



HRPP Policy Number: 301 Version: 6.0 Effective Date: 8/14/25	General Policies and Procedures	Supersedes Document Dated: 12/01/16, 01/23/18, 08/15/19, 08/17/21, 12/11/24
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3.1 Applicable Regulations and Laws

The purpose and responsibility of the Institutional Review Board (IRB) is to protect the rights and welfare of human research subjects. The IRB reviews and oversees research activities involving human subjects and requires that the research complies, as applicable, with Federal regulations at 45 CFR 46, Subparts A, B, C, and D, (or equivalent policies and procedures), the FDA 21 CFR Parts 50, 56, 312, and 812, any tribal laws passed by the official governing body of an American Indian or Alaska Native tribe, and all other pertinent regulations and guidelines. Compliance with this policy or the procedures set forth herein will in no way render inapplicable pertinent laws of the State of Colorado, any local law which may bear upon the proposed activity, or The University of Denver Rules or Regulations of the Board of Trustees. For research that is non-funded, participants are provided the same or equivalent protections.

3.2 Institutional Review Board

3.2.1 Purpose

Safeguarding the rights and welfare of subjects at risk in any research activity, whether financially supported or not, and irrespective of the source of any supporting funds, is primarily the responsibility of the institution. In order to provide for the adequate discharge of the institutional responsibility, all research activity involving human subjects may be undertaken by any faculty, staff, employee or student at The University of Denver (University) unless an IRB has reviewed and approved (or acknowledged for exempt research) the research prior to commencing the research activity.

3.2.2 Designation and Authority

The University has designated one IRB responsible for conducting initial and continuing reviews and providing oversight for all research activities involving the use of human subjects performed by agents or employees of the University. The scope of research reviewed by the IRB is not limited and the IRB reviews all types of research submitted.

The Institutional Official (IO) formally grants the IRB the following authority relative to the protection of human subjects:

1. To approve, require modifications to secure approval, or disapprove all research activities overseen and conducted by the agents of the organization and involving human subjects, based on its consideration of the risks and potential benefits of the research and whether the rights and welfare of the subjects are adequately protected;
2. To require reports for protocol continuing review as required and requested;
3. To continuously monitor the conduct of research with human subjects;
4. To suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected serious risk to subjects;
5. To place restrictions on a study, if necessary to protect human research subjects;
6. To observe, or have a third party observe, the consent process;
7. To observe, or have a third party observe, the conduct of the research.

No official within the organization may approve a protocol or human subjects research activity that has not been approved by the IRB. However, the IO or any other University executive administrative official may disapprove a protocol or research activity that has been approved by the IRB.

3.2.3 Composition and Appointment of the IRB

The IRB is a committee formally appointed by the IO, with input and membership nominations coming from the IRB Chair and IRB members, University department chairs and deans, and is composed of a sufficient number of members to assure complete and adequate review of



activities commonly conducted at the University. The composition of the IRB exceeds the minimum regulatory requirements and is sufficiently qualified through the maturity, experience, and expertise of their members and diversity (experience, expertise, racial, cultural, and gender) of membership to ensure respect for their advice and counsel specific to safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific activities, the IRB is able to ascertain the acceptability of proposals in terms of organizational commitments, regulations, applicable law, standards of professional conduct and practice, and community attitudes and are constituted to meet those requirements.

Scientific members of the IRB generally will have had experience in research involving human subjects, and will be recruited from among active research members of the University. Nonscientific members will be recruited from the faculty at large and will reflect professional expertise in a non-scientific area, such as law, ethics, human or patient rights, etc. The appointment of non-affiliated (community) members and a prisoner representative will also be done by the IO but the IRB Chair and the Research Integrity and Education Director are responsible for determining whether or not the nominees are truly unaffiliated and/or have appropriate expertise to serve as prisoner representative.

Alternates are appointed and function in the same manner as the primary IRB members. The alternate's expertise is comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received. The alternate member will not be counted as a voting member unless the primary member is absent. The IRB minutes will document when an alternate member replaces a primary member.

At times, the IRB may not have the necessary expertise to judge the scientific soundness of a research protocol and may be unable to make a fair and accurate determination of the risk-benefit ratio. For these protocols the IRB Chair, or the primary reviewer after consultation with the IRB Chair, may call upon an ad hoc consultant for assistance in review for scientific merit or to perform an in-depth review of the study. The ad hoc consultants are not considered to be members of the IRB, are utilized only for expert scientific review, have no voting rights and must disclose whether or not he/she has any conflicts of interest with the protocol. The consultants will submit a written report and copies of the report will be distributed to all IRB members. The report and recommendations will be documented in the IRB minutes for the meeting. It is expected that because of the wide diversity of IRB members, the use of ad hoc consultants will be a rare occurrence.

The IO may appoint administrative staff and/or faculty (e.g., legal counsel) at the University to serve as non-voting members of the IRB should the IO, the IRB Chair, or the Research Integrity Director decide that such persons would be of assistance to the IRB in conducting its duties. Individuals involved in the business function or in research development do not serve in any capacity on the IRB and have no involvement in the day-to-day operations of the review process. A non-voting member cannot be counted in the quorum and cannot vote, but can participate in discussions. In addition, funding agencies may have additional IRB membership requirements. For example, the National Institute on Disability and Rehabilitation Research (NIDRR) specifies that when an IRB reviews an NIDRR-funded research project that purposefully includes children with disabilities as research subjects, the IRB must include at least one person whose primary interest is the welfare of children with disabilities. When reviewing these types of research projects, the IRB may use ad hoc reviewers with specific expertise in treating children with disabilities.

