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 {link to https://www.hhs.gov/ohrp/regulations-and-policy/regulations/revised-common-rule-regulatory-text/index.html } as well as in conformity with best ethical practices.

This IRB is established according to a formal, federally approved certification (called an 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 Helsinki) 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 after the Nuremburg trials[1] in 1947 in which accounts of the horrors of human experimentation during the Nazi regime were documented. 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."[2] In order to achieve this necessary element, the Code details what is

[1] For more about the Nuremberg Trials, please visit the US Holocaust Memorial Museum website. (link to https://encyclopedia.ushmm.org/content/en/article/the-nuremberg-trials)

[2] Nuremberg Code, from "Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10", Vol. 2, Nuremberg, October 1946 - April 1949. (Washington, DC: US Government Printing Office, 1949). pp 181-182. Reprinted at https://history.nih.gov/research/downloads/nuremberg.pdf

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[3] outlines similar recommendations to those found in the Code to guide doctors performing biomedical research 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." These international documents provide a framework for the ethical treatment of human subjects in research.

Belmont Report[4]

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 requires researchers to ensure that those who are able to make decisions for themselves are given that opportunity to do so and also requires researchers to protect those who are immature, incapable of autonomous decision-making or 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. Potential 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

[3] World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, adopted June 1964; amended in 1975, 1983, 1989, 1996, and 2000. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

[4] Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Produced by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, published 1979. https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf

information, the information must be adapted to the subject's linguistic, 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 on the part of the researcher(s) to secure the wellbeing of individuals and prevent them from harm by maximizing anticipated benefits and minimizing possible harms.

Investigators should systematically consider the risks presented by the research they propose. Specifically, investigators are asked to consider (in consultation with faculty advisors, if some investigators are students) the probability of physical, psychological, legal, social or economic harm, as well as the severity or magnitude of potential harm to a research subject that could occur as a result of participating in a research study.

Application of the ethical principle of beneficence requires the investigator to consider whether the potential benefits outweigh the potential harm and whether they (the investigators) have taken all appropriate steps to minimize potential harm.

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.

Justice entails the fair distribution of research benefits and burdens. In practice, this means that ethical research should not burden one group while benefiting another.

Application of the ethical principle of justice to the conduct of research demands that investigators carefully select both the pool of potential research subjects and the actual subjects from within that pool, taking care to avoid burdening some potential subjects because they are easy to enroll. 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."

Careful consideration must be taken when vulnerable subjects are involved. Individuals such as those who are 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 Belmont Report, the Department of Health and Human Services (DHHS) revised the regulations on human subjects. These federal regulations became Title 45, Part 46 of the Code of Federal Regulations, also known as the "Common Rule."

In 2011, the government began seeking public input on issues related to the ethics, safety, and oversight of human research. As a result of this and other input, an updated set of guidelines were released; these came into force in July 2018. The guidelines laid out in this Handbook reflect Cornell College IRB's understanding of the new (2018) Common Rule.[5]

[5] Revised Common Rule regulatory text can be found in 45 CFR 46 of the July 19, 2018 edition of the e-Code of Federal Regulations. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/revised-common-rule-regulatory-text/index.html

The "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, and regularly renewed since that time. All faculty members of the IRB are appointed by the President of the College in consultation with the Vice Chair of the Faculty Council. Community members are appointed by the Institutional Representative Officer for the IRB (currently the Dean of the College).

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 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 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 or Fine Arts.

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) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

VI. Definitions

What is research?

Research, according to federal regulations, means "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."[6]

One "test" of whether a project constitutes research rests on whether findings will be disseminated to the public outside the educational setting. For example, findings that are presented outside of Cornell College as a poster or paper at a conference, on a website, or that may be published, will generally be interpreted as "research."

According to federal guidelines, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities focused on individual perspective rather than generalizable knowledge (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship).

Note: Journalists and investigative reporters who are writing stories for news publications such as 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 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 Cornellian, the IRB must review the study prior to data collection.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.

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

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

[6] 45 CFR 46 of the July 19, 2018 edition of the e-Code of Federal Regulations. Available at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/revised-common-rule-regulatory-text/index.html

(5) Research on normal educational practices such as instructional strategies, curriculum or classroom management techniques. Surveys or proficiency tests do not require IRB approval.

What is a human subject?

