the subject of the impending interview. The letter should contain the following information:

1. An explanation of the purpose of the interview and the kinds of questions to be asked.
2. An explanation of how and/or why the subject was chosen to participate in the study.
3. A statement of the amount of time the interview will require.
4. A description of any benefits reasonably to be expected.
5. An instruction that the subject is free to discontinue the interview at any time without prejudice.
6. An explanation of confidentiality.

At the beginning of the interview or electronic survey, the information contained in the letter should be reiterated to the subject again by the interviewer.

In the instance of telephone interviews, and assuming that the information letter is part of the process, the oral consent of the interviewee to continue the interview will be considered to be informed consent.

In the instance of face-to-face interviews, the informed consent document should be in writing. Informed consent should be obtained prior to the interview. The signatures of the subject and the approved person obtaining consent should be contained in the consent document. Like the letter and spoken introduction, the informed consent document should include all the relevant information listed in the Required Elements Informed Consent section.

Submission, Review, and Additional Approval Considerations

Submission

All requests for IRB review must be submitted electronically via the UIW online IRB system at https://uiw.forms.ethicalreviewmanager.com/, regardless of applicant's discipline, college/school, or review category (Exempt, Expedited, or Full Board).

The following materials must be submitted in the indicated accepted formats as part of the IRB Application. The Application Form and Research Protocol are submitted via online forms. Informed Consent Documents, Instruments for Data Collection, and Appendices are uploaded to the Documents section of the online application. Incomplete applications will be returned to the investigator without review.

IRB Application Documents and Accepted Formats *Table 2*

Application Document	**Accepted Formats**
Application Form	Online form
Faculty Supervisor Agreement (if PI is a student)	Online form
Research Protocol	Online form
Informed Consent Documents	Word
Instruments Used for Data Collection (may include): • Surveys • Interview Questions • Forms on which data is recorded	Word, Excel, PDF
Appendices (may include): • Recruitment materials • Informational materials • Site access letters • Excerpts of relevant grant applications with additional information	Word, Excel, PDF

Review

In general, applications will be approved within the timeframe indicated (Table 5). This is an estimate and meant to serve only as assistance for project planning.

Estimated Duration of Reviews by the IRB *Table 5*

Review Level	Risk Level	Submission to Approval
Exempt Review	No personal risk of physical, psychological, or social harm	1 week
Expedited Review	No more than minimal risk	2—4 weeks
Full Board Review	More than minimal risk	8—10 weeks

There are many reasons a review may take longer.

- Incomplete documents (e.g., missing documents, incomplete sections)
- Writing quality (e.g., incomplete sentences, grammatical errors)
- Clarifications needed (e.g., protocol uses undefined jargon)
- Insufficient protection for human subjects (e.g., inadequate consent procedures)

Written notification of the results of the IRB review is sent to the investigator. The review process should be a communicative process between the applicant and the IRB. Comments and suggestions for revision made by the IRB should be considered by the applicant and are made in the spirit of improving protections for the proposed human subjects. Applicants are, however, the subject matter expert of their own research and are welcome to provide justification contrary to IRB recommendations.

Approval

Upon approval, the Office of Research and Sponsored Projects Operations will assign an IRB number for each protocol. An approval letter indicating the investigator's responsibilities (see **Responsibilities of the Principal Investigator for Research in Progress**) is issued. When the letter of approval has been received, the study may begin.

The approval of expedited protocols is reviewed and endorsed at the next convened full Board meeting and is recorded in the minutes. While it rarely occurs, IRB Members have authority to question exempt and expedited approvals.

Additional Approval Considerations

Approval of Other Committees

In addition to IRB approval, a research project may need the approval of other committees before it is implemented. Submission of a protocol to committees other than the IRB is the responsibility of the investigator.

Approval by Other IRBs

The approval of faculty, staff or students' research by another institution's IRB cannot substitute for the requirement to have the protocol reviewed by the UIW IRB. When the study site institution has no IRB, other appropriate administrative approval must be obtained. Consult the IRB office for assistance.

Other Approvals

The proposed research may require the approval of other organizations or individuals. It is the responsibility of the principal investigator to obtain any additional approval before data collection begins.

