CLARION UNIVERSITY of PENNSYLVANIA
Policy and Procedures
for the Protection of Human Subjects of Research
An Overview

Clarion University is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Through our Policy and Procedures for the Protection of Human Subjects of Research and our Institutional Review Board (IRB) we review human subject research on the campus and seek to insure that Clarion is in compliance with the National Research Act.

Who Must Comply with the Policy and Procedures? All Clarion University employees and students engaged in research involving human subjects are subject to Clarion University=s Policy and Procedures for the Protection of Human Subjects of Research. All grants managed or awarded by Clarion University involving human subjects must have IRB approval before the grant will be managed and/or awarded.

What is Considered Research? Research means a systematic investigation designed to develop or contribute to generalizable knowledge. Research development and activities include all formal investigative efforts by faculty, students, and staff that are designed to develop or contribute to generalized knowledge. Research development and related activities include those whose results are intended or used for publication, distribution, or use outside a specific instructional setting. Children are the exception to the before mentioned definition of research. Any classroom instruction, practice, or research involving children as subjects will be considered research. Families shall be fully informed of any proposed research projects and/or classroom instructional practices involving their children and shall have the opportunity to give or withhold consent.

What Types of Research are Included? The policy and procedures cover all research which is either (a) conducted on the premises of the University; or (b) funded through the University; or (c) conducted by faculty, students, or staff or the University who are acting in connection with their responsibilities or relationships to the University or who intend to use the name of the University in any report of the activity; or (d) conducted by use of the records of the University and/or contact its current clients or students to be subjects.

Where Can One Learn About the Policy and Procedures? The complete Policies and Procedures for the Protection of Human Subjects of Research has been placed in each academic department office and on the Internet at www.clarion.edu/admin/facres/irb. Individuals planning to do research involving human subjects should consult the policy and duplicate those forms which should be submitted to the IRB. Questions about the procedure may be directed to Graduate Studies (hereafter known as the Administrative Office) at 393-2337 and/or the Chair of the IRB.

When to Begin the Review Process. At least six weeks prior to beginning to collect data, a researcher should complete an Application for Research Approval (ARA) and submit it with required attachments to the Administrative Office in 108 Carrier Administration Building.

What to submit with a proposal. In addition to the proposal, the researcher must submit the following forms: an Application for Research Approval(ARA), a Consent Form, a Confidentiality Statement, and any other pertinent information.

CLARION UNIVERSITY OF PENNSYLVANIA
Policy and Procedures
for the Protection of Human Subjects of Research

I. Policy Statement

Clarion University of Pennsylvania is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research. As assurance of the University's commitment to the protection of human subjects, an Institutional Review Board (IRB) has been established in compliance with the regulations set forth in the National Research Act, as revised 3/8/83 (45 CFR 46).

II. Institutional Review Board

Board Members

The Institutional Review Board will consist of at least five members. Each academic department of the University may be represented by one delegate and an alternate. Members will be nominated by their departments and appointed by the President to serve for a period of three years. In addition, one graduate student may be appointed to the board to serve a term for one year. At least one person, not affiliated with the University will be appointed by the President, acting on recommendations of the Dean of the College of Graduate Studies. A Department may waive their right of representation by notifying the Graduate Dean and the IRB Chairperson. If a minimum of 5 members is not reached in this manner, the President, in consultation with the Graduate Dean, may appoint additional members, to reach a total of 5 (a federal requirement). A list of the names, degrees and positions of the board members and all records of activities conducted by the Board will be maintained under the direction of the Dean of the College of Graduate Studies.

Board Schedule

The IRB will convene at regularly scheduled monthly meetings with the members being on call for additional meetings when necessary. You may get a schedule by checking the website at www.clarion.edu/admin/facres/irb.

Board Responsibility

The IRB will be responsible for: (a) conducting initial reviews and certification of research involving human subjects, (b) conducting annual review of such research, (c) conducting special and/or additional reviews, (d) approving changes in research methodology, and (e) advising investigators and proper authorities on unanticipated problems, complaints and violations that arise with research of human subjects.