The Research Integrity and Education Director will report changes in IRB membership to OHRP



as required.

3.3 Term of Appointment

IRB members are appointed to two-year, renewable terms. The IRB Chair is expected to hold the position for several years. Upon appointment and again at time of annual reappointment, each IRB member is queried to determine roster information such as affiliation status, relationship of the member to the University, indications of experience and other relevant information. IRB member's performance will be reviewed annually by the IRB Chair and the Research Integrity and Education Director. IRB members who are not performing in accordance with the IRB's mission or policies and procedures or who have an undue number of absences will not be reappointed. Feedback will be provided to the members, as needed, by the IRB Chair and/or by the Research Integrity Director.

3.4 IRB Chair and Vice Chair

The IRB will have a Chair appointed by the Senior Vice Provost for Research and Graduate Education. This individual will be a member of the faculty of the University as a tenured professor, be knowledgeable in human subjects research, including the federal and state regulations, University policies, and ethics relevant to such research. The IRB Chair shall preside over and be authorized to speak for the IRB.

Whenever the Chair is not available, a Vice Chair will be appointed by the IRB Chair and the Research Integrity and Education Director from the current IRB roster of members who meet the criteria for serving as the IRB Chair and assume the responsibilities of the IRB Chair during the period of their absence.

3.5 Meetings

In order to conduct IRB business, there must be a quorum of members present at a convened meeting. If quorum is lost, votes are not taken until it is restored. To be approved, a protocol must receive a majority of votes of members present at the meeting. The IRB shall hold regular meetings at a time and place to be determined by the IRB and posted electronically. Researchers may be invited to attend the meetings to address specific concerns regarding research protocols but will be asked to leave the meeting during all deliberations and votes. Other members of the University community are permitted to attend meetings but must request attendance through the IRB Compliance Analyst, Research Integrity and Education Director and/or IRB Chair. Guests who are allowed during the deliberations and voting portions of the convened meeting will be asked to sign a confidentiality agreement.

Prior to each full board meeting the IRB Compliance Analyst or other designee will assign primary reviewer(s) knowledgeable about or experienced in working with these types of studies. The IRB Compliance Analyst ensures that either the Primary or Secondary Reviewer is present at the meeting or available by teleconference during the convened meeting.

3.5.1 IRB Teleconference Meetings

A convened IRB meeting may be conducted via teleconferencing if the same requirements for conducting an in-person meeting are implemented. A quorum of members must be maintained during the conference call. If quorum is lost, votes are not taken until it is restored. To be approved, a protocol must receive a majority vote of members present at the meeting and be documented through a roll call process. If applicable, researchers may be invited to call in to address specific concerns regarding research protocols and will be placed in a virtual waiting room until the board invites them to join the meeting but will be asked to end the call and exit the virtual meeting during all deliberations and votes. To conduct a teleconference meeting, all members must be provided, in advance, an agenda and be granted access to all study-related materials for protocols listed on the meeting agenda. Minutes of a teleconference meeting will be written and



maintained as outlined in section 3.6 IRB Meeting Minutes.

3.6 IRB Meeting Minutes

IRB meeting minutes are recorded in writing in sufficient detail to allow an outside observer to reconstruct protocol-specific discussions and determinations. The IRB Compliance Analyst monitors quorum at each meeting and records IRB discussion points for the minutes. Meeting minutes are distributed each month to all IRB members. The IRB Compliance Analyst, via a secure website, will post a draft of the minutes for the Research Integrity and Education Director and the IRB Chair to review for comments and/or suggested changes regarding the document's accuracy. After all comments are reviewed and addressed, a pending version of the minutes are available for review by the IRB members who were in attendance at the given meeting, prior to and for discussion at the next IRB meeting. A vote for approval of the final version of the minutes occurs at the next convened meeting. Once approved, a copy of the approved minutes will be posted in the IRBNet system in order to document all actions taken by the IRB.

Minutes shall include:

1. A protocol summary and the deliberations for each protocol and the resulting IRB action.
2. The approval period for each initial review, continuing review and amendment.
3. A record of attendance for each protocol including the names of members who left the meeting due to a conflict of interest and a notation of such.
4. The voting record for each protocol and the previous meeting's minutes reflecting the number of members for, against or abstaining from the vote and when alternate members replaced a primary member.
5. The basis for requiring changes to a protocol, tabling or disapproving research.
6. A written summary of the discussion and resolution of controverted issues.
7. Justification of deletions or substantive modifications of information concerning risks or alternative procedures contained in an HHS-approved consent form.
8. If applicable, summaries of deliberations of protocols for inclusion of vulnerable populations.
9. If applicable, the rationale for significant risk/non-significant risk device determinations.
10. If applicable, protocol-specific justifications for waivers of consent and research involving vulnerable populations.
11. A list of all actions that were taken administratively during the previous month.

3.7 Confidentiality of the Review Process

During the process of initial, continuing review, or amendment of an activity, material provided to the IRB shall be considered privileged information and the IRB shall assure the confidentiality of the data contained therein.