International Research Considerations

Research conducted by University investigators in foreign countries remains under University purview and requirements including IRB approval**.** University researchers seeking to work in foreign countries should be mindful that the requirements for prior review and approval of research is not obviated by the location of the study.

The Office of Human Research Protections has compiled a list of laws, regulations, and guidelines on human subjects protections in over 100 countries and from several international organizations: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/. This compilation should be consulted to determine country-level guidelines applicable to the planned research project. The IRB proposal should include information about the ethics requirements of the country and community where the study will be conducted and provide contact information for that body. The IRB will require additional information and documentation if the research is federally funded.

Researchers may be expected to document relevant experience and expertise related to the cultural norms and conditions of the participants:

1. Researcher qualifications (coursework, experience, training, etc.) that demonstrate international research capabilities.
2. Description of cultural norms, local laws or regulations that govern the conduct of research at the proposed location (e.g. age of majority, parental consent requirements, prior approvals, conditions for continuation, etc.). The researcher(s) must understand that local requirements may influence the design of the inquiry but compliance with U.S. and UIW regulations for the conduct of research is expected and cannot be waived.
3. Researcher identification of the language(s) of the community and ability to read, speak, or write the language of the proposed participants.
4. Describe how researcher(s) have appropriate access to the proposed community (e.g. invitation).
5. Describe the steps to be taken to minimize risk associated with participation in the proposed study in regards to the cultural, political, religious or economic (or other) climate of the community/country where the research is proposed to be conducted.
6. Provide a translated copy of the consent/assent form (as appropriate) and describe the means by which that translation was conducted.
7. Describe the means of communication with the IRB in the event of reportable events or required changes.
8. If the researcher(s) is a student, describe the means of communication with and supervision by the faculty advisor.

At UIW, research projects falling under the Expedited and Full Board review categories must have been approved by the local equivalent of an IRB **before** they are submitted to the UIW IRB. Where there is no equivalent committee, investigators must rely on local experts or community leaders to provide approval. The IRB requires documentation of this "local approval".

While the IRB at UIW cannot impose standards for written documentation on other cultures, the requirements for consent, assent, cultural responsiveness and ethical conduct of research cannot be waived. However, in some instances the IRB may waive some or all requirements for written consent. Research proposals for which this is requested should include explanations of cultural, religious, or other norms or conditions requiring such as waiver.

Preparing an Application for IRB Review

It is essential that the entire application be prepared carefully and completely according to the guidelines on the online forms and in this Manual. The applications become permanent IRB records and are subject to inspection and review by funding agencies and, where applicable, by the FDA and DHHS.

Because funding sources have different application requirements, IRB application forms are designed to allow flexibility in the format of materials submitted for review. Certain elements are required but may vary in form.

There are five essential elements of the IRB Application:

1. Application Form
2. Faculty Supervisor Agreement (if PI is a student)
3. Research Protocol
4. Consent Documents
5. Instruments Used for Data Collection
6. CITI training on research involving human subjects

Application Form

This form provides basic information on the PI, Faculty Supervisor (if PI is a student), other project personnel, the planned research activities, and any funding sources. Additional details on personnel and roles follows:

Principal Investigator: Indicate the name, phone number, e-mail address, mailing address, department, and CITI training date of the individual who assumes responsibility for the overall conduct of the study and preparation of results. The principal investigator will be the responsible correspondent.

Faculty Supervisor: If the Principal Investigator is a student, then a Faculty Supervisor or Thesis/Dissertation Chair must supervise the project. Supervision is defined as:

1. Direct knowledge of and responsibility for the direction and completion of the project
2. Assurance of student compliance with University and Federal human subject protection policies
3. Filing of required documents which verify revision, amendment, annual continuation, or completion of the supervised protocol.

For protocols with a planned duration equal to the duration of a course, the Course Instructor or Faculty Supervisor must ensure that the participating student investigator(s) are informed of the requirement to submit appropriate UIW IRB completion or continuation documents. If it is anticipated or determined during the study that the IRB approved protocol will extend beyond the duration of an investigating student's involvement in the course or graduate program, then a long-term Faculty Supervisor must be designated prior to course, thesis or dissertation completion.

