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Frequently Asked Questions

Below are answers to some of the most frequently asked questions regarding research and the Navicent Health Institutional Review Board (IRB).

For more specific information please refer to:
HHS Federal regulations on Human Subjects Research Protections "2018 Requirements", 45 CFR part 46 at HHS.gov
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

Navicent Health Institutional Review Board Responsibility

The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

The Navicent Health Institutional Review board operates under the guidance of the ***Ethical Principles and Guidelines for the Protection of Human Subjects of Research*.** This report, commonly referred to as the Belmont Report, contains ethical principles regarding all research involving human subjects as identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. All sites within Navicent Health are required to conform to ethical principles of the highest standard as may be determined by the Department of Health and Human Services (DHHS) or Office of Civil Rights (OCR).

The Navicent Health Institutional Review Board (IRB) is charged with the responsibility of reviewing, prior to its initiation, all research (whether funded or not) involving human participants. The IRB has the authority to approve, disapprove, monitor, and require modifications in all research activities that fall within its jurisdiction as specified by both the federal regulations and institutional policy.

Role and Responsibility of the Principal Investigator of a Research Project?

A Principal Investigator is the primary individual responsible for the management and integrity of the design, conduct, and reporting of the research project and for managing, monitoring, and ensuring the integrity of any collaborative relationships. They are ultimately responsible for assuring compliance with IRB policies and procedures, DHHS Federal Policy Regulations, and FDA regulations and for the oversight of the research study and the informed consent process. Although the principal investigator may delegate tasks to members of the research team, s/he is ultimately responsible for the conduct of the study.

Who may serve as a Principal Investigator?

Because the responsibility of the principal investigator involves direct interaction and supervision of the research team, the principle investigator must be a current employee or credentialed staff member of Navicent Health who is operating within their Navicent Health role to oversee the conduct of the study. Principal investigators leaving Navicent Health are responsible for notifying the IRB well in advance of their departure so that they can make arrangements to either close the study or name another appropriately qualified individual to take over as the principle investigator of the study.

Role and Responsibility of a Co-investigator and Research Staff

Appropriately qualified co-investigators and research staff may perform tasks as delegated by the Principal Investigator, but they do not have or accept any primary responsibility for the research study. The general responsibilities of the sub-investigator(s) and research staff include:

- Completing required institutional and protocol specific training
- Adhering to the federal regulations, state and local laws, institutional policies and procedures surrounding the safety and protection of human participants
- Assuring participants privacy and confidentiality according to HIPAA guidelines, institutional regulations.

When am I required to submit a proposal to the IRB?

All research projects must be submitted for review and approval before beginning any activities of the research. This includes proposed research involving existing data and previously collected human fluid and tissue samples, as well as, an advertising or other recruitment procedures.

Does your project Require IRB Review?

Any research conducted by a Navicent Health Entity, employee, staff, or involving any Navicent Health patients, data, or records *MUST* be reviewed and approved by the Navicent Health Institutional Review Board prior to the initiation of any activity associated with the research protocol.

A study requires IRB Review if it meets *both* of the following definitions:

1. It is research ***and***
2. It directly involves human subjects or their private or identifiable information from biological samples, the review of medical records, or deception of research.

Human subject means a living individual about whom an investigator conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens 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.

Is my project considered research?

Research is defined by the Code of Federal Regulation, 45 CFR 46.102 (d), as:

- a *systematic investigation*, including research development, testing, and evaluation
- designed to develop or contribute to *generalizable knowledge*.

Systematic Investigation

Typically, predetermined method for studying a specific topic, answering a specific question(s), testing a specific hypothesis(es), or developing theory. A scientific or scholarly activity involving qualitative or quantitative data collection and/or data analysis that sets forth an objective(s) and a set of procedures intended to reach the objective(s), i.e., to acquire knowledge, develop a theory, or to answer a question. Systematic investigation is an activity that may include:

- Collection of observational or qualitative data;
- Collection of data using surveys, testing or evaluation procedures, interviews, or focus groups;
- Collection of data using experimental designs such as clinical trials; or
- Some demonstration and service activities

- **INCLUDES:** observational studies, interview or survey studies, group comparison studies, test development and interventional research
- **NOT SYSTEMATIC INVESTIGATIONS:** oral histories, journalism, phenomenological activities
- **GRAY AREA:** Program Evaluation – need to assess design and intent

Generalizable Knowledge

Contribution to generalizable knowledge is the public presentation of the study data through any of the following:

- Meetings, conferences, seminars, poster presentations, etc.; **or**
- Publications including journal articles, papers, dissertations, and master's Theses

The intent or purpose of the systematic investigation is dissemination of findings (publication or presentation).

