Trinity College
Institutional Review Board (IRB)[1]
Policies and Procedures Manual
Revised January 2025

[1] The Trinity College IRB has drawn this policy manual in large part from the IRB Manual of Kenyon College, which has generously given permission for use of this material.

Contents

Overview of the Protection of Human Subjects

Trinity College believes ethics and ethical principles extend to all spheres of human activity.

Trinity College is especially concerned with and committed to safeguarding the welfare, rights, and privacy of all persons who participate as subjects in research projects conducted under its auspices, and to ensuring that the subjects of such research are aware of their rights and the protections available to them. Moreover, the college is required to assure the federal government that such safeguards are being provided and enforced for federally funded research involving human subjects.

The role of the Trinity College Institutional Review Board (IRB) is to foster ethical treatment of human research participants and to oversee all research (broadly defined) involving human subjects conducted under the auspices of Trinity College by its faculty, students, and staff.

All research projects involving human subjects regardless of the source of funding require the review and approval from the Trinity College IRB **prior to gathering any data or information from the subjects**.

The Trinity College IRB also reviews research conducted by outside investigators involving Trinity College students or personnel as participants, access to college records, or the use of college facilities. Researchers not affiliated with Trinity College who wish to come onto the Trinity College campus or use Trinity records to identify potential subjects must provide Trinity's IRB with a previously approved application from an IRB at an institution with a Federalwide Assurance (FWA) to be submitted with a new application to the Trinity College IRB. Outside researchers must have approval from the Trinity College IRB before they access Trinity College records or contact Trinity College students or personnel to participate in a study.

Trinity College cannot provide IRB approval or oversight for individuals not affiliated with the college as faculty, staff, or students and who do not have IRB approval from another institution with a Federalwide Assurance (FWA) and who are conducting research wholly independent of the college.

The ultimate responsibility for treatment of human research subjects, however, rests with the researcher. Researchers' informed participation in this process helps to ensure a positive, ethical, and responsible climate for scholarly research at Trinity College.

All Trinity College researchers, whether PI or research assistant, and whether faculty or student, involved in human subjects research must complete the requisite training module at the Collaborative Institutional Training Initiative website (citiprogram.org).

Review of all research proposals involving human subjects research must take place prior to the commencement of such research.

Research involving human subjects carried on at, by or under the auspices of Trinity College must comply with the college's IRB procedures. Research means a "systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102d.)

The IRB will consider each application and decide if the proposal is potentially exempt or requires an expedited or full review.

IRB Mission

Trinity College requires that research investigators, also known as primary investigators or PIs, must protect the rights, privacy and welfare of individuals recruited for participation in research. The Trinity College Institutional Review Board (IRB) holds the primary responsibility to protect human subjects involved in scientific, social, behavioral and educational research conducted by departments, programs, and all administrative divisions and organizations affiliated with the college. The jurisdiction of the IRB includes the authority to review, approve, modify or disapprove research protocol applications submitted by faculty, staff and student investigators. The process of review serves to ensure the safe and ethical conduct of research that ultimately will protect the rights and welfare of human subjects in an atmosphere of mutual trust and scientific integrity in the pursuit of knowledge. It also reviews research conducted by outside investigators using Trinity College students, personnel, or facilities.

1.0 Introduction

The National Research Act of 1974 established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This commission published *The Belmont Report* articulating the ethical principles that guide the conduct of research involving human subjects and continues to serve as the foundation of the Department of Health and Human Services regulations governing the protection of human subjects (hereafter 45 CFR 46).

In the design, conduct, approval and review of research, Trinity College officials, the IRB members, and investigators adhere to the basic principles set forth in *The Belmont Report*: respect for persons, beneficence, and justice.

In consideration of **RESPECT** for persons, Trinity College investigators must seek and obtain voluntary informed consent from potential research participants. Informed consent means that participants are given explicit assurances of the voluntary nature of their involvement in terms that are easy to understand, and that they are not under duress or pressured to serve as participants. The consent process also includes information about the research project that will assist participants in deciding whether to participate in the study. In addition, respect means honoring the privacy of individuals and maintaining confidentiality.

The principle of **BENEFICENCE** requires that researchers maximize the potential benefits to participants, or to society, while minimizing the potential risks of harm. The extent of protection depends on the risks and benefits of the proposed research. All participants should be treated in an ethical manner. Benefits to participants, or benefits in the form of generalizable knowledge gained from the research, should always outweigh the risks. If there are any risks resulting from participation in the research, then there must be benefits, either to the participants or society.

JUSTICE means that subjects must be selected fairly and that both the risks and benefits of research are distributed evenly. In the language of *The Belmont Report:* "Who ought to receive the benefits of research and bear its burdens?" Investigators should take precautions not to select participants simply because of convenient availability, manipulability, their compromised positions, or because of social, racial, sexual, economic, or cultural biases institutionalized in society.

Many U.S. government departments and private funding agencies have their own human subjects research policies. PIs should check to see if a funding agency has policies and procedures that go beyond Trinity College IRB policies.

1.1 Purpose of Trinity College IRB Policies & Procedures Manual

The *IRB Policies & Procedures Manual* serves as a reference guide describing the policies, procedures, and regulations governing research involving human subjects and the requirements for submitting protocol applications for review by the Institutional Review Board of Trinity College. The intended audience of users includes research administrators, principal investigators (faculty, staff and students), and IRB members. The manual describes and explains the various aspects of the review process and regulatory requirements.

The field of human subjects protection is constantly evolving; some parts of the manual may be updated from time to time. The IRB chair will keep the Trinity research community apprised of revisions or new developments as they occur.

1.2 Human Subjects Research Defined and Who Must Submit Protocols

Virtually all federally funded research with human subjects is governed by federal regulations patterned on those of DHHS (Department of Health and Human Services,) described at 45 CFR 46, and known as "the Common Rule." These federal regulations define **research** as: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." **Systematic investigations** are studies that are intended and designed to collect data about human subjects with the purpose of drawing conclusions and reporting research findings.

Human subjects, sometimes called **human participants,** are defined as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information."

"Intervention" includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. **"Interaction,"** on the other hand, includes communication or interpersonal contact between the investigator and a subject such as by way of interviews or survey questionnaires.

"Private information" includes data about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, as well as information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

At Trinity College, all **faculty and staff research** that conforms to these definitions in the Common Rule (45 CFR 46.102) must be submitted for review by the IRB regardless of funding source: federal,

state, local, private or unsponsored. The Trinity College IRB reviews protocol applications from all disciplines. In accordance with the Federalwide Assurance (FWA00013955) issued to Trinity College by the Office for Human Research Protections (OHRP), DHHS, all human subjects research funded by the federal government must be performed in accordance with 45 CFR 46. In addition, the actions of Trinity College officials, researchers, and staff must conform to all applicable federal, state and local laws and regulations.

Student research involving human subjects, for example, all honors theses proposals or undergraduate research intended for publication or wide dissemination such as a web page or presentation outside of the classroom (e.g., at a conference or poster session) must be submitted for review by the IRB. Student research involving human subjects must be supervised by a Trinity College faculty advisor who will assume the responsibility for ensuring that all research procedures comply with federal and state laws and regulations and college policies designed to protect human participants. Classroom projects, problems courses, and independent studies that are exclusively for instructional or mentorship purposes and that do not entail greater than minimal risk to human subjects need not undergo review by the IRB.

Faculty advisors and students are encouraged to follow this *IRB Policies & Procedures Manual* when designing and conducting class exercises, projects or other assignments that involve the use of human volunteers or respondents, even if not submitted for IRB review. All student research that poses GREATER than minimal risk to human subjects must be submitted for IRB review (see definition of minimal risk, section 3.2 of this manual).

1.3 The Role of the IRB

The IRB is charged with two principal responsibilities:

1. Determine and certify that all research protocols conform to the regulations and policies set forth by DHHS regarding the health, welfare, safety, rights, and privileges of human subjects; and
2. Assist investigators in conducting ethical research that complies with federal and other regulations in a way that permits the accomplishment of the research activity.

The IRB meets these responsibilities through a review of applications submitted by principal investigators, negotiations between the IRB and investigators for approval of research, and IRB outreach to the research community. The process of review serves to ensure the safe and ethical conduct of research that ultimately will protect the rights and welfare of human subjects. The dignity and welfare of individuals who participate in research must be a central concern of everyone involved with the protection of human subjects. The College and all faculty, staff and student investigators share in the collective responsibility for the ethical conduct of research.

This collaboration of the research community must operate in a culture of trust, mutual assurance, and integrity by upholding the highest ethical principles in the conduct of research and the pursuit of knowledge.

1.4 Jurisdiction and Authority of the IRB

The Federalwide Assurance with OHRP/DHHS details the relationship of Trinity College and the Office for Human Research Protections within DHHS. This agreement and other DHHS policies empower the IRB with the authority to review, approve, require modification of, or disapprove research activities involving human subjects conducted by Trinity College investigators, including jurisdiction over proposed changes in previously approved human subjects research. For approved research, the IRB also determines which activities require continuing review more frequently than the maximum interval of twelve months.

The IRB must ensure that voluntary informed consent will be obtained by research investigators and their staff in a manner that meets the requirements of Title 45 Code of Federal Regulations Part 46, sections 116 and 117. (See section 5.0 of this manual, Informed Consent: Process and Documentation.) The IRB holds the authority to observe or have a third party observe the consent process when deemed necessary.

IRB decisions and requirements for revisions, if any, are conveyed to investigators in writing, with the provision of an opportunity for appeal to the IRB by the investigator in the case of disapproval. **No committee or official can approve an investigator to conduct any human subjects research that the IRB has not approved.** [See **45 CFR 46.112**.]

IRB approval means that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional and federal requirements.

1.5 Responsibilities of the Investigator and Departments

Federal DHHS regulations, policies, and guidance documents describe the role of investigators, illustrating further the principles of mutual trust, collective responsibility and the nature of decentralized accountability in human subjects research. Researchers must acknowledge and accept their own responsibilities for protecting the rights, privacy and welfare of the human subjects.

The application submitted to the IRB for review must demonstrate full compliance with federal, state, and college regulations and with all components of the Trinity College Federalwide Assurance for the protection of human subjects in research.