Other Project Personnel: Indicate the name(s), role(s), CITI training date(s), and email address(es) of the individual(s) who will take part in the actual conduct of the study and/or preparation of results. When research staff will perform procedures under the supervision of an investigator, include their names as well. Roles of non-investigator research staff should be specified (e.g., residents, fellows, or research nurses who might perform physical examinations.)

Research Protocol

The protocol must include a complete description of the research plan.

Although the main purpose of IRB review is to safeguard the rights and welfare of human subjects who take part in research, the IRB also considers scientific design. It is unethical to put humans at risk as subjects of poorly designed research which does not meet the tests of the scientific method. Therefore, attention should be given to the preparation of an IRB Application so that it demonstrates that the proposed project is well-planned, that the sample size is justified by appropriate methodology, that it will be executed properly, documented accurately, and that the results will be analyzed appropriately.

The following sections are required in the Research Protocol and should be included as complete sentences with appropriate consideration of grammar and syntax.

1. Purpose

   This section must briefly and succinctly state the purpose of the study and should derive logically from the summary of background and significance.

2. Background and Significance

   This section should review appropriate literature to provide a clear rationale for the study including the anticipated outcomes and their significance. It should include discussion of how the proposed project will relate to or differ from what is already known. If the proposed research is a pilot study, make this clear and describe why pilot data are needed.

3. Location, Facility and Equipment to be Used

   This section should identify the location, facility and equipment used to carry out the research project.

4. Subjects and Informed Consent

   This section should describe the subject population and procedures for obtaining subject informed consent. In describing the subject population, include number of subjects, source, and demographic factors. Describe how subjects will be identified, approached, and recruited. Describe specific criteria for inclusion or exclusion in the study and provide justification based on the hypothesis tested. Describe in detail how, when, and where signed Informed Consent will be obtained (particularly for any studies involving special populations or sensitive information), if subjects will be given a copy of the signed informed consent document, and how and where the consent forms will be securely maintained.

5. Subject Compensation

This section should describe in detail whether compensation will be provided as an inducement to subjects to participate in the study. Compensation is commonly offered to offset any inconvenience or expense that the subject may have. State the type and amount of compensation to be offered and when it will be paid. If there will be a delay in the receipt of payment, state the length of time. Whether a particular type of compensation for subject participation in research is appropriate or not will be evaluated on a per-protocol basis. The following guidelines may help investigators in their choice of monetary compensation and payment schedules.

a. The amount of payment provided subjects should not be out of proportion to the level of inconvenience and expected expenses accrued by the subject. If the level of payment is excessively high, this will be considered coercive.

b. Payment for participation should be given to the subject on a prorata basis. This implies that the subject will be paid in direct proportion to his/her actual degree of participation. For example, if a subject completes half of the study, he/she should receive half of what would have been paid for completing the study. Large "balloon" payments at the completion of a study are deemed coercive and will not be approved.

c. Informed consent must, in the case of compensation, contain a detailed account of the terms of payment, including the amount to be paid and a description of the conditions under which a subject would receive partial payment or no payment.

6. Duration

This section should describe the anticipated duration of the study including total time required for subject recruitment, data collection, and analysis.

7. Research Design (Description of the Experiment, Data Collection and Analysis)

This section should describe how the study will be conducted including the methods to be used, experimental design, subject assignment and randomization procedures, duration of testing, data collection methods, and all other details necessary to fully describe the study. If subjects are involved with the study for more than one session, include the length of each session, and the total time required of each subject. Include information such as power analysis to justify the number of subjects to be recruited for the study. Describe who will perform which actions (e.g., which tasks will be performed by the principal investigator or co-investigator(s) or research staff under the supervision of an investigator).

Note: If performing clinical research be sure to differentiate which procedures are to be done (a) experimentally or (b) routinely. If a proposed study involves patients, identify which procedures are experimental and which are part of routine patient care. This information is important to the IRB in assessing risks to subjects.

8. Risk Analysis

This section should identify all risks subjects will be subjected, including their frequency (e.g., x in 100) and severity. The level of risk categorization (e.g., no risk, minimal risk, more than minimal risk) must be stated and special precautions to minimize risk must be described (particularly for any subjects requiring specific precautions). Although medical emergencies are not expected,

accessibility to CPR trained health care professionals should be described, if necessary for the proposal. In greater than minimal risk studies, the IRB may require use of a medical monitor.

