Caldwell University Institutional Review Board

Policy and Procedures

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# Introduction

The Institutional Review Board (IRB) at Caldwell University is an appropriately constituted administrative body established to protect the rights and welfare of human participants recruited to participate in research activities. This policy establishes that under the Federalwide Assurance (FWA) maintained with the U.S. Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP), all human participants research conducted by or under the auspices of Caldwell University will be performed in accordance with Title 45 Code of Federal Regulations, Part 46 (45 CFR 46) and with the policies outlined in this manual. In addition, the actions of the University’s IRB will conform to all applicable federal, state, and local laws and regulations.

The Institutional Review Board of Caldwell University is charged with the responsibility and authority to approve, require modification in, halt unapproved or non-compliant research, periodically monitor the progress of long-term records, or disapprove all research activities involving humans that fall within its jurisdiction. The IRB is responsible for establishing and administering institutional policies and procedures through which the University conforms to federal, state, and local regulations that govern the protection of human subjects participating in research.

All research involving the systematic collection of information, data or specimens / samples from or about human subjects or information, data, specimens / samples gathered from humans at some prior time either by the researchers themselves or someone else, must be reviewed and approved prior to such studies being undertaken. This policy applies to:

* Any research whether new, ongoing, or proposed, regardless of funding status and source, whether conducted at Caldwell University or elsewhere, by anyone affiliated with Caldwell University (i.e., faculty, students, staff)
* Any investigator from outside Caldwell University who wishes to perform research on members of the Caldwell University community or on its campus. These investigators must have a Caldwell University faculty or staff member serve as sponsor or co-investigator. Approval must be given by the VPAA and/or designee for the research to be conducted on campus by anyone not affiliated by the university.

The policy does not apply to a faculty or staff member of Caldwell University who is hired as a consultant to do research outside of the University, and who performs the research outside of their capacity as an employee of Caldwell University.

The terms of the Caldwell University FWA (but not necessarily all of the policies and procedures in this Guide) apply to all subcontractors and collaborators of research conducted by Caldwell University personnel. The Caldwell University principal investigator is responsible for ensuring that appropriate human subjects protections are in place at the collaborating institution and, when they are not, bringing those protocols to the Caldwell University IRB for approval.

The University’s IRB is directed by a chairperson, and is comprised of members with multidisciplinary expertise and backgrounds as required by federal policy. The IRB determines the role and responsibilities of board members and researchers in human subject protection. When appropriate, the IRB reports all violations of guidelines and regulations to the appropriate department chairperson or associate dean, to the Office of the Vice President for Academic Affairs, and/or to the appropriate federal offices. The IRB provides the Vice President for Academic Affairs with an annual report of its activities and makes recommendations for fulfilling membership needs for the following year.

The purpose of the IRB review is to ensure that appropriate steps are taken to protect the rights and welfare of human research participants. To accomplish this process, the IRB will meet periodically to review and approve research protocols and related materials (e.g., informed consent documents, investigator brochures, questionnaires, etc.).

The Caldwell University IRB shall determine that all of the following requirements are satisfied before granting approval to any research (45 CFR 46.111):

* The risks to human research participants are reasonable in relation to the anticipated benefits (if any) to the individual, and the importance of the knowledge that may be expected to result.
* The risks to human participants are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose the research participants to risk
* In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research.
* The selection of human participants for research projects is equitable.
* Informed consent is obtained from each prospective human research participant, or his/her legally authorized representative, in accordance with, and the extent required by federal regulations and IRB policies, unless a waiver/alteration of the consent process is appropriate.
* Informed consent of human research participants is appropriately documented in accordance with, and to the extent required by federal regulations and IRB policies, unless a waiver/alteration of this requirement is appropriate.
* The research plan, when appropriate, makes adequate provision for monitoring the data collected to ensure the safety of the human research participant, and there are adequate provisions to report adverse events to the IRB should any arise.
* There are adequate provisions to protect the privacy of human research participants and to maintain the confidentiality of research data.
* Appropriate additional safeguards have been included in the study to protect the rights and welfare of human research participants who are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, people with impaired decision-making ability, or economically and/or educationally disadvantaged persons).

# Definitions

* **Research** is defined as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

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

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions” (45 CFR 46.102(l))

A defining feature of research is that a fundamental goal of the activity is to learn something that will benefit future participants (not the participants enrolled in the research study).

* A Human **participant** is defined as “a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(1) *Intervention* includes both physical procedures by which information or biospecimens are gathered (*e.g.,* venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(2) *Interaction* includes communication or interpersonal contact between investigator and subject.

(3) *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.,* a medical record).

(4) *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

(5) *An identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen” (45 CFR 46.102 (e)).

