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I. Purpose of this manual

The purpose of this manual is to provide guidance for faculty, students, staff, fellows, and any other members of Cornell College who intend to perform research on human subjects, regardless of the source of funding. This guide offers detailed information about the application process for approval for research involving human subjects, as well as offers the basic ethical principles underlying any inquiry involving human participation.

II. Purpose of IRB

The purpose of the Institutional Review Board (IRB) at Cornell College is to provide local oversight to ensure research practices are in keeping with federal guidelines as well as in conformity with best ethical practices. This IRB is established according to a formal, federally approved, Assurance based upon federal regulations. This Assurance lays out the broad principles that govern Cornell's IRB and the methods it employs in evaluating proposed research. This mechanism fulfills a number of needs at Cornell: (1) it establishes a climate of expectations of appropriate behavior in conducting research, (2) it allows for pursuit of federal funding for researchers who undertake research with human subjects, (3) it offers some legal protection for all parties, including researchers, human subjects, and the College itself, and (4) provides an educational model for students on the appropriate ethical treatment of others, based on the principles of respect, beneficence and justice. Overall, the Cornell IRB is designed to protect and serve human subjects as well as all members of the College community.

III. Ethical Foundations of Research on Human Subjects

Three major documents provide the framework for the ethical foundations of U.S. federal regulations governing research on human subjects: The Nuremburg Code, The Declaration of Helsinki, and the Belmont Report. The international codes of conduct (Nuremberg and Helsinski) provide a modern history on the treatment of human subjects in research. The Belmont Report provides the ethical principles and guidelines designed to protect human subjects in U.S. research.

Nuremberg and Helsinki

The Nuremburg Code was developed out of the Nuremburg trials in 1947 where accounts of the horrors of human experimentation during the Nazi Regime were recorded. The Code outlines the basic ethical principles that ought to govern research involving human subjects. The first principle of the Code represents the essential feature of ethical research on humans: "the voluntary consent of the human subject is absolutely essential."[1] In order to achieve this necessary element, the Code details what is implied by this requirement: legal capacity to consent, freedom from coercion, and sufficient knowledge and comprehension of the nature of the research. The Code provides further requirements for the ethical conduct of human research including the minimization of risk and harm to the subject, a favorable risk/benefit assessment, researchers who are both qualified and who employ proper research design, and the ability for the subject to withdraw at any time during the process. Issued by the World Medical Association in 1964, the Declaration of Helsinki outlines similar recommendations to those found in the Code to guide doctors performing biomedical research

[1] Nuremberg Code, 25 July 2011, <http://ohsr.od.nih.gov/guidelines/nuremberg.html>

involving human subjects. Focusing specifically on medical research, this declaration documents the sources of vulnerability and ways to protect vulnerable populations in carrying out such research. It is the duty of the physician researchers "to protect the life, health, privacy, and dignity of the human subject."[2] These international documents provide a framework for the ethical treatment of human subjects in research.

Belmont Report

Post-WWII efforts for ethical research in the United States resulted in a number of congressional hearings and policy changes. This culminated in the 1974 National Research Act which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission was charged with identifying the basic ethical principles that should govern research on human subjects and creating guidelines to ensure research would be performed according to such principles. In order to achieve this, the Commission considered: (1) the boundaries between biomedical and behavioral research and medical and behavioral practice, (2) risk-benefit criteria to determine appropriate research involving human subjects, (3) proper guidelines to select human subjects for participation in research and (4) the nature and criteria of informed consent.

The 1978 Belmont Report provides the basic ethical principles underlying the conduct of research involving human subjects. These principles are: (1) respect for persons, (2) beneficence and (3) justice.

Respect for persons requires the acknowledgement of individuals as autonomous agents and protection for those individuals with diminished autonomy. An autonomous person is one who is capable of self-determination in deliberating goals and acting under the direction of those goals. Such self-determination in individuals is developmental, and some individuals may lack this capability due to illness, mental disability, or other circumstances. Respect for persons protects those who are immature and incapacitated.

Application of the ethical principle of respect for persons to the conduct of research demands **informed consent.** Informed consent consists of three elements: information, comprehension and voluntariness. Possible research subjects must be given sufficient information about the full nature of the research such as the procedure, the purpose, and anticipated risks and benefits. To ensure comprehension of such information, the information must be adapted to the subject's intellectual and psychological capacities. In those cases in which such capacities are immature or diminished, a third party may be authorized to act in that person's best interest. Consent is only valid when given voluntarily, free of coercion and undue influence.

Beneficence implies an obligation to secure the wellbeing of individuals and prevent them from harm by maximizing anticipated benefits and minimizing possible harms. Achieving this balance may involve a risk-benefit analysis to determine when it may be justifiable to take risks to seek benefits, and when such benefits do not outweigh the risks undertaken.

Application of the ethical principle of beneficence demands the systematic assessment of the probability and magnitude of risks and benefits to the subjects. It is the responsibility of the investigator to ensure that the proposed research is properly designed. It is the responsibility of the IRB to evaluate whether the risks to the subjects are justified.