9. Confidentiality

   This section should describe how individual subject records and computer files will be safeguarded. Describe methods to ensure confidentiality and to whom information will be given, what information will be furnished, and the purpose of the disclosure.

10. Literature Cited

    Literature cited should list relevant references utilized in sections 1-9.

Consent Documents

Consent documents are used in the process of obtaining informed consent to ensure all required information is given consistently to all potential subjects. They serve to document that the consent process took place to the satisfaction and understanding of both the subject and the investigator. All consent documents must be included as part of the Application.

Templates for adequately detailed, stylistically acceptable consent documents are available on the IRB's website. The templates include the required and recommended elements of consent, with additional elements recommended by the UIW IRB and suggested language for each section. It is strongly recommended that UIW investigators use the templates to develop informed consent documents, modifying them as appropriate for their specific studies.

Instruments Used for Data Collection

All surveys, interview questions, and other instruments must be included as part of the Application.

Certificate of Human Research Training

A Collaborative Institutional Training Initiative (CITI) certificate documenting completion of online training to ethically conduct research on human subjects must be current for every investigator on the proposal, including faculty supervisors. An overall score of 85% is required. Initial, CITI human subjects training is good for three years, per UIW IRB policy. Once initial training has been completed, renewal training is also good for three years.

For those investigators that have previously met IRB human subjects training requirements by taking courses offered elsewhere, that training is also good for three years. When training needs to be renewed, investigators may take the CITI refresher course. The CITI courses may be accessed at https://www.citiprogram.org.

Recruitment and Selection of Subjects

The Belmont Report describes how the principles of respect for persons, beneficence, and justice are relevant to research involving human subjects. Justice in particular relates to the selection of research subjects. The selection process needs to be scrutinized in order to determine whether some classes (e.g., welfare recipients, 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 problem being studied. Whenever research leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

The selection of subjects must be fair. Potentially beneficial research should not be offered only to some subjects who are pleasant to work with; likewise, higher risk or research with no potential benefit to the subjects, should not be targeted only at "undesirable" populations. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only under exceptional conditions.

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.

Screening Studies to Identify Eligible Subjects

Minor procedures involving little or no risk, may be performed for the purpose of identifying a population of research subjects. Consent is required.

Solicitation of Subjects through Advertisements

The use of advertisements (e.g., notices on bulletin boards, paid and unpaid newspaper solicitations, solicitation by electronic mail, WEB sites, letters to private practitioners, signs, or pamphlets, etc.) soliciting volunteers for research must have prior IRB approval. Such advertisements are an extension of the informed consent and subject selection process.

The IRB reviews advertisements to determine that (1) they are neither misleading nor coercive to potential subjects; and (2) no claims are made, either explicitly or implicitly, that a proposed intervention is effective or equivalent or superior to any other intervention.

Advertisements should contain the following:

1. The name and address of the investigator.

2. The purpose of the research.

3. In summary form, the eligibility criteria.

4. A straightforward, truthful description of the benefits, if any.

5. The location of the research and the person to contact for additional information

Submission and Approval Procedures:

1. Identify method(s) of advertisement for research subjects in the protocol.

2. Submit bulletin board notices for IRB approval prior to posting. The IRB will return the advertisement with a dated IRB approval stamp. Subsequent changes in the content of an advertisement must be approved by the IRB.

3. If you plan to advertise in a newspaper, a WEB site, or other media advertisements, submit the text or a printed copy of the WEB information or other item for IRB approval. Solicitation of subjects within the context of a published or broadcast "news" release is not appropriate.

4. Submit other forms of advertisement (e.g., electronic mail, letters to private practitioners, letters to potential subjects, etc.) for IRB approval.

Finder's Fees

A proposed recruitment method which involves offering cash and/or tangible non-cash incentives to others (i.e., finder's fees) is not permitted by institutional policy and cannot be approved by the IRB.

