Investigator’s Handbook:

Human Subjects Research
University at Albany
Institutional Review Board (IRB)
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MISSION
The University at Albany (UAlbany) Institutional Review Board (IRB) is charged with helping UAlbany faculty and student researchers in protecting human subjects of research conducted under its jurisdiction.

The IRB is committed to the principal that research at UAlbany must meet the highest standards of ethical conduct. Specifically, the IRB’s obligation is to assure that research on human subjects is planned and carried out in accordance with all relevant regulations, laws, and University policies.

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

The UAlbany IRB applies the policies and guidance in this guidebook for all research involving human subjects that is performed under the auspices of the University at Albany. This means all such research that is:

- conducted by any faculty, staff, or administrator of UAlbany in connection with his or her institutional responsibilities, or
- conducted by any student enrolled at UAlbany.

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

The IRB structure and function is from the Department of Health and Human Services (DHHS) Regulations at Title 45 of the Code of Federal Regulations part 46. These are the federal regulations that address minimum levels of human subject protection in research.

The 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 participants of Biomedical and Behavioral Research entitled, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (“The Belmont Report”) regardless of whether the research is subject to Federal regulation or with whom conducted or source of support (i.e., sponsorship).

All institutional and non-institutional performance sites for the University, domestic or foreign, will be obligated by the University to conform to ethical principles which are at least equivalent
to those of the University or as may be determined by the Dept. of Health and Human Services (DHHS) Secretary.

The Vice President for Research maintains oversight of the University at Albany IRB. The Vice President for Research has designated responsibility for compliance with federal regulations and University policy regarding human participants’ research to the Assistant Vice President for Research for Research Compliance who is the IRB Institutional Official.
The Office of Regulatory Research Compliance (ORRC) provides administrative oversight to the IRB to ensure that the practices and procedures designed for the protection of the rights and welfare of human participants are effective and are in compliance with the requirements of 45 CFR 46.103 and this policy. The management of the membership of the IRB and oversight of member appointments, IRB related activities, communications, and other administrative details are the responsibility of the ORRC.

Principles, Standards, and Guidance

- ORRC promotes a culture of compliance and oversees adherence to the ethical principles outlined in the Belmont Report, the Declaration of Helsinki, Federal and State regulations, and University and sponsoring agency policies and procedures instituted to protect the rights and welfare of human research participants.

- ORRC develops and implements institutional policies and procedures to help ensure the protection of human research participants.

Education and Awareness

- ORRC disseminates information and provides guidance regarding compliance with federal regulations and University and sponsoring agency policies and procedures.

- ORRC develops and implements educational programs and tools to effectively train researchers and staff participating in human participant research and related activities.

- ORRC reviews QA/QI monitoring results to assist in the implementation of education and process enhancements that will raise performance standards related to conduct of research involving human participants.

Administration and Management

- Represents the University to Federal and State regulatory agencies.

- Develops and maintains electronic systems and technology solutions related to the administration of human participant research.

- Recruits and appoints members to serve on the IRB.
Institutional Oversight

- Maintains the sole institutional authority to review, approve, require modifications to, or disapprove human research activities.
- Approves, disapproves, or requires changes to protocols or proposed changes to protocols for all research involving human participants.
- Reviews approved research protocols at intervals appropriate to the degree of risk, but no less than once per year.
- Reviews award proposals to verify adequate funding and protections are available to protect the rights and welfare of human research participants.
- Helps to ensure that all consent documents include the required elements of consent in accordance with Federal and State regulations and University and sponsoring agency policies and procedures.
- Approves all alterations to or waivers of informed consent.

Monitoring

- Conducts internal monitoring of IRB records in accordance with all regulations and policies.

Noncompliance

- Supports and endorses cooperation with University compliance and monitoring efforts and reports instances of noncompliance to the appropriate office.
- Authorizes the suspension or termination of approved research that is not being conducted in accordance with IRB requirements or that has been associated with unanticipated serious harm to participants.

Records and Reporting

- Creates and maintains records for all IRB Committee proceedings and all protocols submitted for review.
- Reports findings of determinations made by expedited review procedures to the appropriate IRB Committee.
- Notifies appropriate individuals and entities of actions to suspend or terminate research that is not being conducted in accordance with IRB requirements or that has been associated with unanticipated serious harm to participants.
- Reports changes in IRB membership to the Office of Human Research Protection in accordance with Federal regulations and University policies and procedures.
INTRODUCTION TO IRB

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

Section 46.102 of the Federal regulations defines **Research** as:

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

And **Human Subject** is defined as:

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

(1) data through intervention or interaction with the individual, or

(2) identifiable private information.

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

**Interaction** includes 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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

**Institutional Review Boards** have been implemented around the world to prevent unethical treatment of human subjects. IRBs in the United States were established as an outcome of Senate hearings (1972) and legislation passed in 1974, and are regulated by the federal government per the Federal Policy for the Protection of Human Subjects (Basic Department of Health and Human Services Policy for Protection of Human Research Subjects in the Code of Federal Regulations Title 45 Part 46.

Prior to the initiation of any research efforts that involve human subjects, IRB review is required.
Institutions found to be in non-compliance with the regulations can lose federal funding of both its research and student programs. In its broadest sense, the purpose of the IRB is to protect the rights and safety of human subjects. In fulfilling its task, the IRB must carefully examine research proposals to arrive at an independent determination that the research will meet the following ethical criteria:

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

The University has established its IRB in accordance with the compositional requirements of Section 46.107 of the Federal regulations. The IRB shall be comprised of at least 5 members from diverse backgrounds to promote complete and adequate review of research activities commonly conducted at the University. Additionally, for each IRB there must be at least one member whose primary concerns are in scientific areas; at least one member whose primary concerns are in nonscientific areas; and include at least one member who is not otherwise affiliated with the University and who is not part of the immediate family of a person who is affiliated with the University.

The Vice President for Research and the Assistant Vice President for Research/Research Compliance Officer shall make appointments to the IRB. The regulations call for diversity of culture, education, experience, etc. of the IRB members. Such diversity helps to promote complete and adequate reviews of the types of research activities commonly reviewed by the IRB. The IRB membership must include:

A. **Nonaffiliated member(s):** The nonaffiliated member(s), who can be either scientific or nonscientific reviewers, should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to recruiting individuals who speak for the communities from which the University will draw its research subjects. The nonaffiliated member(s) should not be vulnerable to intimidation by the professionals on the IRB, and their services should be fully utilized by the IRB.

B. **Scientific members:** Most IRBs include Ph.D. level scientists. Such members satisfy the requirement for at least one scientist. When an IRB encounters studies involving science beyond the expertise of the members, the IRB may use a consultant to assist in the review, as provided by §46.107. Nonscientific member: The intent of the requirement for diversity of disciplines is to include members whose main concerns are not in scientific areas. Therefore, nonscientific members are individuals whose education, work, or interests are not solely in medical or scientific areas.

C. **Representatives of special groups of subjects:** When certain types of research are reviewed, members or consultants who are knowledgeable about the concerns of certain groups may be required. For example, if an IRB reviews research involving prisoners, a member who can represent this group, either an ex-prisoner or an individual with specialized knowledge about this group must be included on the IRB.

D. **Chairperson:** The IRB will have a Chairperson. The Chair will be chosen from the membership of the IRB, who is knowledgeable in human subject research, including the regulations, University and agency policies, and ethics relevant to such research. The Chair generally will serve for two-years. The Vice President for Research may in his/her discretion extend the term. The Chair should provide for a consistent, high quality, and timely review process, and to provide verification of the actions of the IRB. The duties of the Chair include but are not limited to: serving as convener for the IRB, delegating appropriate tasks to IRB members, serving as a liaison (along with the Research Compliance Officer and Research Compliance Administrators) between the IRB and the University community, and monitoring changes in federal regulations and institutional policy for the protection of human subjects in research.
E. The IRB will have alternate members. Such alternate members will have the same qualifications and experience to regular members. Alternate members may be called upon to serve where regular members will be absent from a meeting and there will be less than a quorum at an upcoming meeting. Alternate members will have voting rights and be counted in a quorum only when they replace the respective regular member.

F. Membership is chosen based on the unique expertise that each member brings to an IRB. If a member cannot make a meeting, he/she should provide enough advance notice to the Office of Regulatory Research Compliance so that an alternate can be secured. Because members serve at the pleasure of the University at Albany, failing to regularly attend meetings or the lack of diligence in performing duties will result in removal of a member from an IRB by the Vice President for Research or the Assistant Vice President for Research/Research Compliance Officer.

G. Authority from the Institution. The ORRC/IRB has the responsibility to review and the authority to approve, require amendments of or disapprove research involving human participants conducted by the University’s faculty, students, or staff, or such research involving the use of the University’s facilities, in accordance with administrative policies and procedures established for this purpose. The IRB shall monitor and conduct continuing review of such research at intervals of at least once per year.