Once IRB approval has been obtained, investigators (PIs) must maintain updated records to include the initial approved application (a PDF may be downloaded), modifications requested and approved, continuation or re-approval progress reports, instruments completed, consent forms administered and

signed, correspondence related to the study, adverse event reports, if any, etc. These records must be maintained for review or audit by the IRB for a minimum period of three years after official closure of the study. In the case of student PI's, the sponsoring faculty member, or department or program should maintain the records. (The IRB must also maintain certain records, as described in section 8.0 of this manual.)

If the research is approved by the IRB, investigators must obtain documented and legal informed consent from all research participants involved in each protocol, unless the IRB has granted a waiver, exception or alteration as provided for in the federal regulations and described in section 5.3 of this manual. Research investigators must also promptly report any injuries, unanticipated problems or adverse events to the IRB.

All amendments and modifications to a study need IRB approval before they are implemented. If the investigator wants to change *anything* in the research that would impact the subjects, such as recruitment procedures, key personnel, inclusion/exclusion criteria, research procedures, the informed consent document / process, or data elements collected, the investigator must obtain IRB review and approval prior to implementation of the changes. The only exception is changes necessary to eliminate apparent immediate hazards to a subject. If an investigator is unsure about reporting changes to the IRB, he/she should call the IRB office and ask for guidance. The IRB office can also provide investigators with instructions for submitting a request to modify an IRB-approved research protocol.

Progress reports and any proposed modifications to previously approved research activities must be submitted in writing in the manner prescribed in this manual.

1.6 IRB Membership, Infrastructure and Resources

As required by 45 CFR 46.107, IRB membership will consist of at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The Trinity College IRB consists of the Chair (who is normally a tenured member of the faculty in an appropriate department), and a minimum of four additional members. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall include persons knowledgeable in these areas.

Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or women, including the consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. The IRB may not consist entirely of members of one profession. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB shall include at least one member who is not otherwise affiliated with Trinity College and who is not part of the immediate family of a person who is affiliated with Trinity College.

Members of the IRB are appointed by the Dean of the Faculty with input from the IRB Chair and the Deans of Academic Affairs, as well as from chairs of departments and programs. The IRB must include at least one member of each sex, whenever the composition of the faculty makes it possible.

The Trinity College IRB shall include the following:

One member from the Psychology Department
One member from the Social Sciences Division other than Psychology
One non-scientist member
One member from the community

One member of the Trinity College IRB shall be appointed to undertake the duties of chair.

The IRB chair will serve a three-year term. The role will include the following duties:

- Oversee the general business of the IRB
- Serve as liaison between the IRB and the Dean of Faculties office
- Preside at meetings of the IRB
- Set or approve meeting agendas
- Other duties as required

The Trinity College IRB shall be supported by an IRB administrator and other administrative staff assigned by the Dean of Academic Affairs as necessary.

The role of the IRB administrator includes the following duties:

- Receive and log all protocol applications submitted by investigators
- Conduct a preliminary screen of applications for the necessary forms and attachments
- Maintain all records on a computerized database
- Document actions taken at IRB meetings by way of written minutes
- Maintain the IRB web site

The IRB Chair provides leadership for the development and implementation of policies and procedures for the protection of human subject participants in research. The Chair is also responsible for scheduling timely reviews of the process, conducting training and outreach programs, and submitting reports required by Trinity College and federal agencies.

The IRB Chair presides at the IRB meetings and reports to the Dean of the Faculty. The Dean of the Faculty serves as the Institutional Signatory Official. According to current OHRP instructions for the Federalwide Assurance, the Institutional Signatory Official cannot be the IRB Chair or a member of the IRB.

Trinity College legal counsel and the Office of the Dean of the Faculty provide technical and/or administrative support as needed.

2.0 Submitting Protocol Applications

Applicants to the Trinity College IRB must be investigators with faculty appointments, currently enrolled students, or currently employed staff or administrators who plan on conducting human subjects research under the auspices of an academic department or program or administrative division. Tenured, tenure-track and salaried faculty with letters of academic title and academic division heads may sponsor other investigators and serve as the responsible advisor such as in the case of student research, staff research, or research conducted by part-time faculty, or visiting scholars from other institutions. All outside investigators must have an eligible Trinity sponsor. In all cases, the responsible faculty member or the division head must assure compliance with human subjects research protections and IRB requirements.

All persons submitting proposals—whether or not they are affiliated with Trinity—must fully comply with Trinity's IRB policies and procedures.

Applications submitted to the Trinity College IRB must adhere to both the provisions of 45 CFR 46 and this *Manual*. The online application form and instructions are available at the Trinity College IRB website.

Submission of incomplete applications will result in the delay of the review and approval process. Attachments to the protocol application may include, as applicable: flyers, posters, advertisements, internet postings or other materials utilized to recruit human subjects, as well as any research instruments involved in the study, such as interview guides, surveys and questionnaires.

When completed, the IRB application and all attachments will be automatically forwarded to the IRB administrator.

2.1 Reliance Agreements[2]

In cases where Trinity faculty, staff, administrators, or students wish to rely upon an IRB operated by another institution, the applicant must ensure that this arrangement is documented by a written agreement between Trinity and the other institution or organization operating the IRB. The document, an Institutional Authorization Agreement (available at the Trinity IRB website), should outline their relationship and include a commitment that the other institution's IRB will adhere to the requirements of the Institution's FWA. This agreement will be retained at both institutions/organizations.

[2]From Terms for the Federal Wide Assurance for the Protection of Human Subjects

3.0 IRB Review Process

The IRB retains the sole and final authority at Trinity College for the approval of applications to conduct research involving human subjects.

The IRB review process applies to research conducted by faculty, students, staff, visiting scholars and others whether conducted on Trinity College premises, at off-campus sites, or under subcontracts to other entities.

The review requirement applies to all human subjects research conducted under the auspices of Trinity College, regardless of funding source, sponsored and unsponsored.

The IRB is responsible for ensuring that all approved research complies with the letter and spirit of the human subject protection regulations as well as the ethical principles stated in *The Belmont Report:* **respect for persons, beneficence, and justice**.

The IRB examines research protocols in terms of procedures to recruit human subjects, proposed remuneration if any, and adequacy of the informed consent process. In addition, the IRB evaluates the risks and potential benefits to participants as outlined in each protocol. The broad purpose of this review is to help ensure that investigators recruit subjects in an equitable manner that is non-coercive, that subjects are fully informed about the risks and benefits entailed in the research, and that subjects are not exposed to disproportionate risks.

3.1 Risks and Benefits

The IRB will assess whether the risks to participants are reasonable in relation to the anticipated benefits to the participants or to society. In particular, the IRB reviews proposed studies to ensure that the risks are minimized to the greatest extent possible and to ensure that the benefits of research participation are maximized.

The IRB will consider the scientific merit of the study design, since it would be unethical to place human subjects at risk with a study where methodological procedures are flawed such that little or no reliable information will be obtained.

The IRB also considers any possible benefits a subject may derive from participation in research, and/or the benefits of new knowledge that may justify asking a person to undertake the risks of the study. **Payments or other incentives for participation in research are not considered, and should not be described as, benefits to subjects**.

Risk means the probability of harm, whether physical, psychological, social, legal or economic. Both the probability and magnitude of possible harm may vary from minimal risk to greater than minimal. Risks

also include immediate risks of study participation, risks of breach of confidentiality, inadvertent disclosures, and risks of long-term effects. Risks should be minimized by screening out prospective participants at undue risk, proper monitoring of procedures once in place, and adequate protection of individual privacy and confidentiality. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. A benefit is a valued or desired outcome or an advantage. Benefits of research may accrue directly to the individual participating in the research, or to society as a whole, as is often the case in social, behavioral, and educational research.

3.2 Minimal Risk Defined

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.

Guidance: The IRB considers **minimal risk studies** as comparable to the following examples:

- tests and measures of mental status or memory functioning outside of a clinical setting;
- standardized IQ tests;
- personality inventories;
- consumer preference surveys; or
- other routine, non-sensitive, information, such as data gathered for educational or employment purposes where there is an expectation of standardized tests or routine examinations.

Greater than minimal risk studies may include **research procedures** that employ:

- deception,
- covert observations in settings where privacy is expected,
- collection of data that could result in embarrassment or other personal harms due to a breach of confidentiality,
- infliction of pain or physical discomfort,
- use of medical records or protected health information, or
- the enrollment of participants with impairments, disabilities or psychological disorders.

3.3 Equitable Selection of Research Participants

The selection of participants should be equitable and free of coercion. The IRB will consider the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children,

prisoners, pregnant women, persons with mental disabilities, or economically or educationally disadvantaged persons.

Guidance: Where appropriate, investigators should indicate in their protocol how they will avoid even the appearance of coercion in the recruitment of participants. They should also detail any extra precautions that will be taken to safeguard the rights and welfare of vulnerable populations.

3.4 Identification of Participants and Confidentiality

The IRB will scrutinize the methods for prospective identification and contact of participants. This includes a review of the means proposed by the investigator for insuring participant privacy and confidentiality.

The IRB will also examine the importance of the research, the sensitivity of any information sought from the participants, and the special procedures devised by the investigator for protecting any private or personal information.

3.5 Informed Consent

The IRB will review the process described by the investigator for obtaining informed consent including when, where and how consent is obtained and any provisions for the ongoing consent of participants. (See section 5.0 of this manual for the detailed requirements of the informed consent process, methods for documentation, and any requests for waivers or alterations of written informed consent.)

3.6 Additional Monitoring and Safeguards

The IRB will assess whether a project requires more than annual review and whether a project needs any additional monitoring procedures to ensure the safety of the participants. Both of these determinations generally will be based on the degree of risk in the study. Appropriate safeguards could include monitoring of the consent process, observation of the research procedures, or review of research related results.

When **vulnerable subjects** are included in a project, the IRB will determine whether any additional safeguards are appropriate to protect their rights and welfare, and if so, whether these procedures have been included.