Food and Drug Administration Regulations

In addition to the requirements imposed by DHHS which form the basis of the guidelines in this IRB Manual, the Food and Drug Administration also has regulations involving IRB review, informed consent and protection of human subjects. These regulations apply to all studies of test articles the results of which will be submitted to the FDA. Most of the provisions are identical to those in the DHHS regulations discussed in the general sections of this Manual but there are some additional requirements specific to the FDA, e.g., the requirement to report adverse events and provisions for emergency use of investigational drugs or devices.

Even if FDA regulations are not applicable, research involving investigational practices must conform to IRB guidelines.

Responsibilities of the Principal Investigator for Research in Progress

The final letter of approval sent to the principal investigator outlines the continuing responsibilities that the investigator has to the IRB while the research is being conducted. These responsibilities include:

1. Conducting the study only according to the protocol approved by the IRB.

2. Submitting any change(s) to the protocol and/or consent document(s) to the IRB for review and approval prior to the implementation of the change(s).

3. Ensuring that only persons formally approved by the IRB enroll subjects.

4. Reporting immediately to the IRB any severe adverse reaction or serious problem, whether anticipated or unanticipated.

5. Reporting immediately to the IRB the death of a subject, regardless of cause.

6. Reporting promptly to the IRB any significant findings that become known in the course of the research that might affect the willingness of subjects to participate in the study or, once enrolled, to continue to take part.

7. Timely submission of an annual status report.

8. Completion and maintenance of an active (non-expired) CITI human subjects training certificate.

9. Timely notification of a project's completion.

The procedures for carrying out responsibilities (2), (4), (5), (6) and (7) are described in the sections that follow.

Protocol Amendment

Changes to an approved study must be submitted online by the principal investigator using the IRB Amendment Request Form. Such changes include but are not limited to: the addition or elimination of an investigator, changes in consent form, supportive materials, flyers, questionnaires, surveys, script for person-to person or telephone interviews, etc. After approval, the principal investigator will receive an amendment approval letter listing the approved changes. The changes cannot be implemented until the approval letter is received.

In general, modifications or addenda that do not result in increased risks to human subjects may be considered minor and be eligible for administrative review. However, the IRB Chair may determine that the proposed change is more than minor and requires full Board review. Each request will be judged on a case-by-case basis by the IRB chair who may decide that more than minor changes were made and additional review is required.

Reporting Issues Related to Informed Consent, Adverse Experiences, and Deaths

An unanticipated adverse experience or death occurring during the course of a research project, regardless of cause, must be reported to the IRB immediately (within 24 hours). Initial notification of the event can be made by telephone but must be followed promptly (within 5 days) with a signed written report.

Upon receipt of a Report of Adverse Experience or of Death, the IRB decides whether further investigation of the event is required. In some cases, an investigator may be required to suspend a study pending the outcome of IRB review. It is the responsibility of the investigator to inform the sponsor of the investigation and the FDA of the occurrence of unanticipated adverse reactions, death, or serious adverse experience.

Re-approval of Protocols (Continuing Review)

Continuing Review of Expedited and Full Board Studies
Federal regulations and UIW policy require all non-exempt human subjects research protocols to be reviewed on at least an annual basis throughout the life of the study. The IRB may require more frequent review, depending on the risks and nature of the study.

Continuing Review requests must be submitted online via the Ethical Review Manager system to the IRB as long as any of the research activities described in the protocol are being conducted. For example, if all subjects have completed a study and identifiable data are being analyzed, the study is considered "active" because research activities that create risk for the subjects are being carried out. Any one member of the IRB can call a meeting to review a progress report.

The IRB sends courtesy reminders to investigators with active protocols at 60, 30, and 14 days before expiry of approval (IRB protocols are approved for a one year period).

Administrative Closure
Failure to submit the request for Continuing Review and obtain continuous IRB approval or report the closure of a non-exempt study will result in action to inactivate the study protocol and the administrative closure process will begin. Subsequent reactivation of the study will require complete resubmission of the protocol as a new study.

Upon administrative closure, all research activities must stop, except as necessary to ensure:

1. The rights and welfare of participants are protected
2. Participants are not put at risk
3. Participants receive appropriate care

Subjects currently participating in an administratively closed study should be notified immediately that the study has been terminated. Any adverse events or outcomes should be reported to the IRB and the sponsor.

