

# Institutional Review Board

**Policies and Procedures**

**Trinity Christian College**

# Palos Heights, Illinois

## With acknowledgements to Hope College, Holland, Michigan

### Human Subjects Policies

#### Purpose

Trinity Christian College affirms that all persons are created in the image of God and therefore have inherent dignity and worth. Consistent with this underlying principle the purpose of the Institutional Review Board is to promote ethical research practices by students, faculty, staff, and administrators both on campus and in the broader community.

Trinity Christian College shall comply with the regulations of the United States Department of Health and Human Services for the Protection of Human Research Subjects ([Part 46 of Title 45 of the Code of Federal Regulations](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm), as amended), as well as other applicable federal, state and local laws, and with the principles set forth in the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled “Ethical Principles and Guidelines for the Protection of Human Subjects of Research” (the “[Belmont Report](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm)”). Copies of these documents are available from the Chair of the Institutional Review Board (IRB). The three basic principles set forth in the Belmont Report are ***respect for persons*** (acknowledging autonomy of individuals and protecting those with diminished autonomy), ***beneficence*** (maximizing possible benefits while minimizing possible harm), and ***justice*** (sharing equitably the burdens and benefits in the population).

At Trinity Christian College, the IRB shall have jurisdiction over the process of data collection and analysis in research that utilizes the participation of human subjects. Projects done for pedagogical or administrative purposes where data will be collected for presentation or publication outside the college community shall require IRB approval. Project directors are encouraged to consult with the IRB chair for guidelines applying to a specific protocol. All research done on Trinity Christian College campus with students, faculty, staff, or administrators shall be reviewed by the IRB.

**Definitions:**

***Human Subject*** means a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information or records

***Legally authorized representative*** meanseither an individual or a judicialor other body authorized under applicable law to consent on behalf of a prospective student to the subject’s participation in the procedure(s) involved in the research.

***Minimal Risk*** means that the probability and potential 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.

***Research*** means the 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.

**Outcomes**

The IRB at Trinity Christian College shall be responsible to:

* Design and implement policies and procedures for initial and continuing review of all research at Trinity Christian College involving human subjects.
* Approve research proposals involving human subjects, prior to the enrollment of human subjects and/or collection of any data, at the appropriate level of review as designated in the IRB policies and procedures and by applicable law.
* Educate the college community about ethical and legal research practice including confidentiality and the rights and welfare of human subjects.
* Encourage campus-wide participation and promotion of the adopted review process.

**Basic Ethical Principles**

Trinity Christian College affirms that all persons are created in the image of God and therefore have inherent worth and dignity. The IRB adheres to the following ethical principles in its review of proposals.

1. Welfare of human subjects shall be adequately protected and written, informed, and voluntary consent shall be obtained from all subjects prior to their participation in research.
2. Any costs and risks to human subjects shall be outweighed by the sum of the benefit to the subjects and the importance of the knowledge that is gained.
3. Special consideration and protection shall be provided to human subjects given in research involving human subjects who may lack full capacity to secure their own rights and interests, e.g. children, the mentally ill, the economically or educationally disadvantaged, and those in involuntary custody.

**Structure**

The IRB shall monitor all research involving human subjects conducted by faculty, staff, and students at Trinity Christian College. The IRB also shall play a role in educating the college community regarding the importance of safeguarding the privacy of human subjects and protecting human subjects from any potential risks involved in research.

The President of Trinity Christian College or his/her designee shall appoint the chair of the IRB and other IRB members. The chair of the IRB committee shall submit an annual report to the Provost.

The IRB shall be comprised of at least four members in addition to the chair, representing a broad range of departments across the college. IRB members shall have expertise in various disciplines such as science, social science, ethics, law, statistics and research methodology. In addition the IRB always shall include at least one member not affiliated with Trinity Christian College. The IRB shall not consist entirely of representatives of one discipline. At all times, at least one member shall represent a scientific discipline, and at least one member shall represent a non-scientific discipline. In accordance with federal regulations, every effort shall be made to include qualified persons of both sexes on the IRB.