No decision-making meeting of the IRB may be held without a quorum. A quorum consists of a majority of the IRB members or their alternates. If a quorum does not exist at a Board meeting, the vote may be scheduled via electronic mail following an electronic discussion and received by a date

stipulated by the Chair. The Chair will post the tally of votes by email, no later than one day after the vote. The Board may use the proxy vote procedure on issues that have no opposition prior to the vote.

For full board reviews, at least one member whose primary concerns are in non-scientific areas must be present. Federal regulations specifically refer to the representation of "non-scientific areas." Examples which may include but are not limited to: law, ethics, philosophy, logic, communication, etc. If voting is necessary for full board, decisions are made on the basis of the majority of those present and voting. The investigator may be invited to answer questions but may not be present for discussion and voting. If the IRB is considering a research project with which a member is associated, and that member is present, that member shall leave the room during the discussion and voting in order to avoid a conflict of interest.

In acting upon an Application for Research Approval, the IRB will seek to determine if all of the criteria for IRB approval have been met and then may take one of the following actions:

A. it may APPROVE the research procedures as being adequate to protect the rights and welfare of human subjects and to meet the standards for informed consent;

B. it may APPROVE the research procedures SUBJECT TO MODIFICATIONS regarding the treatment of human subjects to protect their rights and welfare;

C. it may DISAPPROVE the research procedures as violating the rights and welfare of human subjects; or

D. it may DEFER ACTION on the proposal pending receipt of more information or further clarification of specific items.

If an Application for Research Approval (ARA) is disapproved by the IRB and the investigator wishes a further hearing on the matter, an appeal may be made to the Dean of the College of Graduate Studies who will chair the appeals process through the IRB.

III. Procedures

Definition of Research

Within this University all research with human subjects falls under IRB guidelines whether or not the research is funded. University assurances, as well as these procedures, apply to research which is either (a) conducted on the premises of the University; or (b) funded through the University; or (c) conducted by faculty, students, or staff of the University who are acting in connection with their responsibilities or relationships to the University or who intend to use the name of the University in any report of the activity; or (d) conducted by use of records of the University; or (e) conducted by use of the University's records, faculty, students or staff to identify and/or contact its current clients or students to be subjects.

A. Every investigator is responsible for obtaining and completing an Application for Research Approval (ARA). An original and two copies of the ARA should be submitted to the Administrative Office fifteen working days prior to scheduled board meetings for Expedited Review and Full Board Review applications to assure full consideration. Exempt Review applications must be sent directly to the Department Representative.

B. The Administrative Office of the IRB will select two IRB members (one from within the investigator's College and one from a different College of the University) to review the ARA.

C. The two IRB members will review the proposed research and within the fifteen day period advise the Chair on the status of the ARA. The Chair will then direct the following activities based upon the determined status:

EXEMPT REVIEW

The following types of research may be exempted from extensive committee review if proper procedures to assure confidentiality are evident, an informed consent is provided, and subjects are exposed to no more than "minimal risk." The Chair of the IRB determines whether a particular research project is exempt. If exempt, the investigator will be so notified by the Chair within 5 working days of receiving the ARA.

A. Research conducted in established or commonly accepted educational settings involving normal educational practices such as research on comparison among instructional strategies, curricula, or classroom management methods. However, if minors (children under the age of 18) or people with impaired judgment or comprehension abilities are involved, the review level must be at least an EXPEDITED REVIEW.

B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if the data are recorded so that subjects CANNOT BE IDENTIFIED either by the use of names or special coded identifiers.

C. Research involving surveys, interviews, or observations of public behavior except where the following conditions exist:

1. Information obtained is recorded in a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND

2. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; AND

3. Internet survey – Human subjects data gathered via the Internet is subject to full board review if it has open access to anyone. The use of closed list-serves, password protected web-sites, or private email to solicit subjects or receive data on human subjects will be reviewed as exempt, expedited, or full review depending on the content of the survey, possible use of minors or other protected classes (i.e. impaired, prisoners, handicapped) and risk to subjects.