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

1. Data from intervention or interaction with the individual
2. Biospecimens from intervention or interaction with the individual
3. 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. For purposes of this document, the terms “risks,” “costs,” and “harm” are essentially equivalent. (See sections below.)

“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.

Researchers should be aware that even with minimal risk studies, research subjects generally accrue costs associated with the time and energy it takes to serve as participants in research. (See below for more).

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 themself. A person suffering from depression may receive free psychotherapy as part of a research trial. Some benefits may be diffuse. For examples, a research study designed to improve air quality in a particular geographic area offers potential benefits to everyone in that area.

Compensating people for participating in research (in the form of payment, gifts, or course credit) does not constitute a benefit (see below Section VII for more).

What is Informed Consent?

Informed Consent refers to the process of explaining to a potential subject what they can expect from participating in a research study. For more detailed direction on developing an Informed Consent, please see Section VIII.

The Informed Consent process generally consists of

(a) explaining the purpose of the study and the risk and benefits of participation,
(b) securing the uncoerced, freely-given consent of a research subject, documented in writing[7] and
(c) providing the subject with a written document that outlines the purpose, risk and benefits of participation and provides details on how to contact the researcher, the Principal Investigator (PI) and the Cornell College IRB.

[7] In certain circumstances, the need for written consent may be waived, but the practice of informed consent applies to all research projects.

Each Cornell College IRB application must include a draft of the informed consent document(s). If the researcher plans to conduct research in a language other than English, she/ he must also submit copies of the Informed Consent document in that target language and should, as a courtesy to the IRB, make a suggestion for individual(s) with appropriate language competency who can determine whether the target language version of the Informed Consent document meets all of the standards and expectations of the English-language version. (See below: *Research in languages other than English* for more details).

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. At Cornell, the PI can be a faculty member, a staff member, student, or an outside researcher who has secured permission to conduct research at Cornell through the offices of Institutional Research, the Dean of the College, or via an exemption from the Cornell College Institutional Review Board. If the PI is a student, a faculty sponsor must be designated on the IRB application.

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, but not limited to the following:

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 pain or may experience physical discomfort or injury, including physical exertion beyond the subject's normal activity (e.g. a stress test).
- Situations in which the subjects' physiological requirements, such as nutrition, sleep, or light, are manipulated.

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

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 about risky or undesirable behaviors.
- Subjects are presented material or asked questions that they may find offensive, degrading, or threatening or which may encourage them to consider aspects of their own identities about which they were previously unaware (e.g. tests about racist or homophobic attitudes).

- Subjects' psychological environment is manipulated, for example, 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 an invasion of their 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. 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. On the Informed Consent document, the researcher should provide subjects with contact information for resources that could help the subject manage any emotional distress they experience as a result of participating in the study.

Legal, Economic, Academic, Professional, or Social Risks

The disclosure of the subject's information may also create civil or criminal liability, or damage the subject's financial standing, academic standing, employability, or reputation; or may result in embarrassment within a business or social group, loss of employment, or sanctions from the College.

Procedures aimed at decoupling information that could identify an individual from the data that could harm them can mitigate, but not completely eliminate, the potential legal, economic, academic, professional or social risks.

Most of the risk associated with legal, economic, academic, professional or social trouble occurs when a subjects' information is made public. Researchers should be aware, however, that in some settings, the act of simply speaking with or cooperating with a researcher could put subjects at risk.

Such risks include the following:

- Surveys that seek information about criminal activity or harms done others could create civil or legal liability, and could harm that person's reputation and/or 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, label or stigmatize them.
- Non-anonymous surveys of employees that seek information regarding job performance, for example, could place a subject's employment status in jeopardy.
- Non-anonymous survey questions or procedures about a subject's illegal activities or about activities that violate College policies (such as academic dishonesty) could result in disciplinary action by the College.
- 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. Similarly, there may also be state laws requiring the reporting of certain matters such as child abuse.
- 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 stigmatized 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 the designation of codes or pseudonyms. The researcher must clearly specify how this will be accomplished (i.e. how documents linking identifiers to subject information will be kept secure, and who will have access to these 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:

    o Paper records will be kept in a locked file or office.

    o Portable electronic records (e.g., laptop computer, PDA, flash or zip drive, CD or DVD, external hard drive) will be password-protected* and kept in a locked office. When transport is required, electronic records (e.g., laptop computer, PDA, flash or zip drive) will be kept in a locked briefcase and will be password-protected.

o Non-portable electronic records will be password-protected* and 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 PI, must be listed on the informed consent document, must complete Human Subjects Protections training to be kept on file by the PI, and must complete Cornell College IRB Handbook training

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.