- Intended to have an impact (theoretical or practical) on others within one's discipline.
    - Dissemination with the intent to influence behavior, practice, theory, future research designs, etc. are contributing to generalizable knowledge.
    - **CONSIDER:** Would this project be conducted as proposed if the PI knew that he or she would never receive any form of academic recognition for the project, including publication of results or presentation of the project at an academic meeting?

The following activities are NOT research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

A Human subject is:

A living individual about whom an investigator conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; **OR**
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

- **Intervention** includes physical procedures by which data are gathered and manipulations of the subjects or the subjects' environment that are performed for research purposes.
- **Interaction** includes communication or interpersonal contact between investigator and subjects. The interaction may be as remote as an anonymous, online survey
- **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** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Types of IRB Review: Exempt, Expedited, and Full Board Review

Depending on risk and subject demographic, research proposals fall into one of three categories: exempt, expedited, or full board review. Although investigators should request the level of review they feel is appropriate for their project. The researcher cannot make the final determination of the necessary level of review. **Only the IRB Chair, in consultation with committee members, if necessary, can certify the correct level of review necessary.**

Exempt level of review

A research activity may be declared exempt if it is considered low-risk and the only involvement of human subjects will be in the categories outlined in **45 CFR 46.101(b)**. Briefly described, these categories are:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices**.**
2. Research using anonymous or no-risk tests, surveys, interviews, or observations.
3. Research involving benign behavioral interventions in conjunction with the collection of information form adults through verbal, written, or audiovisual recordings..
4. Secondary research for which consent is not required.
5. Research and demonstration projects that are conducted or supported by Federal department or agency, or otherwise subject to the approval of department or agency heads that are designed to study, evaluate, improve or otherwise examine public benefit or service programs.
6. Taste and food quality evaluation and consumer acceptance studies.

Certain kinds of research with human subjects are *not eligible* for exempt determinations:

- **Prisoners:** research involving prisoners as human subjects is *not* eligible for exemption. "Prisoners" are defined as "any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Detainees in administrative cases (such as immigration or deportation) are not considered detainees for this purpose, according to guidance the Emory IRB has obtained from DHHS.
- **FDA-regulated Research:** Exempt research categories do *not* apply to research that involves FDA-regulated products (studies using investigational drugs, biologics, or devices for which the FDA has granted an investigational new drug [IND] or investigational device exemption [IDE], or non-significant-risk devices).
- **VA Studies:** For AVAMC Research or other VA-supported research that is not otherwise subject to FDA Regulations, only the categories of research set forth in the VHA Handbook may be classified as exempt research.
- **Minors (Children):** Research involving minor may not be exempted, with one exception. If the research consists solely of observation of public behavior where the investigator does not participate in the activities being observed, the research may be eligible for exemption. All other research involving minors is not eligible for exemption.

Although subject consent is always needed, signed consent forms are typically not recommended if they are the only identifying variable in an otherwise anonymous project.

Although the IRB may determine that a project meets requirements for exempt status, it must still conduct a modicum of review ("exempt review") to ensure compliance with the ethical principles embodied in the Belmont Report: respect for persons, beneficence, and justice. If the federal HIPAA Privacy Rule applies to the study, the IRB must ensure compliance with that as well.

When a research project has been determined by the IRB to be exempt from further IRB review, annual review and continuing review is not required. However, any modification to the protocol and/or consent must be submitted to the IRB for review and approval. It is also required to inform the IRB in writing when the study has been completed.

Expedited level of review

In general, research may qualify for expedited review if it is judged to involve only minimal risk, does not include intentional deception, does not employ sensitive populations or topics, and includes appropriate informed consent procedures. For example, the collection of physical data through non-invasive procedures is eligible for an expedited review, including:

- Height and weight
- ECG, MRI, Ultrasound
- Moderate exercise
- Blood or other bodily fluids

The full list of categories of research that may be reviewed as expedited can be found in **45 CFR 46.110.**

Research that meets criteria for expedited review does not require a convened board review and is typically reviewed within 30 days after receipt of a completed application. The criteria for approval using the expedited procedure are the same as those for the review by the convened board. Reviewers may exercise all the same authorities of the IRB except that the reviewers may not disapprove the research. Reviewers will make one of the following determinations regarding the research application:

- Approve the research
- Revisions and/or additional information required
- Forward for Convened IRB review

Full board review

A full board review is required for research that is not eligible for exempt or expedited review. In short, research that is judged to involve more than minimal risk, or involves protected populations such as children, prisoners, or disabled individuals, must undergo a full board review. Individuals intending to conduct research that requires a full board review should allow ample time to complete the review process.