3.8 Conflict of Interest

3.8.1 IRB Members – Convened Meeting

The IRB is charged with protecting research subjects from risks in experimental studies. Principles codified in the Nuremberg Code, the Declaration of Helsinki, Belmont Report, and existing federal regulations are employed to provide a framework for ethical considerations and assessment of risk and benefit in individual studies. The decisions made by the IRB are guided by these principles, but the IRB can only be successful if members are free of conflict of interest (COI).

Prior to discussion of protocols at a convened meeting, the IRB Chair will ask if any member has a COI with any protocol being discussed at that meeting. Should an IRB member declare involvement in any way in a research protocol under review by the IRB, or state a COI with the research protocol the following is required:



1. IRB member is excluded from discussion and voting except to provide information requested by the IRB.
2. IRB member leaves the meeting room during discussion and voting.
3. IRB member is not counted towards quorum.

3.8.2 Designated Reviewers for Expedited Review

IRB members (including experienced IRB staff members) who have been designated by the IRB Chair as reviewers for initial or continuing review of research protocols, reports of noncompliance, protocol deviations, unanticipated problems, and amendment requests that qualify for expedited review will self-identify any COI that they may have with the research or PI. In such cases, the review responsibility will be reassigned to another experienced IRB member.

3.8.3 Examples of IRB Member COI

IRB members are considered to have a conflict of interest if they:

1. Are involved in the design, conduct, or reporting of the research study.
2. Have direct administrative powers over the investigators or the study.
3. Are reviewing a proposal from a position who may determine promotion or merit (e.g. reviewing a protocol by the chair of your department or dean of your school).
4. Have a financial and/or ownership interest of any amount in or related to the research and the value can be readily determined.
5. Have a financial and/or ownership interest in or related to the research but the value cannot be readily determined.
6. Received or will receive compensation and/or have ownership interest of any amount with value that may be affected by the outcome of the study.
7. Have received in the past year, currently are receiving, or will receive from the sponsor of the study, honoraria, payments, or compensation of any amount.
8. Have a proprietary interest in the research, including but not limited to a patent, trademark, copyright, or licensing agreement.
9. Serve as directors, board members, scientific advisors or hold other decision making positions in the entity sponsoring the research.
10. Are not an investigator, co-investigator, or consultant on a study, but are closely associated with the investigators on the study being reviewed, or other studies.
11. Have personal, familial, or intimate relationships with the principal investigator.
12. For any reason, believe they cannot be objective concerning a study.

3.8.4 Principal Investigator

All PIs and their research staff are required to disclose any financial COI according to the University COI policy. Disclosed COIs that might affect the protection of subjects must have a management plan in place. Management plans may include: partial or complete divestment, limiting involvement of the conflicted individual, additional oversight, or disclosure. Disclosure alone cannot be used to manage conflicts of interests that might affect the protection of subjects.

When made aware of a possible researcher conflict, the IRB formally refers cases to the Research Integrity and Education Director, which in turn determines if formal COI management strategies are required. If required, a draft COI Management Plan will be prepared by the RIE Director and Institutional Official (IO). The IO and RIE Director will work with the researcher to develop and finalize a COI Management Plan. When finalized, the COI Management Plan will be submitted to the IRB for documentation in the electronic protocol system.

3.9 Interaction with Other University of Denver Components and Commencement of Research Activities



The University is comprised of multiple types of research review and some reviews are accomplished by standing committees, (e.g., Institutional Biosafety Committee (IBC)). The successful fulfillment of the University's intent to protect human research subjects is dependent upon open communication among these various institutional components. Committees and offices exchange information, when necessary, to assure that, in addition to IRB review, human subjects research receives all appropriate review prior to implementation of the research activities. Human subjects research is not allowed to commence until all applicable reviews are complete and notification of approval is received by the IRB.

3.10 Types of Research Conducted at the University

The majority of research at the University is social-behavioral in nature. The University does not participate in planned emergency research described in and covered under 21 CFR 50.54 and OHRP Guidance 97-01.

3.11 Categories of Research Subjects

Human subjects research at the University generally includes normal healthy individuals; adults and/or children. The IRB reviews and approves research proposing inclusion of vulnerable populations. The vulnerable populations most commonly included in research activities are children, prisoners, pregnant women, decisionally impaired adults, and economically or educationally disadvantaged individuals.

3.12 Determining if IRB Review is Required

3.12.1 Determination of Human Subjects Research

Most of the time, it will be obvious whether or not the University and a PI are engaged in human subjects research. However, at times, different determinations will need to be made to determine if the proposed activity constitutes *engagement in human subjects research*, whether or not the activity proposed is *research* (for HHS supported studies) or a *clinical investigation* (for FDA regulated studies). The second determination to be made is whether or not *human subjects* are involved. The determination is made by using the appropriate definitions found in HRPP Policy 201 of this manual. The Office of Research Integrity & Education will also accept and provide guidance for making determination requests by having PIs complete the [Human Subjects Research Determination Form](#) and submitting the form for review. In addition to the Human Subjects Determination Form, information required to make a determination includes providing a description of the activity, submitting all survey or questionnaire documents, and providing data collection methods and describing the research setting. Additional information may be requested to further assess the research project. Once a determination is made, it is the responsibility of the PI to contact the IRB if the proposed activity changes and the project may require IRB oversight.

