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Reviewed and Approved by: Tyler Ridgeway, Director, Research Integrity & Education	Reviewed and Approved by: Julia Dmitrieva, PhD, DU IRB Chair	

Section 4: Initial IRB Review of Research Activities

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4.1 Governing Principles/Regulations

The IRB will evaluate each proposed human subjects research project on an individual basis to assess whether or not the investigator is adequately protecting the rights and well-being of the subjects. The governing principles for the IRB derive from those described and discussed in the Belmont Report. The governing regulations for the IRB are 45 CFR Part 46 and 21 CFR Parts 50, 56, 312, 600 and 812.

4.2 Initial IRB Review at a Convened Meeting

4.2.1 Submission and Review Schedule



If the proposal meets all requirements for full board review, the following is required to be electronically submitted and included in the submission package:

1. A complete IRB application with an electronic signature of the Principal Investigator (and faculty sponsor if student investigator) describing the rationale for the study, research questions to be answered, information that allows the IRB to determine whether selection of participants will be equitable, methods, procedures, data analysis plan, and other required information that will allow the IRB reviewer(s) to conduct an analysis of the risks and potential benefits.
2. An informed consent document
3. Training Verification (CITI profile linked to IRBNet profile for all research staff)(See [HRPP Policy 301, section 3.16 Training Requirements](#)).
4. Recruitment materials; i.e., flyers, posters, web pages, email messages, etc.
5. Copies of all instruments if the study involves the use of questionnaires, surveys, or similar instruments.

If applicable:

7. Waivers of Informed Consent or Waivers of Written Documentation of IC
8. Letters of support for external sites.
9. Review/confirmation from the Institutional Biosafety Committee (IBC) or other committee as needed.
10. Reliance Agreement requests
11. Data Safety and Monitoring Plan
12. Copy of the Health & Human Services (HHS) grant application – Human subjects section.

4.2.2 Data and Safety Monitoring Plans

Research studies in which subjects are at greater than minimal risk of experiencing physical or psychological injury (e.g., clinical/biomedical or behavioral studies that deliver an intervention to subjects) must consider how study data will be monitored and unanticipated problems addressed to assure the ongoing safety and well-being of subjects during the study. In these types of studies, a Data and Safety Monitoring Plan (DSMP) that addresses the following must be submitted:

1. Type of data or events that are to be captured under the monitoring provisions. The monitoring provisions should be tailored to the expected risks of the research, the type of subject population being studied, the nature and size of the study, and the complexity of the research protocol.
2. Frequency of assessments of data or events captured by the monitoring provisions (e.g., at certain points in time or after enrollment of a certain number of subjects).
3. Entity or person(s) responsible for monitoring the data collected, including data related to protocol deviations, and unanticipated problems and their respective roles in the research activities (i.e., investigators, research coordinators, statisticians, independent medical monitor, etc.).
4. Procedures for analysis and interpretation of the data.
5. Time frames for reporting protocol deviations and unanticipated problems to the monitoring entity.
6. Definition of specific triggers or stopping rules that will dictate when action is required and what the range of possible actions is.
7. Reporting mechanisms/procedures for the data monitor and others responsible for communicating with the IRB, the study sponsor, the investigators and other appropriate officials the outcome of the reviews of the monitoring entity.

4.2.3 Assignment of Primary and Secondary Reviewers

IRB Administrators will assign each protocol to an IRB member who, as primary reviewer, will review the protocol in detail and act as a liaison between the IRB and the PI. Primary reviewers are assigned according to their expertise with the research being proposed and/or the subject population(s) being enrolled, and their appropriate scientific or scholarly expertise to review the



protocol. Protocols are not assigned to reviewers who have a conflict of interest (COI) or have academic appointments in the same administrative unit as the PI. The primary reviewer may contact the investigator, co-investigators, other IRB members, or outside sources as necessary to ensure a thorough evaluation of risks and benefits of the proposed research. Secondary reviewers may be assigned when appropriate and hold the same responsibilities as primary reviewers outlined in this paragraph.