D. 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.

EXPEDITED REVIEW

Subjects may not be exposed to more than "minimal risk." Protocols will be reviewed by two IRB members and signed off by the IRB Chair. The reviewers may either approve the protocol or refer it for full IRB review. In the event the IRB does not approve the protocol under expedited review, the Administrative Office will contact the investigator about the next step in the review process.

Categories of research that may be reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure (obtained from OPRR dated 11/9/99)

Applicability

A. 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 following categories, 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 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.

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

C. 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.

D. The expedited review procedure may not be used for classified (governmental) research involving human subjects.

E. IRB's are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

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

   a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that

significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

b. Research on medical devices for which (i) an investigational device exemption application (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.

2. Collection of blood samples by finger stick, heel stick, ear stick, or vein puncture as follows:

a. from healthy, non-pregnant 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, 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.

3. Prospective collection of biological specimens for research purposes by non-invasive means.

Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and 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.

4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the 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.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

   a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

   b. where no subjects have been enrolled and no additional risks have been identified; or

   c. where the remaining research activities are limited to data analysis.

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

FULL BOARD REVIEW

Any research not covered by the conditions of Exemption Review or Expedited Review, including all research which involves more than "minimal risk," or which could not be approved using other review categories, will be referred to the appropriate IRB committee for full review. The full committee must review proposals collecting blood samples from subjects under the age of 18 and human subject data obtained through open access Internet surveys.

INCOMPLETE APPLICATIONS

If the ARA or research procedures are incomplete, the ARA will be returned and the investigator notified of deficiencies.

A. When an ARA is approved, the Chair of the IRB will provide the investigator with a statement outlining his/her responsibility and the procedures for reporting changes and problems in the research.

B. When the IRB approves an ARA a determination will be made, based upon the potential risks to the subjects, of whether a project, (a) requires review more often than annually, or (b) needs verification from sources other than the investigator that no material changes have occurred since previous reviews.

C. The Administrative Office of the IRB will maintain a master schedule of all ARA's approved and their review dates. The Administrative Office will be responsible for (a) notifying investigators of upcoming review dates and (b) scheduling reviews of approved research on the IRB monthly meeting agenda.

D. The Chair will investigate and report violations of these procedures to the investigator, and if not rectified, then to the Dean of the College of Graduate Studies and the President.

IV. Administrative Office Functions and Responsibilities

It is the responsibility of the Administrative Office to assure that the policies and procedures concerned with projects involving human subjects are carried out in accordance with the institutional assurance.

The Administrative Office will also disseminate current policies and procedures to the faculty and departmental offices of the University. Copies of the University Policies and Procedures and the Department of Health and Human Services materials are available online at http://www.clarion.edu/admin/facres/irb or available upon request to faculty, administrators, subjects and any other interested person. Each time a revision occurs, the revised version of the University Policies and Procedures will be mailed to all deans, chairs, and directors of academic units.

In addition, this office has the authority and is responsible for promptly reporting to the National Institute of Health - Office for Protection from Research Risks on a variety of issues. In conjunction with this requirement, the IRB Committee must be prepared to receive and act on information received from a variety of sources, such as human subjects, research investigators, the Graduate office or other institutional staff. For reporting purposes, the IRB Committee will follow the procedures described below:

A. Noncompliance: Any noncompliance by research investigators with the requirements of the IRB Committee shall be reported promptly to the Administrative Office for appropriate follow-up.

B. Injuries to human subjects: Information received by the IRB Committee concerning injuries to subjects shall be reported promptly to the Administrative Office.

C. Unanticipated problems: Information received by the IRB Committee concerning unanticipated problems involving risks to subjects or others shall be reported promptly to the

Administrative Office, which is responsible for reporting to the Office for Protection from Research Risks.

D. Suspension or termination of IRB Committee approval: Whenever the University Committee suspends or terminates approval of research protocols, it shall include a statement of the reasons for the IRB Committee's action and shall report the action promptly to the research investigator, the Administrative Office, and the Office for Protection from Research Risks.

The IRB Committee shall prepare and maintain adequate documentation of IRB Committee activities, including the following:

A. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by research investigators and reports of injuries to subjects.