According to HHS regulations, the University becomes engaged in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes, or (ii) obtain individually identifiable private information or identifiable biospecimens about those individuals for research purposes. Under FDA regulations, the institution becomes engaged in human subjects research when it undertakes a clinical investigation on individuals who are or become subjects in the investigation, either as recipients of a test article or as controls and may be either patients or healthy non-patients.

PIs are automatically considered to be "engaged" in human subjects research whenever they apply for or receive a direct award to support research that includes human subjects, even if all the activities involving human subjects will be carried out by a subcontractor or collaborator. In all cases the institution to which the grant has been awarded bears the responsibility for protecting human subjects under the award.



3.12.2 Course-Related Projects

All activities meeting any one of the definitions of human subjects research and carried out at the University of Denver must be reviewed and approved by the DU IRB prior to the start of the activities. The University also recognizes that some student projects conducted to fulfill course requirements involve activities that, in a different context, might meet the definition of human subjects research. Student class assignments, as a general rule, are not systematic data collection efforts intended to develop or contribute to generalizable knowledge so do not meet the federal regulatory definition of research. Therefore, as a rule, student class assignments do not fall under the jurisdiction of the IRB and do not require an IRB application, an approval, or oversight. It is the policy of the University to not require IRB review of course-related research projects that are designed to teach students research methods **except for the following**:

- Doctoral dissertations;
- Funded research;
- Research conducted through collaborations external to DU;
- Master's theses, and
- Senior Honors theses

These research methods must be reviewed and approved by the IRB before students may begin their research.

3.12.3 Oral History Projects

The following is based on guidance received from OHRP:

A decision whether oral history or other activities solely consisting of open ended qualitative type interviews are subject to the policies and regulations outlined in an institution's Federalwide Assurance (FWA) and HHS regulations for the protection of human research subjects (45 CFR 46) is based on the prospective intent of the PI and the definition of "research" under HHS regulations at 45 CFR 46.102(d): "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Specifically, for the purposes of this policy in order to be subject to the University's human research protections policies, the activity must meet the following standards and general principles for evaluating Oral History type activities:

1. The activity involves a prospective research plan which incorporates data collection, including qualitative data, and data analysis to answer a research question; and
2. The activity is designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.
3. Oral history activities, such as open ended interviews, that only document a specific historical event or the experiences of individuals without intent to draw conclusions or generalize findings would not constitute "research" as defined by 45 CFR 46. For example, an oral history video recording of interviews with Holocaust survivors is created for viewing in the Holocaust Museum. The creation of the video take does not intend to draw conclusions, inform policy, or generalize findings. The sole purpose is to create a historical record of specific personal events and experiences related to the Holocaust and provide a venue for Holocaust survivors to tell their story.
4. Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings) would constitute "research" as defined by 45 CFR 46. For example, an open ended interview of surviving Gulf War veterans to document their experiences and to draw conclusions about their experiences, inform policy, or generalize findings would require IRB review and approval.
5. Oral historians and qualitative investigators may want to create archives for the



purpose of providing a resource for others to do research. Since the intent of the archive is to create a repository of information for other investigators to conduct research as defined by 45 CFR 46, the creation of such an archive would constitute research under 45 CFR 46.

PI's are advised to consult the IRB Office regarding whether their oral history project requires IRB review and approval.

3.12.4 Use of De-Identified Secondary Data

By federal regulation, existing (or secondary) data are defined as data that existed "before the research is proposed" to an institutional official or the IRB. This provision is frequently interpreted as data that were "on the shelf" at the time the protocol was written. Existing data include both those provided to the investigator from any source; and those already in the possession of the investigator.

Using the following types of public data does not constitute federally-regulated human subject research and requires no further action with the IRB.

- Data that is not about living individuals (examples: historical records of deceased individuals, death records, historical archives)
- Publicly available data; i.e. data with identifiable but not private information. (examples: individual public records such as address, phone number, property value; data found on unrestricted website, in publications, phone books, political campaign contributions, or obtained through a Freedom of Information Act request).
- A project that merges public datasets with other datasets containing private information may enable the identification of individuals and requires IRB review.

Secondary data analysis that may not require IRB review

- Non-public, de-identified or anonymous data
- Use of the following types of non-publicly available datasets does not constitute federally-regulated human subjects research, if the provider of the data is NOT involved in the design, conduct or reporting of the research, including sharing any authorship rights:
 - Datasets that are anonymized or
 - Datasets that include coded private information, such that the investigator has not access to identifiable information. In such cases, no further action with the IRB is required.

Investigators are advised to have on file a confidentiality statement from the data provider stating that identifiers were not included in the dataset that they received. (example: de-identified data given by a colleague or provided by a data provider where no collaboration is expected)

- Non-public, identifiable data, but where research does not record, retain, or use identifiers.
- Use of datasets that contain private, identifiable data, but from which no identifiable information will be recorded, retained or used by any member of the research team in a manner that allows the direct or indirect identification of individuals, may be eligible for exemption from IRB review. Investigators are required to submit an IRB Application.

Investigators should include a data security plan that clearly describes measures to ensure that individuals cannot be identified, including the process for de-identifying information.

