Research Security & Integrity

UNIVERSITY OF COLORADO **BOULDER**

INSTITUTIONAL REVIEW BOARD

IRB Policies & Procedures

Approved by:

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Approval Date: 7/28/2025

Sign within 30 days of Effective Date

Effective Date: June 30, 2025

CU Version: 3.0

Last Review Date: June 1, 2025

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HRP-001
POLICY: Definitions

1. PURPOSE

1.1. This policy establishes definitions followed by CU Boulder (hereafter referred to as "CU Boulder") Institutional Review Board.

2. POLICY

2.1. **2018 Requirements**: The Federal Policy for the Protection of Human Subjects requirements contained in 45 CFR §46 Subparts A as revised January 18, 2017, as well as Subpart B, C, and D, exclusive of requirements for reporting to, certification by, or review by a federal department of agency head.

2.2. **Allegation of Noncompliance**: An unproven assertion of **Noncompliance.**

2.3. **Children**: Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

2.4. **Classified Research**: Research involving any information or material, regardless of its physical form or characteristics, that is owned by the United States Government, and determined pursuant to Executive Order 12356, April 2, 1982 or prior orders to require protection against unauthorized disclosure and is so designated.

2.5. **Clinical Investigation**: A synonym for **Research as Defined by FDA**.

2.6. **Clinical Trial**: A research study in which one or more human subjects are prospectively assigned to one or more **Interventions** (which may include placebo or other control) to evaluate the effects of the **Interventions** on biomedical or behavioral health-related outcomes.

2.7. **Committee Review**: All review processes that require a convened IRB.

2.8. **Compassionate Use**: The use of an unapproved device on an individual in a serious situation, in which the device does not have an IDE, no generally acceptable alternative for the condition exists, and in which there is not sufficient time to obtain IRB approval.

2.9. **Conflicting Interest**[1]: An IRB member or consultant has a **Conflicting Interest** if any of the following is true for the member/consultant or an individual in the member's **Immediate Family**:

2.9.1. Involvement in the design, conduct, or reporting of the research,

2.9.2. Equity interest **Related to the Research**, exclusive of interests through mutual funds,

2.9.3. Compensation **Related to the Research** in the preceding 12 months,

2.9.4. Proprietary interest **Related to the Research**, including copyrights, patents, or trademarks,

[1] This term is synonymous with "Conflict of Interest," as used by the CU Boulder Office of Conflicts of Interest & Commitment.

2.9.5. Significant Interest **Related to the Research**: A Financial Interest or other personal interest received from or held in an Entity outside of the university that reasonably appears to be related to the Discloser's Institutional Responsibilities and meets the thresholds as defined in COIC Policy, Section XVII. Definitions.

2.9.6. Any other reason for which the IRB member believes that he or she cannot be objective.

2.10. **Continuing Noncompliance**: A pattern of **Noncompliance** that is likely to continue without intervention, or a failure to work with the IRB to resolve **Noncompliance**.

2.11. **Designated Reviewer**: An **Experienced IRB Member** designated by the IRB Chair or Designee to conduct **Non-Committee Review**.

2.12. **Emergency Use**: The use of an unapproved drug, biologic, or device on an individual in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

2.13. **End Approval Date**: The final date that a study is IRB approved and the last date that a study can be conducted without undergoing continuing review.

2.14. **Experienced IRB Member**: An IRB member who, in the opinion of the IRB Chair or Designee, has gained over a period of time sufficient knowledge and skill in conducting IRB reviews to serve as **Designated Reviewer**.

2.15. **Expiration Date:** The day after the **End Approval Date**.

2.16. **Fetus:** The product of conception from implantation until delivery.

2.17. **Guardian**: An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

2.18. **Human Research as Defined by FDA:** Any activity that is **Research as Defined by FDA** and involves **Human Subjects as Defined by FDA**.

2.19. **Human Research as Defined by HHS:** Any activity that is **Research as Defined by HHS** and involves **Human Subjects as Defined by HHS**.

2.20. **Human Research:** Any activity that is **Human Research as Defined by HHS** or **Human Research as Defined by FDA**.