The following categories of research require full IRB approval:

1. Projects for which the level of risk is determined by the IRB Chair to be greater than minimal.
2. Projects that involve the intentional deception of subjects, such that misleading or untruthful information will be provided to participants.
3. Projects that involve sensitive or protected populations (such as children or cognitively disabled individuals).
4. Projects that plan to use procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial, or legal).

Principal investigators will be required to present their research to the convened board in person.

What is the definition of “Minimal Risk”?

“Minimal Risk” is defined as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Can my research proposal be exempted or expedited?

Only the IRB has the authority to determine which research activities qualify for exempt or expedited review status. You may refer to the questionnaires on Exempted and Expedited Protocol Requirements (available online at http://) to determine if your research proposal may be eligible.

How long will it take for my application to be approved by the IRB?

IRB review will not begin until the IRB office has received a COMPLETE protocol application with ***ALL*** required signatures and any additional documents required to conduct your research (i.e., informed consents and signed permissions and research requests).

Most Exempt, and Expedited reviews are completed within approximately 30 days after a complete application has been received by the IRB.

If the application does not meet criteria for exempt or expedited review, the principal investigator will be required to present the research proposal to a convened IRB. Principal investigators will be notified of the date for IRB presentation. A decision will be provided after the full board review.

Do I need to obtain Informed Consent or Assent?

Obtaining informed consent is a basic ethical obligation and a legal requirement for researchers. Both the Belmont Report and the Nuremberg Code address voluntary informed consent as a requirement for the ethical conduct of human subject research.

Informed Consent means that subjects are well informed about the study, the potential risks and benefits of their participation and that it is research, not therapy, in which they will participate. Informed Consent is the process through which researchers respect individual autonomy, the fundamental ethical principle.

This requirement is founded on the principle of respect for persons, one of the 3 ethical principles governing human subject research described in the Belmont Report. The principle of respect for persons requires that individuals be treated as autonomous agents and that the rights and welfare of persons with diminished autonomy be appropriately protected. The principle of autonomy implies the responsibility must be given to the individual to make the decision to participate. An autonomous individual is one who is capable of deliberation and personal choice.

The Nuremberg Code states that the voluntary consent of the human subject is absolutely essential not only to the safety, protection, and respect of the subject, and to such extent or degree the integrity of the research itself.

The requirement for informed consent is one of these central protections defined by the:

- Department of Health & Human Services (HHS) regulations 45 CFR part 46
- Food and Drug Administration (FDA) regulations 21 CFR part 50

For studies using Protected Health Information (PHI): Research that is using or disclosing protected health Information must be conducted in accordance with the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) and requires complete of the HIPAA section of the study application.

Except as provided in paragraph "c" of 45 CFR 46.117, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

Types of Informed Consent

Consent – Informed **Consent** is obtained from adult individuals being asked to participate in a study, capable of giving permission to participate in a research study, can provide consent. The subject must be 18 years of age and competent to make the decision to participate.

Parental Permission – When children/minors are included in research, the parent/guardian must sign a parental permission consent document. Some situations require permission from at least one parent, while other situations require permission from both parents. In some cases, it may be necessary to waive the requirement to obtain parental permission. Refer to 45 CFR 46*subpart D for more information.

Assent – Informed **Assent** is obtained when the research involves minors. A parent or legal guardian must give permission to allow the child to participate in the research, and children who are able to understand information about participation are asked to "assent" or agree to participate as well. Assent is a child's affirmative agreement to participate in research. If the subject is 7-17 years of age, assent must be obtained. The assent form must be written at the appropriate reading level of the youngest subject in the age range and use simple terminology.

Verbal – Verbal consent still contains all elements of written consent. However, the participant is verbally read the elements and verbally agrees to participate.

Short-Form – A "short form" is generally used when there is a language barrier and an English IRB-approved consent is orally translated in the subject's native language.

Information/Fact Sheet – An information sheet may be used as a form of consent in certain circumstances where a signature could compromise the participant or in studies where signed consent is not required by regulations (research procedures involving minimal/no risk).