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[2] Declaration of Helsinki, 25 July 2011, <http://ohsr.od.nih.gov/guidelines/helsinki.html>

Justice entails the fair distribution of research benefits and burdens. Failure to meet this requirement results in the denial of some benefit to a person entitled to it or an undue burden placed upon an individual.

Application of the ethical principle of justice to the conduct of research demands that there be both fair procedures and outcomes in the selection of research subjects. In choosing subjects for research, researchers should not offer potentially beneficial research only to those subjects in favor or offer potentially risky research only to those subjects considered "undesirable." Distinctions should be made between classes of subjects according to the ability to bear burdens, especially in light of those already burdened. Careful consideration must be taken when vulnerable subjects are involved. Individuals such as those who are economically disadvantaged, institutionalized, or physically unwell should not be selected simply due to their availability. Measures must be taken to prevent any unfairness in the selection process.

IV. Regulatory Foundation of Research on Human Subjects

In 1981, in response to the Commission's Belmont Report, the Department of Health and Human Services (DHHS) revised the regulations on human subjects. These new federal regulations comprise Title 45, Part 46 of the Code of Federal Regulations. This "Common Rule" guides researchers in developing their research proposals, and instructs IRBs in evaluating such proposals. All federally-funded research must adhere to the Common Rule and be evaluated by a federally-assured IRB in the approval, evaluation, and oversight of the research from its inception to its implementation. Cornell, like most institutions, will apply the Common Rule to all research thereby assuring the ethical practice of any research undertaken by members of the Cornell community. Ethical principles and regulations apply to all Cornell research involving human participants regardless of funding.

V. Structure and Function of the IRB (from Faculty Handbook)

The President of the College authorized the development of the Institutional Review Board on July 12, 2010, to ensure the protection of human subjects in research projects conducted or sponsored by Cornell College. The Assurance was filed July 22, 2011. All faculty members of the IRB are appointed by the President of the College in consultation with the Committee on Committees.

Functions

A) Develop, disseminate, and implement federally compliant and institutionally-appropriate procedures for ensuring protection of human subjects in all projects conducted or sponsored by the college involving the collection and analysis of data from human subjects.

B) Conduct reviews of research project proposals involving the collection and analysis of data from human subjects when required by federal regulations to ensure that such research will be carried out in a manner which protects the rights and well being of subjects.

C) Educate members of the Cornell College community about the protection of human subjects and the role of the IRB.

Structure

A) Four members of the full-time teaching faculty, two of whom must have at least one year of full-time experience at the college and two of whom must be tenured members of the teaching faculty. The chair shall be appointed from among the tenured faculty members. The chair shall serve a three-year, non-renewable term and all other members shall serve one-year, renewable terms. These four members shall include:

   1) One faculty member from the Natural Sciences or Mathematics
   2) Two faculty members from the Social Sciences
   3) One faculty member from the Humanities

B) One member of the Student Affairs staff. The Student Affairs member shall serve a one-year, renewable term.

C) One community member with no formal ties to the institution as stipulated by federal regulations. The community member shall serve an open-ended term.

D) The Director of Institutional Research.

E) One faculty member with disciplinary expertise in ethics shall serve as a consultant. This member may overlap as one of the four IRB faculty members whose discipline may be philosophy, religion, or areas of social justice.

VI. Definitions

What is *research*?

According to the federal government, research means a "systematic investigation . . . designed to develop or contribute to generalizable knowledge."[3] The general "test" of whether a project constitutes research rests on whether findings will be disseminated beyond the classroom. For example, findings that are presented as a poster or paper at a conference, at Student Symposium, on a website, or that may be published, will generally be interpreted as "research." This includes student work presented outside of the classroom.

That said, there are a number of activities that are not "research" as defined by the federal government. Here are some examples of things that would not fall under the purview of the IRB:

A. Research on normal educational practices such as instructional strategies, curricula or classroom management techniques.

   Professors who experiment with their class format to improve their teaching or use student evaluations, for instance, do not need the approval of an IRB. In addition, the use of language and other proficiency tests as part of New Student Orientation do not require IRB approval.

B. Journalism

   Journalists and investigative reporters who are writing stories for news publications such as the *The Cornellian* are typically not engaged in research within the scope of IRB oversight. If, however, research requires IRB approval on other grounds, the fact that the author intends

[3] 45 CFR 46, 25 July 2011, <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102>

to publish it in a newspaper does not exempt it from IRB approval. For example, if a researcher intends to publish the results of a psychological experiment involving human participants in the *The Cornellian,* the IRB must review the study prior to data collection.

What is a *human subject*?

Human subject means a living individual about whom an investigator obtains:

A. Data from intervention or interaction with the individual
   OR
B. Identifiable private information (e.g. examining student records to ascertain grade point averages)

What are *risks*?