H. The IRB, or the ORRC acting on behalf of the IRB, has the authority to inspect research facilities and to obtain records and other relevant information relating to projects it has approved and to observe, or have a third party observe, the consent process and research. The IRB affords protections to participants, and may suspend or terminate approval of projects it has approved and take actions that it judges necessary to ensure compliance with regulations and internal policies. Review and approval must be obtained from the IRB prior to a research project being initiated.

I. Reliance on IRBs of Other Institutions. The IO at the University may elect to rely on the IRB of other institutions for review and approval of a study. In order to do so, that IRB must be officially designated on the University at Albany’s Federalwide Assurance and a written agreement must be in place between the two institutions. This is generally used when a study involves a collaborative research activity between UAlbany and an external institution. In such an event, the IRB of the other institution, referred to as the IRB of Record, holds the same rights, authority and responsibility as the IRB of UAlbany. The Assistant Vice President for Research for Research Compliance who is the IRB Institutional Official (IO).

J. Authority of Institutional Individuals. The IO may not approve a project that has not received the review and approval of the IRB or which has been disapproved by the IRB. In addition to the IRB, the IO may require additional review of research and has the authority to disapprove, suspend or terminate research previously approved by the IRB.
IRB MEMBER CONFLICT OF INTEREST

There will be no selection of IRB members by investigators. All Board Members are required to sign a Confidentiality/Conflict of Interest Statement.

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

In accordance with Federal regulations, University at Albany policy requires the Principal Investigator and all other key personnel on a research protocol to satisfactorily complete required education related to the protection of human participants before engaging in research or review of research involving human participants.

The educational requirement is satisfied by completing the CITI (Collaborative IRB Training Initiative) training program or other human subjects training program as designated, provided, and/or approved by the IRB. If the investigator is a student, the student’s faculty advisor must also complete the required training.

The “Principal Investigator” or “PI” is the person who is directing and/or conducting the research project (i.e., UAlbany Faculty, Staff, Administration, or Student).

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

- Day-to-day protocol decision-making related to the study conduct;
- Participant recruitment, selection and eligibility;
- Clarification of the complexities of the protocol to the participant and others;
- Collecting participant information and entering data using procedures to maintain privacy and confidentiality;
- Ensuring that the rights and welfare of participants are monitored throughout the study.

It is the responsibility of the Principal Investigator to determine who should be considered Key Personnel based on the above criteria for each study. The IRB does not make a judgment on the level of engagement of said individual beyond what is reported on the IRB application.

The link to the CITI course is https://www.citiprogram.org. Of the 7 UAlbany Learning Groups available, the most commonly required would be from the 5 listed below:

**Group 1: Biomedical Investigators and Key Personnel** – This group is intended for professors, research personnel, faculty advisors and key personnel who do engage in Biomedical research (for projects which include any physiologically invasive procedure, i.e. blood draws, carbon dioxide inhalation, saliva swabs, etc.).

**Group 2: Social and Behavioral Investigators and Key Personnel** – This group is intended for professors, research personnel, faculty advisors and key personnel who do not engage in Biomedical research.

**Group 3: Graduate Students** – This group is designed for master’s and doctoral
level students engaged in research or research practice, regardless of whether the research is Social and Behavioral, or Biomedical.

**Group 4: Undergraduate Students** – This group is designed for undergraduate students who may be engaged in research, research practica or a research methods class.

**Group 5: IRB Members and Staff** – This group is designed to meet one of the requirements that IRB members and staff receive comprehensive continuing education.
**PROTOCOL SUBMISSION AND INITIAL REVIEW**

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

After the protocol has passed the initial intake review, the protocol review category is determined. This determination is made according to the Federal regulations and University policy. There are three review levels as provided by the regulations:

**Exempt Studies**

Certain broad categories of research projects that involve human participants *that do meet the definition under the regulations* are “exempt” from IRB review. Federal regulations permit the principal investigator to make an initial judgment as to whether the project is exempt; however only the IRB may determine that an exemption is appropriate. “Exempt” in this context means that a project is not subject to, or is *exempted* from the requirements of the regulations spelled out in 45 CFR 46.

Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

1) **[No age limitations on participants]** 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.

2) **[Note: Participants must be adults – legal age of adulthood]** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, 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.

3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under 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.
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.

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 for benefits or services under those programs.

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.

To qualify as an exempt study, the research must fall within one of the above-specified regulatory categories and satisfy all UAlbany institutional requirements. Only the IRB may determine when research is exempt or requires a full or expedited review. Therefore, researchers must submit an application, requesting exempt status to the IRB ensure that the research meets the criteria for an exemption.

The Following CANNOT be Exempted:

- research involving prisoners;
- surveys or interviews of children;
- observation of children when the investigator will interact with them;
- data obtained from adults through administration of educational tests, survey procedures, interview procedures, or by observation of public behavior IF:
  1. the information is recorded in such a way that the identity of individuals can be identified either directly or through identifiers linked to the individuals
  
    **AND**
  2. disclosure of participants’ responses could reasonably place them at risk of criminal or civil liability or be damaging to an individual’s financial standing, employability, or reputation;
• observation of behavior that takes place in settings in which participants have a reasonable expectation of privacy;

• research techniques which expose participants to discomfort or harassment beyond levels encountered in daily life (i.e., greater than minimal risk);

• deception of research participants

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

Criteria for Protection of Human Subjects in Exempt Research

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

1. The PI assures that all those persons listed on the application as being involved in the research have completed the IRB human subjects training requirements.

2. The PI assures that human subjects will voluntarily consent to participate in the research when appropriate (e.g. surveys, interviews, interactions with participants) and will provide subjects with pertinent information e.g. the activity involves research, a description of procedures, that participation is voluntary, risks and benefits, contact information for PI and IRB Chair, etc.;

3. The PI assures that human subjects will be selected equitably, so that risks and benefits of the research are justly distributed;

4. The PI assures that the IRB will be immediately informed of any information, unexpected or adverse events that would increase the risk to the human subjects and cause the category of review to be upgraded to Expedited or Full review;

5. The PI assures that the IRB will be immediately informed of any complaints from participants regarding their risks and benefits; and

6. The PI assures that confidentiality and privacy of the subjects and the research data will be maintained appropriately to ensure minimal risk to subjects, and there are adequate provisions to maintain the confidentiality of the data if there is any recording of identifiable information.

These criteria are specified on the Principal Investigator Assurance Form of an Exempt Project, and the PI's signature acknowledges that s/he understands and accepts these conditions.
Expedited Review (Initial)

Research may be reviewed by the IRB under expedited status if all research activities present no more than minimal risk to human subjects and involve procedures listed in the expedited review categories of the regulations.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

The following 9 categories of research are permitted to receive expedited review. Most behavioral research falls under Category 7.

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

(a) Research on drugs for which an investigational new drug application 21 CFR Part 312 is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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

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

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

(b) weighing or testing sensory acuity;

(c) magnetic resonance imaging;

(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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

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

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

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

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

(b) No subjects have been enrolled and no additional risks have been identified; or

(c) The remaining research activities are limited to data analysis.

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

The following can NOT be reviewed through the Expedited process.

- Research 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.

- Classified research involving human subjects.
- Research that involves more than minimal risk to human subjects (i.e. the probability and magnitude of harm or discomfort anticipated in the research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).

- Research with prisoners is not eligible for expedited review.

**Expedited Review (Continuing Review)**

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

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

**Expedited Review Category (8)**

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

1. The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or

2. No subjects have been enrolled and no additional risks have been identified; or

3. The remaining research activities are limited to data analysis.

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

**Expedited Review Category (9)**

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

Expedited review of research involving human subjects is done by the IRB Chair, or his/her designee in accordance with the requirements set forth in 45 CFR 46.110.

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

**Full Review**

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

Full Board review of protocols will take place only when a majority (one more than 50% of the full committee) of the Committee members are present, including at least one member whose primary concerns are in nonscientific areas. No official actions will be taken at a meeting where a majority of the members, including a non-scientist, are not present.

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

Satisfaction of these two conditions in addition to the standard regulatory requirements will be documented in the meeting minutes.

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

All Committee members’ votes will be deemed equal and no proxy votes (written or by telephone) will be considered.

The IRB will review all new and continuing protocols to determine the appropriateness of the research in the local research context. Review and approval will be based on detailed applicable information provided in the IRB submission forms (e.g. participant population, participant selection, benefits to participants, mechanisms for protecting privacy, method for minimizing the possibility of coercion, etc.).
The protocol is reviewed, discussed, and voted on by the members. The PI (and faculty/staff advisor, if applicable) is invited to attend to the meeting of the IRB to discuss the protocol. The PI may not be present, however, for the IRB’s deliberation or vote.