3.7 Research Involving Vulnerable Populations

Subparts of the HHS regulations in (**45 CFR 46**) require additional protections for the following categories of subjects:

- **Pregnant women, human fetuses and neonates involved in research (**Subpart B)
- Biomedical and behavioral research involving **incarcerated individuals** as subjects (Subpart C)
- **Children** involved as subjects in research (Subpart D)

Research investigators should consult 45 CFR 46, Subparts B, C, and D for descriptions of these additional requirements. In addition to the categories identified in Subparts B, C, and D, vulnerable populations include persons with diminished capacity to freely give informed consent, due to such factors as limited education, lack of fluency in English or other pertinent languages, or limited mental capacity.

3.8 Community-Engaged Research

The IRB should ensure that principal investigators conducting research involving community engagement have considered and articulated how they will work with community partners in a collaborative and mutually beneficial way ensuring that all parties have input appropriate to the level of their involvement. If a community-based organization is involved, the protocol application should list the full name of the organization, the name of a contact, and the organization's role in the research. The IRB should ensure that research personnel have the necessary ethics training. Guidance can be found in the resources section of the Trinity IRB webpages. For details on the various types of involvement, please refer to the *General Guidance for Community-Engaged Research*.

3.9 Students and Research Course Credits

Trinity College students may be recruited for participation in research studies or experiments to include the prospect of earning research course credits or extra credit points for grades. **However**, the investigator or course instructor proposing these studies and credits must demonstrate to the IRB that the students in the subject pool are **not being coerced** and that their consent will be freely given. Care should be taken to eliminate any undue influence of faculty so that participation is **not a course requirement without the possibility of other alternatives**.

In all cases there must be an educational value or benefit to students explicitly described in the protocol and in the consent form, along with measures to protect student autonomy and confidentiality. Students must be provided with choices and options in order to obtain the equivalent course credits or grade incentives.

Examples of alternatives include:

- attendance at a research seminar;
- writing a brief research abstract or journal article report; or
- other assignments with educational value.

Alternative activities should be comparable to research participation in terms of time, effort and convenience. **If evaluated**, these projects should be graded on a credit/no credit scale.

Investigators should avoid any inference that volunteering to join a study will place students in good favor with the faculty in the course in terms of grading, recommendations, or future employment. In the close environment of the college, special attention should be given to the handling of data to minimize any risks of inadvertent breaches of confidentiality. For example, students should not be invited to participate in research that could reveal confidential or private information to their peers and mentors or that may embarrass or compromise the individual student.

4.0 Levels OF IRB Review & Related Topics

The Department of Health and Human Services' Office of Human Research Protections (OHRP) provides a decision tree to help investigators make a decision as to whether human subjects research is eligible for exemption from the human subjects regulations or whether an IRB application is needed. Should any concerns, questions, or doubt arise as to whether an IRB application is needed, contact the IRB to ensure that the correct decision is made. Student investigators should consult with their faculty advisor when using the decision tree. If the investigator determines that an IRB proposal is necessary, it is up to the IRB to determine the appropriate level of review. The HHS website has decision charts that can help determine if research requires review.

If a determination is made that the human subjects research is exempt from the human subjects regulations, nonetheless, the person or persons making that determination should submit to the IRB a statement sufficiently describing the research and basis for the determination that the research is exempt so that the IRB may review the determination. The chair of the IRB or their designee on the IRB shall conduct this review. The IRB shall respond in writing either approving the determination of exemption from the human subjects regulations or indicating that further information is necessary or that an application to it is necessary. Prior to commencing the research project, the investigator must receive a written response from the IRB.

All applications submitted to the IRB should be carefully prepared. When a student is the principal investigator, the faculty/staff/administrative person advising the student investigator should carefully review the IRB proposal before it is submitted. The IRB will determine what level of review is required for the proposal.

4.1 Exempt Research

[Note: Exemption category descriptions below are from the hhs.gov website]

Certain categories of research are exempt from the human subjects regulations when the data collected is not linked or identifiable to participants and any risks present will not cause more than minimal harm or discomfort.

What Exemption Means: "Exemption" as used in this document means exemption from the requirements set forth in the HHS regulations (45 CFR 46), such as the requirement for a written informed consent document. Initial determinations of exemption can be made by investigators using a decision tree provided by OHRP.

What Exemption Does *Not* Mean: "Exemption" does not mean that the research activity is exempt from the laws of the State of Connecticut, and it does not mean that the research need not conform to the canons of sound research ethics.

These exemptions do not apply to research involving incarcerated persons, fetuses, pregnant women, human *in vitro* fertilization, persons with mental disabilities, or certain research involving surveys or interviews of children except where the research involves only educational tests and observations where the investigator does not participate in or manipulate the activities being observed.

A determination that research is exempt does not imply that investigators have no ethical responsibilities to subjects in such research; it means only that the regulatory requirements related to IRB review, informed consent, and assurance of compliance do not apply to the research.

Research activities in which the only involvement of human subjects fits one or more of the categories listed below may qualify for exemption from review. These exempt categories **do not apply** to research involving **deception** of subjects where the investigator does not disclose the true purpose of the research and/or the results of the subject's participation in the study.

Further, a determination of exemption by an investigator does not necessarily exempt investigators from the requirement of gaining consent or permission from subjects. Most research requires the use of an informed consent document (see Appendix 9 for examples), an approved alteration, a letter of explanation, or specific instructions on how to express consent. For minimal risk studies where there are no subject identifiers (i.e., anonymous data are collected) or where subject identifiers have been decoupled from data that has been collected, an information sheet, cover letter or statement in the introduction to the survey or other instrument may be substituted in place of a written and signed consent form. (See section 5.4 of this manual.)

The following categories of research are exempt from the human subjects regulations. A decision that a particular research protocol is exempt should include documentation indicating the specific category justifying the exemption.

Existing Data, Records or Specimens, Recorded Anonymously

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: [**45 CFR 46.101 (d)(4)]**

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Existing data means data from publicly available sources or anonymous sources and applies to retrospective studies involving data that has already been collected and is "on the shelf" when the protocol is submitted. The exemption does not apply if some of the data or materials exist, but the research will gather additional data or materials. In addition, the exemption applies only if the data is anonymous or the investigator records the data in such a way that participants cannot be identified. This means that if any codes exist by which participants could be identified, the exemption does not apply.

Personal identifiers linked to participants include names, initials, date of birth, social security numbers, and agency record numbers.

Database files may qualify for exemption if there are procedures in the release of information from the source that prevent identification of individuals. It is not enough that participants are not identifiable in the final publication. Publicly available sources of data include examples such as telephone books and public records. Data bank, archival or other types of organizational records may be exempt depending on the policies and procedures to prevent the release of personal identifiers.

Surveys, Interviews, Public Observations, and Educational Tests

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: **[45 CFR 46.104(d)(2)]**

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

This exemption is available for research within any of the stated categories involving adults, unless the information is both recorded in such a way that the human subjects can be identified (by links or otherwise) **and** the disclosure of the subjects' responses outside the research could place the subjects at risk or cause personal harm. Thus, **surveys involving sensitive topics** (such as drug or alcohol use, sexual habits, detailed health histories, illegal behavior, etc.) where there are codes or other links between the information and the subject are not exempt.

Studies that use interview methodologies may require IRB review if the interview will be published or publicly presented, and individuals could be identified.

Certain **educational tests** are exempt from the human subjects regulations: tests of knowledge, mastery and skills that do not include individual subject identifiers or ask sensitive information from the subjects.

Observational research involving sensitive aspects of human behavior, or in settings where subjects have a reasonable expectation of privacy, is not exempt.

Sensitive survey research is seldom exempt. A sensitive survey includes questions about illegal activities or highly personal aspects of the subject's behavior, life experiences, or attitudes. Questionnaires or surveys covering sensitive topics, however, may qualify for exemption if they: (a) ensure the anonymity of the subject; (b) inform the potential subjects as to the sensitive nature of the topics they will be asked to address; and (c) the study does not exceed minimal risk.

The exemption does not apply to research involving the observation of children, except for research involving observations of public behavior when the investigator does not participate in the

activities being observed (i.e., the **investigator does not manipulate or influence** the observed activities).

Research under this category that would not otherwise be exempt may qualify for exemption if: (a) it involves elected or appointed public officials or candidates for public office (for example, surveys, interviews or observation of public officials or candidates for public office); or (b) federal statute requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. **[**45 CFR 46.101(b) (3)**].**

Educational Settings and Normal Educational Practices

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. **[45 CFR 46.104(d)(1)]**

To qualify for exemption under this category, all of the research must be conducted in a commonly accepted educational setting and should not involve sensitive topics (e.g., sexual behavior, drug abuse, personal issues) nor increase the level of risk or discomfort beyond normal, routine educational practices. Provisions should be made to insure the existence of a non-coercive environment for all students, including those who choose not to participate. Written permission of the school or appropriate agency should be obtained prior to the implementation of the research, including review of the proposed study by the human subjects research office or committee as applicable to or required by each school site.

Benign Behavioral Interventions

Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met **[45 CFR 46.104(d)(3)]***:*

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Public Benefit Service Programs, Taste and Food Quality Studies

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. **[45 CFR 46.101(d)(5)].**

The federal regulations also exempt *taste and food quality evaluation and consumer acceptance studies if (a) wholesome foods without additives are consumed, or (b) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the EPA or the Food Safety and Inspections Service of the USDA* **[45 CFR 46.101(d)(6)].**

4.2 Expedited Review

Research Categories Eligible for Expedited Review

The categories eligible for expedited review include a number of specific examples approved by the Secretary of the Department of Health and Human Services as published in the Federal Register.

Among others (mostly medical devices or clinical studies of drugs), research activities that may be accepted by the IRB for expedited review include the following:

- Research involving **materials (data, documents, records, or specimens)** that have been collected or will be collected solely for non-research purposes or collection of data from voice, video, digital, or image recordings made for research purposes
- Research on **individual or group characteristics or behavior** (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing **survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies** (some research in this list may be eligible for exemption)
- **Continuing review of research** previously approved by full review of the IRB where the research is permanently closed to the enrollment of new subjects, all subjects have completed research-related interventions, and the research remains active only for long-term follow-up of subjects; or where no subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis

For the full list and additional guidance on the categories of research eligible for expedited review, see the HHS document "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure" .

The IRB may use the expedited review procedure to review either or both of the following: (1) some or all of the research appearing on the HHS list and found by the reviewer(s) to involve no more than minimal risk; and (2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among the members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. (A research activity may be disapproved only after a full review.) The IRB shall adopt a method for keeping all members advised of research proposals that have been approved under the expedited procedure.