At times, the IRB may not have the appropriate expertise to review the study for scientific or scholarly validity. In those cases, the IRB Chair will consider who in the University faculty or community has the appropriate scientific expertise to serve as an expert consultant to perform an in-depth review of the study. Consultants will disclose any COI prior to performing the review, and those with a COI will not be used for protocol review.

4.2.4 Distribution of Submitted Materials to IRB Members

Meeting documents will be accessible to the IRB members at least one week prior to the scheduled meeting. The primary and secondary reviewers are expected to review all materials for their assigned protocol(s). IRB members who are not assigned as primary or secondary reviewers are expected to review at least the application, protocol and consent forms for research studies being considered at the meeting and may review all submitted materials as follows:

1. Part I: Human Research Application.
2. Informed consent document(s)
3. Request to include vulnerable populations as subjects (pregnant women, fetuses, children, prisoners, decisionally impaired adults).
4. Recruitment material.
5. Copies of all instruments if the study involves the use of questionnaires, surveys, or similar instruments.

If applicable:

7. IRB Appendix Forms
8. DSMP, if it meets criteria
9. HHS grant application, Human subject section.
10. Sponsor protocol.

4.2.5 IRB Meeting Schedule

The convened IRB is scheduled to meet monthly, on the second Tuesday of each month. The meeting and submission deadline schedule may be viewed on the [ORIE website](#).

4.2.6 Presentation and Discussion of Protocols

Protocols undergoing initial, modifications and continuing reviews at the convened meeting are presented to the IRB by the Primary and Secondary Reviewers. Principal Investigators may attend meetings to address specific concerns regarding research protocols but will be asked to leave the meeting during all deliberations and votes. IRB Administrators will assure members with appropriate scientific expertise, local knowledge and other expertise specific to the protocols are present at the IRB meeting, along with at least one member who is knowledgeable about or experienced in working with vulnerable subjects, when research involving subjects who are vulnerable to coercion are reviewed. If a member with the appropriate expertise, knowledge, or experience in working with the specific vulnerable population cannot be present, the IRB Administrators will notify the IRB Chair or Director to obtain a consultant, if needed, to provide a written report of their evaluation of the protocol.

To be properly presented and discussed, a quorum of the members, which must include a non-scientist, an unaffiliated member and a prisoner representative (if research including prisoners is discussed) must be present for the entire presentation, discussion, and deliberation. The IRB Analyst (or designee) will determine if a quorum of members is present and inform the Chair



when a quorum is met. Members not present for a substantial part of the discussion and deliberations should abstain from voting. The presence of a quorum of members is documented in the meeting minutes. For those protocols undergoing initial review, the following are discussed in detail (list is not all-inclusive):

1. The regulatory criteria for approval at 45 CFR 46.111 are met.
2. The setting in which the research occurs; i.e., investigators have adequate time, staff and facilities to safely conduct and complete the research.
3. The scientific and ethical justification for including vulnerable populations (children, prisoners, pregnant women, fetuses, decisionally impaired adults), if applicable.
4. Analysis of the procedures to minimize risk that includes PI access to a population that will allow recruitment of the necessary number of participants and the availability of medical or psychosocial resources that participants might need as a consequence of the research.
5. The procedures to be used to ensure protection of subject privacy and data confidentiality.
6. The scientific qualifications and experience of the investigators and their research staff.
7. The human subjects protection training of the investigators and their research staff.
8. Potential or disclosed investigator conflict of interest.

If applicable:

9. The scientific and ethical justification for excluding classes of persons from the research.
10. Data Safety and Monitoring Plan (DSMP)
11. Written consultant reports. (If the protocol was reviewed by a consultant, the consultant will not be present for deliberation and the voting on the protocol.)

4.2.7 Criteria for IRB Approval of Research

In order to approve research, the IRB will provide ethical and scientific review of all human subjects research to the extent necessary to determine that all of the requirements of 45 CFR 46.111 Criteria for IRB approval of research are satisfied. Visit the [HHS website](#).

