

Research with Human Subjects - A Manual for Investigators

Statement of Policy

Thiel College is committed to academic freedom. Research will not be forbidden because it is innovative, unorthodox, sensitive or otherwise extraordinary. The College protects the right of faculty to conduct research when that research has been reviewed and approved by the Institutional Review Board (IRB).

Thiel College is guided by the ethical principles set forth in the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the "Belmont Report"): respect for persons, beneficence and justice. All persons involved in conducting research have an obligation to respect the dignity and integrity of the persons beings studied, including their right not to be the subject of potentially harmful research. Where possible, potential subjects should be provided the opportunity and means to decide freely whether to participate. Researchers who promise confidentiality are responsible for maintaining it and for informing subjects of the limits of their capacity to meet that responsibility. Research procedures should minimize the risk of harm and maximize the possible benefits to the subject and to society. Subjects should be selected for reasons directly related to the problem being studied, not because of their easy availability, their compromised position, or their manipulability. Researchers must exercise special care when the subjects of research are especially vulnerable to harm because they cannot understand the risks or because they are not in a position to refuse their participation in the research.

All research on human subjects conducted by Thiel faculty, students and staff at Thiel or at other institutions and research sites, must conform to these ethical principles. Research that proceeds in violation of this policy is subject to disciplinary action by the appropriate college official, typically the Dean of the College or his or her designee.

The Institutional Review Board

The Institutional Review Board (IRB) is responsible for approving all research with human subjects conducted by faculty, staff, and students of Thiel College, when conducted as part of their work or study for or at Thiel.

The composition and function of the Committee is described in the Faculty Handbook under Committees. The IRB is committee J-7 - Institutional Review Board.

Members serve for three-year terms, which should be staggered. These terms are renewable. In making appointments to the committee, the following guidelines must be observed: There must be both scientists and non-scientists on the board (for the purposes of this committee, faculty from the Psychology Department are treated as 'scientists'); there must be at least one member who has no affiliation with Thiel College (e.g., is not an employee or student and is not a member of the immediate household of an employee or student); there must be one non-faculty employee member of the committee. Efforts should be made to have a balance of gender, ethnicity, and disciplinary specialties on the Board.

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The Chair of the Board is elected by the members of the Board, serving a one-year term as Chair.

While administrators of the College might be able to restrict a research project that has received IRB approval, they may not overturn an IRB decision to disapprove a research project. However, it is the intent of the IRB to work with investigators to mutually agree on a protocol that will receive IRB approval.

Research Subject to Review

Definition of Research with Human Subjects

“Research” means a systematic investigation calculated to develop or contribute to generalizable knowledge. It does not include educational activities whose results are not intended for publication and would not constitute original research in the field. It also does not include institutional research intended for use only at and by Thiel employees or students.

However, it is the policy of Thiel College that all educational activities and institutional research involving human subjects be conducted in accordance with the ethical principles in the statement of policy above. Approval of such activities by the IRB is optional. However, it does offer institutional protection to the investigator and/or faculty supervisor. In addition, the IRB is authorized to investigate complaints from subjects of such activities and report violations of this policy to the appropriate College administrator.

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

1. data through intervention or interaction with the individual, or
2. identifiable private information.

Research that uses data on human subjects gathered in earlier research projects require IRB review, unless the data is "blinded" (so that the investigator is unable to identify the subjects). Some data sets available to Thiel faculty and students have been blinded, or the data is in aggregate form so that individual identification is very difficult. Research with this data does not need to be reviewed, provided the researcher does not attempt to discover identifiable private information.

Research with Other Institutions and International Research

Research conducted at other institutions must be approved by Thiel’s IRB, even if approved by the other institution. Research at schools, camps and other institutions without IRBs must be approved by the principal or other appropriate administrator.

Research conducted by College investigators in foreign countries falls under the College’s purview and guidelines. While we cannot impose our standards for written documentation on other cultures, we do not relax our standards for ethical conduct.

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While human subjects in foreign countries merit the same level of protection as subjects in the United States, acceptable practices vary from place to place. Different mores, traditions, and institutions may require different research protocols, particularly in informed consent, recruitment practices, and documentation. Special attention should be given to local customs and to local cultural and religious norms in drafting written consent documents.