4.3 Full Reviews

Most applications submitted to the Trinity College IRB qualify for either exemption or expedited review. Research that does not qualify for exemption or expedited review must undergo a full IRB review by a

quorum of IRB members at a convened meeting. (A quorum consists of a majority of the members of the IRB, including at least one member whose primary concerns are in nonscientific areas.) The application process and forms remain the same as for the other levels, but a full review may take longer after receipt of a complete, signed application. In the event that no additional information, clarifications or modifications are requested, the IRB may approve a study within a short time period, but the initial full review process often does not result in an outright approval of the research. Minor or major revisions and written clarifications may be requested, adding time to the review process.

In a Full Review, the IRB performs a detailed examination of the review application and all supporting documentation, including the proposed informed consent form and any recruitment materials, questionnaires, or survey instruments.

IRB members with a potential conflict of interest in any review must recuse themselves from voting and participation in the review, except to provide information requested by the IRB. These disclosures should be stated prior to the agenda item where the protocol is presented for discussion. After a full discussion of the complete application, the IRB Chair calls for a vote. Results of IRB decisions are then communicated in writing to the investigator and Trinity College. This letter will justify any conditions required for final approval, may request additional information or revisions, and will indicate the next steps in the review process, if any.

The IRB may come to one of five determinations:

1. **Unconditional Approval**: Approval of the study as submitted without questions or clarifications (in order for research to be approved, it must receive the approval of a majority of those IRB members present at the meeting);
2. **Approval with Stipulations**: Acceptance of the protocol with requests for clarification and/or revisions (minor changes that can be reviewed and accepted by the Chair, a designated IRB member with relevant expertise, or a subcommittee of the IRB);
3. **Deferred Approval**: Deferral of the application pending written responses to major or substantive questions raised by the IRB during the initial review (requires convening of the full IRB for a second deliberation meeting);
4. **Tabling**: Approval is not granted until further information is provided or specific changes are made. When new information is submitted, the protocol is reviewed again by the full IRB.
5. **Disapproval**: Disapproval of the research application (the study cannot be conducted) with the **right of appeal**. Investigators have the right to discuss any of the IRB outcomes directly with the Chair. In the case of disapproval, the letter of determination will include specific reasons for the disapproval with provision of an opportunity for reply and appeal by the investigator. The reply

can be in writing or in person at a convened meeting of the IRB, or both. In the end, the IRB retains final authority for approval of proposed research involving human subjects.

All meetings of the IRB are documented in written minutes to include an agenda of topics; attendance at the meeting; protocols reviewed; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining; reasons for requiring changes or disapproving, suspending, or terminating research; and a written summary of the discussion of controverted issues and their resolution. These minutes are available for review and action by IRB members at subsequent meetings. When approved in final form, the minutes are available for review by the Dean of the Faculty, the signatory official for human subjects research at Trinity, the President of Trinity College, and the Trinity College legal counsel.

4.4 Re-approval Review

Research/study proposals that have been determined to be exempt from review do not need to be submitted for re-approval or continuation review as long as no changes or modifications that will no longer qualify the study for an exemption are contemplated by the investigator. Any substantive departures from or changes to the exempted procedures must be submitted to the IRB as modifications and could result in an upgrading of the study by the IRB to that of an Expedited or Full Review. However, if the research has been conducted according to the initial exemption, the investigator should submit only a Final Report Form upon completion of the study.

Approvals under the expedited and full review categories, on the other hand, are granted by the IRB for not more than one year. Federal regulations require the IRB to conduct *continuing review* of ongoing research, including multi-year studies, no less than annually. The IRB sets the next review date at the time of initial approval based primarily on the degree of risk of the study: the higher the risk, the earlier the IRB may set the expiration date of the initial approval. Other factors include the nature of the study and the vulnerability of the subject population. While the IRB administrator will make an effort to notify the investigator one month in advance of a protocol's IRB approval expiration date, it is the PI's responsibility to keep track of the renewal date and begin the renewal process should it be required.

To apply for continuation of the research, the investigator must *renew* the protocol. This process includes informing the IRB of the status of the research project. The PI should certify that the study will continue to be carried out as described in the previously approved application, or if modifications are to be made, what those modifications are. Research must be in accordance with the research ethics, norms and standards in the respective discipline. In the case of student research, the responsible faculty member must approve and sign the re-approval application.

At minimum, investigators should address each of the issues below that apply to their protocol by including this information in the "Comment" section of the application.

1. How many participants have been enrolled in the study to date?
2. Are participants still being enrolled?
3. Are data still being collected (with current or future participants)?

4. If the study is longitudinal, what are the follow-up or retention rates thus far?
5. Has/have any participant(s) withdrawn? If yes, did the participant(s) initiate the withdrawal or did the PI withdraw the participant(s)? [For this question, please only count participants who explicitly requested withdrawal, as opposed to participants who did not respond to requests for information.]
6. Have there been any unanticipated problems or adverse events? If yes and they have not been reported to the IRB, please reach out to the IRB (irb@trincoll.edu) immediately. If yes and they have been reported to the IRB, please provide a brief summary of the events and their resolution.

Upon submission for renewal, investigators await reviewer feedback and/or approval. If the protocol has expired, research cannot continue until the review of the protocol is complete and approval granted.

Conflict of interest forms must also be submitted with the re-approval application for all investigators, whether continuing or new investigators, who fit the definition of investigator in the Trinity College Conflict of Interest policy.

Projects that initially required full IRB review most often will require full IRB re-approval review unless the project qualifies for an expedited review for one of the following reasons: no changes have been instituted or are contemplated since the initial review; the changes are minor or administrative in nature; the research is closed to the enrollment of new participants; all participants have completed research interventions, and the research remains active only for long-term follow-up of participants; no participants have been enrolled and no additional risks have been identified; or where the remaining activities are limited to data analysis.

4.5 Expiration of Approval Periods

When continuing review of research does not occur prior to the end of the approval period specified by the IRB, the IRB approval expires automatically. Provided the research is ongoing, failure to apply for re-approval prior to the expiration data constitutes non-compliance.

Under any of the review categories, if the ending date expires prior to submission of the re-approval application, the investigator must suspend participant contact and all data collection until the re-approval is obtained from the IRB. The investigator with an expired protocol may be subject to a protocol audit and may be required to submit an application for review and approval as a new study. No new participants may be contacted, recruited, or enrolled during the interim period, and if data has been collected, the data cannot be used in the study.

4.6 Modifications to Currently Approved Research

Modifications to currently approved protocols, research instruments, or the informed consent process must be submitted to the IRB for review and approval prior to implementation. Minor changes that do not increase the risk to participants may receive an expedited review per the eligibility criteria established for the continuation of expedited review studies (see section 4.2).

Modifications that increase the risks to GREATER than minimal are forwarded to the full IRB committee for review.

Changes to approved protocols cannot be implemented prior to IRB review and approval except when necessary to eliminate apparent immediate hazards to a subject.

Any unanticipated risks to subjects, emergency changes in procedures, adverse events, or instances of noncompliance with college, state or federal regulations must be reported immediately to the IRB for appropriate and timely resolution.

Investigators may request modifications to currently approved research by submitting a renewal request through the online application. Modifications can be requested at any time or along with requests for re-approval if a study is about to expire. In Section F of the IRB Progress Report, investigators can specify the proposed modification(s) in terms of participant enrollments, instruments, or any proposed changes in the scope of the project, research methods, risks and benefits, or informed consent, as applicable. Changes in the risks, benefits, or research procedures may require modifications to the consent form and may, in some cases, warrant the re-consenting of participants already in the study. Revised consent forms that are proposed for use must be submitted with the modification request.

The date of approval of the modification does not change the date by which the regularly scheduled re-approval review of the project is to be completed. If a modification involves the changing of principal investigator(s), a letter from the original investigator indicating the need for the change plus a letter from the new investigator accepting responsibility for the research or study should be included along with the modification. In the case of addition or deletion or any assistant investigators, the principal investigator should inform the IRB in Section C of the IRB Progress Report.

Conflict of interest forms must be submitted for all new investigators.

4.7 Notice of Terminated Study

The IRB may issue a Notice of Terminated Study independently under a number of circumstances such as the following:

1. Expiration of study approval period without an application from the investigator for re-approval or to close the study
2. Serious violations of IRB or federal compliance rules for the protection of human subjects
3. Unauthorized use of consent forms without notification to the IRB
4. Audit findings that warrant termination of a study

4.8 IRB Appeals Policy

Any decision, review outcome, or audit finding may be appealed to the IRB. Investigators must submit their appeal in a letter to the IRB Chair outlining the reasons for the appeal and why the IRB decision, review or audit outcome should be reconsidered. If the appeal involves a relatively minor request, the Chair or a subcommittee of the IRB may consider the issue and reach an equitable determination. However, appeals of expedited and full review outcomes or any other substantive matters such as audit findings must be reviewed and decided by the full IRB at a convened meeting. The investigator may request to be present at the meeting or may be invited to do so by the IRB to clarify any issues pertinent to the written appeal. After presentation of the information and review of the documents, the full IRB will vote to approve or not approve the appeal. **The decision of the IRB will be final.**

4.9 Conflict of Interest Policy and Disclosures

Conflicts of interest may occur when an investigator's research responsibilities compete with their private interests, such as financial interests, raising concerns of objectivity and improper gain. Conflicts of interest may exist despite the highest standards of conduct and candor. Fortunately, most conflicts can be successfully resolved and managed without impeding research activities.

Trinity College Financial Disclosure Policy for all Senior Personnel Conducting Research Funded by Federal Grants (Faculty Manual, Appendix A, section 7).

Trinity's policies and rules concerning potential conflicts of interest and disclosures also apply to IRB members when they are assigned protocol applications for review. Each IRB member should consider possible or potential conflicts of interest and determine whether a particular role or relationship could affect their objectivity before reviewing, participating in a protocol discussion, or voting on a protocol application. Possible relationships to consider include the following:

- The IRB member is a listed investigator or advisor on an application.
- The member has a familial or close personal relationship with the investigator.
- The member holds a financial interest in the outcome of the research.
- There are other concerns that warrant abstaining from review, deliberation and voting on a protocol.