* “**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” (45 CFR 46.102 (j)).
* **“Certification** means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance” (45 CFR 46.102 (a)).
* **“Clinical trial** means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes” (45 CFR 46.102 (b)).
* **“Department or agency head** means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated” (45 CFR 46.102 (c)).
* **“Federal department or agency** refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency)” (45 CFR 46.102 (d)).
* **“Public health authority** means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate” (45 CFR 46.102 (k)).
* **“Institution** means any public or private entity, or department or agency (including federal, state, and other agencies) (45 CFR 46.102 (f)).
* **“IRB** means an institutional review board established in accord with and for the purposes expressed in” regulatory text of 45 CFR 46 (45 CFR 46.102 (g)).
* **“IRB approval** means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements” (45 CFR 46.102 (h)).
* **Informed consent** means the knowing, legally effective consent of any individual or the individual’s legally authorized representative. “Such consent can be obtained only under circumstances that provide the prospective participant or representative sufficient opportunity to consider whether to participate and that minimizes the possibility of coercion or undue influence” (45 CFR 46.116).
* **“Legally authorized representative** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research" (45 CFR 46.102(i)).
* **“Dead fetus** means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord” (45 CFR 46.202 (a)).
* **“Delivery** means complete separation of the fetus from the woman by expulsion or extraction or any other means” (45 CFR 46.202 (b)).
* “**Fetus** means the product of conception from implantation until delivery” (45 CFR 46.202 (c)).
* “**Neonate** means a newborn” (45 CFR 46.202 (d)).
* **“Nonviable neonate** means a neonate after delivery that, although living, is not viable” (45 CFR 46.202 (e)).
* “**Pregnancy** encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery” (45 CFR 46.202 (f)).
* **“Secretary** means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated” (45 CFR 46.202 (g)).
* “**Viable**, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a neonate is viable” for purposes of 45 CFR 46 subpart B. (45 CFR 46.202 (h)).
* **“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 a 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)).
* **“Children** are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted” (45 CFR 46.402(a)).
* **“Assent**means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent” (45 CFR 46.402(b)).
* **“Permission** means the agreement of parent(s) or guardian to the participation of their child or ward in research” (45 CFR 46.402(c)).
* “**Parent** means a child's biological or adoptive parent” (45 CFR 46.402(d)).
* **“Guardian** means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care” (45 CFR 46.402(e)).
* **“Written, or in writing**, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format” (45 CFR 46.102 (m)).
* **Noncompliance:** Any failure to comply with Caldwell University IRB policies and procedures and federal guidelines, or failure to appropriately follow through with IRB determinations and requests. Noncompliance may result from the action of the investigator, research personnel, or a participant, and may or may not impact the rights and welfare of research participants or others or the integrity of the study. Noncompliance may range from minor to serious, be unintentional or willful, and may occur once or several times.
* **Serious Noncompliance:** Noncompliance which significantly increases risk to participants and/or significantly decreases potential benefits.
* **Continuing Noncompliance:** A pattern of non-compliance that indicates a lack of understanding or disregard for the regulations or institutional requirements that protect the rights and welfare of participants and others, compromises the scientific integrity of a study such that important conclusions can no longer be reached, suggests a likelihood that non-compliance will continue without intervention, or involves frequent instances of minor non-compliance. Continuing non-compliance may also include failure to respond to a request from the IRB to resolve an episode of non-compliance or a pattern of minor non-compliance
* **Unanticipated Problem:** Any unanticipated problem related to the research, whether serious or not, that adversely affects the safety, rights, or welfare of subjects or others.
* **Sponsor:** For the purposes of research conducted by investigators unaffiliated with Caldwell University, a sponsor is a Caldwell University faculty or staff member who can vouch for the investigator and agrees to be the point person for any recruitment and research activities happening on the Caldwell University campus or with Caldwell University employees and/or students. After the research is approved by the IRB and the VPAA/designee, the sponsor must be willing to oversee that the research is conducted according to the policies outlined in this document.
* **Co-investigator**: For the purposes of research conducted by investigators unaffiliated with Caldwell University, a co-investigator is a Caldwell University faculty or staff member willing to serve as an investigator on the proposed research project. This co-investigator must take responsibility for the portion of research activities happening on the Caldwell University campus or with Caldwell University employees and/or students.

# Statement of Principles

Caldwell University is committed to the pursuit of excellence in teaching, research, and public service. Founded in 1939 by the Sisters of Saint Dominic, Caldwell University is a Catholic institution in the Judaeo-Christian tradition with a heritage of eight centuries of Dominican commitment to higher learning. Serving a diverse population of all ages, Caldwell University provides an excellent liberal arts education, which promotes spiritual, intellectual and aesthetic growth. Upon this foundation the University offers career-related programs, which prepare its graduates to take advantage of opportunities in a complex society. In pursuit of truth and life-long learning, Caldwell University fosters the well-being of this and future generations. Through a curriculum and extracurricular program rooted in the Catholic humanist tradition, the University seeks to empower its students to comprehend community and global issues and to act responsibly toward self and others. Concomitantly, Caldwell University seeks to protect the welfare of every person who may be involved in research and training projects. Members of the Caldwell University community, although upholding the highest standards of freedom of inquiry and communication, accept the responsibility this freedom offers: For competence, for objectivity, for consideration of the best interests of Caldwell University and society, and for the welfare of every participant in a project. Caldwell University assures that it will comply with the federal policy for the Protection of Human Subjects (or “The Common Rule” as it is sometimes called, 45 CFR 46, as amended) in accordance with the guidelines set forth by the OHRP of the U.S. Department of Health and Human Services. The following principles are affirmed and should be interpreted in the broad context provided by the code of general and medical ethics promulgated by the World Medical Association as the Declaration of Helsinki, by the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research known as the Belmont Report, and for funded research, any additional human participants regulations and policies of the supporting Department or Agency.