"Risk" means the probability of physical, psychological, legal, social or economic harm occurring as a result of participating in a research study. At a minimum, subjects accrue costs in terms of volunteering their time and energy in serving as participants in research. For purposes of this document, the terms "risks," "costs," and "harm" are essentially equivalent. (See sections below.)

What are *benefits*?

Benefits to subjects refer to direct advantages subjects may obtain by participating in the research. For example, an individual with cancer may be included in experimental trials of a drug at no charge to him/herself. A person suffering from depression may receive free psychotherapy as part of a research trial. Compensating people for participating in research (in the form of payment, gifts, or course credit) does **not** constitute a direct benefit. (See sections below.)

What is *Informed Consent?*

Informed Consent refers to a written document that informs subjects about what they can expect in participating in a research study. Informed Consent is a cornerstone in respecting the rights of human subjects, and is discussed extensively in the Belmont Report and the federal regulations. Drawing from these regulations, the IRB has developed specific guidelines in constructing Informed Consent forms. On rare occasions, the IRB may waive the written form, but the principle of informed consent applies to **all** research projects. (See separate documents for completing informed consents.)

What is a *principal investigator*?

Although many research projects may involve collaboration among individuals, one person must be designated as the principal investigator (PI). This individual is the "point person" for communicating with the IRB.

VII. Risks and Benefits

Types of Risks to Subjects

There are a variety of potential risks to subjects of which the researcher should be aware, including the following:

Psychological Risks

The experience of participating in a study may cause a subject more, or more persistent, psychological disturbance (anxiety, depression, stress, feelings of guilt, feelings of embarrassment or shame, or loss of self-esteem) than the subject would ordinarily experience in daily life or during routine physical or psychological tests. At Cornell, such risks may involve the following:

- Survey questions or procedures may ask subjects about embarrassing or painful memories or raise unresolved issues (e.g. interviews about survivors of violence).
- Survey questions or procedures about risky or undesirable behaviors (e.g. sexual practices, illegal drug use or other illegal behaviors, being the victim of an assault or abuse, experiencing an unwanted pregnancy, being involved in an accident or natural disaster, etc.).
- Subjects are presented material or asked questions that they may find offensive, degrading, or threatening.
- Subjects' psychological environment is manipulated, e.g. through deception, isolation, negative messages, etc., and the manipulation itself or subsequent debriefing may induce psychological disturbance beyond what the subjects would experience in daily life.
- Subjects may experience stress when the researchers manipulate the subjects' environment – as when 'emergencies' or fake 'assaults' are staged to observe how passersby respond.
- Survey questions or procedures may force subjects to confront facts about themselves about which they were previously unaware (e.g. tests about racist or homophobic attitudes).
- Subjects may experience an invasion of his or her privacy (for example, through covert observation).

Most psychological risks are minimal and transitory, but the investigator and the IRB must be aware of the potential for serious psychological harm, particularly for fragile or especially sensitive individuals. To complicate matters further, different subjects may experience different types or levels of risk from the same research procedure.

Researchers should word survey or interview questions to cause as little psychological disturbance as possible. It is often helpful to also provide referral information (e.g. a list of local self-help groups).

Physical Risks

The most obvious sort of risk that could result from research is physical risk. At Cornell, such risks may involve the following:

- Subjects may be exposed to minor pain (such as venipuncture or finger stick to draw blood), or may experience physical discomfort or injury, including physical exertion beyond the subject's normal activity (e.g. a stress test).
- The subjects' physiological requirements, such as nutrition, sleep, or light, are manipulated.

Researchers should have appropriate safety and/or emergency training to enable study procedures to be carried out as safely as possible.

Legal, Economic, Academic, Professional, or Social Risks

The disclosure of the subject's information may cause civil or criminal liability, or damage the subject's financial standing, academic standing, employability, or reputation; or may result in embarrassment within one's business or social group, loss of employment, or sanctions from the College. Such risks include the following:

- Survey questions or procedures may expose subjects to civil liability if they are asked to answer questions which seek information about harm that they have done to others.
- Surveys that are not anonymous and that seek information about criminal activity, for example, could serve not only to create legal liability for a person, but also harm the person's reputation and financial standing.
- Surveys questions or procedures that ask subjects to provide confidential information about private matters such as illegal drug use, mental illness, or about a subject's health history may place the subject at risk
- Non-anonymous surveys of employees that seek information regarding job performance, for example, could place an employee in jeopardy.
- Non-anonymous survey questions or procedures (e.g., information about a subject's illegal activities, such as illegal drug use or underage drinking, or about other activities that violate College policies, such as academic dishonesty) could result in disciplinary action by the College.
- Surveys questions or procedures may yield information about individuals that could 'label' or 'stigmatize' the subject.
- State reporting laws may also pose legal risk. If a research participant reveals that he or she is likely to harm someone, there may be a legal duty to warn the threatened person.
- There may also be state laws requiring the reporting of certain matters such as child abuse and various diseases. If a researcher asks parents how they discipline their children, information about child abuse may be obtained and must be reported.
- In addition, researchers may at some point be faced with a subpoena for records relating to criminal activity of their research subjects.