All research involving human subjects that is subject to the applicable government regulations requires Full Review unless it meets the criteria for the exceptions as outlined above.
IRB AUTHORIZATION AGREEMENTS – CEDED REVIEW

OHRP supports the idea of IRBs from collaborating institutions to cede review of a human subjects research application to just one of the collaborating IRBs. This eliminates redundancies in the review of a study, and may provide a more efficient process.

An IRB Authorization Agreement is used when an external organization engages in non-exempt human subjects research in collaboration with a UAlbany Investigator and:

1. the external organization/institution is not one with whom UAlbany currently has a cooperative review arrangement, and

2. either the UAlbany IRB or the external organization/institution IRB agrees to be the IRB of record to avoid dual review.

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

(a) data about the subjects of the research through intervention or interaction with them;

(b) identifiable private information about the subjects of the research; or

(c) the informed consent of human subjects for the research.

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

Collaborations with Assured Institutions

Designating UAlbany IRB as IRB of Record

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

This type of agreement is documented by way of an executed IRB Authorization Agreement signed by the signatory officials designated in UAlbany’s and Institution B’s Federalwide Assurance.

The agreement may be limited to a specific research project(s) or may be broader in scope. The Authorization Agreement will specify the scope of the agreement.
The UAlbany IRB will report its findings and actions to Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the UAlbany IRB’s determinations and with the Terms of its Federalwide Assurances. The Authorization agreement will be kept on file by both parties and will be provided to OHRP upon request.

**Designation of external Institution's IRB as IRB of Record**

Alternatively, in other certain circumstances the UAlbany IRB may ask Institution B to agree to be designated as the IRB of record. When this occurs, Institution B’s IRB assumes responsibility for the review and continuing oversight of research on behalf of UAlbany.

Again, the agreement is documented in an executed IRB Authorization Agreement signed by the signatory officials designated in UAlbany’s and Institution B’s Federalwide Assurances.

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

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

**Collaborations with non-Assured Institutions**

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

In this instance, the other institution will be required to:

(a) apply for a Federalwide Assurance, complying with all of the requirements, and

(b) designate the UAlbany IRB as the IRB of record for the research.

When this occurs the UAlbany IRB assumes responsibility for the review and continuing oversight of the specified research on behalf of Institution B.
Unaffiliated Investigator Agreements

UAlbany may also extend its Federalwide Assurance to unaffiliated investigators collaborating with UAlbany if the unaffiliated investigator is not affiliated with an assured institution. Both institutional and independent investigators must meet the conditions for extending a Federalwide Assurance.

The extension of UAlbany’s Federalwide Assurance is documented by way of an executed Individual Investigator Agreement signed by the non-assured institution designee or independent investigator and the signatory official designated in UAlbany’s Federalwide Assurance. The agreement may be limited to specific research projects or may be broader in scope. The Individual Investigator Agreement will specify the scope of the agreement. When UAlbany extends its Federalwide Assurance to another institution or individual the UAlbany IRB becomes the designated “IRB of Record” for the non-assured institution or independent investigator with respect to the research project(s) covered by the Individual Investigator Agreement.

Any unaffiliated individual (as opposed to an institution), who is key personnel on a protocol (i.e., engaged in collaborative research with a UAlbany Investigator) an Individual Investigator Agreement must be submitted to the IRB with the protocol. The UAlbany Investigator should assist the unaffiliated individual investigator in completing the form.

Submit the original document, signed by the unaffiliated individual investigator, to the IRB. After the document has been signed by the UAlbany IRB Institutional Official (or designee), a copy of the document will be provided to the UAlbany Principal Investigator and to the Unaffiliated Individual Investigator.)

If the unaffiliated investigator is conducting research under their own institution’s FWA and that institution has designated UAlbany as the IRB of record, a valid IRB Authorization Agreement must also be in place between the two institutions.
PROTOCOL APPROVAL CRITERIA

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

1. Risks to subjects are minimized.

2. Risks are justified in view of anticipated benefits, if any, to the participants.

3. Selection of subjects is equitable.

4. Informed consent is sought from each prospective subject or legally authorized representative.

5. Informed consent is appropriately documented (when applicable.)

6. Adequate provisions are made for monitoring data collection to ensure safety of subjects (when appropriate).

7. Adequate provisions are made to protect the privacy of subjects and to maintain confidentiality of data (when appropriate).

8. Adequate provisions are made to protect the rights and welfare of participants who are vulnerable to undue influence or coercion (children, pregnant women, mentally disabled persons, economically or educationally disadvantaged, when appropriate).
PROTOCOL REVIEW AND APPROVAL PROCESS

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

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

Review Actions for Exempt and Expedited Studies

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

1. **Final approval** - There are no changes needed in the study and the investigator can proceed with the research without further delay;

2. **Provisional approval** - There are minor revisions that the Board member stipulates. After the stipulated revisions/clarifications are completed the Chair or designee will grant final approval.

3. **Referred for Full Review** - The Reviewer conducting and expedited review does not have the authority to disapprove an application. Disapproval is an action that may be taken only at a convened meeting. Instead, the submission will be referred for full review at a convened meeting.

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

Review Actions for Full (convened meeting) Studies

Review actions for studies reviewed at fully convened meeting of the IRB must be determined by a majority vote of the quorum. A quorum of the IRB is defined as a majority of the total active membership, and in order for official Board business to be conducted, a majority must be present.

A unanimous vote, complete concurrence of the action is not required. A member may vote for FOR or AGAINST approval of a protocol. A member may also ABSTAIN from the vote entirely.
When a study is reviewed and voted on at a full meeting of the IRB Board, there are four possible actions.

1. **Final approval** - There are no changes needed in the study and the investigator can proceed with the research without further delay;

2. **Approved with Provisions** – The IRB has voted to approve this protocol; however the PI may not begin the activity until he/she has made minor revisions and/or clarifications that the IRB stipulates. After the revisions are completed, the IRB Chair or designee may grant the protocol final approval.

3. **Tabled** - There are major problems or concerns with the study that impact the protection of the human subjects. The study will require review again by the IRB at a subsequent meeting after the investigator has addressed all of IRB’s questions or requests for clarification.

4. **Disapproved** – The protocol will require resubmission. Although it is rare, the IRB will disapprove research protocols involving excess risk to the human subjects. In most cases, the IRB tries to work with the researcher to modify his/her protocol in a way that provides appropriate levels of protection for the participants. Specific reasons for disapproving research will be communicated to the PI. The study may not be resubmitted unless completely revised.
PROTOCOL MODIFICATIONS OR AMENDMENTS

All modifications or amendments to approved research must be reviewed and approved prior to implementation. Investigators submit their requests for modifications into the ORRC and include, as appropriate, the revised protocol, consent form, recruitment materials, etc.

A minor modification is defined as a change that:

1. would not materially affect an assessment of the risks and benefits of the study or
2. does not substantially change the specific aims or design of the study. Minor changes that do not increase the risk to research subjects may receive an expedited review.

Examples of minor modifications include:

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

A major modification is defined as:

1. A change that materially affects an assessment of the risks and benefits of the study, or
2. Substantially changes the specific aims or design of the study.

**NOTE:** Major modifications to approved protocols that may increase the risk to subjects require a full board review.

The IRB may only approve modifications submitted during a current approval year to the end of that period. For example, if the new or annual review takes place on January 2, 2010, the protocol will have an expiration date of January 1, 2011. If a modification is approved during this time, the expiration date still remains January 1, 2011. All modifications, amendments, and, when applicable, informed consent forms should be incorporated into the renewal application for IRB consideration during the annual review.
CONTINUING REVIEW OF PROTOCOLS

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

Investigators are required to report any study-related adverse or unanticipated problem that occurs during the protocol approval period. Unanticipated problems involving risks (such as a breach of confidentiality, subject complaints, or protocol deviations) can occur in all types of human subject research - both behavioral and biomedical.

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

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document, and (b) the characteristics of the subject population being studied;

- Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the drugs, devices or procedures involved in the research); and

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

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

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

Based upon such information, the IRB may reconsider its approval of the study, require modifications to the protocol and/or consent process, or revise the continuing review timetable.
SUSPENSION OR TERMINATION OF IRB APPROVED OF RESEARCH

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

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

1. is not being conducted in accordance with the IRB’s requirements and federal regulations;
2. is not being conducted in accordance with applicable rules and regulations or the IRB’s requirements;
3. has been associated with unexpected serious harm to participants;
4. creates a potential threat to the safety and welfare of research participants, the research community and/or others.

Any suspension or termination of approval includes a statement of the reasons for the IRB’s action and is reported promptly to the principal investigator, other investigators involved in the research, department chairs/heads, the institutional official, OHRP and funding sources.

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

Protocol approval automatically expires at the end of the approval period. Investigators will be notified by the IRB at least annually following the initial approval of the research. At these notification intervals, investigators must submit either a continuation request or a closure form.