* The basic ethical principles set forth in the Belmont Report, respect for persons, beneficence, and justice underlie the requirements for the ethical conduct of research involving human participants at Caldwell University. Respect for persons means that individuals should be treated as autonomous agents and that persons with diminished autonomy or impaired decision-making ability (e.g., individuals with cognitive disabilities, Alzheimer’s Disease, etc.) are entitled to protection. Beneficence entails an obligation to do no harm and maximize possible benefits and minimize possible harms. Justice requires that the benefits and burdens of research be distributed fairly. That is, individuals should be selected to participate in research for reasons directly related to the problem being studied, not because they are easily available, their compromised position, or their manipulability.
* All research projects at Caldwell University will be held to the same standards. Because the participation of humans in research and training projects may raise fundamental ethical and civil rights issues, no distinctions in the monitoring of projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, or between projects carried out by students, faculty, or other Caldwell University employees, on-campus or off-campus.
* All activities involving humans as participants must provide for the safety, health, and welfare of every individual. Rights, including the right of privacy, must not be infringed.
* The direct or potential benefits to the participant or the importance of the knowledge gained must outweigh the risks to the individual inherent in the proposed research. As stated in the Common Rule, “Risks to subjects are minimized” and “risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may be reasonably expected to result (45 CFR 46.111(a) (1,2)).
* Participation in projects must be voluntary, and informed consent must be obtained from all participants, unless the IRB of Caldwell University specifically waives this requirement in accordance with this policy and federal guidelines outlined in 45 CFR 46.116 and 46.117. Methods that are in accordance with the requirements of 45 CFR 46.116 and 46.117 and adequate and appropriate to the risks of the project must be used to obtain the participants’ informed consent.
* When required, consent must be obtained from the participants themselves whenever possible. Further, if a participant is not legally or physically capable of giving fully informed consent, a legally authorized representative should do so. Careful consideration shall be given to the representative’s depth of interest and concern with the participant’s rights and welfare. Parents, for example, may not expose their child to more than minimal risk except for the child’s direct benefit. In research with children, assent may be required when age and cognitive capability allow for assent.
* An individual does not abdicate any rights by consenting to be a research participant. Informed consent forms should include language indicating that a participant has the right to withdraw from a research project at any time or to refuse to participate, without loss of benefits to which the participant would otherwise be entitled. Further, a participant has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information, and to be free from undue physical risk, embarrassment, discomfort, anxiety, and harassment. These rights need to be clearly defined for all potential participants.
* The IRB acknowledges the potential for a conflict of interest or coercion in an academic setting where participants in research studies are also students in a course. The primary investigator is responsible for minimizing these effects in recruiting participants. Conflicts of interest may involve promotion, tenure, grants, fame, or monetary reward, among others. The investigator must disclose potential conflicts of interest to the government (if receiving funding), the institution, the IRB, and most importantly, to the research participants.
* Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the investigator. Investigators should detail to the IRB what security measures will be taken to ensure that privacy will be maintained. Records containing personal information shall be destroyed as soon as possible in keeping with the long-range goals of the project. Specific participant information shall not be communicated to others unless one of the following conditions is met:
  + Explicit permission for the release of identifying data is given by the individual
  + Information about individuals may be discussed only for professional purposes and only with persons clearly involved in the project. Written and oral reports should present only data germane to the purposes of the project, and every effort should be made to avoid a breach of confidentiality.
  + The investigator is legally required to provide such information (e.g., child abuse, sexual abuse, or other illegal activities revealed by a participant).
* An individual involved in the conduct and/or supervision of a specific project shall not participate in the IRB review, except to provide information. Thus, members of the IRB must recuse themselves from deliberations involving research where they are primary investigators, faculty sponsors, advisors, or department chairs where the research is proposed by students or faculty in their own department.
* All individuals involved in the conduct, supervision, and or review of research activities with human participants must demonstrate an understanding of the ethical principles and policies governing the treatment of human research participants. To this end, all individuals involved in the conduct, supervision, and or review of these research activities must submit regular evidence of having received appropriate education/training in these standards. This education/training must be from an IRB-approved source and be renewed at least every three years.

# IRB Composition and Function

1. IRB Membership

The membership of the IRB shall include at least one community representative (unaffiliated with the university), the Vice President for Academic Affairs or his/her designated representative who will serve ex-officio, and a minimum of five faculty members. Faculty members will be selected according to the research needs of Caldwell University, but shall include at least one member whose primary expertise is in a non-scientific area (e.g., law, religion, ethics, etc.) and one whose primary expertise is in a scientific area (e.g., biology, chemistry, psychology, etc.). Ideally, the Board should include members from a variety of disciplines on campus.

The Board shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including considerations 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 participants (45 CFR 46.107(a)). If the IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects. The Board may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond or in addition to that available on the Board. These individuals shall have no voting rights.

1. Appointments and Term Limits

Appointments to the Board shall be made by the Vice President for Academic Affairs, taking into account any specific gaps or needs identified by the IRB chair. Faculty representatives, with the exception of the chair, shall typically serve three-year terms, with one-third rotation each year.

The Chair of the IRB will be appointed by the VPAA, taking into consideration experience and familiarity with IRB polices and federal guidelines for research with human participants. The chair will serve a five-year term. A Vice-Chair and a Secretary will be elected from among the remaining board members by a majority vote of the board. Officers of the IRB, with the exception of the chair, will maintain their position until the end of their term or for a three-year period, whichever comes first. There are no limits to the number of terms a member may serve, so they may be reappointed/re-elected.

Decisions of who will be replacing members rotating off will be made by December of the previous fall to allow for schedule adjustments. IRB members that resign will be replaced by the VPAA from the same or a closely related discipline. A current list of IRB members will be posted on the Caldwell University IRB webpage.

1. Expectations for IRB Members

It is expected that IRB members will have the necessary education/training in the protection of human research participants. Evidence of completion of training in the protection of human research participants by all IRB members should be kept by the IRB chairperson, and this training should be updated at least every three years, or sooner if any changes occur in federal guidelines. Each IRB member is also responsible for familiarizing themselves with Caldwell University IRB policy and with the federal regulations established for IRB functioning and approval of research.

The IRB shall generally schedule three meetings per semester. IRB members are expected to attend all meetings. It is acknowledged that at times conflicts may arise that prevent attendance. However, it is expected that members will make every effort to attend each meeting. If an IRB member does not attend more than half the meetings in an academic year, they may be removed from the IRB.

In addition to reviewing all proposals needing full review, IRB members are expected to complete a fair share of expedited reviews as assigned by the IRB chairperson. IRB members may also be asked to complete exempt reviews as necessary. IRB members are expected to review and carefully consider all applications they will be approving or voting on. IRB members must ensure that each application meets the minimum criteria for IRB approval of research activities.

Members of the IRB must recuse themselves from any deliberations involving research where they are primary investigators, faculty sponsors, advisors, thesis/dissertation committee members, or department chairs where the research is proposed by students or faculty in their own department.

1. IRB Meetings

There will generally be three IRB meetings scheduled per semester. These meetings will be scheduled for one Tuesday a month from 10 AM to 12 PM, in rotation with other scheduled university meetings (e.g., Graduate Academic Foundations Committee, Curriculum Committee, etc.). The dates for these IRB meetings will be posted on the IRB webpage. These meetings will be run by the Chairperson (or Vice-chair, in the Chair’s absence) and the IRB secretary is responsible for keeping minutes for these meetings.