The IRB may, at its discretion, invite individuals with competencies in areas of specialty to assist in the review of issues which require expertise beyond or in addition to that available on the IRB, but such individuals shall not be considered IRB members and shall not vote on the issue of approval of any research. Any IRB member with a vested interest in a research project shall be disqualified from participating in decision making with respect to that project. Such a member shall be required to report such interest to the chair as soon as he or she becomes aware that the IRB will be considering such research. The chair shall appoint someone with a similar background to the IRB for consideration of that research project

**Procedures**

*Submission of Proposals*. Before any activity involving human subjects be undertaken at Trinity Christian College, the investigator shall first submit for approval by the IRB six copies (one copy for each committee member plus a copy for the records of the plan of investigation.) No research shall commence without prior approval by the IRB.

The plan of investigation shall include each of the following:

1. A completed Application for Review of Research Involving Human Subjects.
2. A brief description of the project. The description shall follow the outline specified on the application form.
3. Copies of any materials to be used, including research and interview protocols and survey instruments that comply with all applicable laws and policies.
4. A copy of the informed consent form. All human subjects or their legally-authorized representatives shall sign a copy of the form for the investigator’s files and shall receive a copy of the form for their own use.

The informed consent form shall:

1. Include a statement that the study involves research, and explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and the identification of any procedures that are experimental;
2. Describe any reasonably foreseeable risks or discomforts to the subjects;
3. Disclose appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
4. Describe any benefits to the subject or to others which may reasonably be expected from the research;
5. Describe the extent, if any, to which confidentiality of records identifying the subject will be maintained (a separate form may be used to obtain authorization under the Health Insurance Portability and Accountability Act, where applicable);
6. For research involving more than minimal risk, explain whether any compensation and whether any medical treatment is available if injury occurs, and if so, what they consist of, or where further information may be obtained;
7. Inform participants to contact the chair for answers to questions about the research, about their rights as subjects and about any research-related stress or injuries;
8. State that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

In addition, where appropriate, the informed consent may:

1. state that the particular treatment or procedure may involve risks to the subject (or embryo or fetus, if the subject may become pregnant) which are currently unforeseeable;
2. include anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent;
3. identify any additional costs to the subject that may result from participation in the research;
4. state the consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. state that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject; and
6. include the approximate number of subjects involved in the study.

In research involving children, where applicable law requires written assent, a copy of such assent form shall also be provided to the IRB.

When surveys are administered through the mail or over the telephone, it may be necessary to ask subjects to return a signed copy of the informed consent form, if required by law, or if the IRB makes doing so a condition of approval.

The IRB may approve a consent procedure that does not include, or alters some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, as allowed by law.

The chair shall place in the Provost’s office copies of all correspondence with committee members, correspondence with investigators, and minutes of all meetings (including discussions of substantive issues, the resolution of those issues, and any vote counts). All records shall be retained for at least three years, and records related to research which is conducted shall be retained for at least 3 years after completion of the research. A longer period may be required under federal, state, or local law.

*Notification:* The IRB chair shall notify all investigators of the IRB’s decisions regarding their applications. Approval of applications shall remain effective for twelve months. Investigators shall be given an expiration date when they receive their approval. In the event that the IRB denies an application, the chair shall explain to the investigator, in writing, why approval was not granted and shall specify the changes that would be necessary for the application to be approved. The chair also shall notify investigators of their right to appeal IRB decisions to the Provost’s office.

*Continuing review:* The IRB shall conduct continuing review of research that it approves at intervals appropriate to the degree of risk, but not less than once per year.

**Review of Proposals:**

All research involving humans done on Trinity Christian College campus with students, faculty, staff or administrators shall be reviewed and approved, prior to the collection of any data or enrollment of human subjects, at the appropriate IRB level of review as noted below. The level of review necessary for a specific investigation shall be based on the content and methodology of the study.

**\* Click on the**  **for your selection.**

#### Level 1: EXEMPT REVIEW

The IRB shall require that research that falls into the “Exempt” category be submitted to the IRB and be reviewed by the chair. For the purposes of the IRB, the word “exemption” does not mean that a review is not needed, but rather that the project may be exempt from a full IRB review.

Research activities in which the only involvement of human subjects is in one or more of the following categories shall qualify the proposal for Exempt Review.

NOTE: If children (persons who have not attained the legal age for consent to treatments or procedures involved in the research) or other vulnerable populations are involved and identified, the proposal shall not be exempt.