To ensure that all regulatory requirements for review have been met, a reviewer checklist may be utilized.

4.2.8 Scientific/Scholarly Review

As stated in Section 3.17.3, the IRB relies upon the IRB administrative staff to assure that submissions contain appropriate information to facilitate IRB review. The IRB is ultimately responsible for the scientific/scholarly and ethical review of the research. The IRB may evaluate methods to the extent that the research design impinges upon the consideration of risk and benefit to the participants and may provide advice or make recommendations on methods even in instances where an evaluation of methods does not affect approvability.

4.2.9 Length of Approval Period for Full Board Review Submissions

The IRB will also determine the interval for the continuing review of the research, appropriate to the degree of risks that will be experienced by subjects. The interval for continuing review for more than minimal risk research will be at least once per year (not to exceed 365 days; 366 days during a leap year) but may be shorter. If the protocol was approved or approved with explicit conditions, the expiration date is calculated from the date of the convened meeting. Protocols that have not undergone a required continuing review will expire at midnight on the expiration date. Research activities classified as more than minimal risk may not continue after midnight of the expiration date. The following conditions are likely to require review more often than annually:

1. There is a high degree of risk to subjects.
2. The stage of research is such that many of the risks are unknown.



3. The proposed procedures have not been used in humans.
4. There have been confirmed instances of serious or continuing noncompliance.
5. An IRB member believes more frequent review is required.
6. Other reasons for which the IRB requests closer monitoring.

4.3 Research Appropriate for Expedited Review

If a protocol has been determined to be minimal risk, it may be considered for expedited review provided that it fits one of the categories authorized by [45 CFR 46.110](#) for expedited review. The expedited review proposal may be reviewed and approved by the IRB Chair or another IRB-experienced designated reviewer appointed by the IRB Chair.

4.3.1 Submission and Review Schedule

Protocols submitted for expedited review may be submitted at any time. There is no timeframe or submission deadlines. The IRB Chair or a designated reviewer reviews the complete protocol, including any protocol modifications previously approved by the IRB.

4.3.2 Submission Requirements/Materials Reviewed

If the protocol meets all requirements for expedited review, the following must be electronically submitted:

1. A completed original IRB application, with an electronic signature of the PI. If a student is serving as the PI, their faculty sponsor must also provide an electronic signature.
2. An informed consent document.
3. Training verification. (See [Section 3.16 Training Requirements](#)).
4. Recruitment materials; i.e., flyers, posters, web-pages, email messages, etc.

If applicable:

6. Copies of all instruments if the study involves the use of questionnaires, surveys, or similar instruments.
7. Site letters for extramural research.
8. Institutional Biosafety Committee (IBC) approval documentation, if required.
9. Sponsor protocol.
10. Copy of the HHS grant application – Human subject section.

4.3.3 Assignment of Expedited Reviewer

Upon processing, the IRB Analyst(s) will verify that the protocol is appropriate for expedited review. They will work with the PI to assure that all required documentation has been uploaded and the application is complete. Designated reviewers will be experienced IRB members. IRB Analyst(s) will assure that reviewers do not have a conflict of interest.

4.3.4 Reviewer Considerations

Protocols undergoing expedited review are reviewed to assure:

1. The research meets all applicability criteria (See Section 4.3.5 below) and falls into one or more categories of research eligible for review using the expedited procedure. [45 CFR 46.110](#)
2. The regulatory criteria for approval are met. (See Section 4.3.6 Criteria for IRB Approval of Research below)
3. Investigators and their research staff have appropriate and sufficient qualifications, expertise, and training. (See [Section 3.16 Training Requirements](#)).

4.3.5 Applicability Criteria

The following criteria should be considered for research undergoing expedited review:

1. The research procedures present no more than minimal risk to subjects.



2. The identification of subjects or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation or be stigmatizing, unless reasonable and appropriate protections will be implemented so that the risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
3. The research is not classified.