1. Recordkeeping

IRB members must be kept aware of all IRB functions. All applications, supporting documentation, and approval letters will be kept in an electronic location accessible to all IRB members. The IRB will also maintain a reviewer rotation (for expedited applications), as well as a list of all protocols submitted along with IRB actions and decisions in each case. All email and written correspondence between investigators and reviewers will be maintained for a period of three years by the IRB Chair. Three years refers to 3 years following the date of the correspondence or in the case of an approved study, 3 years after the study is formally closed.

The electronic submission procedures, along with these policies and procedures, sample consent forms, and links to information concerning the use of human participants in research may be found on the Caldwell University IRB webpage. This site is maintained by the IRB chair and the Caldwell University web strategist under the direction of the Vice President for Academic Affairs.

1. Education and Training

The IRB will establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, relevant ethical principles, relevant Federal Regulations, OHRP guidance, other applicable guidance, state and local laws, and institutional policies for the protection of human participants.

1. Departmental Review Committees

Departments with graduate students conducting research with human participants are expected to establish and operate Department Review Committees (DRC). Other departments may also establish DRCs as necessary. These committees shall provide preliminary reviews of their departments' proposals prior to review by the University's IRB, but shall not replace the review of the University's IRB. The Caldwell University IRB will not consider a proposal unless it has been approved by the DRC, once the DRC has been instituted and made active.

# IRB Review Procedures

The IRB of Caldwell University must review and approve all research activities involving human participants that fall within its jurisdiction prior to the implementation of such research activities. There are three categories of IRB review of proposed studies: exempt review, expedited review, and full board review.

1. General Submission Process

Individuals seeking IRB approval of research activities involving human research participants must submit an electronic application along with all supporting documentation to the Caldwell University IRB email address ([irb@caldwell.edu](mailto:irb@caldwell.edu)). Any documents requiring an electronic approval stamp (i.e., application, consent documents, recruitment documents, etc.) must be submitted in doc/docx format. All documents submitted for review are uploaded to an electronic location accessible by all IRB members and will be kept there for record-keeping purposes.

At minimum, the following documents must be provided:

* **Current Application**: Individuals should use the most current electronic application form that matches the appropriate category of review. All information must be complete, accurate, and in sufficient detail to allow IRB members to understand the research activities and assess risk to human participants.
* **Consent Documents:** Individuals should submit electronic copies of all informed consent, broad consent, assent, and release documents with the application. All consent documents must meet the criteria established in this policy and in 45 CFR 46.116, 46.117, and subpart D and must follow the template posted on the Caldwell University IRB webpage.
* **Recruitment Materials:** Individuals should submit electronic copies of all recruitment materials with the application. This includes flyers, emails, letters, wording for social media, and other materials used to recruit participants for research.
* **External Site Approvals:** When appropriate, individuals should submit copies of all external site permission letters and/or IRB approvals.
* **Conflict of Interest Disclosure:** When appropriate, individuals should submit a conflict of interest disclosure form.
* **Departmental Review Committee Approval:** When applicable, individuals should submit any approvals and/or support letters from their Departmental Review Committee.
* **External Funding Proposals:** Individuals should submit a copy of the complete proposal with the application.
* **Evidence of Training in the Protection of Human Research Participants:** All individuals must submit evidence of education/training in the standards that protect human research participants. This applies to all investigators in a project. The completion of this training must be dated within the past three years from the date of submission.
* **Additional documentation:** Individuals should submit any additional supporting documents that might aid the IRB in the review process. The IRB may also request additional documents as needed.

The most current forms and templates will be made available through the Caldwell University IRB webpage.

1. Exempt Review

Research studies for which the only involvement of human participants will be in one or more of the categories listed below and for which there is no more than minimal risk to the participants, are exempt from the Common Rule. However, Caldwell University policies do not allow individuals to make their own determination of exemption and require IRB review of human research activities appearing to meet these exempt criteria so as to ensure regulatory compliance. Following an initial determination of exempt status, exempt research activities are no longer subject to continuing IRB oversight. Individual researchers should be aware that sometimes even subtle changes in research protocols may move research out of exempt status. It is the responsibility of the individual researcher to contact the chair of the Caldwell University IRB should changes in research protocols or any unanticipated adverse events occur, and submit either an expedited or full board review form if necessary.

Exempt Review Categories:

The following eight categories of research are eligible for review under exempt review procedures:

1. **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.

2. **Educational Tests, Surveys, Interviews, and Observation of Public Behavior:** 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:

(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 45 CFR 46.111(a)(7).

3. **Benign Behavioral Interventions:** (i) 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:

(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 45 CFR 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.

4. **Secondary Research:** Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(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.

5. **Research and Projects Conducted by Federal Agencies:** 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.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. **Taste and Food Studies:** Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. **Storage/Maintenance for Secondary Research:** Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.111(a)(8).

8. **Secondary Research with Broad Consent:** Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Exceptions to the Application of Exempt Categories:

Research with prisoners cannot be exempt unless the research is aimed at involving a broader subject population that only incidentally includes prisoners (45 CFR 46 subpart C). Research with children can be exempt under categories 1, 4, 5, 6, 7, and 8. Research with children can only be exempt under category 2 with educational tests and the observation of public behavior if the investigator(s) do not participate in the activities being observed. Research under category 2 (iii) and category 3 cannot be exempt with children (45 CFR 46 subpart D). The application of the exempt categories at times involves judgment calls, and the IRB may recommend a protocol undergo expedited or full review procedures if it is determined that the application of a category is not clear or if it is determined that there is more than minimal risk to participants.

Exempt Review Process

All exempt review applications are reviewed by the IRB chairperson or a designee. The approximate turnaround time for initial review of exempt applications is two weeks from September to December (Fall Semester) and from February to May (Spring Semester). Should turnaround times be increased for any reason, the IRB chairperson should make reasonable attempts to keep individuals informed. Any exempt applications received after December 1st for the Fall Semester and after April 20th for the Spring Semester will not be reviewed until the IRB recommences activities the following semester.