Research subjects who are being interviewed about illegal or undesirable activities need to be informed about the limits of confidentiality before the interview begins.

Breach of Confidentiality/Lack of Respect for Participants

Confidentiality is of supreme importance in respecting human subjects. In addition to the potential harms discussed earlier, a breach of confidentiality (for example, when private information about a subject is shared with another party without the consent of the subject) can result in a variety of harms:

- Research participants may find their sudden loss of privacy psychologically traumatic.
- Research regarding political activities in some countries may put subjects in serious jeopardy.
- Information about subjects may be disclosed to others who may use that information in unpredictable ways. For example, if teachers are given information about preschoolers' behavior problems, the teachers' attitudes and assumptions might negatively affect the children's success at school.

Accordingly, the IRB expects researchers to take great pains to protect the subjects' confidentiality. In virtually all studies in which information about subjects is collected, the researcher must guarantee that the information will remain confidential. This means that:

- To every extent possible, identifying information is completely separated from data.
- If it is necessary to link subjects to their data (e.g. in longitudinal studies), identifiers (names, etc.) are separated and masked through coding. The researcher must clearly specify how this will be accomplished (i.e. how the "crosswalk" documents linking identifiers to subject information will be kept secure, and who will have access to the "crosswalk" documents.)
- In the rare instance it is necessary to maintain links between the subjects' identity and their data (i.e. the subjects' information includes identifiers and anyone with access to the raw data will be able to link subject information with subject identity), the researcher must **explicitly** describe how the data will be kept secure and who will have access to the data. In this case, this information must be stipulated in the subject's informed consent form.

Additional Data Security

Storage of Data: In order to assure confidentiality, researchers should take the following measures:

- Identifying information or coding keys should be destroyed as soon as possible. (Note, however, that Consent Forms must be kept for three years after the research project ends.)
- Raw data will be archived in a secure location:
    - Paper records will be kept in a locked file or office.
    - Portable electronic records (e.g., laptop computer, PDA, flash or zip drive, CD or DVD, external hard drive) will be kept in a locked office.
    - Non-portable electronic records (e.g. data accessed via the Web) will be maintained on a network with restricted access (e.g., a shared drive).

Access to data: The researcher must specify which additional individuals will have access to identifiable data. This could include the course instructor or supervisor, co-investigator(s), research assistants or data analysts and student workers. Each of these individuals must sign a confidentiality form to be kept by the researcher.

Reporting of data: Identifiable information about individual subjects will not be disclosed during any phase of the project without the subject's **explicit** consent, and data will be kept secure. Aggregated (grouped) data will be reported with potentially-identifying information

(e.g., demographic descriptors) removed. This is particularly important for small and distinctive groups.

Special Risks for Vulnerable Populations.

The federal government is particularly concerned with the protection of children (persons under age 18), pregnant women and fetuses, and prisoners. Other potentially vulnerable populations include persons with mental disabilities, residents of long-term care facilities, patients in health-care facilities, and "economically or educationally disadvantaged persons." Such vulnerable persons may be at greater risk of psychological, social, economic, or physical harm from a research project that would impose only minimal risk on other participants. Investigators are expected to include in their study design "additional safeguards to protect the rights and welfare of these subjects."[4]

Types of Benefits to Subjects

There are two types of benefit that may accrue from a project: benefits to society (or to a specific community within the broader society), and benefits to the subjects themselves.

- Typically, societal or community benefits are defined in terms of the knowledge or understanding the project is intended to produce, which may lead to improved health, safety, satisfaction, economic security, etc.
- Sometimes participation in a project conveys benefits to the subjects themselves beyond the knowledge that the project as a whole is intended to generate. For example, a thought-provoking questionnaire may be intellectually stimulating to the survey respondents, or may enhance self-understanding, or may make the respondents aware of services or resources with which they were previously unfamiliar.

However, a number of research projects provide no direct benefits to subjects, and it may be many years before the results of the research are promulgated and useful to society or to groups of people. They may never be. Thus, promises of a benefit to science or society are not adequate descriptions of benefit. Regardless of whether or not there is a direct benefit to subjects, they must be told what the researcher is trying to learn and why (except when deception is a necessary element of the design). Compensation to subjects is not considered a benefit in the risk/benefit analysis, nor is the fact that the participants may find it rewarding to be helpful.

Compensation is NOT a benefit

Researchers may pay research subjects for their participation or offer gift certificates or vouchers. However, it is important that payments or gifts not be so ample as to coerce participation from those who might otherwise decline to be a part of the study (for example, offering $50 to a person who is homeless). Payment should not encourage subjects to participate or continue to participate against their better judgment. Subjects should receive at least partial payment if they withdraw from a study. Withholding all payment until participation is complete is coercive. A modest lump sum can be paid after a subjects' participation is complete if the arrangement is thoroughly documented in the consent form.