4.3.6 Criteria for IRB Approval of Research

In order to approve research, the IRB will provide ethical and scientific/scholarly review of all human subjects research to determine that all of the **requirements** of 45 CFR 46.111 criteria for IRB approval of research are satisfied.

Protocols that may be minimal risk but are not included on the list of activities that may undergo expedited review are reviewed at a convened meeting of the IRB. The IRB may then designate that a protocol is minimal risk and determine that the protocol may undergo an expedited review process under [Category 9](#) during its subsequent reviews for continuation.

4.3.7 Scientific/Scholarly Review

As stated in [Section 3.17.3](#), the IRB relies upon the IRB Administrator to assure that submissions contain appropriate information to facilitate IRB review. The IRB is ultimately responsible for the scientific/scholarly and ethical review of the research. The IRB may evaluate methods to the extent that the research design impinges upon the consideration of risk and benefit to the participants and may provide advice or make recommendations on methods even in instances where an evaluation of methods does not affect approvability.

4.3.8 Length of Review Period for Expedited Review Projects

A review date, also referred to as a Next Report Due Date, is assigned to expedited review projects at the time of approval. A review date is entered into the IRBNet system in the "Next Report Due" field; two years at the time of approval for faculty and staff and one year for students.

Effective January 22, 2019, formal continuing review was no longer required of expedited review protocols but the IRB has the authority to require continuing review if certain circumstances are identified to require an annual report. Only protocols reviewed and approved by the full board or under specific circumstances determined by the convened board for expedited protocols, must submit a continuing review.

4.3.9 Reporting of Expedited Review to the IRB

The protocol number, title, PI name, and the category of research for which each protocol that was approved using an expedited review procedure is reported to the IRB at the next scheduled meeting through posting all approved expedited protocols that were approved on the IRB agenda.

4.4 Exempt Research

For HHS-funded research, exemptions do not apply if research includes prisoners as research subjects or if the research is FDA regulated. If the research is not HHS-funded, the exemptions will apply for research including prisoners as research subjects unless the research involves interaction with prisoners (including obtaining informed consent).

Research qualifying for exempt status must be in accordance with the University's ethical standards and training requirements.



The HHS and FDA regulations define some research as exempt from IRB review. The IRB recognizes the exempt categories described in Section 5.4.1 below. However, depending on the potential risks subjects may experience, the IRB may require a higher level of review either through the expedited process or by the IRB at a convened meeting. PIs must submit the IRB application into IRBNet, following the same process for review and approval as expedited projects. PIs are not allowed to make the final determination of exemption. PIs are not authorized to begin until receipt of the determination letter.

Modifications that affect the exempt category or the criteria for exempt determination must be submitted as an amendment and will be processed as an acknowledgement.

4.4.1 Exempt Research (Not FDA Regulated)

The categories for exemption are as follows:

1. 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 or special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. 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). the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:
 - a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - b. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Note: For HHS-funded research that involves children as subjects, the procedures cannot involve i) survey procedures; ii) interview procedures; or iii) observation of public behavior where the investigators participate in the activities being observed (observation of public behavior where the investigators do not participate is allowable).

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) above, if:
 - a. Human subjects are elected or appointed public officials or candidates for public office; or
 - b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available



or if the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.

Note: This exemption would not apply if the investigator(s) collects data in a coded manner since the code would enable subjects to be identified via the code. "Existing" means that the data, documents, records, or specimens must exist and be de-identified at the time the research proposal is submitted.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine:
 - a. Public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service programs (e.g., social supportive or nutrition services as provided under the Older Americans Act);
 - b. Procedures for obtaining benefits or services under those programs;
 - c. Possible changes in or alternatives to those programs or procedures; or
 - d. Possible changes in methods or levels of payment for benefits or services under those programs. In addition:
 - e. The research must be conducted pursuant to specific federal statutory authority.
 - f. There must be no statutory requirement that an IRB review the research.
 - g. Research must not involve significant physical invasions or intrusions upon the privacy of the subjects.
 - h. The exemption should have authorization or concurrence by the funding agency.
6. Taste and food quality evaluation and consumer acceptance studies if:
 - a. Wholesome foods without additives are consumed.
 - b. A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or
 - c. 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
 - d.