Exempt review applications will be considered exempt if:

* The research clearly meets one or more of the categories designated by 45 CFR 46.104(d)
* The research does not involve any of the exceptions for subpart C and D as listed in 45 CFR 46.104(b)
* The IRB determines there is no more than minimal risk to the participants.

Once an application has been determined to meet the exempt criteria, exempt research activities are not subject to annual renewal requirements. If an application is determined to not be exempt, then the IRB will inform the individual that the research must undergo either expedited or full review procedures and the individual may resubmit using the correct process. Any changes to the research protocol must be submitted in writing to the IRB. If such changes move the research activities out of exempt status, a new application may be required.

**Course Exemptions**

For courses in which students regularly conduct research that is considered exempt and no risk to participants, and for which the research protocols are generally similar, faculty members may apply for a course exemption rather than have students submit individual exempt applications. The faculty member must submit an application for every section of the course. In these cases, faculty members must indicate under which categories students will be conducting research and must outline the general pattern that the research protocols will follow. Faculty members must also submit all recruitment and consent documents to be used by students for approval. Once designated exempt, any research conducted in the course is exempt as long as the research activities clearly fit the parameters outlined in the original exempt application and meet federal guidelines for exemption. Faculty members are responsible for ensuring that the exemptions are properly applied in all student research and that any protocols deviating from the original parameters be instead submitted to the IRB for review. It is also the faculty member’s responsibility to renew course exemptions every three years.

1. Expedited Review

IRB regulations recognize that there are certain categories of research which involve procedures that pose no more than minimal risks to subjects and for which clear standards can be set (45 CFR 46 and FDA regulations at 21 CFR 56). Research studies that fall into one or more of the categories listed below may be reviewed using an expedited process, as long as all research activities involve no more than minimal risk to the human research participants. In addition to the categories listed below, expedited review procedures may also be used for minor changes in previously approved research during the period for which approval is authorized; or research for which limited IRB review is a condition of exemption under 45 CFR 46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8). The expedited review process may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. Investigators should be aware that even though applications for the expedited review are less complicated to review and, if there is no need for revision or modification, are generally approved more quickly than other proposals, there can be no guarantee that this will be the case.

Expedited Review Categories

The following nine categories of research are eligible for review under expedited review procedures:

1. **Certain Clinical Studies:** Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required, or (ii) the medical device is cleared / approved for marketing and the medical device is being used in accordance with its cleared approved labeling.

2. **Blood Samples:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or (b) from other adults or children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

3. **Biological Specimens:** Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removal at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane before or during labor; (h) supragingival and subginvival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; and (j) sputum collected after saline mist nebulization.

4. **Noninvasive Procedures:** 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: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. **Data for Nonresearch Purposes**: 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).

6. **Recordings:** Collection of data from voice, video, digital, or image recordings made for research purposes.

7. **Group Characteristics/Behavior:** Research on 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.

8. **Continuing Review:** Continuing review of research previously approved by a convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for the long term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

9. **Continuing Review of Certain Drug Studies:** Research not conducted under an investigational new drug application or investigational drug exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Expedited Review Process

All expedited review applications are reviewed by two IRB members. The approximate turnaround time for initial review of expedited applications is three weeks from September to December (Fall Semester) and February to May (Spring Semester). Should turnaround times be increased for any reason, the IRB chairperson should make reasonable attempts to keep individuals informed. Any expedited applications received after December 1st for the Fall Semester and after April 20th for the Spring Semester will not be reviewed until the IRB recommences activities the following semester.

Expedited review applications will be approved if:

* The research clearly meets one or more of the categories designated by 45 CFR 46 and FDA regulations at 21 CFR 56.
* The designated IRB reviewers determine there is no more than minimal risk to the participants.
* The designated IRB reviewers determine that the research activities satisfy all of the criteria for approval as listed in 45 CFR 46.111 and in this document.

All IRB members involved in an expedited review must agree that the application satisfies all of the criteria for undergoing expedited procedures, that the research poses no more than minimal risk to the participants, and that it adequately addresses all the necessary criteria for IRB approval of research. Any IRB member engaged in an expedited review may object to the application of the expedited review procedure or may have further questions that the investigator must answer. Similarly, each IRB member has the option of referring the application to the IRB for full review. The designated IRB members will review all applicable documents and send their comments, questions, and recommendations to the IRB chairperson. The IRB chairperson is responsible for communicating with the investigator regarding any needed clarifications, revisions, or IRB decisions.

If the application is approved using expedited review procedures, the IRB Chair will issue an approval letter with a protocol number and will upload this document to the IRB electronic files so that all IRB members are aware of the approval and for record-keeping purposes. A copy of the letter will be sent to the investigator, faculty advisor (if appropriate), and DRC (if applicable). If the application requires clarification or revisions to adequately address all the necessary criteria for IRB approval of research, the IRB will inform the investigator in writing as to what clarifications and/or revisions are required. Revised applications may be sent for rereview if modifications are extensive, or they may be approved by the IRB chair or designee if modifications are minor. If the application is disapproved at the expedited level, it must then be submitted to the IRB as a full board review as federal guidelines do not allow research proposals to be rejected at the expedited level.

1. Full Review

Research protocols that do not qualify for exempt or expedited reviews must be reviewed by the full IRB board at a regularly scheduled meeting.

Full Review Process

The full review process at Caldwell University is a two-tier process that involves review by IRB and approval by the VPAA/designee. All full review applications are reviewed by all IRB members. Full review applications must be reviewed at regularly scheduled meetings, so the turnaround time depends on when the next scheduled meeting is (generally there are three meetings in the Fall semester and three meetings in Spring Semester). Any applications needing full review must be submitted at least two weeks in advance of a scheduled meeting to allow IRB members adequate time to carefully read the application. The schedule of meetings will be clearly posted on the Caldwell University IRB webpage. Investigators should note that if modifications are required, this could delay the approval of research by the full IRB.

Full review applications will be approved if:

* A majority of IRB members determine that the research activities satisfy all of the criteria for approval as listed in 45 CFR 46.111 and in this document.
* The VPAA and/or designee does not veto approval by the IRB.