[4] 45 CFR 46 111 (b), 25 July 2011, < http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111>

Researchers may arrange with course instructors to offer course credit for participation in research. However, researchers and course instructors **must** offer alternative comparable credit that does not require participation in research. For example, if a student spends 30 minutes as part of a research study, the course instructor must offer an alternative credit that would also require about 30 minutes for students who desire the credit but do not want to participate in research.

VIII. Informed Consent

An individual's right to privacy is generally protected by the right to refuse to participate in research. In making that judgment, the individual must have as much knowledge as possible about what to expect in participating in the project. Thus, information presented on the Informed Consent form is of crucial importance. This means that:

- To every extent possible, subjects are explicitly informed before they choose to participate in the project that may cause psychological disturbance (anxiety, depression, stress, feelings of guilt, feelings of shame, or loss of self-esteem, embarrassment).
- To every extent possible, subjects are explicitly informed before they choose to participate in the project that some study procedures may result in physical discomfort or injury.
- Subjects are explicitly informed of their right to refuse to participate in the project, or to withdraw at any time during the study, and to request withdrawal of any of their data provided to that point in time.
- Subjects are explicitly informed before they choose to participate in the project of resources to alleviate any psychological disturbance attributable to their participation, or to alleviate any physical discomfort or injury attributable to their participation.

Detailed instructions for writing an Informed Consent form and examples are shown in the separate Handbook on writing Informed Consents.

IX. Special Considerations

Children and Adolescents as Research Subjects

Special considerations apply when children or adolescents are the research subjects. Minors (under age 18 in the State of Iowa) cannot give legal permission to participate in research. In these instances, the researcher must prepare an Informed Consent form for parents (or legal guardians) to sign on their child's behalf. Additionally, children must also agree (*assent)* to participate in the research study, either in writing or verbally. Written assent will typically be appropriate for children age 8 and older.

Deception and Incomplete Disclosure

There are two types of deception: *passive*, wherein the researcher does not fully disclose the purpose or expectations of the research (also referred to as deception by omission), and *active*, wherein the researcher deliberately misleads the subject (also referred to as deception by commission).

Withholding information from or providing incomplete or erroneous information to research subjects is only allowable if the study's scientific or educational merit specifically requires the deception, and subjects are placed at no more than minimal risk due to the deception. Approval will not be given if deception involves matters such as physical or psychological risks that would affect the subject's willingness to participate in the study. Deception may not be used to recruit subjects to a study. When feasible the consent form should indicate that deception may be used or that full disclosure of the research protocol is not possible until completion of the study.

Subjects must be informed of the deception and of the actual purpose of the research and procedures as soon as feasible either at the end of their participation or upon completion of the study. Procedures must also be in place to relieve any distress subjects may encounter due to the deception.

Applications involving deception must include a justification for the deception, a full description of the debriefing process and procedures for relieving possible distress to the subject caused by the deception.

Oral Consent

In certain cases, the Principal Investigator may determine that oral consent is more appropriate and more adequately safeguards the subject. Oral consent shall consist of a written consent document presented orally to the subjects (or his/her legally authorized representative). The IRB shall approve the written text of what is said to the subject or representatives. A copy of the information that is read to the subject should be given to the subject or the representative to keep. There should be a witness to the oral presentation who can attest that the information was given as stated.

In certain cases, oral consent may be more appropriate and more adequately safeguards the subject than a written consent document signed by the subject. Oral consent shall consist of a written consent document presented orally to the subject (or the subject's legally authorized representative). The IRB must approve the written text of what is said to the subject or representative. In addition, there must be a witness to the oral presentation who can attest that the information was given as stated and who signs the written consent document affirming this. A copy of the written consent document that is read and containing the signature of the witness will be given to the subject or the representative to keep.

Waiving Written Informed Consent

If the research could not practicably be carried out without the waiver or alteration, the researcher may request that informed consent be waived. Put another way, it would not be practicable to perform the research (as it has been defined in the protocol by its specific aims and objectives) if consent was required (the emphasis being that it is impracticable to perform the research, and not just impracticable to obtain consent). The following concepts will help the IRB determine whether the research could not be practicably carried out without the waiver of consent:

- Scientific validity would be compromised if consent was required. Examples of this might include the following:
    - The sample size required is so large (e.g., population-based studies, epidemiology trials) that including only those samples/records/data for which consent can be

obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.

- The subjects for whom records would be reviewed are no longer followed and may be lost to follow-up. For example, the proportion of individuals likely to have relocated or died may be a significant percentage of the subject population and the research results may not be meaningful and lose statistical power.
- The disclosure of the study's purpose as part of the consent process would bias the research subjects so that the results will not be meaningful.

- Ethical concerns would be raised if consent were required. For example:
  - There is a risk of creating additional threats to privacy by having to link otherwise de-identified data with nominal identifiers in order to contact individuals to seek consent.
  - There is a risk of inflicting psychological, social or other harm by contacting individuals or families.
- There is a scientifically and ethically justifiable rationale why the research could not be conducted with a population from whom consent can be obtained. Practicality should not be determined solely by considerations of convenience, cost, or speed; the principal investigator must justify the request for the waiver.