Research projects must have been approved by the local equivalent of an IRB before they are presented to the College IRB. Where there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. The IRB requires documentation of this "local approval" before it gives approval.

Student Research

Independent class projects (when intended as research and not simply as fulfilling a course requirement), senior theses, research projects and similar exercises must be independently submitted to the IRB by the student-researcher. However, when students conduct research as part of a course of study, a faculty member ultimately is responsible for the protection of the subjects, even if the student is the primary researcher and actually directs the project. Faculty advisors shoulder the responsibility for students engaged in independent research, and instructors are responsible for research that is conducted as part of a course.

As assurance that the College's guidelines will be followed, the advisor or instructor is required to sign the student's application for IRB approval.

Investigator Responsibilities

Investigators are responsible for the ethical conduct of their research and the conduct of participating faculty, students, and staff. Investigators ensure that research involving human subjects is reviewed and that this review takes place **before** the research is initiated.

The investigator must also:

- Seek approval for making changes in the research protocol
- Report to the IRB unanticipated problems or adverse events
- Reapply for approval when approval expires
- Retain copies of IRB approval documents
- Retain copies of signed consent forms for three years after the completion of the research

IRB Review Criteria

The IRB will consider the following questions in reviewing proposals:

- Have the risks to subjects been minimized?
- Are the risks reasonable in relation to anticipated benefits?
- Is the selection of subjects equitable?

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- Are adequate procedures in place to ensure privacy and confidentiality?
- Has informed consent been sought and documented?

The IRB will consider the merits of the research only insofar as it affects the balance of risks and benefits. For example, research should be both valid and of value to justify any risks to or deceit of human subjects.

Risk/Benefit Analysis

Risk

The ethical principle of beneficence requires a favorable balance of benefits to risks. "Risk" means the probability of physical, psychological, social or economic harm occurring as the result of participation in a research study.

Behavioral research usually does not involve risks to a person's health, but there are, nevertheless, risks which must be considered by the investigator and the IRB:

Information about a subject's activities may place him/her at risk of legal action. For example, if a researcher asks parents how they discipline their children, information about child abuse may be obtained and must be reported.

Even information concerning illegal activities that the investigator is not required to report may be subject to subpoena if names can be linked to particular responses.

A breach of confidentiality is often the greatest risk to participants in behavioral and social science research. Reputations may be damaged or employment jeopardized if confidentiality is not maintained. Research regarding political activities in some countries may put subjects in serious jeopardy.

Information about subjects may be disclosed to others who may use that information in unpredictable ways. For example, if teachers are given information about preschoolers' behavior problems, the teachers' attitudes and assumptions might negatively affect the children's success at school.

Questions or procedures may cause psychological stress to the subjects. Questions may raise painful memories or unresolved issues. Interviews of survivors of violence, for example, may be very stressful. Questions about risky behavior may cause embarrassment or feelings of guilt when that behavior is generally stigmatized. Subjects may also feel distress when debriefed about deception in a study. Most psychological risks are minimal and transitory, but the investigator and the IRB must be aware of the potential for serious psychological harm.

In many cases risk can be eliminated or reduced by careful procedures for ensuring confidentiality. Psychological support and referrals can be built into studies when emotional distress may be an outcome. Consent forms describing the kinds of questions the researcher will ask allow participants to choose whether they wish to divulge certain types of information or explore certain issues.

Benefit

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

Researchers may pay research subjects for their participation, or offer gift certificates or vouchers. Researchers should not offer course credit for participation in their own research or in research of students they are supervising. Payment arrangements must be disclosed to the IRB and are subject to a stringent review. Payment arrangements affect the fairness of recruitment plans, the balance of risks and benefits, and the adequacy of informed consent. Although there are no fixed formulas for determining whether payment plans are acceptable, the IRB restricts payment arrangements that appear to be coercive.

Payment should not encourage subjects to participate or continue to participate against their better judgment.

Subjects should receive at least partial payment if they withdraw from a study. Withholding all payment until participation is complete is coercive. A modest lump sum can be paid after subject's participation is complete if the arrangement is thoroughly documented in the consent form.