- Non-public, identifiable data where research has access to and records private identifiable information.



- Use of non-publicly available data when members of the research team or their collaborators have access to and plan to use private identifiable information about living individuals, is considered human subjects research requires review by the IRB. Investigation using such data are required to submit an application to the IRB.

Written Agreement for Restricted Access or Licensed Data

An investigator planning to obtain data under contractual terms, such as a restricted access data agreement or licensed data agreement, must utilize a data use agreement that is reviewed and signed by an authorized DU signatory official. DU representatives will negotiate the terms of that agreement on behalf of the University. DU investigators are not authorized to sign data use agreements.

3.13 Coded Private Information as Relates to Human Subjects Research

The OHRP does not consider an institution or PI to be engaged in human subjects research if the PI consults or collaborates on human subjects research by obtaining coded private information or human biological specimens from another institution, engaged in the research, which retains the code. However, one of the following four conditions must be met:

1. The key to decipher the code is destroyed before the investigator receives the coded information.
2. The consulting or collaborating PI and the holder of the key enter into an agreement prohibiting release of the key under any circumstances.
3. The releasing institution has IRB-approved written policies and procedures applicable to the research project that prohibit release of the key to consultants or collaborators under any circumstances.
4. There are other legal requirements prohibiting release of the key to consultants or collaborators.

OHRP also does not necessarily consider authorship as a factor in determining whether or not an institution is engaged in human subjects research. It is possible that the authors of a paper or presentation were not involved in obtaining “data about subjects of the research through intervention or interaction with them” or “identifiable private information about the subjects of the research.” If a PI simply receives unidentifiable or coded information about human subjects, OHRP has determined that analysis of the information and/or publication of conclusions based on analysis of the information does not constitute being engaged in human subjects research.

3.14 Collaborative Activities

The IRB shall have special responsibilities in the review and approval of proposals involving collaborative activities. Collaborative activities are those in which the University faculty, staff or students, obtain access to human subjects involved through one or more collaborating institutions, or when PIs from collaborating institutions obtain access to human subjects at the University.

When a PI plans to conduct research at a site external to the University, the PI must respond to questions in a protocol application that informs the IRB of:

1. The contact information of the site(s);
2. Whether the site(s) has an IRB;
3. Whether the site(s) has granted permission for the research to be conducted and;
4. If the site has an IRB, has the IRB approved the research or does the site plan to defer to the DU IRB.

For research that will be conducted off-site, the IRB requires a letter from an appropriate official from that site, i.e. schools, prisons, non-profit service organizations, when they are partners in a research project. If the research will be conducted outside the U.S., it is required that the PI obtain appropriate authorization and observe any local laws and regulations established in the



foreign country. Depending on the location, identifying a local partner when conducting international research may also be required.

3.14.1 IRB Authorization Agreements (IAAs)

If an external site defers, or cedes to the DU IRB, the site must submit a request to rely on the DU IRB as the IRB of record.

If a non-DU affiliated investigator, defined as an individual who is affiliated with another academic institution or organization that maintains a Federalwide Assurance with the federal government, collaborates on an exempt research project with a DU investigator, the unaffiliated investigator must obtain IRB approval from their own institution's IRB. A reliance agreement, also referred to as an IRB Authorization Agreement (IAA), will need to be executed between DU and the external site before a non-exempt research project can be initiated.

The Reliance Agreement is a document that delineates the specific roles and responsibilities of each participating institution. The DU Office of Research Integrity & Education, in coordination with the Institutional Official, determines whether ceding IRB review is appropriate on a case-by-case basis.

If a DU investigator requests to cede to another institution's IRB, the following considerations will be used to make a final determination:

- The role of the DU personnel is limited to activities such as data analysis, consultation, or other administrative roles;
- The study is minimal risk and the role of DU personnel is either limited or very straightforward (e.g. administration of a single survey, assisting with recruitment of subjects);
- If the project is externally funded, DU is not listed as the primary awardee.

DU will not typically consider ceding IRB review for certain types of studies, including, but not limited to, the following:

- DU serves as an enrolling site or coordinating center for a non-industry sponsored clinical trial with some exceptions (e.g. select cooperative group protocols) or is listed as the primary recipient on the grant or funding source;
- The study is more than minimal risk and the role of DU personnel is substantial (e.g. interaction with subjects, conduct study procedures);
- The proposed IRB of record does not have sufficient knowledge of local context (as required by federal guidelines) to assume IRB oversight for sites that fall under DU purview;
- A DU study team member has a conflict of interest that requires a management plan and the management plan prohibits or limits activities that the individual can engage in related to human subjects research;
- The study likely qualifies as an exemption; and/or
- Studies for which administrative or campus policies otherwise prohibit or limit options for IRB reliance.

Study teams who wish to have DU cede to another IRB a formal request must be submitted and the proposed IRB of record must be contacted to inquire whether they are willing to serve as the IRB of record for the study. Not all IRBs will agree to serve as IRB of record for another institution. An IRB Authorization Agreement will also need to be signed by a DU Authorized Signatory Official and the other institution's signatory official.