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

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

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

Principal investigator exits UAlbany (e.g., graduates, changes jobs, etc.)

The policy at UAlbany is that review of research by its IRB is limited to research done under its own auspices. This means that only research involving human subjects that is conducted by UAlbany faculty and staff in carrying out the duties of their employment or for students in carrying out research in fulfillment of educational requirements at UAlbany may be reviewed by the UAlbany IRB.

Thus, when a principal investigator terminates employment or other association with UAlbany, all research protocols under the purview of the UAlbany IRB will be closed.

It is the responsibility of the principal investigator to notify the IRB if he or she is leaving the University and submit a closure form.

The principal investigator may also request to transfer the protocol to another principal investigator at UAlbany via a modification request.

Notice of study closure or request to transfer to another principal investigator should be submitted to the IRB within 30 days of closure or transfer of the study.
IRB REVIEW CONSIDERATIONS

Determining Minimal Risk or Greater than Minimal Risk

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

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

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

When a research protocol is determined to involve minimal risk, IRBs are given the latitude to waive certain consent requirements, so long as certain conditions are met. Moreover, IRBs may expedite the review of research protocols—relying on the review by a single member, that typically involve minimal risk.

The application of this concept can be difficult in practice. For example, a "typical" minimal risk encountered in everyday life may be perceived differently by some individuals with certain disorders. Determination of what constitutes minimal risk in the context of research is often more difficult than it would appear to be on the surface. At one end of the spectrum are research projects that obviously involve only minimal risk and on the other end are research projects that certainly present greater than minimal risk. Between these two ends of the spectrum lies the research in which risk determination may be a matter of judgment. And, all too often, research projects that may appear at first glance to involve no more than minimal risk actually have the potential for harm that is more than minimal.

Webster's Dictionary defines minimum, as "... The least quantity or amount possible, assignable, allowable, etc." Risk is defined as "exposure to the chance of injury or loss; a hazard or dangerous chance." Although Webster's offers no definition of minimal risk per se, we can extrapolate the meaning as "the least possible exposure to the chance of injury or loss" this appears to be a clear definition, but it is not the definition that IRBs use when determining minimal risk.

What constitutes discomfort? How does one quantify probability? The "daily life" of whom? The concept of minimal risk is qualitative rather than quantitative and considerable room for interpretation exists. Dr. Gary Ellis, of the Office for Protection from Research Risks (now known as the Office of Human Research Protections) stated that "this system of protection of human subjects in research is based on a succession or chain of judgments made by people
in the context of Federal regulations...there is no computer program for this; there is no generic formula..."

Dr. Ellis continues: "...so our office prefers to interpret the concept of daily life as meaning the daily life of all people, which includes the research subjects, which includes healthy people, includes people who are less than healthy. So if you proceed in that manner, you would not ever come to the conclusion that you can inflict harms or discomforts on people who are in considerable harm or discomfort because it's no worse than they are anyway (sic), and it would be most protective for human subjects."

IRB members must consider the risk that is encountered in the daily lives of a broad spectrum of people, and cannot consider only the day-to-day experiences of the lives of the subgroup of people at whom the research is directed. This concept may seem confusing, but, as Dr. Ellis has stated, it "allows IRBs the latitude they need to use their best judgment when reviewing research in the context of their local conditions." IRBs are asked to make judgments, and determination of risk is one of those judgments that may differ from board to board. If IRBs are mindful of both the letter and spirit of the regulations, the differing levels of acceptable risk will be slight.

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

Evaluation of the risk/benefit ratio is the major ethical judgment that IRBs must make in reviewing research proposals. The risk/benefit assessment is not a technical one valid under all circumstances; rather, it is a judgment that often depends upon prevailing community standards and subjective determinations of risk and benefit. Consequently, different IRBs may arrive at different assessments of a particular risk/benefit ratio.

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

The benefits of research fall into two major categories: benefits to subjects and benefits to society. For instance, frequently, the research subjects are undergoing treatment, diagnosis, or examination for an illness or abnormal condition. This kind of research often involves evaluation of a procedure that may benefit the subjects by ameliorating their conditions or providing a better understanding of their disorders. Patients and healthy individuals may also agree to participate in research that is either not related to any illnesses they might have or that is related to their conditions but not designed to provide any diagnostic or therapeutic benefit. Such research is designed principally to increase our understanding and store of knowledge about human physiology and behavior.

Research that has no immediate therapeutic intent may, nonetheless, benefit society as a whole. These benefits take the form of increased knowledge, improved safety, technological advances, and better health. The IRB should assure that the anticipated benefits to research subjects and the knowledge researchers expect to gain are clearly identified.
Direct payments or other forms of remuneration offered to potential subjects as an incentive or reward for participation are not be considered a "benefit" to be gained from research. Although participation in research may be a personally rewarding activity or a humanitarian contribution, these subjective benefits should not enter into the IRB's analysis of benefits and risks.

**Equitable Selection of Subjects**

The requirement for an equitable selection of subjects helps ensure that the burdens and benefits of research will be fairly distributed. In the 19th and early 20th centuries, the burdens of research fell largely upon poor patients in hospital wards, while the benefits flowed primarily to private patients. This inequity was starkly revealed in the Tuskegee syphilis study, in which disadvantaged blacks in the rural south were recruited for studies of the untreated course of a disease that was by no means confined to that population. The IRB must scrutinize the investigator's selection of participants to determine whether some classes (e.g., welfare patients, 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.

**Informed Consent**

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

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

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

No one can guarantee that another person has understood the information presented; one can only inform prospective subjects as clearly and completely as possible. No one can guarantee that another’s choice is voluntary; one can only attempt to remove obvious impediments to free choice by being alert to coercive aspects of the consent procedure.

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

If the research presents significant risk, or if subjects are likely to have difficulty understanding the information to be provided, the IRB may suggest that investigators employ devices such as audiovisual aids, tests of the information presented, or consent advisors.
Because obtaining informed consent is an educational process, the IRB should do what it can to enhance the prospective subject's comprehension of the information presented. It should consider the nature of the proposed subject population, the type of information to be conveyed, and the circumstances under which the consent process will take place (e.g., manner, timing, place, personnel involved).

Consent is not a single event; rather, it is a process. Since subjects always retain the right to withdraw from a research project, their continuing consent is important. IRBs should be aware that subjects often seem to forget they are involved in research or have difficulty distinguishing research interventions from diagnostic and therapeutic interventions.

When a research proposal is first approved, the IRB should determine whether consent should be renegotiated as a formal matter during the course of the research. If renegotiation is required, the frequency and/or events that will trigger this process should be decided upon and made clear to the investigators.

**Required elements of Consent**

1. **Study Title**
2. **Investigator(s) are listed, and her/his affiliation with UAlbany is described**
3. **Purpose of this Research Project** (does the consent document include):
   a. A clear statement that the study involves research
   b. Nature of the study
   c. Purpose for conducting the research
4. **Procedures**
   a. Step-by-step explanation of what will be expected from study participants
   b. Length and frequency of each study procedure and total time commitment for the subject
   c. Location of the research
   d. The instruments / documents that will be used and conditions involved (include an explanation of the instruments in appropriate language)
5. **Risks**
   a. All potential risks described (mental, social, financial, legal, dignity, or physical). [Note the use of survey questions of a sensitive nature may pose emotional distress caused by remembering unpleasant experiences]
   b. Safeguards that are to be employed to reduce or minimize risks
6. **Benefits**
   a. All direct or indirect benefits
b. If no benefits accrue to the subjects, the larger societal benefits

c. Note, Compensation is not included/described in this section

7. **Extent of Anonymity and Confidentiality**
   a. Extent to which subjects will be identifiable

   b. Explanation of how the study will provide the utmost confidentiality or anonymity [confidentiality = individual can be identified directly or through identifiers, but the researchers promise not to divulge that information; anonymity = individuals cannot be identified by anyone, including researchers]

   c. Explanation of the use of study ID/codes, if applicable

   d. Explanation of who will have access to the data

   e. Statement, “It is possible that the Institutional Review Board (IRB) may view this study’s

   f. collected data for auditing purposes. The IRB is responsible for the 
   oversight of the protection of human subjects involved in research.”

   g. Description of when data will be destroyed

8. **Compensation**
   a. Subjects informed whether compensated or not

   b. Amount of compensation (including extra credit, if applicable)

   c. If extra credit is offered, what comparable alternative means of obtaining extra credit will be offered to those who decline to participate in the study

9. **Freedom to Withdraw**
   a. Statement that subjects are free to withdraw from the study at any time without penalty.

   b. If study involves compensation, statement that subjects will be compensated for the portion of their time spent in the study (if applicable) or fully compensated if they choose to withdraw.

   c. Statement that subjects are free not to answer any questions or respond to experimental situations that they choose without penalty.

   d. Optional: Statement describing that there may be circumstances under which the investigator may determine that a subject should not continue as a subject. The subject must be compensated for the portion of the project completed.
10. **Subject’s Responsibilities (When applicable)**
   a. Statement, “I voluntarily agree to participate in this study. I have the following responsibilities:”

   b. List of subject’s responsibilities.