A quorum of the members of the IRB, including at least one member whose primary concerns are in non-scientific areas, must be present at a meeting in order to conduct business. Federal guidelines define a quorum as a majority of IRB members. An IRB member will be considered present if they are available through videoconferencing or phone for the entirety of the meeting. IRB members who are not present can send in comments or concerns, but cannot vote. Should the quorum be lost during a meeting, the IRB cannot vote on any proposals and must reconvene within two weeks to review any outstanding applications.

The principal investigator (and faculty sponsor, if appropriate) may be invited to meetings held to consider the proposal. Even if the consensus of the IRB is favorable, the IRB may elect to impose additional restrictions or recommendations under which the project shall be conducted. Final approval by the IRB shall require a majority vote by members present. In cases where only minor revisions are required, the IRB may vote to approve the application and designate an IRB member to confirm that the revisions are completed before an approval letter is generated.

If the IRB agrees that the proposed research protects human participants in accordance with established standards and meets criteria for approval, the IRB Chair will then send the application to the VPAA and/or designee for final approval. The VPAA and/or designee may not approve research that has been disapproved by the IRB, but they may veto approval. If the application receives final approval from the VPAA and/or designee, the IRB chair will issue an approval letter with a protocol number and will upload this document to the IRB electronic files for record-keeping. A copy of the letter will be sent to the investigator, faculty advisor (if appropriate), and DRC (if applicable). If the application requires minor clarification or revisions to adequately address all the necessary criteria for IRB approval of research, the IRB will inform the investigator in writing as to what clarifications and/or revisions are required before any approval letter is given. If the application is disapproved, the investigator will be informed in writing. If the researcher decides to modify the proposed research in such a way as to overcome the objections of the IRB, the investigator may resubmit the proposal for consideration.

# IRB Approval of Research

The Caldwell University IRB has the authority to approve or disapprove all research using human participants conducted on campus or by Caldwell University students or employees. Unapproved research may not be conducted on campus under any circumstance. Individuals connected with Caldwell University must have their off campus human research approved or exempted if the researcher indicates to the participants an affiliation with Caldwell University, if Caldwell University funds or equipment are used, or if the research will be used to fulfill a degree requirement at Caldwell University. Investigators are also responsible for being aware of and adhering to any policies and regulations that may exist at external sites, including the need to get additional approvals to conduct the research. All external IRB approvals, site approvals, and Institutional Authorization Agreements must be filed with the VPAA’s office prior to commencing research activities on site.

Primary responsibility for adherence to high ethical standards, to federal and state laws, and to Caldwell University regulations must remain in the hands of the individual faculty, staff members, and students who comprise this institution. They must make the initial decision as to whether their activities are or are not "human research" subject to review by the IRB. At times, this decision is not easily made. If any investigator is unclear as to whether proposed research is subject to review, it is recommended that the investigator seek the advice of the IRB Chair. When the investigator is a student, ultimate responsibility for the conduct of this research and the supervision of human participants lies with the faculty sponsor. Following project approval, the faculty sponsor must provide oversight and review to ensure that participant recruitment, informed consent procedures, and subsequent contact with participants are in conformity with approved guidelines.

Outside investigators (non-Caldwell faculty, students, or employees) conducting human participant research on the Caldwell University campus or conducting research associated with Caldwell University are subject to the principles, procedures, and responsibilities outlined in this manual. In addition, they must have a sponsor from Caldwell University faculty or staff and are subject to VPAA and/or designee approval for conducting the research on campus.

1. Approval Periods and Continuing Review

When granting initial approval of a proposal, the IRB will indicate the minimum intervals needed for re-evaluation of the project in order to assure continued acceptance of the proposal. Routine projects will be reviewed at yearly intervals; more complex and/or potentially dangerous projects will be reviewed at a frequency commensurate with the related risks. Renewal projects should include a progress report as well as a description of any anticipated design changes. In order to ensure continuity of the research, project renewals must be submitted a minimum of 30 days prior to the expiration date of the research project. Projects may also be reevaluated if someone involved in the research lodges a complaint with the IRB or the Office of the Vice President for Academic Affairs, or if the principal investigator reports problems with the research. In the latter case, the IRB may elect to review the data accumulated by the investigator and may interview both the research staff and persons at risk.

1. Basic Requirements for IRB Approval of Research

The Caldwell University IRB will determine that the following requirements are satisfied in order to approve research covered by this policy (45 CFR 46.111(a)(1-7)):

1. Risks to subjects must be minimized

1. By using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
2. Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes
3. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this statement, the IRB should take into account 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, people with impaired decision-making ability, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 46.116.

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by 46.117.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected, to ensure the safety of participants.

7. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

1. Additional Factors for IRB Approval of Research

1. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, people with impaired decision-making ability, or economically or educationally disadvantages persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

2. The project protocol will be evaluated to determine whether risks to participants are reasonable relative to the anticipated benefits, if any, to the participants and/or to the importance of the knowledge that may reasonably be expected to result. The IRB will not allow the use of human participants in poorly designed projects that are unlikely to produce meaningful results. The primary responsibility for research design quality lies with the faculty sponsor. When necessary, the IRB will withhold project approval until the investigators adapt or adopt an adequate design.

3. Research covered by this policy that has been approved by the Caldwell University IRB may be subject to further appropriate review and approval or disapproval by officials of Caldwell University. However, those officials may not approve the research if the Caldwell University IRB has not approved it.

4. The Caldwell University IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB’s action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

1. Informed Consent Process

Informed consent means the knowing, legally effective consent of any individual or the individual's legally authorized representative. Such consent can be obtained only under circumstances that provide the prospective participant or representative sufficient opportunity to discuss and consider whether to participate, and that minimizes the possibility of coercion or undue influence. Informed consent is more than a signed document, it is a process. Written informed consent (either paper or electronic) documents this process, but cannot serve as a substitute for it. The IRB must have enough information to determine whether the process used will meet these basic requirements.