Private vs. Public Behavior

The IRB must review observations of public behavior which are recorded in a way that would allow the subject to be identified and "if made public" could reasonably place the subject at risk of criminal or civil liability or damage to subjects' financial standing, employability, or reputation.

X. Risk-to-Benefit Ratio

Federal guidelines suggest that there must be a favorable risk-to-benefit ratio to allow research to proceed. In reality, because most research at Cornell College is likely to result in very few direct benefits to subjects, the burden is on researchers to minimize potential risks to subjects.

XI. Levels of risk

In general, the higher the risk involved in the project, the more detailed the explanation, precautions, and informed consent must be. The nature and type of informed consent is determined by the level of risk. Accordingly, the following broad guidelines for degrees of risk may be of assistance in making a necessary determination:

No greater than minimal risk: the risk of psychological, social, or physical harm or discomfort is no greater than what would ordinarily be experienced in daily life or during routine physical or psychological tests. (This would generally, although not always, correspond to Exempt Review.)

Greater than minimal risk: the risk of psychological, social, or physical harm or discomfort exceeds what would ordinarily be experienced in daily life or during routine physical or

psychological tests; see examples below. (This will generally require either Expedited or Full Board Review.)

XII. Responsibilities of Faculty, Staff and Student Researchers

Responsibility for securing review

- Research on human subjects conducted as a requirement for a class is the responsibility of the faculty member(s) teaching the class. Students in the class should be made aware of the review and the review process.
- Research on human subjects conducted by a student principal investigator (as an independent project, capstone project, etc.) is the responsibility of the student investigator. Faculty supervisors should ensure that student principal investigators are aware of the review process and advise students involved in the process, but it is ultimately the student principal investigator's responsibility to complete the review process.
- Research on human subjects conducted by a faculty or staff principal investigator(s) is the responsibility of the faculty or staff member(s) performing the research. Students involved in the research as student employees or research assistants should be made aware of the review and the review process **and must sign a Confidentiality Statement.**

Responsibility for completing the approval process and for engaging in ongoing monitoring

- The principal investigator must obtain IRB approval prior to beginning to work with human subjects.
- The principal investigator should inform co-investigators and subjects of the IRB's approval and contact information.
- As the research progresses, the principal investigator must obtain IRB approval for any changes in methodology or protocol before the changes are implemented.
- The principal investigator must contact the IRB if any incidents that harm or may harm a human subject arise during the research.
- The principal investigator must inform the IRB when the research project has been completed.

XIII. Initiating the IRB Review Process

Doing research that involves human subjects is a privilege, not a right. The IRB will work with applicants on meeting the federal requirements.

However, the IRB cannot approve projects submitted after the fact. *Prior* review is necessary to insure compliance with federally defined criteria for ethical treatment of human subjects, particularly when the intent is to contribute to generalizable knowledge. **THUS RESEARCH DONE**

WITHOUT IRB APPROVAL MUST NOT BE USED IN ANY PUBLIC PRESENTATION OR PUBLICATION.