Subject Selection

The IRB must determine that the selection of subjects is equitable, being particularly aware of the special problems of research involving vulnerable subjects. Justification must be provided for limiting a subject population to one ethnic group or gender. Recruitment is part of the research protocol and requires review.

Additional protections are required for research on vulnerable populations such as pregnant women, prisoners, and children.

Prisoners

If the research involves prisoners, a prisoner or a prisoner representative will be asked to participate in review of the research. The IRB will employ a heightened level of review for such proposals, as set out in 45 CFR sec. 46.305. In general, only research seeking knowledge about criminals or prisoners as a class or penal practices will be approved.

Pregnant Women and Neonates

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If the research involves pregnant women, the investigator must consider risks to both the woman and the fetus, and inform the subject of risks to the fetus. No inducement may be offered to terminate a pregnancy. The IRB will employ a heightened level of review for research on pregnant women and neonates, as set out in 45 CFR secs. 46.201 through 46.207.

Children

The protections for children are set out in the sections on informed consent. The IRB will review research proposals according to the criteria set out in 45 CFR secs. 46.403 through 46.409.

Privacy and Confidentiality

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

Records

If a data set with information about individuals is publicly available and the information it contains cannot be linked to the individual subjects, there are no privacy concerns. In such cases, the research probably does not qualify as "research with human subjects," and thus, no IRB review would be required.

Observations of Public Behavior

The IRB must review observations of public behavior which are recorded in a way that would allow the subjects to be identified and (if made public) could reasonably place the subject at risk of criminal or civil liability or damage the subject's financial standing, employability, or reputation. The IRB must determine that the knowledge to be gained is important enough to involve unconsenting subjects.

Confidentiality

Virtually all studies in which information about subjects is collected must provide that the information remain confidential. If confidentiality is promised, identifying information should not be stored with the research data. Every effort should be made to protect identifying information through the use of passwords, locked computers, locked cabinets, etc. Identifying information or coding keys should be destroyed as soon as possible. (Consent forms must be kept for three years after a research project ends.)

Informed Consent

Informed consent must be sought from each subject and appropriately documented, except where deception or incomplete disclosure is necessary.

Informed consent must:

- Describe what the research is about;

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- Tell the subjects what they will be asked to do and for how long;
- Explain any risks and benefits. If there is no direct benefit to the subject, the investigator should explain what the study hopes to discover and why;
- Describe how confidentiality will be maintained;
- Describe any compensation the subject will receive and conditions under which no, or partial, payment will be made;
- Make it clear that participation is voluntary;
- Tell subjects that they may skip questions or withdraw from the study at any time without penalty;
- Give the subjects the name and number of persons to contact if they have questions about the study;
- Tell the subjects that if they have questions or concerns about their rights as research subjects, they may contact the Chair of the IRB.

If appropriate, the consent form should also provide a referral for counseling or support if the subjects may be distressed by questions or memories elicited by the questions.

The reading level of the consent form should match the reading level and background of the subject. Use simple declarative sentences, short words, and avoid jargon. It is best to construct the form using “you” rather than “I” as there may be confusion about who “I” refers to. Use large print and wide margins for readability. Internal headings will also make the form more readable.

If the subjects’ first language is not English, the form must be submitted to the IRB in both English and the appropriate foreign language.

Waivers of Written Consent

The IRB may waive the requirement of written consent in some cases, as when the consent form provides the only link to a subject and a breach of confidentiality constitutes a major risk to subjects, or where securing written consent is impracticable. Written consent may also be waived when culturally appropriate or when subjects are illiterate. Waiving written consent does not mean that need to secure consent is waived. It means the process for securing consent is modified.

Deception and Incomplete Disclosure

Investigators may plan to withhold information about the real purpose of the research or give false information about some aspects of the research. This means that the subjects’ consent will not be fully informed. In deciding whether to approve such studies, the IRB will consider whether:

- The research involves no more than minimal risk;
- The nature of the study is such that it could not be carried out without deception;
- The waiver of consent will not adversely affect the rights and welfare of the subjects.