The information given to the participant, or the participant's legally authorized representative, must be in simple, easily understood language. Ideally, the language should be an approximately 8th grade level, unless the population under investigation warrants a different level. If the participant does not speak English, the informed consent must be presented in the appropriate language. In cases where the sample includes illiterate participants, additional processes may be necessary to ensure informed consent.

Informed consent must “present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate” (45 CFR 46.116 (5)). It must also be presented in an organized and easy to follow manner, beginning with a key information section that is concise and focused containing all the reasons a participant may or may not want to participate in the research.

In most cases, documentation of the consent process is required. Unless consent is specifically waived by the IRB, the participant or participant's legally authorized representative must sign the consent form. If the participant is a minor (under age 18) or has impaired decision-making ability, written consent of a parent, guardian, or legally authorized representative is required, unless waived by the IRB. Such a waiver, in accordance with 45 CFR 46.116, will be granted only if the investigator can provide adequate justification for the request. In addition to obtaining parental consent, the investigator must obtain assent of the child unless the child is incapable of giving assent and the IRB has waived the requirement.

In the case of certain surveys in which the only record linking the participant to the research or data would be a written signed consent form, the IRB may waive the use of a signed consent form. Nonetheless, a statement describing the procedures and objectives of the research must be supplied to the participants in a written format. For example, the IRB may waive the use of a signed consent form for a project using a questionnaire that is distributed and returned anonymously through the mail. A cover letter sent with the questionnaire would include all the elements of informed consent listed in this section. If informed consent is to be obtained orally (i.e., prior to a telephone interview), a written summary of what participants will be told must be provided to the IRB for review and approval.

Under no circumstance may informed consent, whether oral or written, waive or limit in appearance or in fact the participant's legal rights, including any release of the institution or its agents from liability or negligence.

The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws, which require additional information to be disclosed, in order for informed consent to be legally effective.

1. Requirements for Informed Consent

Key Information Section

Unless a waiver or alteration is approved by the IRB, all informed consent documents must begin with: “A concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research” (45 CFR 46.116 (5)). Therefore, the IRB requires that a key information section contain the following:

* + 1. The fact that consent is being sought for research and that participation is voluntary;
    2. The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research;
    3. The reasonably foreseeable risks or discomforts to the prospective subject;
    4. The benefits to the prospective subject or to others that may reasonably be expected from the research; and
    5. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.

Basic Elements of Informed Consent

In addition to a key information section, consent documents must contain all of the following unless a waiver or alteration is approved by the IRB.

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others that may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
   1. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
   2. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional Elements of Informed Consent

As appropriate, one or more of the following elements of information should also be included:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study;
7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Documentation of Informed Consent

Unless a waiver or alteration is approved by the IRB, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form (45 CFR 46.117).

A written consent form may be either of the following:

(1) A written informed consent form that meets the requirements of informed conssent. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.

(2) A short form written informed consent form stating that the required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative, and that the required key information was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

Federal law mandates that copies of all informed consents be retained for a minimum of three years after the completion of the research. The principal investigator is responsible for the maintenance and retention of such records. If the principal investigator is a student, the faculty sponsor is responsible for the maintenance of these records. The IRB and or VPAA may request to review all documentation of informed consent at any time.

1. Broad Consent

As an alternative or an addition to informed consent, broad consent may be sought for the “storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes). If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative” (45 CFR 46.116 (d)):

1. A description of any reasonably foreseeable risks or discomforts to the subject;
2. A description of any benefits to the subject or to others that may reasonably be expected from the research;
3. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
4. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
5. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
6. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
7. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);
8. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
9. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
10. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

Researchers should note, that if they seek broad consent in addition to informed consent, they must keep track of which participants do and do not provide broad consent for the storage of their identifiable private information or identifiable biospecimens for other purposes.

1. Waiver/Alterations of Consent Process

Waiver/Alteration of the Elements of Informed Consent

An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Waiver/Alteration of the Documentation of Informed Consent

An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

1. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

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

# Research with Populations Needing Additional Protections

Research involving fetuses, pregnant women, human in vitro fertilization, prisoners, and children are all subject to additional federal regulations. This document will outline some of the basic requirements for research involving these populations, however, these regulations are complex. Before submitting a proposal, investigators contemplating research utilizing these populations should obtain a copy of the most recent revision of the Code of Federal Regulations (45 CFR 46, Protection of Human Subjects), Subparts: B - Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Neonates; C - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects; and D - Additional Protections for Children Involved as Subjects in Research.

1. Research Involving Fetuses, Pregnant Women, and Neonates

Pregnant Women and Fetuses

Research studies involving **pregnant women or fetuses** can only be approved by the IRB if the following requirements of 45 CFR 46.204 are satisfied:

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
3. Any risk is the least possible for achieving the objectives of the research;
4. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of 45 CFR 46.116 and 46.117;
5. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of 45 CFR 46.116 and 46.117, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
6. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
7. For children who are pregnant, assent and permission are obtained in accord with the provisions of 45 CFR subpart D;
8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
10. Individuals engaged in the research will have no part in determining the viability of a neonate. Researchers should note that child-bearing capability it not on its own a reason to exclude people from a research study, however, research studies involving any risk to pregnant women, fetuses, or neonates should include provisions as to how pregnancy will be determined.

Neonates

Research studies involving neonates of uncertain viability and nonviable neonates can only be approved by the IRB if the following requirements of 45 CFR 46.205 are satisfied:

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
3. Individuals engaged in the research will have no part in determining the viability of a neonate.
4. The requirements below have been met as applicable.

(a) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions are met:

The IRB determines that:

* + 1. The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
    2. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
    3. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

(b) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:

1. Vital functions of the neonate will not be artificially maintained;
2. The research will not terminate the heartbeat or respiration of the neonate;
3. There will be no added risk to the neonate resulting from the research;
4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
5. The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of 45 CFR 46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph.
6. Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of 45 CFR.