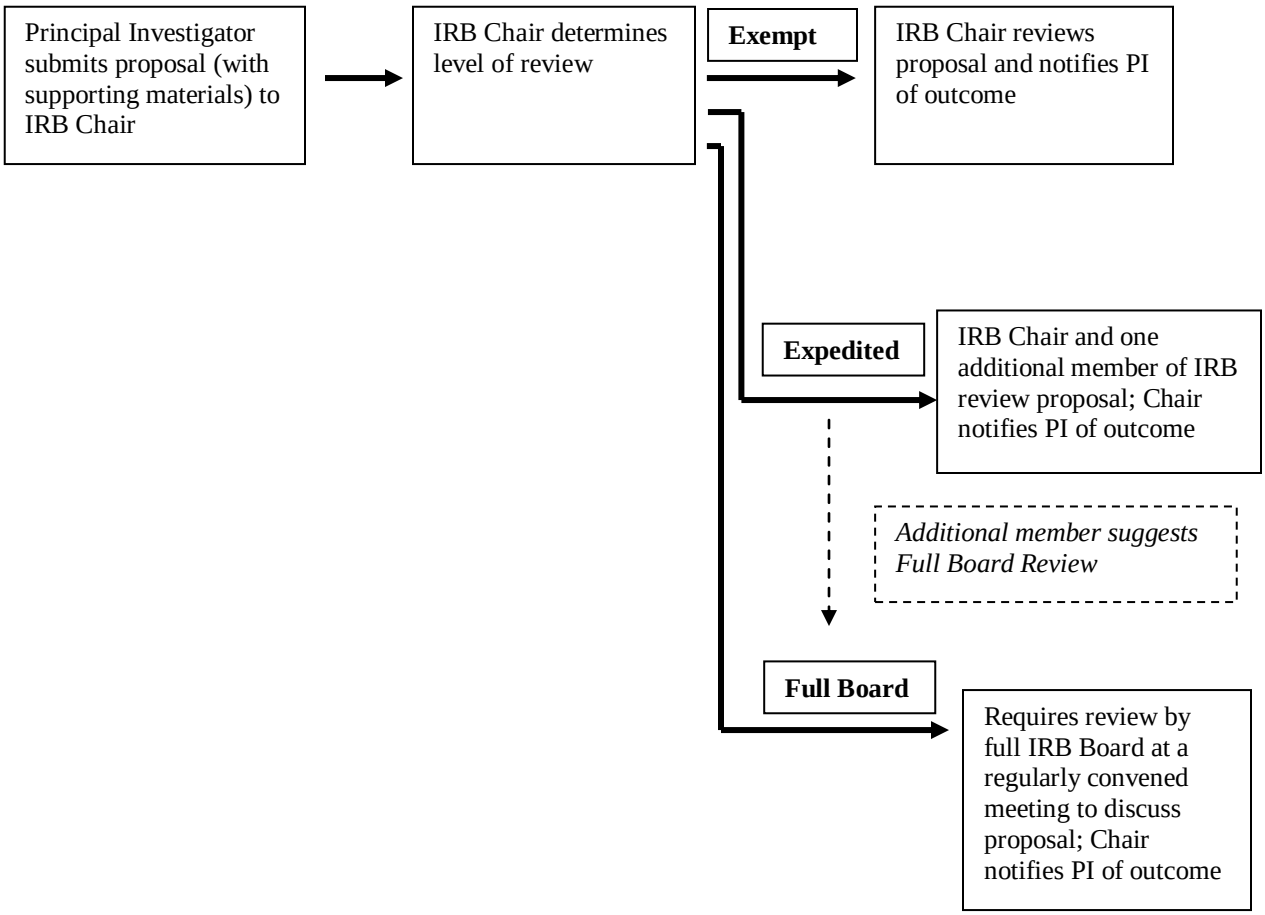
By teaching students about the ethical treatment of human subjects, working with them on the applications, and treating this matter as an opportunity for ethical reflection rather than an irksome requirement, faculty are helping to prepare students to understand obligations they may be expected to shoulder in the future and to be responsible members of an ethical community.

Application. Faculty members, staff members, or students who are planning research projects involving human subjects are responsible for beginning the review process by submitting the **Application** for Approval of Human Subjects Research form to the Chair of the IRB.

Researchers must submit a fully-developed **research plan** and **accompanying documentation** (e.g. a questionnaire or scripts when the subjects are likely to be interviewed; as well as the **Informed Consent** Form). Among other things, the Informed Consent Form describes the potential **risks** and **benefits** to potential human subjects. In the case where students are the researchers, the applications must be reviewed by faculty or staff serving as the **Research Advisor** before they are processed by the IRB.

XIV. After Submission: The Review Process

All submitted proposals are assigned by the IRB to one of three review categories: **Exempt, Expedited,** or **Full**. **The level of the review can only be determined by the IRB.** Even if you believe your proposal is exempt, you must submit it so that the board has the opportunity to make this determination. Furthermore, to fully protect subjects the IRB must approve a project before investigators start work on it, even before they begin to recruit subjects, since recruitment strategies are part of the review. This is reflected in the following flow chart.



Levels of Review

Exempt

Research may be **Exempt** from IRB review because it either makes use of existing records, involves standard educational/psychological tests, or for other reasons listed in the federal regulations. However, it is up to the IRB (not the researcher) to determine whether a project is Exempt. In the case of Exempt research, the IRB Chair will review the proposal and advise the principal investigator of the outcome.

In general, procedures that are free of foreseeable risk to the subject are likely to be Exempt. Following are examples likely to be considered Exempt from review.

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, where information is recorded anonymously (i.e., so that the human subject cannot be identified, directly or indirectly through identifiers linked to the subject). All survey/interview/observational research in which elected or appointed public officials or candidates for public office serve as subjects is Exempt, whether or not data collection is anonymous. Such research is Exempt unless any disclosure of the human subjects' responses outside the research could place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.
- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. These sources must be either publicly available or the information must be recorded anonymously (i.e., in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject).
- Research evaluating (i) public benefit or service programs (e.g., social security, welfare, etc.); (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. Such research that also involves interaction with human subjects (e.g., interviewing, surveying) is not automatically Exempt.
- Research on instructional strategies conducted in educational settings, involving normal educational practices (such as research on regular and special education strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods).

Expedited

Research that poses only minimal risk to participants can be handled as **Expedited**. "Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. In the case of Expedited research the IRB Chair and one other member of the Board will review the proposal and advise the principal investigator of the outcome.