According to the above regulations, the IRB must report the closure action promptly to the investigator, appropriate institutional officials [academic dean or provost and dissertation/thesis advisor(s)], and any funding agencies supporting the research.

Continuing Review of Exempt Studies
Exempt studies do not require Continuing Review. In lieu of Continuing Review, an annual notification is sent 60, 30, and 14 days before expiry of approval to the Principal Investigator requesting either closure of the study or confirmation that the study is ongoing. The annual notification includes a reminder of the

Principal Investigator's responsibilities, including the responsibility to report changes to the protocol, adverse events, serious problems, and/or significant findings that might increase the risks to subjects. Failure to respond to the annual notification with a Study Status Update within the 60 days will result in administrative closure of the protocol. Subsequent reactivation of the study will require complete resubmission of the protocol as a new study.

Terminating Faculty or Staff

If a principal investigator leaves a project or leaves the University and the project is an institutional project, the IRB must be informed of the new principal investigator or termination of the research.

For those studies being discontinued when the principal investigator leaves, a formal, written final report must be filed with the IRB. If available, the original PI should submit this document. If not available, co-investigators will need to do this. If no one is available, the College/School IRB Representative or chair will submit.

The Conduct of Human Subjects Research without IRB Approval

From time to time, the IRB is made aware of research using human subjects that is being conducted without IRB review and approval of the research protocol. The sources of this information and the procedures that are followed when such information becomes available are outlined below.

Sources of Information and Disposition of Reports

The IRB occasionally discovers that human subject research which has not been reviewed by the IRB is being conducted. Investigators may report to the IRB themselves about unapproved human subject research in which they are involved. Other reports are received from faculty, staff, subjects, and anonymous persons.

Reports may be oral or in writing and should include as much pertinent factual data as possible. Reports are transmitted immediately to the Associate Provost for Research and Graduate Education (or to the IRB Chair).

Whistleblowers reporting unauthorized research activity or research misconduct are protected under federal and state whistleblower laws and cannot be retaliated against in any manner for reports made in good faith.

Determination of Alleged Infractions of Institutional or Federal Policy

The Associate Provost for Research and Graduate Education will notify the Dean of the College/School (or, absent the Dean, the Provost) of the person involved. The Dean of the College/School interviews the investigator to seek additional information to help determine whether or not an infraction of institutional rules has occurred. Emphasis in the interview is placed on fact finding.

If it is determined by the Dean of the College/School that no infraction has occurred, that Dean will notify the Associate Provost for Research and Graduate Education, and no further action is taken.

If it is determined that an infraction has occurred, the investigator is notified in writing, by the Dean of the College/School, of the procedures he or she must follow to comply with institutional policy regarding the review of human subject research. The procedures are outlined below.

Documentation and Review of Non-Approved Research

The investigator is required to suspend the research and, if the investigator plans to continue the research to submit a protocol to the IRB within 7 days. If the research has been completed, or if the investigator does not plan to continue the research, the investigator is required to document as fully as possible the research that was conducted without IRB review. This documentation should include a description of the procedures that were followed, the number of subjects studied, and results of the study.

The Dean of the College/School is notified of the above actions.

When an investigator wishes to continue the non-approved research, and a protocol has been received by the IRB, it is processed in the usual manner. The minutes of the appropriate meeting of the IRB will indicate that the protocol was submitted as a result of determination by the IRB that the investigator had been conducting human subject research without IRB approval.

Data collected prior to IRB approval will not be approved for publication or presentation purposes.

If the investigator fails to submit a protocol within the designated time, the IRB sends a written report, including a description of IRB actions, to the Dean of the College/School or next higher level of administrative authority for appropriate action within 3 days. Failure of the Dean to act or comply, is reported to the Provost with a recommendation for appropriate actions.

Determination of an Alleged Repeated Infraction of Institutional Policy

The procedures outlined in "Determination of Alleged Infractions" above will apply for a repeated alleged infraction. If it is determined that a second or additional infraction has occurred, the IRB promptly notifies the President, the Provost, and the Dean of the College/School in writing, with the recommendation that the investigator's privilege to do research be suspended at once, that the funding agency be notified of the suspension, and that unused funds be returned.

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