11. **Subject’s Permission**
   a. Statement, “I have read the Consent Form and conditions of this project. I have had all my questions answered. I hereby acknowledge the above and give my voluntary consent.”

   b. Signature line for subject

   c. Optional: Signature line for witness (when applicable)

12. **Contact information of Investigator(s)**

13. **IRB Contact Information and Human Rights Statement.** Include the following required text after the principal investigator contact information.

   a. Required text: “If you have any questions concerning your rights as a research participant that have not been answered by the investigator or if you wish to report any concerns about the study, you may contact the University at Albany’s Office of Regulatory Research Compliance at 518.442-9050 or orrc@uamail.albany.edu.”

   **[NOTE: If any of the participants in your study will be outside the 518 calling area, please substitute the toll-free number: 800.365.9139.]**

12. **Format and Structure of Consent Document**
   a. Language of the consent form is directed toward the individual signing the form (avoiding use of jargon, scientific terms, and concepts not readily comprehended by the non-scientist public)

   b. The text and readability of consent form is appropriate for the age, mental capacity and maturity of the individual signing the form

   c. The consent form does not contain any exculpatatory language through which the subject or the representative is made to waive or appear to waive any of his legal rights or release the investigator, the sponsor, the institution or its agents from liability for negligence.

   d. The final draft of the consent document has been reviewed for grammatical and typographical errors.
Documentation of Informed Consent

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

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

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

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

Before a short form can be used, the IRB must first review and approve a written summary of what will be presented. Each oral presentation must be witnessed by a third person, who must sign both the consent form and a copy of the written summary of the presentation. A copy of the summary must be provided to those who sign the consent form so that they have the information available for future reference.

The regulations allow an IRB to waive certain consent requirements for research. However, the IRB must still make sure that the subjects will be provided adequate information about the research. The IRB may decide that, in some cases, subjects should be provided written copies of the information conveyed despite the fact that they are not asked to sign a consent form.

Waiver of some or all of the Required Elements of Consent

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

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

Or
The IRB may approve a waiver of some or all of the consent requirements provided that:

- the research involves no more than minimal risk to subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- the research could not practicably be carried out without the waiver or alteration; and
- whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study.
- The research is not FDA regulated.

**Participant Withdrawal**

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

The consent form should include information regarding what the PI will do with the information that he/she has gathered from that subject if s/he withdraws from the study. The regulations do not require that the investigator return the data to the participant or destroy what has been already collected.

For example:

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

or

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

or

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

**Protocols and consent documents must address incentives payments and provide either:**

1. describe the plan for pro-rated distribution of incentives to participants if they choose to withdraw voluntarily from the protocol or if, upon the suggestion of investigator, early withdrawal is necessary,
OR

2. provide justification(s) to why prorated distribution of incentives is not being offered to the participants

**Participant Compensation**

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

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

Any credit for payment should accrue as the study progresses and not be contingent only upon the subject’s’ completing the entire study. Unless it creates undue inconvenience or a coercive practice, payments to subjects who withdraw from the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn.

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

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

**Guidelines for compensating research participants for their time and effort**

Investigators are responsible of informing the IRB of payments to research participants in the IRB Application for Initial Review. Investigators are responsible for disclosing to research participants any payment being offered for their participation in the research study in the informed consent form.
1. The IRB and participant should be informed how payment will be prorated or provided in total.

2. The participant should be informed when/how payment will be disbursed.

3. The IRB reviews all payment arrangements to participants for the following criteria:
   
   a. Payments to participants cannot be of such a nature to affect the equitable selection of participants;

   b. The amount of payment and the proposed method and timing of disbursement must be neither coercive nor present undue influence;

   c. Credit for payment must accrue as the study progresses, and not be contingent upon the participant completing the entire study;

   d. Describe the plan for pro-rated distribution of incentives to participants if they choose to withdraw voluntarily from the protocol or if, upon the suggestion of investigator, early withdrawal is necessary, or

   e. Provide justification(s) to why prorated distribution of incentives is not being offered to the participants.

   f. The entire payment may not be contingent upon completion of the entire study;

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

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

The federal regulations require that IRBs give special consideration to protecting the welfare of particularly vulnerable subjects, such as children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons.

For research to which the regulations are applicable, the regulations set forth specific provisions on research involving:

- fetuses,
- pregnant women,
- human in vitro fertilization;
In general, these special regulations allow IRBs to approve research that is of minimal risk or that will benefit the subjects directly.

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

Research involving prisoners, fetuses, pregnant women, or human in vitro fertilization is not eligible for administrative or exempt review.

Also, the exemption for research involving survey or interview procedures, or observation of public behavior, does not apply to research involving children except for research involving observations of public behavior when the investigator does not participate in the activities being observed.

**Research Involving Prisoners**

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

“Penal” means relating to the punishment of offenders under the legal system; subject to punishment by law.

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

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

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

- the research falls into one of the following permitted categories (45 CFR 46.306)
 study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

 study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

 research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject;

 in cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only with the approval of the Secretary of the Department of Health and Human Services;

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

 the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

 procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners; unless the PI provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for the particular research project;

 the information is presented in language which is understandable to the subject population;

 adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

 where there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners’ sentences, and for informing participants of this fact.

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

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

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

Research that does not involve direct intervention with children does not usually require parental consent or child assent. However, permission of the school (superintendent or principal) and compliance with the provisions of FERPA (Family Education Rights and Privacy Act or “the Buckley Amendment”) are required.

Examples of research that does not involve direct intervention with children include:

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

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

Examples of research that involves direct intervention with children include:

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

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

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

- the risk is justified by the anticipated benefit to the subjects,
- the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches, and
- adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

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

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

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

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

Children who are wards of the State or any other agency, institution, or entity can be included in research approved under section 46.406 of the regulations (Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition) or section 46.407 (Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children).

A “ward” is defined as: Any child who is under the protection of the state or any other agency, institution or entity.

In New York State, any foster child should be considered a ward. A foster child is any child in the care and custody of the local social services commissioner or an authorized agency, who is placed for temporary or long term care. If research is to be conducted in a state other than New York, the investigator should check appropriate state and local laws and regulations before conducting research to determine the definition of a ward. The IRB can provide assistance with this determination.

Children who are Wards may be included in research only if the IRB determines that such research is:

(a) Related to their status as wards; or

(b) Conducted in schools, camps, hospitals, institutions or similar settings in which the majority of children involved as subjects are not Wards.

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

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

Children Categorized as PINS (Person In Need of Supervision)

Under New York State law, Persons in Need of Supervision (PINS) are juveniles less than 18 years of age (minors) for whom complaints were filed with local probation departments because of non-criminal misconduct, such as truancy from school, incorrigibility, ungovernability or habitual disobedience. Complainants in these cases are generally parents or school officials who are seeking the formal intervention of the family court to control a juvenile's misconduct. PINS cases are recorded in the county in which a PINS complaint is filed.
PINS cases are governed by the Office of Children and Family Services (OCFS). A PINS placement is not considered a criminal adjudication or a sentence. Accordingly, these children would be considered wards and not prisoners.

**Requirement of Assent for Research Involving Children**

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

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

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

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

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

As a "rule of thumb," many IRBs use the age of seven years as the approximate time when it becomes appropriate to seek assent. Seven is of course a mystical number, and moral theologians have used this age for several centuries as the "age of reason," at which one becomes capable of sin. They may not have been far off, as more recent scholarship would indicate that complex decision making, especially that including altruistic motivation and personal autonomy, is taking shape in many children by age seven. But, it is more important to look at the child than it is to look at the birth certificate. A bright child who's asking questions should be involved in the process, even if s/he's only 5-1/2. A child who's more sluggish and passive may be hard to involve until later. And of course, a child with mental retardation may not be capable of assent until much later.

**Documentation of Assent**

There is no absolute regulatory or ethical standard for documentation of assent. The regulations that "When the IRB determines that assent is required, it shall also determine whether and how assent must be documented." That being said, there’s a strong implication
that documentation would be the usual requirement. That is, the regulations go to the extent of giving the IRB the authority to waive the requirement for assent in certain circumstances. That level of regulatory oversight suggests that failure to solicit assent is considered to be a serious violation; that in turn suggests that there should be a mechanism for knowing whether such a violation has occurred.