For PIs performing research in which the University is the lead or coordinating institution, the PI should note in the initial IRB application that the University is the lead or coordinating institution of



a multi-site study. The PI should also provide the following information:

1. The name(s) of each participating institution that will be engaged in human subjects research.
2. Confirmation that each participating institution has an FWA.
3. The contact name and information for the PI at each institution.
4. The contact name and information for the IRB of record at each institution.
5. The method of multilateral communication between institutions/IRBs of any unanticipated problems involving risks to subjects or others and other study related information.

The researcher should also upload copies of IRB approved documents and relevant correspondence between participating sites.

3.14.2 Individual Investigator Agreements (IIA)

If a non-DU affiliated **independent investigator**, defined as an individual who does not work at another academic institution, organization, or entity that has a Federalwide Assurance (FWA) with the federal government, collaborates with a DU investigator on a research project, an Individual Investigator Agreement will be required. The IIA must be included in the IRB application for IRB review and approval.

The Individual Investigator Agreement is a document that outlines the specific roles and responsibilities of the independent investigator verifying that the non-DU affiliated investigator will comply with the standards and requirements of the Belmont Report and the HHS regulations for the protection of human subjects along with the relevant institutional policies and procedures. The DU investigator is responsible for the primary oversight of the independent investigator and for ensuring all regulations and policies are followed by this individual if added to their research protocol.

3.15 Undue Influence of the IRB or Research Integrity & Education Staff

It is the policy of the University that the human subjects research review process and implementation of IRB policies and procedures are conducted objectively and without undue influence over deliberations or processes. Individual members of the IRB whether employed by the institution or community members, have the right and obligation to report any undue pressure upon them to make decisions that would favor an individual PI over subject protections, during the initial and continuing review processes or when conducting or participating in other IRB related business. The IRB member or staff person is asked to document the issues related to the case in writing to both the Research Integrity & Education Director and the IO in order to open a formal report. The IO will formally review the information and may convene a meeting and/or otherwise obtain additional information as necessary. The Research Integrity & Education Director will then subsequently inform the IRB of the findings. The IO has the authority to take corrective action in consultation with the IRB.

Upon resolution, the IRB will determine if the attempted, inappropriate influence represents an unanticipated problem involving risks to subjects or others and will determine if reporting to OHRP is appropriate.

3.16 Training Requirements

3.16.1 Researchers and Research Staff

The University IRB policy requires training for all faculty, faculty mentors, researchers, and students, including researchers from other institutions who wish to conduct human subjects



research at the University. All key personnel (PI, Co-PI, Faculty Sponsor), originally listed or later added to a study through an amendment, must complete the required human subjects training. In order to comply with the policy, researchers are required to complete the University's training affiliated with **Collaborative Institutional Training Initiative (CITI)** (modules relating to ethics, regulations, risk assessment, informed consent and privacy and confidentiality). Based on the type of research conducted, additional training modules may be required. Completion of this training must be accomplished every four years. Protocol submissions (initial, continuing, amendments) are checked to make sure all researchers and research staff have completed training. For student investigators, the faculty sponsor must also complete and maintain valid training per the IRB policy. Protocol actions are not approved until training is completed by all listed on the protocol.

3.16.2 IRB Members and Chairs

IRB members and their alternates and the chair must complete the required human subjects training upon being appointed to the IRB and every four years for the duration of their membership. Initial training consists of modules relating to their service as IRB members. At the time of initial appointment, IRB staff will also provide IRB orientation information (meeting schedules, locations, etc.)

As a part of annual evaluation of members, the IRB staff provides the Chair with the training status for all members. Members in need of completing their training are reminded by the IRB Compliance Administrator of this requirement. Failure to complete the training may result in removal from the IRB. Continuing educational materials are distributed at IRB meetings in the form of relevant periodicals or articles. Webinars and local conferences are made available to the members to attend.

3.16.3 Research Integrity & Education / IRB Staff

IRB staff must document that they have completed the CITI training. Attendance at regional and national meetings, (e.g., PRIM&R) is encouraged and supported for IRB staff. Research Integrity & Education staff are encouraged to attend any additional training, such as webinars, that are offered.

3.17 Roles and Responsibilities

3.17.1 Principal Investigators

The following are the PI responsibilities and are not all inclusive:

1. As the Principal Investigator, assure that all faculty and staff personnel listed on the IRB application have completed the required Human Research Protections training.
2. If the project is federally-funded, any University employee serving as a co-investigator or any other person at DU who is responsible for a portion of the design and conduct of instructional, research, service activities, or any other sponsored activity have submitted an annual Research Financial Conflict of Interest disclosure and has valid Conflict of Interest training and Responsible Conflict of Interest training.
3. Assure that any students listed as Principal Investigators on the research protocol have completed the human subjects research training and their Faculty Sponsor have completed the valid training per IRB policy.
4. Submit protocols for IRB review and approval of proposed research activities prior to commencing the research activities.
5. Employ sound study design in accordance with standards of the PI's discipline.
6. Assure that adequate time and resources are present before conducting a research study to assure participant protections.
7. Maintain appropriate oversight of each research study, as well as research staff, and appropriately delegate research responsibilities and functions.
8. Make sure that the research is conducted according to the protocol, any signed