Destruction of data: As noted above identifying information or coding keys should be destroyed as soon as possible after the completion of the data collection. Consent forms should be maintained for three years after the research project ends and then destroyed.

Data breach: A data breach (i.e., defined as any situation where confidential research data is lost, stolen, or accessed by someone outside the research team) should be reported immediately to the IRB Chair

Special Risks for Vulnerable Populations.

The federal government is particularly concerned with the protection of vulnerable individuals, specifically subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or 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."[8]

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.

* Note: For potentially sensitive data, file encryption is recommended, as it offers a higher level of protection than password protection.

[8] 45 CFR 46 111 (b), 25 July 2011, < http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111>

However, many 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.

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. Per Federal regulation, essential components of the Informed Consent include:

(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

(ii) The Informed Consent must not include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

(iii) The Informed Consent should provide research subjects with information about resources they may seek to alleviate any psychological disturbance attributable to their participation, or to alleviate any physical discomfort or injury attributable to their participation.

(iv) The Informed consent must include:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's

participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject, including psychological disturbance (anxiety, depression, stress, feelings of guilt, feelings of shame, or loss of self-esteem, embarrassment) and/or physical discomfort or injury.

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

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

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

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

(v) If the research involves the collection of identifiable private information or biospecimens, the Informed Consent should include:

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

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

(vi) As appropriate, the Informed Consent should also include:

(11) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

(12) Any additional costs to the subject that may result from participation in the research;

(13) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(14) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

(15) The approximate number of subjects involved in the study;

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

(17) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(18) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.*, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

(vii) If the researcher is seeking Broad Consent (i.e., the use, storage, and potential use of specimens for future secondary research), the Informed Consent must also include the following:

(19) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

(20) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

(21) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

(23) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

(24) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

(25) An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

Sample informed Consent forms can be obtained via request from the IRB Chair.

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, 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 should 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. If witnesses will not be sought for important cultural or social reasons, this process must be outlined to and approved by the IRB.

A copy of the consent document that was read to the subject ~~and containing the signature of the witness~~ must be given to the subject 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 be given opportunity to review research that includes 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.

Research in languages other than English

When researchers plan to enroll subjects that are not proficient in English, they must create a plan for communicating with those subjects at every phase of the research process, including enrollment, consent, data collection and follow-up. Materials (including consent forms) must be submitted to the IRB in both English and the target language. The IRB also requests that researchers include the name and contact information of a person fluent in the target language and English who might assist the IRB in evaluating the appropriateness of materials not in English.

The researcher should explain in their IRB application whether members of the research team speak the target language at a level appropriate to conduct the research and/or whether an interpreter will be used. If a translator will be used, they will be required to sign a confidentiality agreement.

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 (Remember this is only required if the research will be published or presented in a public forum outside of Cornell College.)

- Securing approval for 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.
- Securing approval for research on human subjects conducted by a student investigator (as an independent project, capstone project, etc.) is the responsibility of the student investigator. Faculty supervisors (Principal Investigators or PIs) should ensure that student investigators are aware of the review process and advise students involved in the process, but it is ultimately the student investigator's responsibility to complete the review process.
- Securing approval for research on human subjects conducted by outside researchers, faculty or staff principal investigator(s) is the responsibility of the faculty, staff or outside researcher 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, complete the Human Subjects training, and complete the Cornell College IRB Handbook training.

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 and document the changes via a protocol amendment form submitted to the IRB Chair.
- The principal investigator must contact the IRB if any incidents that harm or may harm a human subject arise during the research and document the incidents via a serious adverse events form submitted to the IRB Chair.
- 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[9] OR PUBLICATION outside of the Cornell College campus.

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

[9] Presentations of student work in a classroom, on the OC or in another campus-only forum will not be considered a public presentation. Thus, research done without IRB approval may be presented in these spaces.

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.

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

Research with Human Subjects can be evaluated according to the following categories:

- Exempt (Self-determination)
- Exempt (Limited IRB Review)
- Non-exempt (Expedited Review)
- Non-exempt (Full IRB Review)

All submitted proposals are assigned by the IRB to one of these four review categories.