The IRB has expected investigators to describe what they are doing about assent of minors in research, and how they’re documenting it. We often encourage the use of a written assent form for a couple of reasons:

1. First of all, it is symbolic – saying that the child’s right to involvement in this process is real.
2. The form, if well done, is a useful tool in explaining the study to a child, and serves as a reference source for that child.
3. Making the investigator think through a study well enough to be able to write a clear and simple assent form may make the researcher actually understand the study better and do a better job on the adults’ consent form, too.
4. The use of a form satisfies the documentation issue.

An oral assent process with less detailed documentation may certainly also be acceptable, especially in studies of very low risk. Researchers may wish to propose this option.

Research Involving Decisionally Impaired Subjects

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

Individuals in a wide variety of situations may have impaired decision-making capacity. For example, impairment may occur at times of great stress. Impaired capacity is not limited to individuals with neurologic, psychiatric, or substance abuse problems; conversely, individuals with neurologic, psychiatric, or substance abuse problems should not be presumed to be decisionally impaired. Some research questions may only be answered by research that involves persons with impaired decision making capacity; precluding this research would contribute to needless suffering. The most severely impaired individuals have the greatest need for the benefits of research and treatment. While this area is controversial, limiting research to the least impaired individuals would hamper research on the underlying causes and potential therapies of many disorders. Not all research will directly benefit the individual participant but may offer future benefits to others who have or will develop the condition or disorder.

Unlike research involving children, prisoners, pregnant women, and fetuses, no additional regulations specifically govern research involving persons who are cognitively impaired. But, additional scrutiny by IRBs and investigators is warranted for such research.
As a general rule, all adults, regardless of their diagnosis or condition, should be presumed competent to consent unless there is evidence of serious mental disability that would impair reasoning or judgment. Even those who do have a diagnosed mental disorder may be perfectly able to understand the matter of being a research volunteer, and quite capable of consenting to or refusing participation. Mental disability alone should not disqualify a person from consenting to participate in research; rather, there should be specific evidence of individuals' incapacity to understand and to make a choice before they are deemed unable to consent.

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

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

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

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

Because no generally accepted criteria for determining competence to consent to research (for persons whose mental status is uncertain or fluctuating) exist, the role of the IRB in assessing the criteria proposed by the investigator is of major importance. The selection of an appropriate representative to consent on behalf of those unable to consent for themselves must be accomplished without clear guidance from statutes, case law, or regulations. Within the boundaries of existing legal precedents, IRBs can be creative in helping investigators formulate appropriate procedures in these uncertain areas.

Options for Additional Safeguards

- A sliding scale involving assessment of risks, benefits, and capacity to consent should guide the IRB’s decisions regarding additional safeguards. Many strategies are available as options for investigators as they develop their research protocols and for IRB members as they evaluate them. In considering increasing levels of risk and/or impairment, investigators should be creative in choosing appropriate protections, seeking strategies used successfully in other situations.

- Use of an Independent Monitor. When reviewing greater than minimal risk research involving individuals with questionable capacity to consent, IRBs should discuss and document the potential value of an independent monitor. A monitor can be appointed to be present when investigators invite individuals with impaired decisionmaking capacity to participate in a research study. The consent process should be visible throughout, and IRBs have a right to observe recruitment, assessment, the informed consent process, and debriefing of research participants (and/or their family/surrogates).

- Use of a Surrogate. Where permitted by law, individuals with impaired capacity may have a family member or other legally authorized representative serve as a surrogate for research decisions, with this role documented during the consent process. Surrogates should be informed of the risks, benefits, and alternatives to the research when they are providing permission for an individual to participate. Whenever possible, surrogates should make research decisions based on substituted judgment, reflecting the views of the individual expressed while decisionally capable. Best interest standards should be used if the values of the individual are not known. It is important that surrogates receive some education about their own role, the cognitive and health status of the research participant, as well as about the study in which the participant may be involved.

- Use of Assent in Addition to Surrogate Permission. The autonomy of individuals with impaired decision making capacity should be respected. Their assent to participation in research should be obtained whenever possible and their decision to withdraw from a study at any time should be honored.

- Use of Informational/Educational Techniques. Because informed consent is an ongoing process throughout the course of the protocol, assessing and enhancing
comprehension at each stage is essential. Single sheet summaries of important information about key elements of a study may be useful when provided on a regular basis. Questions from potential participants and family members should be encouraged, and handouts of frequently asked questions and answers regarding specific human subject protections can be prepared. Model consent forms and procedures can be developed. Communication between members of the research team and participants and their families is key to successful research participation.

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

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

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

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

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

One of the challenges presented with student participation in research conducted in schools is the possibility that their agreement to participate will not be freely given. Students may volunteer to participate out of a belief that doing so will place them in good favor with their teacher (e.g., that participating will result in receiving better grades, recommendations, employment, or the like), or that failure to participate will negatively
affect their relationship with the investigator or teacher generally (i.e., by seeming "uncooperative," etc.)

To avoid any potential for undue influence, the Principal Investigator should formally delegate this responsibility to someone who does not have the teacher/student or employer/employee relationship to the potential subject, and the person delegated should receive appropriate training, to perform the informed consent process and, if applicable, the recruitment process.

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

The involvement of students, staff or employees in such studies requires a statement in the consent form acknowledging that refusal to participate will have no influence on grades, recommendations or job status.

**Principal Investigator’s Clinical Patient Population**

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

**Non-English Speaking Subjects**

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

If an investigator intends to enroll subjects who speak a language other than English, a translated version of the informed consent form must be submitted to the IRB for approval prior to use. A person who is fluent in both English and the participant’s language must participate in the informed consent process.

If the person authorized to obtain informed consent in the research protocol is not fluent in the participant’s language, an interpreter should be obtained. Family members and friends of the potential subject may not act at the sole translation/interpretation source for enrollment and participation in a research protocol, as they are not familiar with research terminology, may withhold information during the translation process, or may change the meaning of what is said by the potential subject or research staff.
All other study related documents that will be filled out by the participant (e.g., surveys, data collection forms, self-assessment tools, etc) must also be translated into the subject’s native language. If the study involves more than one study visit, a plan must be developed to ensure that an appropriate party is available to conduct all study visits in the subject’s native language.

**Monitoring Data Collection**

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

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

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

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

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

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

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

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

Assuming that respect for privacy is a critical component of ethical research, the IRB will have to determine whether or not particular activities constitute invasions of privacy. Such determinations are complicated because differentiating between public and private behavior is not always easy and because concepts of privacy vary from culture to culture.

An individual's right to privacy from research inquiry is generally protected by the right to refuse to participate in research. Privacy issues arise when investigators wish to use personally identifiable records without obtaining consent or conduct covert observation or participant observation.

Ensuring Confidentiality

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

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

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

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

If confidentiality is promised, identifying information should not be stored with research data. Every effort should be made to protect identifying information through the use of passwords, locked computers, locked cabinets, etc.
Reportable Disclosures – Mandated Reporting

While any person may make a report if they have reasonable cause to believe that a child or elder was abused or neglected, New York law mandates that certain persons who suspect child abuse or neglect report this to the New York Department of Children and Family Services as appropriate.

However, in the role of researcher, or Principal Investigator, at UAlbany, it is more likely that you will not be acting in your “professional capacity” or “official capacity” (i.e., as elementary school personnel or social worker, etc.) and, therefore, will not be required to report and, thereby, breach confidentiality.

Reporting information disclosed to you by a research participant, to whom you have promised confidentiality, without his or her consent, is a breach of that promise.

If there is cause for the Principal Investigator to believe that such a breach may be necessary in carrying out the research protocol, the IRB requires clear, explicit information be given to prospective participants and the solicitation of informed consent from all adult research subjects and assent from children involved as research subjects, in addition to the consent of their parents/legal guardians.

In New York State, mandated reporters are required to report suspected child abuse or maltreatment when, only when they are acting in their professional or official capacity.

The Abused and Neglected Child Reporting Act (P.A. 79-65, cite 325 ILCS 5/1 et seq.), approved June, 1975 states:

Sec. 4. Any physician, resident, intern, hospital, hospital administrator and personnel engaged in examination, care and treatment of persons, surgeon, dentist, dentist hygienist, osteopath, chiropractor, podiatrist, physician assistant, substance abuse treatment personnel, Christian Science practitioner, funeral home director or employee, coroner, medical examiner, emergency medical technician, acupuncturist, crisis line or hotline personnel, school personnel, educational advocate assigned to a child pursuant to the School Code, truant officers, social worker, social services administrator, domestic violence program personnel, registered nurse, licensed practical nurse, advanced practice nurse, home health aide, respiratory care practitioner, director or staff assistant of a nursery school or a child day care center, recreational program or facility personnel, law enforcement officer, registered psychologist and assistants working under the direct supervision of a psychologist, psychiatrist, or field personnel of the New York Department of Public Aid, Public Health, Human Services (acting as successor to the Department of Mental Health and Developmental Disabilities, Rehabilitation Services, or Public Aid), Corrections, Human Rights, or Children and Family Services, supervisor and administrator of general assistance under the New York Public Aid Code, probation officer, or any other foster parent, homemaker or child care worker having reasonable cause to believe a child known to them in their professional or official capacity may be an abused child
or a neglected child shall immediately report or cause a report to be made to the Department."