1. Research in established or commonly-accepted educational settings, involving normal educational practices, where students are not identified.\*

2. Research using educational tests (cognitive, diagnostic, aptitude, achievement) unless information obtained is recorded in a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation;

3. Research involving survey procedures, interview procedures, or observation of public behavior, that is not exempt under 2. above, if the human subjects are elected or appointed officials or candidates for public office; or federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter;

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects;

5. Research and demonstration projects that are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs;

6. Taste and food quality evaluation (call IRB chair for specifics).

\*Identifiers are, for example, Social Security number, place of employment, code numbers, medical record numbers, position title, etc. . . that can be linked to individual people and perhaps also to associated medical, financial, or employment information (Some demographic data might be specific enough to be considered an identifier.) Code numbers substituted for names, kept by the investigator ARE considered identifiers.

**Level 2: EXPEDITED REVIEW**

Research activities involving no more than minimal risk to human subjects and involving procedures listed in one or more of the following categories may be reviewed through the IRB “Expedited Review” process. Such research proposals shall be reviewed by two members of the IRB who shall communicate their decision to the IRB chair. The members conducting the Expedited Review may exercise all of the authority of the IRB, but may not disapprove the research. In the event that either of the members feel the proposal should receive full review, the investigator shall be informed and the proposal shall be put on the agenda for a “full” IRB review.

Research activities in which the only involvement of human subjects is in one or more of the following categories may qualify your proposal for EXPEDITED review.

NOTE: The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the Expedited Review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. This list is subject to amendment.

1. Collection of data from voice, video, digital, or image recordings made for research purposes.

2. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis) and is not otherwise exempt.

3. 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, interviews, oral history, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies, if not otherwise exempted.

4. Research of drugs or medical devices for which an investigational new drug application (21 CFR Part 312) or an investigational devise exemption (21 CFR Part 812) is not required, or where a medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

5. Prospective collection of biological specimens for research purposes by noninvasive means, such as collection of hair and nail clippings, in a nondisfiguring manner; deciduous teeth at the time of exfoliation or if routine patient care indicates a need for extraction; and permanent teeth if patient care indicates a need for extraction; excreta and external secretion including sweat, uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

6. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). Examples include the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy. Procedures such as weighing or testing sensory acuity, magnetic resonance imaging, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic infrared imaging, echocardiography, and electroretinography.

7. Collection of blood samples by venipuncture, in amounts not exceeding 550 milliliters in an 8-week period and no more often than two times per week, from subjects 18-years of age or older and who are in good health and not pregnant.

8. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

**Level 3: FULL REVIEW**

The third level of review, “Full Review,” shall be required for research that does not fall into the previous two categories.

Examples of research that shall require Full Review include research involving:

1. Vulnerable populations including children less than 18 years of age, pregnant women, handicapped or mentally disabled persons, prisoners, or economically or educationally disadvantaged persons.

2. Possible sources of physical, psychological or social risk including but not limited to aversive stimuli, sensory deprivation, sleep deprivation, or food deprivation.

3. Potential violations of rights to privacy and free choice (any situation involving possible deception in which full informed consent cannot be obtained before the study begins).

The chair shall distribute copies of the plan of investigation to each committee member and shall schedule a meeting to discuss the research proposal. The investigator of the proposed research shall also be present at the meeting. No meeting shall be held with fewer than four IRB members present.

The IRB shall make a reasonable effort to prevent the delay of research projects. Decisions of the IRB may be appealed to the Provost’s office of Trinity Christian College followed by revision and resubmission of the proposal to the IRB for review.

Individuals are encouraged to consult the IRB with questions regarding the appropriate level of review for a study.

**Definitions**

The following definitions are based upon the Department of Health and Human Services guidelines (45 Code of Federal Regulations POR 46.102).

RESEARCH: A systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

HUMAN

SUBJECT:A living individual about whom an investigator conducting research, obtains data through intervention or interaction with the individual or through records of identifiable private information.

IRB

APPROVAL:The determination of the Institutional Review Board (IRB) that the research has been received and may be conducted within the constraints set forth by the IRB and by other institutional requirements.

MINIMAL

RISK:The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those inadvertently encountered in daily life or during the performance of routine physical or psychological examinations or tests.