B. Minutes of IRB Committee meetings which shall be in sufficient detail to show the names of attendees at the meetings; actions taken by the IRB Committee; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controversial issues and their resolution; and dissenting reports and opinions. If a member in attendance has a conflicting interest regarding any project, minutes shall show that this member did not participate in the review, except to provide information requested by the IRB Committee.

C. Records of continuing review activities.

D. Copies of all correspondence between the IRB Committee and the research investigators.

E. A list of IRB Committee members as required by 45 CFR 46.103 (b) (3).

F. Written procedures for the IRB Committee as required by 45 CFR 46.103 (b) (4).

G. Statements of significant new findings provided to subjects, as required by 45 CFR 46.116 (b) (5).

The IRB Committee and the Administrative Office shall provide for the maintenance of records relating to a specific research activity for at least 3 years after termination of the last IRB Committee approval period for the activity.

IRB Committee records shall be accessible for inspection and copying by authorized representatives of Department of Health and Human Services (DHHS) at reasonable times and in a reasonable manner, or shall be copied and forwarded to Department of Health and Human Services when requested by authorized DHHS representatives.

The Administrative Office will maintain records for each project which will be available for audit at any time. Minutes of each meeting of the IRB Committee will be kept by this office which acts as a liaison office processing the proposals, applications, notices of approval, and review requests. Project directors/principal investigators will be responsible for maintaining files, through the Administrative Office,

of signed informed consent statements obtained from individual subjects. These files may be subject to audit by appropriate authorities. The office in conjunction with the Chair of the Committee will develop an annual report.

Certification Requirements

The Administrative Office is responsible for submitting a certification to the Department of Health and Human Services, and when otherwise required by DHHS, a supplement to an original protocol, when:

A. It is proposed to involve human subjects, and the activity previously had only indefinite plans for the involvement of human subjects; or

B. It is proposed to involve human subjects, and the activity previously had no plans for the involvement of human subjects; or

C. It is proposed to change the involvement of human subjects and that involvement is significantly different from that which was initially approved by the IRB Committee.

In addition, the Administrative Office shall ensure that no human subjects are involved in research projects for which the filing of a supplement is required by Department of Health and Human Services, prior to review of the submitted supplement and approval by appropriate DHHS officials.

Reporting Requirements

The Administrative Office shall be responsible for promptly reporting information, as appropriate, to the IRB Committee, the Office for Protection from Research Risks, and research investigators and department heads on a variety of issues. Information may flow from sources such as human subjects, research investigators, IRB Committee or other institutional staff. Specifically, the Administrative Office shall:

A. Report promptly to the Office for Protection from Research Risks any instances of injuries to subjects and unanticipated problems involving risks to subjects or others;

B. Report to the IRB Committee information received concerning noncompliance by research investigators, injuries to subjects, unanticipated problems involving risks, changes proposed in research activities and the progress of the research;

C. Maintain information concerning the IRB Committee's reasons for the termination or suspension of IRB Committee approval; and

D. Report promptly any changes in IRB Committee membership to the Office for Protection from Research Risks.

Retention of signed consent documents

Principal investigators are responsible for placing the consent documents signed by human research subjects in a repository approved by the Administrative Office. These documents shall be retained for at least three years after termination of the last IRB Committee approval period.

Submission of report of injury and/or unanticipated problems involving risks

A. Principal investigators are responsible for promptly reporting (in writing) to the Administrative Office, through their department heads, of any injuries to human subjects.

B. Principal investigators are responsible for promptly reporting (in writing) to the Administrative Office, through their department heads, any unanticipated problems which involve risks to the human research subjects or others.

Reporting changes in the research

A. Research investigators are responsible for reporting in writing promptly through their department heads to the IRB Chair any proposed changes in a research activity.

B. Changes in research during the period for which IRB Committee approval has already been given shall not be initiated by research investigators without IRB Committee review and approval, except where necessary to eliminate apparent immediate hazards to the subject. In such occurrence the IRB Committee is to be notified as soon as possible.