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Investigators should justify, in detail, in the protocol, the reasons for deceiving or withholding information from subjects, including an explanation of: a) the necessity for deceiving subjects; b) how the potential benefits of the research justify the use of deception; and c) how the investigators will conduct the debriefing. In addition, investigators should include a debriefing script or statement that indicates the information subjects will receive regarding their participation in the research.

Whenever appropriate, the subjects will be debriefed after participating in the research. While deceit should be revealed whenever possible, debriefing should be carefully considered. The IRB in collaboration with the investigator will determine whether subjects should be debriefed either after unwittingly participating in research or after knowingly participating in research that involved deception. The IRB may require debriefing when it contributes to the subject's welfare, i.e., when it corrects painful or stressful misperceptions, or when it reduces pain, stress, or anxiety concerning the subject's performance. For example, if a subject is led to believe through participation in deceptive research that s/he has committed a crime or has a disease, a debriefing session may correct the induced stress, pain, anxiety, etc.

Research with Children

Parental consent must be secured when research subjects are minors, as well as the assent of the child (if the child is 8 or older). Whether a research subject is a minor is determined by the law of the jurisdiction in which the research is conducted. The age of consent in Pennsylvania is 18. **College freshmen under 18 are minors and are subject to this provision.** As long as the research poses minimal risk (risks no greater than those normally encountered in the subject's daily life), the consent of only parent and the child is needed.

Most 8-year-olds have the cognitive and emotional maturity to understand a research project and to decide whether they want to participate in it. The child's assent should be documented with an "assent form," a child friendly document that outlines the essential information about the research. The form should be limited to one page if possible, and should:

- Tell why the study is being conducted;
- Describe what will happen and for how long or how often;
- Say it's up to the child to participate and that it's OK to say no;
- Tell them they can stop at any time;
- Explain if it will hurt and for how long or how often;
- Say what the child's other choices are;
- Describe any good things that might happen;
- Ask for questions.

Some children under 8 may be capable of granting or withholding consent, and the IRB expects the investigator to be sensitive to the needs of these children on an individual basis.

The Mechanics of Securing Approval for Research

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Procedures

The investigator is responsible for:

- determining whether the project involves research with human subjects, and
- submitting a complete application for approval with all supporting documents.

After reviewing the application and its supporting materials, the IRB may ask the investigator to explain some elements of the protocol and may require revisions in the protocol. When the investigator revises a project, the IRB reviews the project again to see whether its concerns have been adequately addressed.

To fully protect subjects, the IRB must approve a project before investigators start to work on it—even before they begin to recruit subjects, since recruitment strategies are part of the review.

Research projects are reviewed at one of three levels, depending on the IRB's interpretation of the project's risk to the human subjects and on the federal guidelines that define the categories of review, which are:

- screening for exemption from full IRB review
- expedited IRB review
- full IRB review

The level of review can be determined only by the IRB.

Exempt Research

Investigators do not have the authority to determine whether research involving human subjects is exempt from full review (45 CFR 46.101(b) and (c)). Hence, while research that involves only minimal risk to human subjects is sometimes exempt from full IRB review that does not mean that it is exempt from peer review. Researchers must file an application requesting that a project be classified as exempt.

In general, the federal guidelines for research on human subjects allow a project to be exempt from full review only if the research involves no risk to the subject.

Criteria of exempt research include:

1. Routine Instructional Research:

Research on instructional strategies conducted in educational settings, involving normal educational practices (such as research on regular and special educational strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods).

2. Anonymous Survey and Public Behavior Research (on adults):

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Research involving the use of educational tests (cognitive, diagnostic aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) the information obtained is recorded in such a manner that human subjects can be identified; and (b) any disclosure of the human subjects' responses outside the research could place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. This exemption does not apply to research involving children, except for research involving observation of public behavior in which the investigator does not interact with the child.

3. Survey and Public Behavior Research on Public Officials:

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior if: (a) the human subjects are elected or appointed public officials or candidates for public office or (b) federal statutes(s) require(s) without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter.

4. Research on Existing Data and Specimens:

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified (i.e., so-called "blinded" data sets).

Investigators should note that a survey is anonymous when there is no possible way to identify the participants from the data collected. In most cases, the omission of names or other specific identifiers, such as social security numbers or student id numbers, is sufficient to qualify a study as anonymous.