In the event of a potential conflict of interest, the IRB member should not accept the protocol for review and should return the application for assignment to another member; or at full review meetings, any member(s) should disclose conflicts or simply state that participation is not appropriate and then recuse themselves from discussion and voting on the protocol.

4.10 HIPAA and the Privacy Rule

The Health Insurance Portability and Accountability Act (HIPAA) protects the confidentiality of individually identifiable health information maintained or transmitted by a covered entity in any form or medium, including the following:

- Demographic information
- Medical history
- Information relating to the past
- Present or future physical or mental health or condition of an identifiable individual
- The provision of health care to an individual or the payment for the provision of health care
- Physical examinations, blood tests, or x-rays
- Other diagnostic and medical procedures

Privacy standards within HIPAA limit the use and disclosure of health information; restrict most disclosures to the minimum intended purpose; establish new requirements for access to records by researchers; and protect the confidentiality and integrity of health information.

Research protocols, which include the gathering of health or mental health information and are submitted in accordance with HIPAA's privacy standards, restrictions and other requirements, must develop and submit a HIPAA Authorization form that contains core elements in the HIPAA Privacy Rule: description of the information to be used or disclosed; identification of the persons or class of persons authorized to make the use or disclosure of the protected health information; identification of the persons or class of persons to whom the covered entity is authorized to make the use or disclosure; and expiration date or event; the individual's signature and date; and, if signed by a personal representative, a description of their authority to act for the individual.

For more information and templates go to the NIH webpage on HIPAA Authorization for Research (http://privacyruleandresearch.nih.gov/authorization.asp).

4.11 Subaward Agreements with Subcontractors

For research projects and studies involving subcontractors or other subrecipients, Trinity College policy requires documentation and monitoring of human subjects compliance by way of specific language to be contained in all Subaward Agreements. Research investigators at Trinity College should contact the Grants Office to determine if subawards or subcontracts involving human subjects research conform to College policy.

5.0 Informed Consent: Process and Documentation

Informed consent is fundamental to insuring the continuous and adequate disclosure of research risks and benefits. Informed consent is an educational process between the investigator and the participant. The process begins with the initial presentation of a research activity to a prospective human subject by the investigator (or a member of the study/research team) and continues through the end of the research activity and the closing of the research study. Most subjects make their decision regarding whether to participate in research during the initial contact. The researcher should avoid the potential for any misunderstandings and provide the subjects with sufficient time to reflect on the nature of their proposed participation.

The second step in the consent process is the presentation of a written consent form to individuals who express an interest in participating in the study, unless the research qualifies for an exception, waiver or alteration of documented informed consent. Written informed consent is not always necessary or appropriate in some educational, social and behavioral science research (see section 5.3 below for waivers and exceptions). When written informed consent is appropriate, a member of the study team should ensure that the subject reads and understands the consent form. Federal regulations require that all consent form statements describe the nature of the research and the request for human subjects' participation in language that is understandable to each potential subject. Consent forms should avoid technical jargon or terminology that is not defined; the forms should also adjust for educational backgrounds, mental abilities and ages of the intended participants.

All subjects who agree to participate in a study should be provided their own copy of the signed consent form. Signatures of both the participant and the investigator (or study team member) are required.

The consent process does not end with the signing of the informed consent form.

Research is an ongoing process, which involves the constant re-evaluation of current information and procedures. Therefore, investigators are ethically obligated to keep subjects apprised of issues related to their participation in the study as appropriate. Any new information or changes in procedures that affect the participants should be presented to them in writing; in most cases this will involve the signing of a new consent form or a revision of the original form.

Sample consent and assent forms are available from Trinity's IRB Policies and Procedures Manual, Appendix 9. Many disciplines have their own consent form guidelines or templates which you may use. Consult professional association web sites appropriate to your research (e.g., APA for Psychology).

5.1 Description of Informed Consent Form

The consent form provides potential research subjects sufficient written information to decide whether to participate in a research study based on an explanation of the proposed research and the nature of the participation that is requested of them.

The form should be easily identified in bold text as **"Consent to Participate in Research"** at the top of the first page. The title of the research should be descriptive and not overly technical. Section headings should be used to identify the basic and any additional elements of informed consent.

Once approved, the consent form reviewed by the IRB is the only one that can be copied and administered to research participants. Any changes to approved consent forms must be submitted to the IRB as proposed modifications prior to their use.

5.2 Elements of Informed Consent

The federal requirements for informed consent are found at 45 CFR 46.116. Unless an exception, waiver, or alteration applies, written consent forms shall include the following points of information:

- A statement that the study involves **research**
- An explanation of the purpose of the research and the expected duration of the subject's participation
- A description of the procedures to be followed
- Identification of any experimental procedures
- A description of any reasonably foreseeable **risks** or discomforts to the subject
- A description of any reasonably foreseeable **benefits** to the subjects or to others
- A description of **alternative procedures** or courses of treatment, if any, that might be advantageous to the subject
- A description of whether and how **confidentiality** of records and data linked to the subject will be maintained
- A statement that **participation** is voluntary; that refusal to participate will not be penalized; and that the subject may discontinue participation at any time without penalty
- *For research involving GREATER than minimal risk, an explanation of what medical treatment or professional services are available should injury occur and whether any compensation is available for these services*
- *For research that involves GREATER than minimal risk, a statement regarding the rights of research subjects: "By signing this consent form, you are not waiving any legal claims, rights or remedies because of your participation in this research study."*
- A **final statement** identifying the investigators and how to contact them for answers to questions about the research or research subjects' rights or to report any difficulties or injuries;

and the name and phone number of the IRB chairperson (or another individual as designated by the IRB), in the event of complaints or other participant concerns

Additional elements of informed consent, when appropriate, may include:

- A statement to the participant that a particular treatment or procedure may involve risks that are currently unforeseeable
- A description of anticipated circumstances under which the participant's involvement with the study may be terminated by the investigator without regard to the subject's consent
- an explanation of any additional costs to the participant from involvement in the study
- a description of the consequences of a participant's decision to withdraw from the study and procedures for an orderly termination of participation
- a statement that significant new findings developed during the course of the study that may relate to the participant's willingness to continue in the study will be provided to the participant
- A description of the approximate number of participants involved in the study

If **incentives** such as financial payments will be offered for participation in research,

- the investigator must describe the manner and circumstances under which the incentive will be provided;
- incentives must not be described as benefits and should not constitute the reason for "voluntary" participation;
- the amount of the incentive must be commensurate with the time, effort or expenses of participation;
- financial payments must be pro-rated in the event of termination; and
- there must be reasonable alternatives to financial payments.

On some occasions, incentives may be offered that involve meeting a research participation requirement for a Trinity College course or earning extra credit for a Trinity College course. When this is the case, the investigator may use the consent form to collect information, so that the relevant Trinity College course may be identified and the relevant instructor may be notified.

No informed consent, whether oral or written, may include any exculpatory language through which the subject or the 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.

5.3 Exceptions, Waivers and Alterations

Written informed consent is not always appropriate in some educational, social and behavioral science research, e.g., some ethnographic, field, or qualitative research studies. The Trinity College IRB may provide a waiver, an exemption or otherwise approve alterations of documented informed consent if the investigator justifies that:

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

When applying for exceptions, waivers or alterations, the investigator must explicitly address each of the conditions above and propose alternative measures for obtaining and documenting informed consent. Deception research must always include a request for a waiver of consent and documentation since the research could not be practicably carried out without a waiver.

5.4 Documenting Informed Consent

Informed consent shall be documented by having the subject (or legally authorized representative) sign the written consent form and receive a copy. The investigator or research team member must also sign the consent form.

The IRB may waive the requirement to obtain a signed consent form if it finds **either**:

1. That the only record linking the subject to the research would be the consent form and the most serious risk would be breach of confidentiality (each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern); **or**
2. That the research involves no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

For research studies of minimal risk involving the use of questionnaires, the required elements of informed consent may be included in an introductory letter or information attached to the instrument which includes a statement that completion and submission of the questionnaire (hard copy or electronic) will constitute consent to participate in the study.

5.5 Short Form Alternative

The IRB may also approve the use of a "short form" of consent, described in 45 CFR 46.117(b)(2)**.**

The investigator will prepare and submit the short form for review by the IRB stating that the elements of informed consent will be presented orally to the subject or the subject's legally authorized representative. When this method is used, there must be a witness to the oral presentation. The IRB must approve a written summary of what is to be said to the subject or the subject's representative.

Copies of this summary must be signed by the witness and the investigator obtaining consent. The short form document itself must be signed by the subject or representative and the witness. The subject or representative signs only the short form but will be provided copies of both the short form and the written summary.

5.6 Parental/Guardian Consent

If a subject in Connecticut is under eighteen years of age, the consent of the subject's parent or guardian is required, unless the subject is married or emancipated by court order. Parental or guardian consent must be documented in writing.

If the research does not involve greater than minimal risk, the permission of one parent is sufficient.

If the research involves GREATER than minimal risk, consent of both parents must be obtained unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. (See 45 CFR 46.408(b)

Parental consent may be waived by the IRB if it is not a reasonable requirement to protect the subjects (for example, neglected or abused children). However, the investigator requesting the waiver must propose an alternative mechanism for protecting the children who will be participating in the study.

5.7 Assent by Children

Assent means a child's affirmative agreement to participate in research. In all instances where children are capable of providing assent, the investigator shall develop a separate assent form written in language appropriate to the educational level of the child. As a guideline, children aged seven and older are considered capable of assenting.

In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably

be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with 45 CFR 46.116.

5.8 Limits on Confidentiality

In general, any information obtained in connection with research that identifies particular subjects must remain confidential and may be disclosed only with written permission from the participant(s) or as required by law. Consent forms should detail the extent to which confidentiality will be protected and how specific records identifying the participant(s) will be maintained and kept secure and ultimately how and when they will be destroyed, if applicable. The more sensitive the research material, the greater the care required in obtaining, handling, coding, storing and securing the data.

Depending on the subject matter of the research, there may be limits to the investigator's promise of confidentiality to the subject(s). For example, most states require persons who know or have a reasonable suspicion that a child is being abused or neglected to report such suspicion to local law enforcement personnel. Therefore, if the research might reveal child abuse, the consent form should include a statement that under Connecticut law the privilege of confidentiality does not extend to such information and the investigator is required to report known or suspected child abuse to the appropriate authorities.