4.4.2 Exempt Research (FDA)

The categories of research qualifying for exemption are as follows:

1. Any investigation that commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB that meets the FDA requirements in effect before July 27, 1981;
2. Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date;
3. Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review;
4. Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or 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.



4.4.3 Criteria to Determine that Subjects of Exempt Research are Protected

Although exempt research is not covered by the federal regulations, it is not exempt from institutional ethical considerations. The individual making the exempt determination will assure the research meets the criteria of one of the categories for exemption listed in Section 5.4.2 above and that ethical standards are met regarding risks, equitable selection of subjects, privacy and confidentiality, and informed consent. The Principal Investigator is responsible for assuring the following during the conduct of the research:

1. All research personnel are trained in ethical principles, relevant federal regulations, and institutional policies governing human subjects research.
2. All subjects are provided pertinent information (e.g., risks and benefits, contact information for investigators and ORIE), are selected equitably, and voluntarily consent to participate.
3. Information or unanticipated problems that may increase the risk to the subjects and cause the category of review to be reclassified as expedited or full board review are immediately reported to the IRB.
4. Complaints from subjects regarding their risks and benefits are immediately reported to the IRB.
5. The privacy of the subjects and confidentiality of the research data will be maintained appropriately to ensure minimal risks to subjects.
6. Reporting, by submission of an amendment request, any changes in the research study that alter the level of risk to subjects.

4.4.4 Length of Review Period for Exempt Research

Formal continuing review is not required for exempt research, but a two-year review period is assigned to faculty or staff investigator exempt research projects at the time of granting exemption status. Investigators will be contacted every two years to determine whether the research is still ongoing. If the research is completed prior to the two year period, investigators are requested to notify the IRB of the study's closure.

Exempt research conducted by student investigators will be assigned a one-year review period at the time of granting exemption status. The review period is entered into the IRBNet system in the "Next Report Due" field. Student investigators will be contacted every year to determine whether the research is still ongoing. If the research is completed prior to the one year anniversary date, student investigators are requested to notify the IRB of the study's closure.

4.4.5 Modifications to Exempt Research

Researchers should notify the IRB of proposed modifications to research determined to be exempt to assure that the research activities remain exempt from IRB review and exempt determination.

4.5 Possible IRB Protocol Determinations for Full Board and Expedited Review Projects

4.5.1 Projects reviewed at a convened meeting or through an expedited review process will render one of the following determinations:

1. **Approved:** Approved by the IRB as written with no explicit conditions.
2. **Approved with Conditions:** Approved with requirements for minor changes or simple concurrence of the PI. These will be identified to the PI and must be completed and documented prior to beginning the research. For these conditions, the IRB Administrators, in consultation with IRB Chair's designated reviewers, upon reviewing the PI's response(s) to the conditions, may approve the research on behalf of the IRB. PI