Activities approved in the federal regulations for Expedited review include:

- collection of biological specimens through noninvasive means; for example, electrocardiography, electroencephalography, thermography, Doppler blood flow, echocardiography, functional magnetic resonance imaging;
- clinically routine noninvasive procedures such as muscular strength testing, moderate exercise, body composition assessment, flexibility testing involving healthy subjects;
- research on individual or group characteristics or behavior (including but not limited to research involving perception, cognition, surveys, interviews, and focus groups) as follows:
    - involving adults, where (i) the research does not involve stress to subjects, and (ii) identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation;
    - involving children, where (i) the research involves neither stress to subjects nor sensitive information about themselves, or their family; (ii) parents/guardians will complete the usual consent form (i.e. there is no request for a waiver); (iii) identification of the subjects and/or their responses would not reasonably place them or their family members at risk of criminal or civil liability or be damaging to the financial standing, employability, or reputation of themselves or their family members;
- collection of data from voice, video, digital or image recordings, as long identification of the subjects and/or their responses does not place them at risk for criminal or civil liability, or damage their financial standing, employability or reputation;
- research involving existing *identifiable* data, documents, records, or biological specimens (including pathological or diagnostic specimens), where these materials have been collected prior to the research for a purpose other than the proposed research, and, although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio or-videotapes, names will be recorded, even if they are not directly associated with the data);
- continuing review of nonexempt research previously approved by the IRB, where no new subjects will be enrolled or where the research involves no greater than minimal risk.

Full Board Review

All research that is not exempt or expedited is given a **Full Review**. This means that the proposal is reviewed during a convened meeting of the IRB, during which discussion of the proposal occurs. A majority of the Board members, and specifically, the community member, must be present.

These are some of the situations likely to require Full Review:

- The proposed research involves active or passive deception.
- The researcher asks for a waiver of written Informed Consent.
- The proposed research involves vulnerable populations (there may be instances of research with children that do not require full review; refer to Expedited category above).
- The proposed research involves topics of a sensitive nature (sexual behaviors, illegal behaviors, drug or alcohol use, sensitive demographic data, etc.). The key principle used to

determine whether a project involves sensitive information is that it has the potential for provoking a negative emotional reaction from a subject.

- The procedures of the research involve more than minimal risk to the subject (where more than minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).
- The proposed research involves observation where the individual could reasonably expect privacy (i.e. in the individual's home).
- The proposed research requires links between the individual and his/her behavior (e.g. a longitudinal study).
- The proposed research includes collection of data from voice, video, or image recordings where identification of the subjects and/or their responses could place them at risk for criminal or civil liability, or damage their financial standing, employability or reputation.
- The proposed research involves pharmaceuticals, nutriceuticals, or other chemical agents.
- The research involves physically invasive procedures (e.g. blood drawing or other tissue collection).

Criteria in Evaluating IRB Proposals

The IRB will consider the following factors in reviewing research proposals:

1. Have the risks to subjects been minimized?
2. Are the risks reasonable in relation to anticipated benefits?
3. Is the selection of subjects equitable (e.g., free from racial, gender or other types of bias)?
4. Can the Informed Consent be easily understood? Does it adequately reflect what the subject can expect?
5. Has the researcher indicated how the data will be protected (to assure the privacy of the research subjects)?
6. Are any of the participants vulnerable to coercion or undue influence?

XV. Outcomes

There are three possible outcomes to a review:

Approved: No further action is required from the investigator prior to initiating the study.

Revise and Resubmit: Changes are required before the study may begin. Additional or revised information must be submitted to the IRB prior to approval.

Denied: The proposed research, because of the level of risk involved, cannot be initiated.

XVI. Appeals

In the event that an application is denied because the Institutional Review Board feels the risks outweigh the benefits of the research, and the investigator disagrees with the committee's disapproval

decision, the researcher may initiate an appeal by submitting a letter presenting the researcher's arguments for approval; and any other pertinent information in support of the appeal.

XVII. Reporting Complaints or Unanticipated Problems

If a researcher encounters unanticipated problems involving risks to subjects or complaints about the research, the researcher should immediately report these problems to the Chair of the IRB. These problems may result in possible suspension or termination of the research.

XVIII. Changes in Protocols

Researchers who want to make significant changes in a previously approved protocol must obtain prior permission from the IRB. This includes changes in the (approved) consent form, sample composition, sample recruitment, or study procedures.

XIX. Expiration Date/Continuing Reviews

Approval of a human subject research proposal is good for **one year**. (However, if research involves extreme risk to subjects, the IRB may review it more frequently or alternatively asked to be kept apprised of all research activity.) In the event that the study continues longer than the initial approval period, the principal investigator is responsible for requesting an extension. To request an extension the principal investigator is responsible for submitting a status report of the project to date including:

- how many subjects have participated to date;
- a summary of any changes to the research protocol (as previously approved by the IRB);
- any other relevant information, especially information about risks associated with the research.

The IRB will conduct an Expedited Review of these applications, unless the research protocol has been modified or new subjects are to be added. This may trigger a Full Review.

XX. Research Conducted Outside of the United States

Research conducted outside of the United States by Cornell faculty members, students, or staff must be reviewed in accordance with Cornell College IRB review procedures. Such research must also conform to the standards for research involving human subjects of the host country. Collaboration with colleagues at a local institution in the host country often provides a good method for ensuring compliance with host country law and human subject conventions in research.