For information concerning certificates of confidentiality, Trinity researchers should contact the IRB Chair. Federal law allows researchers to apply for an advance grant of confidentiality known as a "Certificate of Confidentiality." If granted by a federal agency, these certificates provide protection against compulsory disclosure, such as a subpoena, for research data about sensitive issues, e.g., illegal conduct, alcohol or drug use, mental health, or sexual practices or preferences.

Informed Consent Resources

- NIH has resources including templates and checklists here.
- Informed Consent Templates may be found on Learning Tools page of Trinity's IRB website.

6.0 Recruitment and Selection of Subjects

Distributive justice, the third principle of The Belmont Report, requires the fair selection of participants and the equitable distribution of the risks and benefits of research.

The systematic selection of participants because of their availability, their compromised status, or because of social, racial, sexual, economic or cultural biases institutionalized in society, may result in an uneven distribution of the benefits and the burdens of research. For example, students, patients, clients, or employees are compromised to the extent that their grades, access to health care and other services, or their jobs are dependent on those interviewing or those investigators recruiting them for research. The research application should clearly articulate how recruitment activities will avoid even the appearance of coercion when selecting participants who are in a dependent relationship to the investigators or their agents.

To ensure that certain populations are not recruited solely because of their availability, for example, prisoners or patients in mental health institutions, the National Commission for the Protection of Human Subjects recommends a hierarchy of preference in the selection of subjects for research: adults before children, competent individuals before incompetent individuals, and non-institutionalized persons before institutionalized persons.

Further, the National Institutes of Health has issued guidelines to ensure that the risks and benefits of participation in research extend to women and minorities. These guidelines indicate that researchers should recruit and include minorities and women in study populations so that the research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study.

There are special ethical requirements for the recruitment of children. Children are in a dependent relationship to adults and can be easily manipulated in a school or clinical setting; for this reason, they are entitled to extra protections as a "vulnerable subject population" as determined in federal regulations. Investigators should take every precaution to ensure that a child's decision to participate in research is both voluntary and free from coercion. Refusal to participate should not be met with a negative response or any form of punishment. In an educational setting, school officials or teachers do not have the authority to give consent for the participation of children, unless the research qualifies for exemption or exclusion from the human subjects regulations. **Only a parent or legal guardian may allow a child, with the child's assent, to participate in a research study that is not exempt or excluded from the human subjects regulations.**

With all populations, the process of recruitment begins at the first point of contact with a potential human participant prior to the initiation of the procedures for obtaining informed consent. In many ways, recruitment is the introduction to the consent process, and may take the form of a flyer, a newspaper

advertisement, or a verbal exchange between a member of the study team and the potential participant. Recruitment techniques must respect the rights of all individuals to decide whether or not they will participate voluntarily. They should not feel coerced; nor should they fear the loss of some benefit to which they are otherwise entitled if they choose not to participate. A person in authority, for example, a teacher recruiting students, should take special precautions to ensure that a decision to participate is not based on subtle pressures such as grades or a fear of loss in benefits such as counseling services. **All flyers, posters, advertisements, letters, postings on the internet or any other recruitment materials should be attached to the research protocol for examination by the IRB and must be approved prior to their use.**

In general, recruitment messages/flyers should contain the following information:

- A clear statement that the project is a "research" study
- A brief description of the study appropriate for a non-expert
- The expected time commitment
- Any compensation
- Any inclusion criteria
- Briefly, how a person participates (e.g., in-person interview, anonymous survey, etc.)
- Contact information for the lead researcher or research assistant
- Statement that the Trinity College IRB has approved the research

7.0 Reporting Adverse Events

Investigators must report any unanticipated problems, complications or complaints to the IRB in a timely fashion. **An adverse event is an undesirable and unintended, though not necessarily unexpected, result of therapy or other intervention, including unanticipated problems involving risks to subjects or to others in medical and non-medical research alike.**

Investigators must report to the IRB in writing the nature of the problem within five working days of the occurrence. In addition, any injury or physical or emotional harm to a participant must be reported immediately to the IRB. Other examples include, but are not limited to, a breach in confidentiality or privacy, problems with recruitment and/or the consent form process, noncompliance with federal regulations or IRB policies, complications or complaints occurring during the research, or any other problem that presents changes in the risk-benefit ratio and affects the rights, welfare and safety of subjects. A separate report must be filed for each incident summarizing the problem or difficulty encountered along with a statement by the investigator indicating whether a change in the protocol and/or consent form is warranted and whether, in the investigator's opinion, the adverse event was related to the research activity.

Following receipt of an adverse event report, the IRB will review the information to determine whether any further actions, beyond any changes or amendments to the protocol that are proposed by the investigator, are warranted. The IRB reserves the right to review and approve all the proposed changes and determine whether the study should be continued as originally approved, modified, or discontinued. Further, the IRB is required to report to the Dean of the Faculty and any Sponsoring Agency, all adverse events that caused injury to human subjects or other major effects that involved unanticipated risks or problems; investigators must also comply with any reporting requirements in the protocol itself or as stipulated by the Sponsoring Agency in grant documents or agency regulations.

8.0 IRB Records and Protocol Monitoring

The Trinity College IRB office maintains the following records in electronic or hard copy for each study: copies of all research proposals reviewed; scientific evaluations, if any, that accompany the proposals; approved sample consent documents; progress reports submitted by investigators; reports of injuries to subjects or other adverse events; minutes of IRB meetings; records of continuing review activities; copies of all correspondence between the IRB and the investigators; a list of IRB members; written procedures for the IRB; statements of significant new findings provided to subjects; recruitment flyers or postings; and notifications of IRB decisions and outcomes.

These records shall be retained for at least three years, and records relating to research that is conducted shall be retained for at least three years after completion of the research. Records related to HIPAA authorization forms or HIPAA waivers are retained for a minimum of six years from the date of their creation or the expiration date, whichever comes later. Investigators should maintain duplicate files for their own records and for use during IRB audits while the study is still in progress and for three years after closure of the study.

The IRB office maintains records of IRB convened meetings: agendas, minutes, protocol status reports, applications reviewed with attachments, and other related material. Copies of inquiries and miscellaneous correspondence are also maintained by the IRB.

The minutes of meetings will include standard information such as attendance record; a summary of protocol discussions and the controverted issues; motions, actions and outcomes determined by the IRB; and the votes in favor of approval, disapproval or abstentions. The IRB office also maintains IRB member records to include curricula vitae of current members and a roster of names, affiliations, representation capacities, experience certifications, and terms of appointment with expiration dates.

8.1 Audits of Approved Protocols

Federal rules require that IRBs conduct self-monitoring activities in order to ensure that investigators comply with regulations and carry out protocols as approved by the IRB. Verification can take place by observing research in progress, especially the enrollment and consenting of participants, auditing of research records on a random basis, and by establishing procedures for the receipt and proper review of complaints from participants in the research. The Trinity College IRB adheres to these methods of verification and also conducts periodic reviews to determine if protocols are implemented as approved. Data reviewed at the time of audits may include the following:

- Currently approved protocol
- Recruitment procedures as implemented
- Status of participant enrollments

- Individual subject records
- Consent and assent forms as implemented and filed
- Modifications to protocols
- The reporting of adverse events, if any

All adverse events that are attributable to study procedures will require an audit of the respective protocol to determine compliance and to evaluate whether changes in procedures or in the consent form are warranted or if the study should be suspended until further inquiry can be conducted.

8.2 IRB Non-compliance Inquiries and Reporting of Findings

The IRB may become aware of possible non-compliance by any of several venues. These may include the following:

- Complaints or concerns from research participants, research staff or employees of the unit
- Audit findings
- Continuing reviews for re-approval
- Adverse event reports submitted by investigators
- Quality improvement reviews conducted by the IRB

Reports of possible non-compliance may be forwarded to the Trinity IRB Chair or administrator. Contact information can be found at the Trinity IRB webpage.

Anyone, regardless of affiliation, who suspects non-compliance may submit a complaint or concern. The person submitting the report may be asked to describe the problem or the concern in writing, unless the person chooses to remain anonymous.

Upon receipt of a report, the IRB Chair will evaluate the concern and determine next steps. Minor violations may be disposed of administratively following an initial inquiry by the Chair or an IRB subcommittee. All serious or continuing noncompliance with regulations or the determinations of the IRB will be reported promptly to the IRB members at a full review meeting and to other college officials, the federal Office of Human Research Protections (OHRP), and the federal Department or Agency Directors as applicable.

Examples of non-compliance include the following:

- Serious violations discovered after completion of a protocol audit
- Instances where non-exempt research was conducted without IRB review and approval or without appropriate informed consent procedures
- Implementation of significant modifications without IRB prior approval

- Instances of repeated or multiple problems with noncompliance by principal investigators even after IRB warnings

Allegations or any evidence of serious non-compliance will constitute sufficient cause for the IRB to initiate a protocol audit or investigation upon written notification to the principal investigator. Audits or investigations may be conducted by the IRB Chair or a subcommittee of the full IRB in a manner that will protect human subjects and provide the investigator with due process, including the right of appeal. The seriousness of the allegations and any preliminary evidence will determine whether a temporary suspension of the research should be imposed by the IRB pending a full inquiry and a final determination at a convened meeting.

Suspensions and final reports detailing the implementation of corrective actions must be reported to the Dean of the Faculty and other college and federal officials depending on the seriousness of the violations after the IRB has determined that noncompliance has occurred. Notification to the Dean of the Faculty or other officials as appropriate will include the following pertinent information:

- Name of principal investigator
- The project title
- Protocol and grant numbers
- Detailed description of the non-compliance
- Actions taken or planned to address or correct the violations.