NOTE: Observational research involving sensitive aspects of subjects' behavior, or in settings where subjects have a reasonable expectation of privacy, is not exempt. Similarly, sensitive survey research is seldom exempt from review. A sensitive survey includes questions about illegal activities or highly personal aspects of the subjects' behavior, life experiences, or attitudes. Examples include chemical substance abuse, sexual activity or attitudes, sexual abuse, criminal behavior, sensitive demographic data, detailed health history, etc. The potential for provoking a negative emotional reaction from subjects is a principal determining factor of sensitive survey research.

Additional consideration for exemption includes whether there is a risk associated with a possible breach of confidentiality (i.e., accidental disclosure of drug use to law enforcement personnel or disclosure about a subject's mental health state where such information might harm the person's reputation). In surveys with potential psychological risk, review for exemption includes risks associated with surveys about sensitive topics as well as those resulting from a breach of confidentiality. When confidentiality is an issue, the presence or absence of subject identifiers may be a decisive factor.

Questionnaires or surveys covering sensitive topics may qualify for a Claim of Exemption if they fulfill the following:

- anonymity of the subject is guaranteed,

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- potential subjects are informed of the sensitive nature of the topics prior to their participation, and
- the study does not exceed minimal risk.

Screening for exempt status streamlines IRB procedures with no diminution of protection of human subjects. The Chair of the IRB or other designated IRB member decides whether the project qualifies as exempt, and the decision is confirmed in writing, typically within one week. If the project does not qualify as exempt, it will be considered for expedited or full review.

Expedited review

To qualify for expedited review, a research project must involve one of the activities that are federally approved for expedited review and incur no more than minimal risk for participants, or be a minor change in previously approved research that involves no additional risk to the research subject.

Activities approved in the federal regulations for expedited review include:

- Collection of small amounts of blood from healthy adults;
- Collection of biological specimens (like hair or nail clippings) through noninvasive means;
- Research on existing data or specimens (note: some research in this category is exempt);
- Collection of data from voice, video, digital or image recordings;
- Research on individual or group characteristics or behavior or involving surveys, interviews, oral history or focus groups (note: some research in this category is exempt);
- Continuing review of non-exempt research previously approved by the IRB, where no new subjects will be enrolled or where the research involves no greater than minimal risk.

Note: There are a few other categories eligible for expedited review, but they involve clinical studies seldom performed at Thiel. These additional categories are listed in 45 CFR 46.

The researcher must show on the application how the proposed project activities fall into one or more of these categories.

The IRB chair assures that all of the elements essential for review, including consent forms and supporting information, have been submitted. The application is then forwarded to a designated committee member for review and decision. Either the research is approved by the committee member or it is forwarded for full review.

Full review

A project that involves greater than minimal risk requires approval by the IRB committee.

Survey research that involves sensitive questions or information about AIDS is subject to full review, in keeping with federal guidelines that identify AIDS sufferers as a vulnerable population and that identify information about AIDS as likely to cause stress to survey participants. Any survey or interview that is likely to be stressful for the subject requires full review.

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Full review means that a convened meeting of a majority of the IRB members occurs, during which discussion of the proposal occurs. Among the members present there must be at least one scientist and one non-scientist, and the member who is otherwise unaffiliated with Thiel College. Because of scheduling issues, investigators should expect that full review of a proposal can take up to several weeks.

Continuing Oversight

All non-exempt research is subject to at least annual review and renewal. If research involves extreme risk to subjects, the IRB may require more frequent review and may ask to be kept apprised of all research activity. The investigator is responsible for re-applying for approval after the initial IRB approval expires. The IRB will conduct an expedited review of these applications, unless the research protocol has been modified or new subjects are to be added and full review is otherwise appropriate.

Procedure for Addressing Complaints from Research Subjects

If possible, subjects must be told that they can direct complaints about the conduct of the research to the Chair of the IRB. If the research is on-going, the IRB will document complaints and review research procedures. If the research is completed, the IRB will investigate the complaint, including discussing it with the investigator, and prepare a report. The report will be forwarded to the investigator and to the appropriate college administrator.