- agreements, in compliance with all applicable laws and regulations and organizational policies and procedures with the highest of ethical standards.
9. Submit for review and approval all proposed protocol and consent form changes prior to implementing the changes in the protocol except where necessary to eliminate apparent immediate hazards to human subjects.
 10. Obtain legally effective informed consent from subjects prior to commencement of research activities, unless the requirement is waived by the IRB.
 11. Ensure the rights, safety and welfare of the research subjects are upheld and protection of a study, honor all commitments that were agreed to as part of the approved research, e.g., providing information about the study results to research subjects or honoring commitments for reimbursements to subjects.
 12. Upon completion of a study, submit a Closure Report to the IRB.
 13. Update financial conflicts of interest disclosure at least annually and within 30 days of acquiring a new significant financial interest (SFI).
 14. Retain records as required by the regulations, the sponsoring entity and local policy for the appropriate time period.
 15. When PI is the lead researcher for a multi-site study, applications must include information about the management of information that is relevant to the protection of research participants, e.g., interim results; protocol modifications; how unanticipated problems involving risks to participants or other unanticipated problems will be managed.; how communication of unanticipated problems to all sites will occur; how protocol modifications will be managed; is there a formal agreement in place delineating each site's roles and responsibilities.
 16. If the PI holds an IND/IDE, adhere to sponsor responsibilities in addition to investigator responsibilities as per 21 CFR Parts 312/812.
 17. If appropriate, assure that applicable clinical trials (includes some of the NIH funded trials) are registered on the governmental database at <http://www.ClinicalTrials.gov>. Applicable clinical trials are defined by Federal Statute (Public Law 110-85) and completes the required Good Clinical Practices (GCP) training. Generally, these trials include:
 - a. Trials of Drugs and Biologics: Controlled clinical investigations, other than Phase I investigations, of a product subject to FDA regulation; and
 - b. Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric post-market surveillance.
 18. Address research participant's concerns, complaints, or requests for information.
 19. Follow reporting requirements for problems that require prompt reporting (see [Section 24](#)).
 20. Submit requested data at specified times for continuing review, as determined by the IRB, of ongoing research activities.

3.17.2 Faculty Sponsors

The responsibilities for a Faculty Sponsor (FS) are equivalent to those for a principal investigator and should not be accepted lightly. Acting as a FS is time-consuming and requires an enthusiastic commitment to the students and to the research project. The FS must be actively involved in the research, from protocol design to data analysis and report preparation. In many cases, it may be the student's first experience with formal research. The success of the student's experience will be measured not only in the outcome of their projects, but also in what they learn from the faculty sponsor. These experiences will help form their perception of scientific research, and in some cases, determine whether a career in academic research is right for them. The following are the faculty sponsor responsibilities and are not all inclusive:

1. Advise the student on the selection of a topic, the content and preparation of their research proposal. Understand the research hypothesis, goals and methodology. Guide and interact with the student throughout the research project.
2. Assist the student with the preparation of the IRB application. Complete and sign forms



- as required. Ensure the student obtains all necessary approvals (i.e., IRB) before initiating the project, implementing any changes in the research activities and continuing the research activities after an approval has been granted.
3. Serve as the IRB protocol Principal Investigator for any ongoing research when the student leaves the institution prior to completing the research protocol.
 4. Ensure that the student is provided with, or has access to, information on University policies relating to the administration of their protocol.
 5. Assure the student understands the underlying ethical principles for conducting research with human subjects and the applicable research regulations and local policies, and procedures. Stay abreast of the status of the protocol and ensure ongoing compliance with federal regulations and institutional policies and procedures relating to human subjects research and IRB required reporting.
 6. Ensure that all study documents and data are archived at the end of the study in accordance with federal, state and local policy and regulations.
 7. Be available to the student during the active research period.
 8. Complete and maintain valid human subjects research training per IRB policy.

3.17.3 Institutional Official

The IO is designated by the Provost to have responsibility for the Institutional Review Board (IRB) with the authority to delegate activities as may be necessary to fulfill the following responsibilities:

1. Assure compliance with institutional policies and all applicable regulations for the protection of human research subjects.
2. Is legally authorized to represent the institution in matters regarding human subjects research and is the signatory authority for all the Federal-Wide Assurance to the Office for Human Research Protections.
3. Responsible for review and evaluation of reports on HRPP performance and QI activities.
4. Responsible for further institutional review and approval or disapproval of research approved by the University IRB (neither the IO nor any other University official can approve research that was disapproved by the IRB).
5. Reviews copies of all IRB meeting minutes containing the results of QI audits, and noncompliance findings and other issues as needed.
6. Signs all correspondence and reports sent to federal regulatory agencies regarding PI or institutional noncompliance.

3.17.4 Institutional Review Board

IRB main responsibilities are to safeguard the rights and welfare of subjects as follows, and are not all inclusive:

1. Conduct review of initial protocol submissions, continuing reviews, and all revisions to protocols of human subjects research conducted by the University researchers.
2. Approve, require modifications to secure approval, defer (table), or disapprove research activities overseen and conducted under the auspices of the University, regardless of the location of the research activities.
3. Systematically analyze protocols for benefits to subjects and importance of knowledge to be expected and assess the potential benefits in relation to the potential risks involved in the research.
4. Report in writing the findings and actions of the IRB to the PIs, IO, and, when applicable, to federal regulatory agencies or departments, as necessary.
5. Determine the interval at which ongoing studies need to be reviewed by the IRB.
6. Determine which studies need verification from sources other than the researchers that no material changes have occurred since the previous IRB review.
7. Observe, or have a third party observe, consent processes and/or the conduct of research.
8. Ensure prompt reporting of any changes in research activities to the IRB by



researchers.