- responses to conditions deemed to be significant or that are directly relevant to regulatory criteria must be reviewed by the IRB at a convened meeting.
3. **Deferred:** Generally, the protocol or consent form has deficiencies that prevent accurate determination of risks and benefits or requires significant clarifications, modifications, or conditions that, when met or addressed, require full IRB review and approval of the PI's responses and revisions. The deficiencies will be specified to the PI, and on occasion the PI is asked to attend the full board meeting in order to clarify the points in question. The PI must revise the protocol, consent forms, or other documents as specified by the IRB and re-submit the entire protocol for full review at a convened meeting. The PI may request reconsideration of determination by submitting a written response to the IRB. The IRB will invite the PI to the IRB meeting if the IRB has additional questions. The IRB will reconsider its original decision in light of new information presented by the PI. The second decision is final.
 4. **Disapproved:** This determination may only be made at a convened IRB meeting. The protocol describes a research activity that is deemed to have risks which outweigh potential benefits or the protocol is significantly deficient in several major areas. The protocol and/or other documents will need to be completely re-written and re-submitted as a new submission. PIs may request reconsideration of disapproved studies by submitting a written response to the IRB. The IRB will invite the PI to the IRB meeting if the IRB has additional questions. The IRB will reconsider its original decision in light of new information presented by the PI. For those protocols reviewed using the expedited review process, the designated reviewer may render decisions of approved, approved with explicit conditions, or deferred to full board. The designated reviewer may not render a decision of disapproved. A decision of protocol disapproval may only be rendered by the IRB at a convened meeting.
 5. **Referred to Full Board:** This determination may be made by an Expedited Reviewer if the reviewer determines that the Full Board is more appropriate or necessary to review due to concerns about the protocol design or insufficient human subjects protections.

Due to the volume of protocols reviewed by the IRB, any protocol for which no PI response or communication to the IRB has been received **within 30 days** after a formal determination letter has been issued regarding approval with conditions or a deferred decision, the protocol will be withdrawn from IRB consideration. Reconsideration of the protocol may require a complete re-submission.

4.5.2 Possible IRB Protocol Determinations for Exempt Projects

Projects reviewed through an exempt from IRB review process will render one of the following determinations:

1. **Exemption Granted:** The IRB has granted an exemption for the proposed study. The study may proceed as written.
2. **Unable to Grant Exempt Status:** The IRB reviewer may require further clarification or revisions before an exempt status can be applied to the proposed study. If a study does not qualify under one of the exempt categories, it may qualify under an expedited category.
3. **Determined to Not Qualify as Human Subjects Research:** A review may determine that the proposed project may not qualify as "human subjects research". The PI will be instructed to complete the Human Subjects Research Determination Letter form.

4.6 Notifications of Determinations



4.6.1 Full Board Review

Within five working days after each IRB meeting a letter is prepared and sent to the PI of each protocol notifying them of the IRB determination for the protocol. An approval letter requires no further action and the PI can begin research.

Letters giving approval with conditions will contain a list of required conditions and PIs will not receive final approval until all required stipulations have been met. Along with the determination, the IRB will determine whether the PI's responses to the stipulations will need to be reviewed for appropriateness and completeness at another IRB convened meeting or by the IRB Chair or designated reviewer. Responses to clarifications that are directly relevant to regulatory criteria must be reviewed by the convened IRB. When the PI has responded to all conditions appropriately and completely in a letter to the IRB office and the convened board has granted that the IRB administrative staff then final approval may be granted. The PI will be notified by an approval letter that research can begin and when the protocol will require continuing review.

For deferred protocols, the PI will be notified by letter the reasons the protocol was deferred. The entire protocol, with all supporting documents, must be revised as needed and resubmitted.

The PI of protocols that are disapproved will receive a letter that delineates the reasons for disapproval.

4.6.2 Expedited Review

Within five working days after the protocol is reviewed by a designated reviewer, the PI will receive a letter of the IRB determination. An approval letter requires no further action and the PI can begin research.

Letters giving approval with stipulations will contain a list of required conditions and PIs will not receive final approval until all conditions have been met. When the PI has responded appropriately and completely in a letter to the IRB office addressing all conditions, then final approval is granted. The PI will be notified by an approval letter that research can begin and will state the length of the review period for the project for two years for faculty and staff, and one year for student projects.

For deferred protocols, the PI will be notified by letter of the reasons the protocol was deferred. In order to have the protocol reviewed again, the PI must respond to all the tabled reasons by adjusting the submission documents or attaching additional supportive documentation.

Due to the volume of protocols reviewed by the IRB, any protocol for which no PI response to approved with explicit conditions or as a deferred determination is not received in 30 days the project will be withdrawn from IRB consideration. Reconsideration of the protocol will require a complete re-submission.