**What does “professional” or “official” capacity mean?**

An example would be a doctor examining a child in her practice who has a reasonable suspicion of abuse. The doctor must report her concern. In contrast, the doctor who witnesses child abuse when riding her bike while off-duty is not mandated to report that abuse. The mandated reporter’s legal responsibility to report suspected child abuse or maltreatment ceases when the mandated reporter is not officially practicing his/her profession.

If you are not acting in your professional capacity in conducting the research, you may maintain the confidentiality of the data that you collect without making the report or disclosure.

**If you will be conducting research while in your professional or official capacity**

If conducting research while in your professional or official capacity and through interview or measurement, the subject is likely to disclose illegal or dangerous behavior (e.g., if the subject reports any kind of abuse or serious harm to self or others):

- You must make yourself known as a “mandated reporter to parents of children under age 18, to subjects who are children, and to subjects who are potential victims of elder abuse or neglect.

- The investigator must disclose whether and to whom information will be reported. The investigator should include a description of the limits to confidentiality within the consent document.

- The intent-to-report statement must be clearly stated in the consent form, must be **bolded**, and must state clearly/describe the **specific circumstances** under which the researcher/research team will make the report, and **explain the actions that will be taken**.

- Whenever there is the possibility of such reportable disclosure or mandated reporting, the risk level of the protocol will be “**more than minimal risk**”, and the protocol will require **full review** at a fully convened meeting of the IRB.

Investigators should consult the IRB for guidance and assistance for determination regarding mandatory reporting requirements.

**Certificates of Confidentiality**

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

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

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

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

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

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

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

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

**Research Using Deception or Withholding Information**

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

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

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

Where deception is involved, the IRB needs to be satisfied that the deception is necessary and that, when appropriate, the subjects will be debriefed. (Debriefing may be inappropriate, for example, when the debriefing itself would present an unreasonable risk of harm without a countervailing benefit.)

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

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

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

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

**Secondary Subjects and Third Parties**

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

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

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

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

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

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

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

The IRB And HIPAA

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

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

Authorization forms that assure research is HIPAA compliant are available from the covered entities where the study is conducted. The original authorization must be on file at the covered entity and a copy must be on file with the UAlbany IRB. The privacy rule does not override the federal regulations for human subjects research.

A **covered entity** is:
- a health plan
- a healthcare clearinghouse, or
- a healthcare provider

that transmits any health information in electronic form in connection with healthcare transactions.

The following 18 individual identifiers are **Protected Health Information** (PHI):
- Names
- Geographic subdivisions smaller than State (e.g., cities, streets, counties)
- All elements of dates (except year) for dates directly related to an individual, e.g., birthday, date of death, date of hospitalization
  
  ◊ Note: All ages over 89 must be aggregated into a single category called "age 90 or older"
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
Web Universal Resource Locators (URLs)

Internet Protocol (IP) address numbers

Biometric identifiers, including finger and voice prints

Full face photographic images and any comparable images; and

Any other unique identifying number, characteristic, or code, except as permitted by the provision for re-identification.

Under certain circumstances, however, the Privacy Rule permits a covered entity to use or disclose PHI for research without an individual's Authorization. One way a covered entity can use or disclose PHI for research without an Authorization is by obtaining proper documentation of a waiver of the Authorization requirement by an Institutional Review Board.

An IRB’s authority to approve a waiver or an alteration of the Privacy Rule's Authorization requirement is in addition to, not in lieu of, the traditional IRB authorities to protect research participants from risks.

Research Use / Disclosure with Individual Authorization

The Privacy Rule permits covered entities to use or disclose protected health information for research purposes when a research participant authorizes the use or disclosure of information about him or herself. In this case, documentation of IRB approval of a waiver of authorization is not required for the use or disclosure of protected health information.

To use or disclose protected health information with authorization by the research participant, the covered entity must obtain an authorization that satisfies the requirements of 45 CFR 164.508. The Privacy Rule has a general set of authorization requirements that apply to all uses and disclosures, including those for research purposes.

Special provisions apply:

- Unlike other authorizations, an authorization for a research purpose may state that the authorization does not expire, that there is no expiration date or event, or that the authorization continues until the “end of the research study;” and

- An authorization for the use or disclosure of protected health information for research may be combined with a consent to participate in the research, or with any other legal permission related to the research study.

Research Use / Disclosure without Individual Authorization

To use or disclose protected health information without authorization by the research participant, a researcher must obtain documented Institutional Review Board (IRB) Approval. An alteration or waiver of research participants’ authorization for use/disclosure of information about them for research purposes must be approved by the IRB.
The waiver form must accompany the IRB application upon submission for review and must satisfy these criteria:

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
   - an adequate plan to protect the identifiers from improper use and disclosure;
   - an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
   - adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

2. The research could not practicably be conducted without the waiver or alteration; and

3. The research could not practicably be conducted without access to and use of the protected health information.

De-identified Protected Health Information

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

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

Data that does not contain both health information and identifiers, such as de-identified data, which used and stored by a covered entity may be used without authorization or disclosure.

The IRB and FERPA – Use of Educational Records in Research

The Family Educational Rights and Privacy Act of 1979 (FERPA or the Buckley Amendment) is a federal law which states that “An educational agency or institution shall obtain the written consent of the parent of a student, or the eligible students before disclosing personally identifiable information from educational records of a student, other than directory information. Thus, for any research which involves obtaining identifiable information from student records, the investigator must obtain written permission from the parents. Blanket permission giving access to any information in the records is not acceptable.
Although this is not a human subjects issue, per se, the IRB cannot approve a research project unless the procedures for complying with FERPA are acceptable. This is true regardless of the willingness of the school district to release the information without permission. Although this is a school responsibility, the University (and the investigator) would also be liable for any violation of this law.

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

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

**Directory Information**

**K-12 Students**

Name of student in attendance or no longer in attendance; address; date and place of birth; telephone listing; dates of attendance; participation in officially recognized activities and sports; height and weight, if member of athletic team; awards and honors received; and other similar information.

**College Students**

Names, addresses (including email), and telephone numbers; Dates of attendance (including term units carried and full-time/part-time status); Classification (e.g. sophomore, senior, graduate student); Major/minor/degree program; Degrees conferred (including dates/anticipated dates); Previous institution(s) attended; Awards and academic honors; Participation in officially recognized sports and activities; Physical factors (weight and height) of members of athletic teams.

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

- Consent to disclose educational records for those under the age of 18 must be given by parent(s), legal guardian(s), or other designated person(s).

- For students over 18, only the student can consent to such disclosure. Such information includes course schedules, reports of concern, grades, disciplinary records, and student account information.

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

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

Research subjects must be informed prospectively that such recording will occur, and be provided with information about the storage, confidentiality, and future use of the resulting recording.

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

Elements for consideration:
- Type of recording that will be utilized;
- Specific identifiers that will be recorded, e.g., partial facial features, full facial features, subject’s name;
- People who will have access to the recording(s)/image(s);
- Mechanisms in place to protect the confidentiality of the person(s) being recorded;
- Clear indication of when the recording(s)/image(s) will be destroyed or that recording(s)/image(s) will be kept indefinitely;
- Use(s) of the recording(s)/image(s), including educational or commercial purposes, analysis by the research team; or future unspecified use;
- Compensation, if any, to subjects for allowing themselves to be taped/photographed.

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

If the recording is not required as part of the research procedures, then the consent document must include a specific statement indicating that participation in the research study is not contingent upon agreeing to be recorded. A separate consent signature for permission to record will be necessary. This permission can be in the form of a consent addendum, which includes the considerations listed above, or a separate signature line on the informed consent document labeled specifically for permission to tape or photograph. If a separate signature line is used, the considerations listed above must be included within the body of the informed consent document.
The consent addendum must be reviewed and approved by the IRB prior to implementation. This approval will be documented in accordance with the University approval stamp guidelines.

**Computer and Internet-Based Data Collection**

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

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

**Recruitment**

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

Unsolicited e-mail messages to multiple users are prohibited unless explicitly approved by the appropriate authority. All messages must show accurately from where and from whom the message originated, except in the rare, specific cases where anonymous messages are invited.

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

**Data in Electronic Formats**

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

It will be helpful to keep in mind that electronic records can be quickly and readily replicated and circulated without any obvious indications that this has happened. It is
also true that electronic records can be easily modified, so it’s important to consider controls that help to maintain its integrity.

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

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

**Collection**

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

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

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

**Storage**

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

- Where feasible, consideration should be given to backups in the event of loss or damage to the primary data collection.