9. Ensure prompt reporting, by PIs, to the IRB and/or federal agencies or departments (where applicable) of:
 - a. Unanticipated problems involving risks to subjects or others.
 - b. Serious or continuing noncompliance with regulations.
 - c. Suspension or termination of IRB approval.
10. Determine if studies involving drugs need an investigational new drug (IND) number designated by the FDA.
11. Determine if studies involving investigational devices pose significant or non-significant risk and whether an IDE is required.
12. Suspend or terminates approval of research not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to subjects.

3.17.5 IRB Chair and Vice Chair

The IRB Chair's main responsibilities are as follows and are not all inclusive:

1. Serve as public spokesperson for the IRB.
2. Chair convened meetings of the IRB.
3. Ensure adequate expertise for review and determinations.
4. Review protocols, continuing review reports, unanticipated problem and deviation reports, and other documentation submitted to the IRB.
5. Obtain an individual vote on all IRB actions (For, Against, Abstain).
6. Vote on each IRB action.
7. Delegate review responsibilities as necessary and applicable.
8. Maintain up-to-date knowledge of human subjects regulations and pertinent events.
9. Consult with investigators as necessary.
10. Suspend the conduct of research when individuals are placed at an unacceptable level of risk.
11. Collaborate with the Research Integrity Director to provide continuing education for IRB members.
12. Collaborate with the Research Integrity Director to resolve IRB-related issues with faculty or subjects.
13. Recognize and support partnership with ORI to assure IRB efficiency and effectiveness.

3.17.6 IRB Members

IRB members responsibilities are as follows and are not all inclusive:

1. Be familiar with IRB policies and procedures and federal, state, and local regulations policies or guidelines relating to human subjects research.
2. Review submitted proposals as assigned by the Chair or Chair's designee.
3. Review meeting documents in advance of IRB meetings and be prepared for discussion of submitted protocols.
4. Act as a primary or secondary reviewer of protocols when assigned.
5. Maintain confidentiality of IRB proceedings.
6. Disclose conflicts of interest, as applicable.

3.18 Monitoring/Verification of Compliance from Sources Other than the PI

In accordance with 21 CFR 56.108(a)(2) (FDA) and 45 CFR 46.103(b)(4)(ii) (OHRP), it is incumbent upon the IRB to assure itself, by whatever method it deems appropriate, that the rights and welfare of human subjects are being protected. This applies to international research and research taking place in other states and in Colorado. In doing so, the IRB may determine that it is appropriate to use sources other than reports from the investigator to verify that no material changes in the protocols have occurred since their most recent review, and that investigators are conducting the research in compliance with all regulations, laws (domestic and international), policies, and guidelines. Also, the IRB may determine that the consent process for some higher



risk protocols should be observed.

To assess whether there have been no material changes in the protocols as stated above, the IRB may request that members of the IRB and/or IRB staff conduct an observational visit for a specific protocol. This review will help ensure that investigators are not implementing protocol changes prior to IRB review and approval, except when necessary to eliminate apparent immediate hazards to subjects.

3.19 Contacts for Questions, Concerns, Complaints or Input

Faculty, research staff, students, and research subjects or any other person who has a question, concern, complaint, suggestion, or input regarding the HRPP or feels that they have been subjected to coercion or undue influence regarding aspects of human subjects research, or feels that they have observed issues of concern regarding human subjects research, may contact:

University of Denver Institutional Review Board
Phone: (303) 871-2121
E-mail: IRBAdmin@du.edu

OR

Anonymous Compliance/Ethics Reporting Hotline
Phone: 866-780-0002
Email: reports@lighthouse-services.com

Any and all concerns, complaints, input or suggestions regarding the Human Research Protection Program and all allegations of coercion, undue influence or noncompliance are thoroughly investigated and, if applicable, corrective actions taken to rectify the situation. Ultimately, the Research Integrity & Education Director is responsible to assure that all concerns, complaints, and allegations have been addressed appropriately and that input and suggestions related to the HRPP are considered when reviewing the program. If it appears that the concern/complaint could be an incident of noncompliance, further inquiry will follow procedures delineated in [Section 22](#). If the concern/complaint appears to involve an unanticipated problem involving risks to subjects or others, it will be reviewed according to [Section 9](#) of this manual.

3.20 Record Retention Policy at the University of Denver

In order to allow a reconstruction of a complete history of IRB actions related to the review and approval of protocols, the IRB records include copies of:

- Protocol applications, research protocols, consent documents and all other documents submitted for review of proposed human subject research
- Scientific evaluations, when provided by an entity other than the IRB
- Progress reports submitted by researchers
- Reports of injuries to participants
- Data and safety monitoring reports, if any
- Modifications to previously approved research
- Unanticipated problems involving risks to subjects or others
- Documentation of noncompliance
- Significant new findings

Records related to IRB operations (as well as research related records) are retained for at least three years. Acceptable storage for research records must be maintained as outlined in the study protocol describing data security (i.e. on a password-protected computer or in a secured, locked cabinet).