2.21. **Human Subject as Defined by FDA:** An individual who is or becomes a participant in **Research as Defined by FDA**, either as a recipient of the test article or as a control, or an individual on whose specimen an investigational device[2] is used.

2.22. **Human Subject as Defined by HHS**:

2.22.1. For **Research as Defined by HHS** subject to **Pre-2018 Requirements**: A living individual about whom an investigator conducting **Research as Defined by HHS** obtains (1) data through **Intervention** or **Interaction** with the individual, or (2) information that is both **Identifiable Information** and **Private Information**.

[2] Investigational device means a device, including a transitional device, that is the object of a clinical investigation or research involving one or more subjects to determine its safety or effectiveness.

2.22.2. For **Research as Defined by HHS** subject to **2018 Requirements** or **Hybrid Requirements**: A living individual about whom an investigator conducting **Research as Defined by HHS**:

2.22.2.1. Obtains information or biospecimens through **Intervention** or **Interaction** with the individual, and uses, studies, or analyzes the information or biospecimens; or

2.22.2.2. Obtains, uses, studies, analyzes, or generates **Identifiable Private Information** or **Identifiable Biospecimens**.

2.23. **Hybrid Requirements**: **2018 Requirements** exclusive of 45 CFR §46.103(e), §46.109(e), §46.116(a)(5), §46.116(b)(9), §46.116(d)(7)-(9), §46.116(e)(1)-(2), §46.116(f)(1)-(2), §46.116(f)(3)(ii)[3].

2.24. **Identifiable Information**:

2.24.1. For **Research as Defined by HHS** subject to **Pre-2018 Requirements**: Information for which the identity of the **Human Subject as Defined by HHS** is or may readily be ascertained by the investigator or readily be associated with the information.

2.24.2. For **Research as Defined by HHS** subject **to 2018 Requirements** or **Hybrid Requirements**: Information or a biospecimen for which the identity of the **Human Subject as Defined by HHS** is or may readily be ascertained by the investigator or readily be associated with the information.

2.25. **Identifiable Private Information**: **Private Information** for which the identity of the **Human Subject as Defined by HHS** is or may readily be ascertained by the investigator or associated with the information.

2.26. **Identifiable Biospecimen**: A biospecimen for which the identity of the **Human Subject as Defined by HHS** is or may readily be ascertained by the investigator or associated with the biospecimen.

2.27. **Immediate Family**: Spouse and dependent **children**.

2.28. **Impartial Witness**: A person who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the entire consent process and reads the consent document, and any other written information supplied to the subject as part of the consent process.

2.29. **Intake Review**: Review of submissions for administrative and institutional compliance issues.

2.30. **Intake Reviewer**: Individual who conducts an **Intake Review**.

2.31. **Interaction**: Communication or interpersonal contact between investigator and **Human Subject as Defined by HHS**.

[3] 45 CFR §46.103(e), §46.109(e), §46.116(b)(9) and, §46.116(d)(7)-(9) are requirements of the Federal Policy for the Protection of Human Subjects as revised January 18, 2017 that are not requirements of the Federal Policy for the Protection of Human Subjects requirements published in the 2016 edition of the Code of Federal Regulations. 45 CFR §46.103(e) is the requirements for reliance agreements. §46.109(e) is the criteria when continuing review is not required. §46.116(a)(5) is the criteria for the concise summary. §46.116(b)(9) is required consent disclosures. §46.116(d)(7)-(9) is required additional disclosures. §46.116(e)(1)-(2), §46.116(f)(1)-(2), §46.116(f)(3)(ii) are the limitations on wavier and alteration of consent.

2.32. **Intervention**: Physical procedures by which information or biospecimens are gathered as well as manipulations of the **Human Subject as Defined by HHS** or the Human Subject's as Defined by HHS environment that are performed for research purposes.

2.33. **Legally Authorized Representative**: An individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

2.33.1. For **Research as Defined by HHS** NOT subject to FDA regulations and NOT subject to **Pre-2018 Requirements**: Where there is no applicable law addressing this issue, **Legally Authorized Representative** means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective **Human Subject as Defined by HHS** to the human subject's participation in the procedure(s) involved in the research.