4.6.3 Exempt Research

If the research study is determined to meet the criteria for exempt status, the IRB Analyst or a designated member will send an Exempt Determination letter to the PI. The exempt determination will be recognized for two years for faculty and staff investigators. The exempt determination for student investigators will be recognized for one year.



By agreeing to the PI Attestation outlined in the IRB Application, the investigator assures that all investigators and co-investigators are trained in the ethical principles, relevant Federal Regulations and institutional policies governing human subjects research. The investigator assures that:

1. Human subjects will voluntarily consent to participate in the research when appropriate (e.g., surveys, interviews) and will provide subjects with pertinent information such as risks and benefits of participation, contact information for investigators and the IRB office, etc.
2. Human subjects will be selected equitably, so that the risks and benefits of the research are justly distributed.
3. The IRB will be immediately informed of any information, unanticipated problems that would increase the risk to the human subjects and cause the category of review to be upgraded to Expedited or Full Board Review.
4. The IRB will be immediately informed of any complaints from participants regarding their risks and benefits.
5. Confidentiality and privacy of the subjects and the research data will be maintained appropriately to ensure minimal risk to subjects.

4.7 Final Approval, Expiration Dates and Next Report Due Dates

If a study is approved with no conditions, the final approval is effective the day the study is approved, i.e., the date of the convened IRB meeting for full board protocols. For expedited protocols, the final approval is the date of reviewer's approval for expedited protocols. For studies that are reviewed and categorized as exempt, these projects are granted exemption status and is recorded as the date of the reviewer's exempt determination was issued.

If a study is approved with explicit conditions, the final approval is effective on the day the protocol was reviewed and conditions were imposed by the IRB at a convened meeting (full board protocols) or the date that the reviewer approved the expedited protocol. This determination will be documented in the IRB meeting minutes.

An expiration date will be applied to projects that are more than minimal risk and reviewed by the full board due to the risk classification or other circumstances that places the subjects or investigator at a higher risk. Full board approval is based on the date it was approved at a convened meeting or approved by a designated reviewer. For projects reviewed by the full board and are assigned an expiration date, the expiration date will be no longer than 365 days (366 days if during a leap year) from the approval date, but may be sooner if more frequent review is stipulated by the IRB.

Expedited protocols no longer are issued expiration dates per the revised Common Rule, implemented January 2019. The IRB will issue a two-year review period for all faculty and staff research projects that are processed through an expedited review process. A one-year review period will be assigned for all student research projects. A Next Report Due date will be entered into the IRBNet system in order to monitor and track projects that will not undergo ongoing continuing review. The two-year review period will not utilize an expiration date. Investigators will receive notifications to contact the IRB Office before the Next Report Due date if the study is ongoing. If the study will continue, the PI must notify the IRB via email or through Project Mail to extend the project before the Next Report Due date then an additional two-year review period will be administratively posted in the IRBNet project file. If the project has ended, the PI is responsible for submitting a Final Report/Closure Report for formally close the project. If no response is received from the PI to extend the project, the IRB will administratively close the research project in IRBNet and issue a closure letter.

Exempt protocols will be issued a two-year review period for all faculty and staff research projects that are processed and classified as exempt. A one-year review period will be assigned for all



student research projects. A Next Report Due date will be entered into the IRBNet system in order to monitor and track exempt projects. Exempt projects do not assign expiration dates. Investigators will receive notifications to contact the IRB Office before the Next Report Due date if the exempt project is ongoing. If the study will continue, the PI must notify the IRB via email or through Project Mail to extend the project before the Next Report Due date then an additional two-year review period will be administratively posted in the IRBNet project file. If the project has ended, the PI is responsible for submitting a Final Report/Closure Report to formally close the project. If no response is received from the PI to extend the project, the IRB will administratively close the research project in IRBNet and issue a closure notification.

If a student investigator has graduated or left DU prior to the completion of their research without submitting a final report, the Faculty Sponsor identified on the study protocol is responsible for submitting a closure report for the project.