In part, the review category will be determined through the IRB determination process which follows a series of decision rules. If questions arise regarding which review category a project will require or for a copy of the decision rules, investigators are encouraged to contact the IRB Chair directly.

Researchers must secure IRB approval a project before investigators start work on it, even before they begin to recruit subjects, since recruitment strategies are part of the review. Categories of review are outlined below.

Exempt Research

"Exempt" human subjects research is a sub-set of research involving human subjects that *does not require* comprehensive IRB review and approval because the **only** research activity involving the human subjects falls into one or more specific exemption categories as defined by the Common Rule (see below)

- Exempt projects are not subject to continuing review
- Amendments are required only if changes to the project could alter the exempt determination
- An exempt determination does not lessen the investigator's ethical obligations, including the completion of human subjects protections training

The Federal government has identified eight categories of research that qualify for exemption:

1 – Educational Exemption
2 – Surveys, Interviews, Educational Tests, and Observations of Public Behavior
3 – Benign Behavioral Intervention
4 – Secondary Research (with identifiable private information and/or biospecimens)
5 – Public Benefit/ Service Program Research (conducted by Federal Demonstration Projects)
6 – Taste or Food Quality Evaluation and Consumer Acceptance

7 – Storage and/or Maintenance of Identifiable Data and/or Biospecimens obtained with "Broad Consent"
8 – Use of Identifiable Data and/or Biospecimens obtained with "Broad Consent"

For each of these kinds of exemptions, some projects may secure approval through the self-determination process while others may require Limited IRB review.

The IRB application process can help researchers understand the differences between these, but some general guidelines:

Exempt (Self Determination)

Broadly speaking, projects may qualify for Exempt (Self Determination) if they meet the following requirements:

1. The research must fit one of the above eight categories of qualified exempt research
2. If the PI seeks Exemption #1 (Educational Exemption), the project must
    a. be conducted in an established educational setting;
    b. be part of normal educational practice;
    c. not have an adverse impact on teachers or students
    d. not include personal data protected by federal law (FERPA or PHI)
3. If the PI seeks Exemption #2 (Surveys, Interviews, Educational Tests, and Observations of Public Behavior), the project must fit one of two categories:
    a. Research that involves data collection involving adults which uses surveys, interviews, educational tests, or observations of public behavior and which does not include any sensitive data or identifiable data (including PHI).
    b. Research that involves data collection involving children which uses educational tests or observations without interaction and which does not include any sensitive data or identifiable data (including PHI).
4. If the PI seeks Exemption #3 (Benign Behavioral Intervention), the project must:
    a. be data collection involving adults which uses Benign Behavioral Interventions and which does not include any deception, or collection of sensitive data or identifiable data (including PHI).

Exempt (Limited Review)

If a project meets the definition of an exempt category of research, but does not meet all of the requirements for Exempt (Self Determined), the project may still qualify for Limited Reviews. Determination of whether a project should be considered Exempt (Limited IRB Review), Non-exempt (Expedited Review) or Non-exempt (Full IRB Review) will be made by the IRB Chair. PIs are encouraged to submit the research for consideration if exemption status is unclear and the data will be published or presented in setting external to Cornell College.

Non-exempt (Expedited Review)

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.

Non-exempt (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 Informed Consent.
- The proposed research involves vulnerable populations.The proposed research involves stigmatized behaviors or topics of a sensitive nature (sexual behaviors, illegal behaviors, drug or alcohol use, sensitive demographic data, etc.).

- 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 their 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, nutraceuticals, 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.

Exempt: The project does not require IRB approval or is deferred to the IRB of the project host institution.

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 and document the events on a serious adverse events log. 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 via the completion of a project amendment form. This includes changes in the (approved) consent form, sample composition, sample recruitment, or study procedures. Certain research situations may arise that necessitate a temporary change to the IRB-approved research protocol. In these cases, a protocol deviation form should be completed.to track such events. The protocol deviation form should be submitted at annual renewal or project closure. If the deviation represented a significant change to participant risk, the deviation should be reported within 24 hours of occurrence. Please note protocol deviations are distinguished from protocol amendments in that they are not lasting or uniform across participants but represent isolated incidents in which the approved protocol was not followed. Sample protocol deviation forms are available from the IRB Chair.

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.

If a project is not to be renewed, the PI will complete a project closure form.

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.