Possible outcomes or corrective actions by the IRB may include the following:

- Education requirements for the investigator and research staff engaged in the research
- Temporary or permanent suspension of the research and/or the investigator
- Random audits of the research or investigator
- Disallowance of research use of data collected
- Other actions deemed appropriate by the IRB and communicated in writing to the investigator in a final notification

The inquiry process of the IRB will include the following stages:

1. *The Complaint or Concern*: Review by the IRB Chair to determine seriousness and validity
2. *Initial Inquiry*: Administrative review by the IRB Chair or a subcommittee with notification to investigator of complaint or concerns, which may result in minor corrective actions for resolution, or referral to full IRB at a convened meeting

3. *IRB Investigation*: Audit of protocol by IRB Chair or IRB subcommittee with a report of findings at a convened meeting with notification to investigator, which may result in major correction actions, suspension, or termination of study
4. *Appeal Hearing*: Investigator responds in writing and/or in person at an IRB convened meeting
5. *Final IRB Determination*: Report of full IRB meeting with any corrective actions, resolutions or stipulations regarding the future of the research study or its termination if warranted

9.0 Outcomes

An IRB review may result in the following outcomes:

1. The research project is considered exempt from further review, and research may begin immediately.
2. The research project qualifies for an expedited review and is assigned by the IRB chair or administrator to a member of the IRB review committee, who reviews the application and judges the research project as approved or not approved.
    a. **Approved.** The proposal is within acceptable guidelines and the research may begin immediately/
    b. **Not Approved**. The proposal requires a full IRB review.
3. The research project requires a full IRB review and is considered in a regularly convened IRB meeting where it may be judged as follows.
    a. **Approved** as written, may begin immediately.
    b. **Not Approved** as written. The PI is informed of the parts of the proposal that were not acceptable. The PI may rewrite and resubmit the proposal.
    c. **Disapproved.** The PI is informed that the research project may not be done under the auspices of Trinity College.

IRB decisions and requirements for revisions, if any, are conveyed to investigators via email with the provision of an opportunity for appeal by the investigator in the case of disapproval. Although research may receive IRB approval, the department chair or other administrative officials may conclude that the research project does not meet the policies and goals of the college and may disapprove, suspend, or terminate a project. However, IRB decisions to require modifications in, disapprove, suspend or terminate a project are final. No other committee or official can override these IRB decisions. Further, no committee or official can approve an investigator to conduct any human subject's research that the IRB has not approved. [See **45 CFR 46.112**.]

The IRB's approval may be suspended if the following conditions are not followed:

- No subjects may be involved in any study procedure prior to the IRB approval date or after the expiration date (not more than 1 year). (PIs are responsible for initiating Continuing Review proceedings.)
- All unanticipated or serious adverse events must be reported to the IRB within five working days.
- All protocol modifications must be IRB approved prior to implementation. This includes any change of procedures, investigator, or faculty adviser.
- All protocol deviations must be reported to the IRB within five working days.
- All recruitment materials and methods must be approved by the IRB prior to being used.

10.0 IRB Meetings

Meetings

The IRB will meet once per semester and as necessary during the academic year. If an emergency meeting is necessary, a meeting may be called by the IRB Chair. If an emergency meeting is necessary, a meeting may be called by the IRB Chair.

Quorum and Voting

A quorum of the IRB is defined as a majority of the total active membership, and in order for official Board business to be conducted, a majority must be present. No member of the board shall be involved in either the initial or continuing review of an activity in which he or she has a professional responsibility, except to provide information requested by the IRB, and the member shall not vote on any activity in which he or she has a conflicting interest.

Meeting Minutes

Provision must be made for taking written minutes or recordings of the proceedings of all meetings. Such minutes or recordings must include at least the following information: the date, time and place of meeting; attendance at the meeting; all actions proposed and the names of the members who proposed each action; research protocols discussed; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controversial issues and their resolution; and a list of all approvals by the Chair or IRB Administrator since the previous meeting.

All minutes shall be retained for at least three years, and minutes relating to research which is conducted shall be retained for at least three years after completion of the research.

11.0 IRB Documentation

IRB records [45 CFR 46.115]

The Trinity College IRB shall prepare and maintain adequate documentation of IRB activities, including the following (records may be maintained electronically and/or in hard copy):

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

2. Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution

3. Records of continuing review activities

4. Copies of all correspondence between the IRB and the investigators

5. A list of IRB members in the same detail as described in [45 CFR 46.108 (2)]

6. Written procedures for the IRB in the same detail as described in [45 CFR 46.108 (a) (3) and (4)]

7. Statements of significant new findings provided to subjects, as required by [45 CFR 46.116 (c) (5)]

The records shall be retained for at least three years, and records relating to research which is conducted shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the applicable federal department or agency at reasonable times and in a reasonable manner.

12.0 Duties of the IRB Chair

The IRB Chair duties shall include the following:

1. Serve as convener for the IRB, including scheduling reviews, and certifies IRB actions.
2. Serve as a reviewer and consult with IRB administrator as necessary regarding the routing of protocol applications.
3. Serve as the focal point for interaction of the IRB with the college community
4. Oversee the development and execution of the educational efforts of the IRB on campus
5. Monitor changes in federal regulations and institutional policy for the protection of human subjects in research
6. Make sure that all IRB procedure is appropriately documented, including, but not limited to, reporting of IRB actions to the Dean of the Faculty, liaison with the staff support, and liaison with faculty in general
7. Be familiar with the Common Rule (45 CFR 46)

Appendix 1: Definitions

Beneficence see *The Belmont Report*.

Concealment is involved when the researcher intentionally does not reveal initially to the participant all details of the protocol (not the whole truth).

Deception is involved when participants intentionally are told something untrue (not the truth).

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(2) Data through intervention or interaction with the individual, or
(3) Identifiable private information.

Interaction includes communication or interpersonal contact between the investigator and a subject such as by way of interviews or survey questionnaires.

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

Informed consent is the term given to the communication process that allows individuals to make an informed choice about participation in a research study. This process is reflected in an informed consent document that contains specific, required information about the research study. The informed consent document serves as the formal authorization by an individual of their agreement to participate in the proposed research. Some research protocols may not require signed consent, or in some rare circumstances, the consent process may be waived.

Justice, see *The Belmont Report*.

Principal Investigator (PI) is the lead person who is responsible for the design, conduct, and reporting of a research project. The PI is responsible for initiation of an IRB review, completing all required training, completing the IRB application form, and gathering all required documentation and signatures. The PI is also responsible for requesting IRB approval for any protocol changes after IRB approval and for reporting any adverse events taking place during the research. The PI must apply for IRB renewal for projects lasting longer than one year.

Private information includes data about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, as well as information that has been provided for specific purposes by an individual in circumstances or conditions where the individual reasonably expects the information will not be made public. Private information must be individually

identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Protected health information is individually identifiable health information maintained or transmitted by a covered entity in any form or medium and includes: demographic information; medical history; information relating to the past, present or future physical or mental health or condition of an individual that is identifiable; the provision of health care to an individual or the payment for the provision of health care; physical examinations, blood tests, x-rays; and other diagnostic and medical procedures.

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

> **Systematic investigations** are studies that are intended and designed to collect data about human subjects with the purpose of drawing conclusions and reporting research findings.

Respect for persons see *The Belmont Report*

Risk should be interpreted in a broad sense to mean not just physical risk but also legal, psychological, social, and economic risk. Discomfort, pain, and embarrassment should be minimized and justifiable in terms of anticipated benefit(s).

> **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. Designating a project "minimal risk" does not diminish the responsibilities of either the IRB or the investigators, nor does it eliminate the requirement for obtaining informed consent.

Vulnerable populations include those defined 45 CFR 46 Subparts B (Pregnant Women), Subpart C (Prisoners), and Subpart D (Children), and those mentioned in 45 CFR 46.111(b). Circumstances resulting in vulnerability to coercion, manipulation, or undue influence and reduced or limited voluntariness may include:

- **Children/minors** have a wide range of capacity depending on age, maturity and psychological state. There is potential for control, coercion, undue influence, or manipulation by parents, guardians, or investigators, particularly of young children.
- **Pregnant women,** the concern is focused on the fetus.

- **Embryos and fetuses** have absolutely no capacity and are under the direct control of the mother.
- **Prisoner** "means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing." [45 CFR 46.303(c)] Included are individuals in hospitals or alcohol and drug treatment facilities under court order and individuals in work-release programs or in at-home detention programs. The definition applies to minors as well as to adults.
- **Individuals with mental disabilities** may have impaired decision-making capacity, which may be continuous or fluctuating, depending on the disability. In addition, these individuals may have limitations on voluntariness because often they are institutionalized or hospitalized, are economically and educationally disadvantaged, and suffer from chronic diseases. As a result, they are potentially subject to control, coercion, undue influence, or manipulation.

Appendix 2: Frequently Asked Questions

1. **What and why an IRB?**

   The institutional review board (IRB) is a committee of faculty and community members who review the involvement/participation of individuals in research programs/projects conducted by any Trinity College researcher, faculty, student or staff. The IRB is mandated by federal regulations for any federally funded research. Federal regulations on the protection of human subjects and the Trinity College IRB manual were enacted to protect research participants from violation of their human rights.

2. **Is what I am doing human subject research?**

   Research is any activity which gathers information on individuals participating in any activity. Research means any systematic investigation designed to develop or contribute to knowledge or understanding about a question. It includes surveys, testing, program evaluation, interviews, and focus groups. Research is collecting information (data) on people and using that data in reports presented, published, or reported outside of the activity. If the data are only for program/activity improvement and not reported to anyone or anywhere else **ever,** then it is not research and does not have to go to the IRB. If, after conducting the program/activity, the findings are so exciting or insightful or ground-breaking that they need to be disseminated or communicated to a larger audience, then those findings become research and the IRB must be consulted.

3. **When is research exempt?**

   Consult the HHS regulations for the protection of human subjects, Title 45 CFR, Part 46. The Department of Health and Human Services' Office for Human Research Protections (OHRP) also provides decision charts on human subjects research, which canaid IRBs, investigators, and others in understanding when human subjects research may be eligible for exemption.

4. **If I think my research is exempt, why should I go through human subjects training?**

   If your research involves human subjects (HS), even if you think your project will be exempt, you must complete HS training. Trinity College believes all research should be governed by ethical research methodology and concern for human subjects. The Trinity College IRB requires all investigators to complete an online ethics training module at the Collaborative Institutional Training Initiative website (citiprogram.org). As noted in Appendix 5, student researchers are required to show proof of completion of this training if submitting a research protocol to the IRB.