Waiver of Documentation of Informed Consent ("Verbal" or "Online" consent) – Waiver of documented consent occurs with participants consent to be in the study, but do not sign a consent form. A waiver of documentation of informed consent can be obtained when the written consent is the only link to the study and record of the subject's name could compromise the participant. In this case a verbal or information sheet can be used, or the consent may be read to the subject. A waiver for documented consent may be requested when the research is associated with minimal risk involving:

- Surveys sent through the mail or conducted over the internet
- Telephone interviews
- The collection of sensitive information without a written record that could identify participants

Waiver of Elements of Informed Consent – A waiver of elements of informed consent may be obtained from the IRB for some research projects that could not practically be done without an alteration to the required elements.

Waiver of Informed Consent (research is conducted without obtaining consent from the subject)
A waiver of informed consent may be requested in the following instances:

- Medical chart reviews
- Analysis of existing data
- In rare cases, when secondary participants may be involved, and it would either be prohibitive or potentially dangerous to obtain consent.

The Board may alter or waive the general requirements for consent if the following apply:

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

Broad Consent – A new type of regulatory consent under the Common Rule for non-exempt storage, maintenance, and research use involving identifiable information and biospecimens. Broad consent may be used as a substitute for traditional informed consent in a range of defined circumstances.

Required Elements for Informed Consent

(Please refer to DHS HHS OHRP 45 CFR 46.116 General requirements for informed consent and 46.117 Documentation of informed Consent)

Basic Required Elements of Informed Consent *(new elements of 2018 in bold)*	Citation
A statement that the study involves research	_.116 (b)(1)
An explanation of the purposes of the research	
The expected duration of the subject's participation	
A description of the procedures which are to be followed	
Identification of any procedures which are experimental	
A description of any reasonably foreseeable risks or discomforts to the subject	_.116 (b)(2)
A description of any benefits to the subject or to others which may reasonably be expected from the research	_.116 (b)(3)
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject	_.116 (b)(4)
Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and what records may be examined by the research staff, IRBs, sponsor, their representatives, and possibly the FDA or OHRP.	_.116 (b)(5)
For research involving more than minimal risk, a statement that emergency medical care will be arranged for a study-related illness or injury, and an explanation of whether funds are set aside to pay for this care and/or compensation, and if so by whom (e.g., sponsor, subject, insurer). Language must not be exculpatory.	_.116 (b)(6)
Identification of whom to contact (a) on research team with questions, concerns, complaints or about a research-related injury; and (b) at the IRB for same issues and information about research subjects' rights.	_.116 (b)(7)
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.	_.116 (b)(8)
(Broad Consent) This element is required to describe how identifiable private information or identifiable biospecimens may be stored, maintained, and used in future (secondary) research. • **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** • **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**	**_.116 (b)(9) (i) and (ii)**
Identification of funding source(s)	IRB requirement
Additional Elements as Appropriate	
A statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable	_.116 (c)(1)
Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent	_.116 (c)(2)
Any additional costs to the subject that may result from participation in the research	_.116 (c)(3)
The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject	_.116 (c)(4)

A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject	_.116 (c)(5)
The approximate number of subjects involved in the study	_.116 (c)(6)
A statement that he 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.	_.116 (c)(7)
A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and	_.116 (c)(8)
For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)	_.116 (c)(9)
If monetary payment will be given, a statement informing the participant that their personal information (name, address, and social security number) will be collected for tax purposes and will be reported to the IRS if they receive over $600 in one year from Emory.	IRB requirement
All information concerning payment, including the amount and schedule of payments	IRB requirement

Additional IRB Requirements
In the case of minors (< 18yrs), the assent form is worded in age-appropriate reading level of the youngest subject in the age range and use simple terminology
A signature line for the subject, date of signature, printed name of the subject
A signature line for the principle investigator and date of signature
A witness' signature line

What documents are required for a complete IRB application?

A complete application required for IRB review includes the following:

(Please arrange your documents in the following order)

1. IRB Application
2. Exempt or Expedited Request (if applicable)
3. Copy of the protocol
4. FDA form 1572 (if applicable)
5. CV for all investigators listed on the application
6. Copy of a certificate of completion of Education on Human Subject Protection
7. Investigator's brochure (if applicable)
8. Consent Document(s)
9. Consent Check List
10. Recruitment Materials
11. Copy of Data Collection Instruments (data collecting forms)
12. Permission Letters (if applicable)
13. Application Fee Form

Note: An IRB application will only be accepted as one complete packet containing all required documentation arranged in the appropriate order.