Placenta, Dead Fetus or Fetal Material After Delivery

“Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

If information associated with material above is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.” (45 CFR 46.206)

1. Research Involving Prisoners

Requirements for IRB

For research involving prisoners, the IRB must first meet certain requirements before reviewing the research:

1. A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.
2. At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

Criteria for Approval

Research studies involving prisoners can only be approved by the IRB if the following requirements of 45 CFR 46.305 are satisfied:

1. The research under review represents one of the categories of research permissible with prisoners;
2. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
3. The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
5. The information is presented in language which is understandable to the subject population;
6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
7. Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

Categories of Permitted Research

1. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
2. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
3. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary (the Secretary of Health and Human Services, or any other officer or employee of the Department of Health and Human Services to whom authority has been delegated) has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research; or
4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research.
5. Research Involving Children

Exempt Research

Research with children can be exempt under exemption categories 1, 4, 5, 6, 7, and 8 as outlined in this document. Research with children can only be exempt under category 2 with educational tests and the observation of public behavior if the investigator(s) do not participate in the activities being observed. Research under category 2 (iii) and category 3 cannot be exempt with children.

Research Involving No Greater Than Minimal Risk

The IRB will approve research that involves no greater than minimal risk to children, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, unless a waiver or alteration is appropriate and approved.

Research Involving Greater Than Minimal Risk With Direct Benefits

The IRB will approve research that involves more than minimal risk to children and involves an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

1. The risk is justified by the anticipated benefit to the subjects;
2. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
3. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

Research Involving Greater Than Minimal Risk With No Direct Benefits

The IRB will approve research that involves more than minimal risk children and involves an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

1. The risk represents a minor increase over minimal risk;
2. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
3. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
4. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

Permissions and Assent

The following guidelines are outlined in 45 CFR 46. 408 for soliciting permission from parents/legal guardians and soliciting assent from minors:

1. The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. 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 45 46.116.
2. The IRB shall determine, in accordance with and to the extent that consent is required by 45 CFR 46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404 or 46.405. Where research is covered by 45 CFR 46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
3. In addition to the provisions for waiver contained in 45 CFR 46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.
4. Permission by parents or guardians shall be documented in accordance with and to the extent required by 45 CFR 46.117.
5. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

# Reporting to the IRB

All expedited and full review studies needing reapproval beyond the expiration date must submit a continuing review application. As part of this application, investigators should summarize all procedures and interactions with human participants in the study during the year.

Principal investigators, co/sub-investigators, research personnel, or other individuals must promptly report to the IRB, appropriate institutional officials, the relevant Department or Agency Head, any applicable regulatory body, and OHRP of any unanticipated problems that have occurred in approved research and that involve risks to participants or others within five (5) working days of the occurrence. Principal Investigators, co/sub-investigators, research personnel, or other individuals who believe that an instance of serious or continuing noncompliance has occurred must report it to the IRB within five (5) working days of becoming aware of the noncompliance. When reporting the noncompliance, Investigators should include a plan of action for correcting and preventing similar incidences.

Changes to approved research protocols may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the participant.

# IRB Investigations, Suspension, and/or Termination of Research Activities

As set forth in 45 CFR 46.113 "an IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action, and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.” The policies and procedures outlined below for IRB investigations, suspension, and termination of research activities hold true for all research activities involving human research participants, even if previously determined to be exempt.

1. Procedures for Launching IRB Investigations

If the IRB receives a complaint or is made aware of any research that is not being conducted in accordance with the requirements set forth in this policy manual or in established federal guidelines and that may increase risk/decrease benefits to participants, the IRB will promptly notify any appropriate institutional officials and launch an investigation into the allegations and/or status of noncompliant research. The research activities will be suspended pending the outcome of the investigation. The initial investigation will be undertaken by the IRB chairperson and the VPAA/designee as to determine the potential impact to human research participants. The IRB chairperson and VPAA/designee may review any and all records and communications related to the research in question. If the research in question is determined to be compliant, then the IRB chairperson will issue a letter with the reasons for this determination and the research activities may recommence.

1. Noncompliance

Should the IRB chairperson and VPAA/designee determine that the research in question is noncompliant, but did not significantly increase risks or decrease benefits to the research participants, the IRB chairperson and VPAA/designee will issue a letter stating the reasons for this determination and outlining any corrective actions that must be undertaken by the investigator in order to bring the research activities into compliance and the research activities may recommence.

1. Serious Noncompliance and Continued Noncompliance

Should the IRB chairperson and VPAA/designee determine that the research in question is noncompliant AND has the potential to significantly increase risks or decrease benefits to the research participants, or if it is considered that there is a pattern of continued minor noncompliance, then the next step will be to convene the full IRB. Note, if research activities involving human participants are undertaken without IRB approval, this will immediately be considered serious noncompliance. A determination of continued noncompliance does not rest on any previous determinations, for example, if the investigator demonstrates a pattern of noncompliance within a short period of time. The convened IRB will make a judgment as to whether there was serious noncompliance or continued noncompliance, and it will make decisions on any corrective actions, modification to protocols, and/or need to terminate research activities. The convened IRB will review all supporting evidence and consider mitigating factors when making their decision on corrective action. Serious noncompliance/continued noncompliance may warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare or rights of the subjects or others. The IRB chairperson will issue a letter outlining the IRB’s decision, rationale for that decision, and any corrective actions needed.

1. Possible IRB actions

Possible IRB actions in cases of noncompliance may include but are not limited to:

* + Remediation or educational measures required of PI and research team.
  + Monitoring of research activities by appropriate person(s).
  + Notification of past or current research participants.
  + Re-consenting of participants.
  + More frequent continuing review/approval schedule.
  + Periodic audits by the IRB/VPAA or designee.
  + Restrictions to the PI’s research practice (e.g., limiting the privilege to minimal risk or supervised projects).
  + Suspension or termination of approval for one or more of the PI’s studies.
  + Reporting to federal agencies (OHRP and FDA), including funding agencies (e.g., NIH)
  + Removal of PI from study or all studies

Note that the role of the IRB is limited to reviewing research studies for compliance and mandating corrective actions. While the IRB will not be involved in any decisions related to academic status or employment, determinations of serious and continuing noncompliance can have other serious consequences.