5. **If I think my research is exempt, why should I submit my determination for IRB review?**

   You must submit your determination to the IRB to have your research proposal approved as exempt unless your research is clearly *excluded* from needing any IRB review. **Otherwise only the IRB** can finally decide if your research project will be exempt from further review.

6. **All I'm doing is a survey; do I have to apply to the IRB?**

   The IRB has three levels of review: exempt, expedited, and full review. Some things are clearly

excluded from IRB review such as administrative research and classroom tests. Much of what takes place at Trinity College, such as surveys and questionnaires, may fall under the "exempt" status, which will require submission to IRB review.

7. **Are evaluations research?**

Evaluations are considered research when the findings of the evaluation are reported or going to be reported outside the program. Findings can be data from surveys, focus groups, interviews, questionnaires (such as attitude or knowledge questionnaires), or observations. If a program is evaluated solely for the purpose of education or program improvement, and NOT EVER reported to any one or any group outside the program, the evaluation protocol does not need IRB approval. However, if after conducting the program, the findings will be disseminated or communicated to a larger audience, then IRB approval is needed to do that. It is easier to get IRB approval at the beginning of a program than to go back after a program is completed and try to track down all the participants.

8. **Is my Oral History Project subject to IRB review?**

Often it is. Because of concerns about confidentiality, Trinity College requires oral history research to be reviewed.

9. **I'm submitting a grant proposal to an outside funding agency. What do I have to do regarding the IRB?**

All sponsored programs/projects involving human subjects need Trinity IRB approval. Some funding agencies will not even review a proposal without IRB assurances. Almost all government funding agencies require an IRB assurance and some agencies and government departments have their own human research protection requirements. Some funding agencies will conduct a proposal review with the assurance that the IRB review will follow by the time the award is made. This is called a pending review. Trinity College requires all grant proposals involving human subjects to have a Trinity IRB review. No research may be done under the auspices of Trinity College without IRB review. The principal investigator/program director is responsible for completing and filing the IRB review.

10. **What are IRB reviewers looking for in my application?**

See the Reviewer Checklist, Appendix 8.

11. **What is minimal risk?**

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.

12. **What is an FWA?**

FWA stands for Federalwide Assurance. An institution must obtain an FWA in order to conduct any human subjects research that is supported by the US Department of Health and Human Services. The FWA is essentially the legal permission to do such research. The Office for Human Research Protections (OHRP) is authorized to restrict, suspend or revoke an FWA if it finds that the

institution, its IRB or an investigator using the IRB failed to comply with regulations. Each institution that receives an FWA from OHRP is assigned a unique FWA number. Ours is FWA00013955

13. **My data collection is complete, but the project itself is not yet complete. The IRB approval for the data collection has expired. Do I need to apply to the IRB for approval to continue the project even though I am no longer collecting data?**
    Yes, you need IRB review because according to 45 CFR 46.102 (f) you are still conducting research that involves human subjects (you are still using their identifiable private information).

If you have questions or examples you think might benefit others by being on this page, please contact the IRB Office Administrator.

Appendix 3: Training

REGARDLESS of funding agency requirements, all applicants, and the research staff working with them, must complete research ethics training available online at the Collaborative Institutional Training Initiative (CITI) website (citiprogram.org). Student researchers are required to show proof of completion of this training when submitting a research protocol to the IRB.

Social & Behavioral Research – Basic Course ID #133293. The intended audience for this course is investigators/researchers involved in social and behavioral research.

Biomedical Research – Basic Course ID #133921. This course is intended for investigators/researchers in the biomedical field.

Students - Class Projects ID #65557. This course is designed for students performing research for a class project that involves minimal risk studies. In addition to the Class Project module, students involved in school-based research are required to also complete the following module from the optional listing: **Research in Public Elementary and Secondary School - SBE (ID: 508).** Similarly, students involved in internet-based research are required to also complete **Internet-Based Research - SBE (ID: 510).**

Training modules available for IRB administrators and committee members:

IRB Chair (ID: 66701). This course is intended for current and future chairs of the Institutional Review Board (IRB).

IRB - Institutional/Signatory Official: Human Subject Research (ID: 116113). This course provides a general introduction for institutional officials who, on behalf of the college, have the responsibilities of a signatory official.

IRB Members - Basic/Refresher (ID: 65555). This course is intended for persons who have responsibilities for setting policies and procedures (IRB committee members). It covers topics in both biomedical and social-behavioral fields.

Appendix 4: Duties of the Principal Investigator (PI) and Faculty Advisors

All researchers must complete human subjects protection training before signing an IRB application.

Principal Investigators (PIs)

1. The PI is the lead person who is responsible for the design, conduct, and reporting of a research project.
2. The PI is responsible for initiation of an IRB review, completing all required training, completing the IRB application form, and gathering all required documentation and signatures**.**
3. The PI is responsible for requesting IRB approval for any protocol changes after IRB approval.
4. The PI is responsible for the reporting of any adverse events taking place during the research.
5. The PI must apply for IRB renewal for projects lasting longer than one year.

Faculty Advisors

1. Faculty research advisors or faculty members assigning research projects involving human subjects must take an active part in preparing students for the role of researcher, instructing them in the ethical conduct of research and assisting in the preparation of applications for human subjects research approval. Advisors shall take an active role in ensuring that the conduct of the research meets the highest ethical standards.
2. Faculty research advisors shall ensure that their advisees do the following:
    a. Minimize the risk to human subjects
    b. Understand the elements of the consent process
    c. Develop a readable consent form
    d. Plan and accomplish appropriate recruitment strategies for identifying subjects
    e. Establish and maintain strict guidelines for protecting anonymity and confidentiality
    f. Conduct their research in accordance with these policies and procedures
3. The faculty advisor must be listed in the personnel section of the online IRB application form. By agreeing to serve as faculty advisor, the advisor is agreeing that these essential aspects of research have been addressed, and that the advisor is ultimately responsible for the protection of human subjects in student research.
4. The faculty research advisor's signature affirms the following:
    a. The study purposes, rationale, design and methods are clearly stated and are scientifically sound.
    b. The protocol conforms to the norms, ethical standards and methods of procedure of the scholarly discipline.

c. The proposed study involves no known risks to human subjects other than those specified.
d. The principal investigator and other researchers are qualified to conduct the proposed study.
e. The study facilities and resources are adequate for the safe conduct of the research
f. The subject population, sampling procedures, and data to be collected are justified and adequate to meet study objectives.

Appendix 5: Advice to Student Researchers

Before You Start Your IRB Application

Complete the online training at Collaborative Institutional Training Initiative website (citiprogram.org). This is REQUIRED

Key Issues to Consider When Preparing Your Application

Description of the Project

- The protocol narrative is critical to the IRB understanding your research question(s), methodology, and engagement of human participants in your investigation. As such it is critical to adequately and fully describe the purpose of your proposed research and what risks participants may encounter as well as the benefits.
- If you are using instruments, include citations for their validity (if appropriate) and what level of training is required to administer and interpret these instruments. If you are using oral interviews please provide a script. If you are asking open ended questions, please provide a list of the seed questions.
- Project Timelines and Dates: Be sure to allow sufficient time for obtaining signature approvals, permission letter(s) from school districts or other entities, and IRB review and approval. Protocols should have the specific start and end dates of the research project, not semester starting and ending dates.

Informed Consent Documents

- Informed consent documents should be personable and informative to allow participants to decide if they want to be part of the study. Contact names and contact information should be on all consent forms: for instance, the researcher, the faculty sponsor if appropriate, and the IRB office administrator. This allows multiple contacts in the event that parents, participants or agency heads have questions concerning the proposed research.
- If you wish to have the IRB waive the requirement for signed written and/or verbal informed consent, be sure to address the reason you are requesting the waiver. See OHRP for guidance.
- If you are using deception in any way, please address why and describe how you will debrief the subjects.
- Finally, be sure to include that you are a Trinity College student and that the information obtained will be used for your honors thesis, senior exercise, or other research project. It is

required that an unsigned copy of the informed consent be given to the participant to keep, whereas the researcher keeps a signed copy.

For additional guidance, see Reviewer Checklist (Appendix 8)

Appendix 6: International Research

If you are planning to do research outside of the United States, you must comply with any existing research requirements of all the countries in which you will be doing research.

The **"International Compilation of Human Research Protections"** (**http://www.hhs.gov/ohrp/international/index.html**) is a resource you may consult for known international research protections.

The Trinity IRB will ask for information on the country's regulations and requirements and, especially in the case of student PIs, request that a formal connection to an educational, research, or government institution be made. (This could be a college/university department or faculty member willing to act as adviser to the Trinity student.)

Faculty PIs may find that a collaboration with an academic in the country of interest will increase the likelihood of permission to do research in that country.

Appendix 7: Ethical Standards of Professional Disciplines

All researchers should educate themselves about the principles and standards in their disciplines. For example, the American Psychology Association published these documents to provide guidance: Ethics documents

Appendix 8: Reviewer Checklist

The APPLICATION/PROTOCOL should address the following:

1. Exemption category information and justification
2. Background, objectives, description of research, and role of subjects
3. Number of subjects, records or specimens
4. Whether subjects are over age 18
5. Whether health information is not collected or health information is collected and a HIPAA De-Identification Certification form is attached
6. Expected duration of study and subject participation
7. Risks/benefits to the subject and to society
8. Explanation of how risks have been minimized
9. Procedures for protecting anonymity or confidentiality
10. Data security
11. Recruitment procedures
12. Access to study population and authority to review records
13. Description of how subjects will be informed (cover letter, recruitment statement)
14. Consent/assent process and forms
15. Experience and role of investigators
16. Conflicts of interest explained
17. Accompanying materials provided (sample survey questions, data collection sheet)
18. Do the benefits of the research outweigh the risks?

RECRUITMENT STATEMENT/COVER LETTER/DEBRIEFING and/or CONSENT documents should be clearly written in lay language and formatted for easy reading; translated for subjects who are not English speakers; and address the following:

1. Investigators' names and positions
2. Explanation of purpose and justification of research
3. Description of subject's participation and duration (tasks and time)
4. Description of risks and minimization of risks
5. Explanation of how confidentiality/anonymity is maintained
6. Method for data collection/recording
7. Description of benefits to subject/society
8. Explanation of voluntary participation
9. Statement naming investigator who will answer questions and phone number, IRB contact information