Reporting of noncompliance

Research investigators and department heads are responsible for reporting promptly to the Administrative Office and the IRB Committee any serious or continuing non-compliance with the requirements of this assurance or the determinations of the IRB Committee.

Attending University Committee meetings

To facilitate the review of research and the protection of the rights and welfare of human subjects, research investigators and department heads are encouraged to attend IRB Committee meetings.

Other responsibilities of the Administrative Office

A. Retention of signed consent documents.

The Administrative Office shall designate procedures for the retention of the signed consent documents. These documents shall be retained for at least three years after termination of the last IRB Committee approval period.

B. Reporting requirements (in writing).

The Administrative Office shall be responsible for promptly reporting information, as appropriate, to the IRB Committee, the Office for Protection from Research Risks, and research investigators and department heads on a variety of issues. Information may flow from sources such as human subjects, research investigators, the IRB Committee or other institutional staff. Specifically, the Administrative Office shall:

1. report in writing promptly to the Office for Protection from Research Risks any instances of injuries to subjects and unanticipated problems involving risks to subjects or others;

2. report in writing to the IRB Committee information received concerning noncompliance by research investigators, injuries to subjects, unanticipated problems involving risks, changes proposed in research activities and the progress of research;

3. maintain information concerning the IRB Committee's reasons for the termination or suspension of IRB Committee approval; and

4. report promptly any changes in IRB Committee membership to the Office for Protection from Research Risks.

V. Procedures for Special Circumstances

In research projects involving audio/ video taping of subjects, working with minors or others who are unable to give consent, using previously collected data, collecting oral histories, and archive data on human subjects, the following guidelines apply:

A. A release must be obtained from the subjects or guardian (following same guidelines as informed consent 3.1.1) before taping of the interview takes place; this release statement may be included on the tape;

B. In studies which do not include written informed consent (i.e., taped interviews in person or over the telephone), the elements of informed consent as they are explained to the subjects should be included as a preamble to the taped procedure;

C. Before consenting to being taped, subjects should be informed of the current and planned use of the taped materials including storage and access by persons other than the researcher. Normally, this information will be contained in the release form;

D. The researcher must make proper arrangements for secure storage of all audio and video tapes and assure that their use complies with the guidelines outlined in the release form. Plans may include archiving, erasing, or destroying after a given time period.

Any research that uses electrical, electronic or mechanical equipment with which the subject will in contact must supply the Committee with:

A. Trade name B. Manufacturer
C. Model number
D. Schematic diagram, picture or other representation of the equipment including a demonstration or other means of showing the Committee the machine's normal operation;
E. Verification of safety including UL certification or other certification;
F. For old equipment that has been out of usage, equipment that has been moved, or equipment of local fabrication and/or not available from commercial vendors, the researchers must provide evidence of recent inspection and certification for safety.

In cases where subjects are recruited from other institutions (hospitals, community agencies), the first contact with potential subjects should be made by institutional staff who, after outlining the researcher's interest and ascertaining the potential subject's interest, will refer the person to the researcher.

All research that includes the study of subject use or abuse of controlled substances will be required to state their intent to acquire a Certificate of Confidentiality from the National Institute of Drug Abuse or other appropriate agency before the research can begin. Certification must be shared with the Committee before research begins.

Research with Acquired Immune Deficiency Syndrome (AIDS) patients is subject to additional precautions prescribed by the federal guidelines. This information will be shared with all interested researchers.

Researchers should allow extra time for review of protocols for studies involving this population.

Federal guidelines require that all subjects give their assent or consent to be involved in the research study. This includes minors, people with impaired judgment or comprehension abilities, and bedridden elderly. Consent forms must be written in language that the subject can understand, federal guidelines suggest no higher than an eighth grade reading level. It is the researcher's responsibility to ensure that the subject understands what it is that they are consenting/assenting. Researchers working with pre-collected data from human subjects or working with agencies must provide written consent on letterhead from the original researcher or agency involved. This excludes publicly accessible and/or commercially sold data. Whenever potential subjects are capable of giving assent, the researcher must obtain their assent in addition to obtaining informed consent of their guardian before involving the individual in a study.