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

- Personally identifying information (e.g., IP addresses) should be kept separate from the data.

**Transmission**

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

- Password protection is the most common form of access control. Password protection can be implemented at various levels, e.g., the computer, folder, file, database. When combined with encryption, it assures that even if the media fall into the wrong hands, the data cannot be retrieved.

- Other forms of access control include two-factor, such as smart cards, and digital certificate based authentication.

- Physical access controls should not be overlooked when planning for adequate access controls. Physical controls (such as locks) when combined with technical controls (such as passwords or smartcards) provide for defense in depth.

Destruction and Disposal

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

Server Administration

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

- The server is administered by a professionally trained person with expertise in computer and internet security,

- Access to the server is limited to key project personnel and is configured with firewalls to minimize the possibility of external access to the server data,

- There are frequent, regularly scheduled security audits of the server, and

- The server is subject to the periodic security scans.

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Oral History Projects

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

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

Moreover, oral history narrators are not anonymous individuals, selected as part of a random sample for the purposes of a survey. Nor are they asked to respond to a standard questionnaire administered to a broad swath of the population. Those interviewed are specific individuals selected because of their often unique relationship to the topic at hand. Open-ended questions are tailored to the experiences of the individual narrator. Although interviews are guided by professional protocols, the way any individual interview unfolds simply cannot be predicted. An interview gives a unique perspective on the topic at hand; a series of
interviews offer up not similar "generalizable" information but a variety of particular perspectives on the topic.

For these reasons, then, oral history interviewing, in general, does not meet the regulatory definition of research as articulated in 45 CFR part 46. The Office for Human Research Protections concurs with this policy statement.

While most oral history projects fall outside the purview of the IRB, there are still those that fall within the category of “research” and contribute to generalizable knowledge. Therefore, the policy of the University is for all oral history projects be submitted to the IRB for evaluation to determine whether IRB review is required.

**Program Evaluation**

Just as with certain Oral History projects, there are Program Evaluation projects that may not be subject to the requirements of the regulations and can be excluded from IRB oversight because they do not involve research as defined by the regulations.

When questioning if your program evaluation project needs IRB review the researcher should ask: Does the project meet the definition of research as defined in the human subject protection regulations? That is, is it a *systematic investigation, including research development, testing and evaluation designed to contribute to generalizable knowledge*?

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

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

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

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

- Does the activity alter the timing or frequency of standard procedures? If **not**, the activity is probably not research.

- Is the entity in which the activity is taking place paying for it? If **yes**, the activity is probably not research.

- Is the activity part of a research project? If **yes**, the activity probably is research.

**Funded and Sponsored Projects**

The regulations require that each application or proposal for HHS-supported human subject research be reviewed and approved by the IRB. It is the University’s policy to provide review for all human subject research regardless of the sponsor or if it receives funding at all.

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

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

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

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

**International Research**

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

- Information about where the research will be conducted (both the geographic location and the performance site, where applicable).
- A copy of local IRB or equivalent ethics committee approval, where possible.
  - OR - Alternatively, the IRB asks the researcher for letter of support and contact information from someone familiar with conducting research in the proposed country. The IRB may contact this person if it has additional or follow-up questions.
  - OR - A letter of approval from local university department sponsoring the research, a local institutional oversight committee, or an indigenous council. In areas where government-issued research visas are required, a copy of the visa should be submitted.
- Information about the investigator's knowledge of the local research context, including information about the current social, economic, and political conditions. This should include a detailed description of the investigator's personal experience conducting research (or studying or residing) in the region.
- Information about whether there are any additional risks subjects might face as a result of the population being studied and/or the local research context.
- The language(s) in which consent will be sought from subjects and the research will be conducted, as well as whether the investigator fluent in this language, or whether a translator will be used. If a translator will be used, it should be clear what risks, if any, this might pose for subjects, as well as how it will be minimized.
- Copies of the translated informed consent documents and instruments, including verification of the accuracy of the translation(s).
- If the research is federally funded, information about the status of the assurance for the performance site, where applicable.
- When composing an IRB protocol for an international research project, researchers should clearly demonstrate that the proposed procedures are appropriate given the culture, norms, and mores of local communities. Whenever practical, researchers should include local community representatives in the design of the research and consent processes to ensure that local concerns about research practices, goals, or uses of collective cultural or intellectual property are considered. Community collaboration in research design demonstrates concern for the ethical principles of justice (by articulating the equitable distribution of research risks and benefits in relation to community needs) and respect for persons (by recognizing the right of individuals to form groups with corporate agency).
**Pilot Studies**

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

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

**Record Retention and Storage**

**Investigator Records**

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

- Records must be kept for at least three years.
- Maintain records in a secured place with limited access for the research team, to maintain the confidentiality that has been promised to the subjects, as well as to the sponsors.
- Before transferring custody of the records or destroying study records, they must contact the sponsor of the study if applicable.

**IRB Records**

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

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

The IRB documents above must be retained for every protocol it reviews for at least three years after completion of/closure of that protocol.

**IRB Member Records**

Curricula vitae of active members of the IRB will be maintained in the files of the ORRC and will be updated in content as necessary. Each member's membership term status will be monitored and updated, as necessary.

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

The ORRC’s mission is to ensure that the practices and procedures designed for the protection of the rights and welfare of human participants at UAlbany are effective and are in compliance with relevant ethical principles, federal and state law and institutional policies for the protection of research participants. To accomplish this objective, ORRC conducts periodic routine audits or evaluations to verify that research was reviewed and conducted in compliance with federal regulations, NDSU policy, and the IRB approved protocol.

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

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

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

1. Stop recruitment of subjects and/or restrict activities
2. Suspend approval of the protocol

3. Notify officials who will take appropriate action (e.g., notify sponsors, etc.)

The IRB determines what actions to take in consultation with the Research Compliance Officer. Results of all quality assurance reviews are reported in writing to the Principal Investigator with copies to the IRB Administrator, and other personnel (e.g., sponsors, etc.) as appropriate.

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

**Protocols Selected for Audit**

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

1. Routine Evaluation of Protocol,
2. For Cause Evaluation of Protocol, and

**Routine Evaluation**

Monthly evaluations of randomly selected protocols. These protocols will be identified at random by performing queries of the IRB database using established criteria. The purpose of the routine evaluation is to determine if the rights and welfare of research participants used in studies have been properly protected in accordance with all applicable regulations, laws, and policies.

**For Cause Evaluation**

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

**IRB Evaluation**

Routine evaluations of the IRB, its operations, and records will be conducted through random selection of protocols identified. The purpose of the Internal Evaluation is to determine the adherence of IRB records to applicable federal regulations, law, and policies governing human research and to provide ongoing assessment of IRB operations for continuous quality improvement.
Protocol selection may also include, but is not limited to:

- At the direction of the IRB
- Research subject, family, or research personnel complaint
- Follow-up of corrective actions resulting from routine or for-cause audits
- Investigator request prior to sponsor auditing

**Documents reviewed**

The following are examples of documents that will be reviewed by Quality Assurance staff during the audit process:

- All IRB submissions and correspondence
- Regulatory essential documents
- Sponsor documents and correspondence
- Study protocol
- Recruitment and consent documents
- Research subject files
- Adverse/Unanticipated Problems reports
- Protocol deviations
- Staff training records
- Other documents, as necessary, may be reviewed specific to the type and situation of the audit being conducted.

**Audit Process**

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

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

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

Non-compliance means significant failure by an investigator to abide by University policy and relevant government regulations for protecting human subjects in research. Instances of non-compliance would include, but are not limited to beginning research before securing Institutional Review Board approval, misuse or non-use of approved consent forms, failure to secure IRB approval before introducing changes in an on-going protocol, and continuing to gather study data from subjects after IRB approval expires.

Non-compliance with IRB guidelines is a violation of University at Albany policy and federal regulations for the protection of human subjects. Incidents of non-compliance must be reported both to ensure the protection of the rights of human subjects and to uphold the University’s Assurance to the Federal government. Non-compliance presents a serious challenge to the IRB. Regardless of investigator intent, unapproved research involving human subjects places those subjects at unacceptable risk. Any incident of non-compliance with IRB guidelines must be reported immediately to the Office of Regulatory Research Compliance or the Chair of the IRB.

If, after deliberation, the IRB determines that non-compliance has occurred, appropriate action will be taken to protect the rights and welfare of human subjects. In the case of serious or continuing non-compliance, the IRB and the University will address the question of the investigators’ fitness to conduct human subject research. The IRB will also take remedial action, as necessary, regarding the welfare of the subjects and the research data gathered in noncompliance. Further, the IRB will refer instances of serious non-compliance to the Research Compliance Officer (as designee of the Vice President for Research) who will carry out the procedures as provided in the University’s Policy and Procedures on Misconduct in Research and Scholarship.