- □ All forms must be filled out completely. No missing information.
- □ Spelling and grammar must have been checked on all documents and are correct.
- □ Application has been signed in writing by the Principal Investigator, and Navicent Health Department Chair. **Electronic Signatures are not acceptable**.
- □ IRB fee form has been completed including billing information if check not submitted.

What training is required by the IRB in order to conduct research?

Navicent Health requires investigators and research staff must successfully complete the CITI Program for training in the ethical conduct of research with human participants and must be updated at least once every 5 years. A certificate of completion (dated within the last 5 years) for each investigator is required as part of the application submission.

Are Electronic Signatures Accepted on Application documents?

No – All applications and forms must contain original hand-written signatures

Do I need a Statement of Investigator, Form FDA 1572?

The Statement of Investigator, Form FDA 1572 (1572), is an agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigational drug or biologic.

The 1572 serves two purposes: 1) to provide the sponsor with information about the investigator's qualifications and the clinical site that will enable the sponsor to establish and document that the investigator is qualified and the site is an appropriate location at which to conduct the clinical investigation, and 2) to inform the investigator of his/her obligations and obtain the investigator's commitment to follow pertinent FDA regulations.

Whenever a sponsor selects a new investigator to participate in a clinical investigation that is being conducted under an investigational new drug application (IND), the sponsor must obtain a completed and signed 1572 before permitting the investigator to begin participation in the clinical investigation (21 CFR 312.53)).

A completed 1572 must be submitted as part of the application, if the form is required by the sponsor or if any information on a submitted form is updated.

When does a modification (amendment) to an approved research study need to be submitted?

Any changes to an approved research study must be submitted to the IRB for review and approval prior to implementing the change(s). Investigators must submit an Amendment application if there are significant changes involving any of the study protocols, design, informed consent procedures, or principal investigator team.

Examples of types of changes that require an amendment:

Does the approval of an amendment to an approved research study extend the original approval date?

No. The expiration date of the original approval is not changed by the review and approval of an amendment

Continuing Review

DHHS (45 CFR 46) and FDA (21 CFR 56) regulations require the IRB to perform Continuing Review of research at intervals appropriate to the degree of risk but *not less* than once per year. It is the responsibility of all investigators to submit an Application for Continuing Review in sufficient time to permit the IRB to complete a meaningful Continuing Review of the research.

The primary purpose of Continuing Review is to ensure that:

1. Selection of subjects is equitable
2. The risk/benefit relationship of the research remains acceptable
3. The consent document contains information that is accurate, complete, and up-to-date
4. Adequate safeguards for human subjects are in place.

In addition, at this institution, some of the information that is requested will be reviewed by the Research Office for purposes of institutional oversight.

Continuing Review and re-approval of on-going research serves to verify the correctness of the decisions made by the both the investigator and the IRB using the study results to date and other relevant information to make this judgement. Continuing Review is designed to help ensure that the rights and welfare of subjects continue to be fully protected in on-going research.

The IRB cannot grant extensions or temporary approval. Should suspension occur, all subject accrual must cease as of the date of suspension. Research related procedures can no longer be done on human subjects who are enrolled in the study for follow-up or other reasons. If suspension is a health hazard to the subjects, the IRB may grant an exception upon receipt of written justification.

What do I need to do if my research protocol has passed the one-year expiration date assigned by the IRB?

It is the principal investigator's responsibility to submit a request for renewal at least 60 days prior to the protocol expiration date in order to obtain timely renewal approval.

If the IRB approval of the research expires, all study procedures related to the protocol must cease, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection of private identifiable information until such time as the protocol has been approved for continuation by the IRB. Continuing human research procedures once a protocol is expired is a violation of federal regulations.

Unanticipated Problems/Adverse Event Reporting

Serious adverse events must be reported the IRB immediately, with a written report by the principal investigator following within 24 hours of the principal investigator becoming aware of the event.

A Serious Adverse Event (SAE) is defined as:

1.) Death of a research participant
2.) Serious injury to a research participant.

All other non-serious unanticipated events/problems should be reported to the IRB within 2 weeks of the principal investigator or other researcher becoming aware of the event. Prompt reporting is important, as an unanticipated event may require some

modification of the study procedures, protocols, and/or informed consent process. Such modifications require IRB review and approval.

Note: The IRB may temporarily discontinue a research project until an investigation has been conducted. The IRB may discontinue or request changes to a research protocol and/or informed consent processes based on findings of the investigation.