2.34. **Meeting Chair**: The IRB member running a convened IRB meeting.

2.35. **Minimal Risk**: The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

2.35.1. The IRB interprets the phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests" to refer to normal healthy individuals in general and to exclude the risks that certain subcategories of individuals face in their everyday lives. For example, the IRB does not evaluate the risks imposed in research focused on a special population against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

2.35.2. For **Human Research as Defined by HHS** that involves **Prisoners** as **Human Subjects as Defined by HHS**: The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

2.36. **Neonate**: A newborn from 0 to 30 days of life.

2.37. **Neonate of Uncertain Viability**: A **Neonate** after delivery that, although living, is uncertain to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

2.38. **Non-Committee Review**: All review processes that do not require a convened IRB including non-**Human Research** determinations, non-engagement determinations, exemption determinations, and expedited review.

2.39. **Non-significant Risk Device**: An investigational device that is not a **Significant Risk Device**.

2.40. **Noncompliance**: Failure to follow applicable regulations or the requirements or determinations of the IRB.

2.41. **Nonviable Neonate**: A **Neonate** after delivery that, although living, is unable to survive (given the benefit of available **medical** therapy) to the point of independently maintaining heartbeat and respiration.

2.42. **Pregnant Woman**: A woman during the period of time from implantation until delivery.

2.43. **Pre-2018 Requirements**: The Federal Policy for the Protection of Human Subjects requirements contained in 45 CFR §46 Subparts A as published in the 2016 edition of the Code of Federal Regulations, as well as Subpart B, C, and D, exclusive of requirements for reporting to, certification by, or review by a federal department of agency head.

2.44. **Prisoner**: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

2.45. **Private Information**: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

2.46. **Protocol Deviation**: Failure to follow the IRB-approved protocol.

2.47. **Regulatory Review**: Review of administrative and regulatory issues unrelated to the regulatory criteria for approval that under applicable regulations must be determined by a convened IRB or reviewer using the expedited procedure.

2.48. **Regulatory Reviewer**: Individual who conducts **Regulatory Review**.

2.49. **Related to the Research**: A financial interest is **Related to the Research** when the financial interest is in the sponsor, or the product or service being evaluated.

2.50. **Reliance Agreement**: Documentation describing the reliance of an institution on an IRB for the oversight of research and the responsibilities that each entity will undertake to ensure compliance with regulatory requirements, which can be embodied in a written agreement between the institution, an institution-wide policy directive, or a research protocol.

2.51. **Research as Defined by FDA**: Any experiment that involves a test article and one or more **Human Subjects as Defined by FDA**, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the **Act**, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit, where:

2.51.1. **Act**: The Federal Food, Drug, and Cosmetic Act, as amended (§§201-902, 52 Stat 1040 et. seq., as amended (21 USC 321-392)).

2.51.2. **Test article**: Any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the **Act** or under sections 351 or 354-360F of the Public Health Service Act.

2.52. **Research as Defined by HHS**: A systematic investigation designed to develop or contribute to generalizable knowledge.[4]

[4] The following activities are deemed not to be Research as Defined by HHS: (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. (2) Public health surveillance activities, including the collection and testing of

2.53. **Restricted**: A status for investigators indicating that new submissions will not be accepted for review.

2.54. **Serious Noncompliance**: **Noncompliance** that adversely affects the rights and welfare of subjects.

2.54.1. For **Human Research** conducted or funded by DOD, **Serious Noncompliance** is failure of a person, group, or institution to act in accordance with applicable regulations such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.

2.55. **Significant Risk Device**: An investigational device that:

2.55.1. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;

2.55.2. Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;

2.55.3. Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or

2.55.4. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

2.56. **Single Patient Expanded Access**: Treatment with an investigational drug[5] under an IND where the FDA granted an IND pursuant to 21 CFR §312.310.

2.57. **Suspension of IRB Approval**: Temporary or permanent withdrawal of IRB approval for some or all research procedures short of **Termination of IRB Approval**.

2.58. **Termination of IRB Approval**: Withdrawal of IRB approval for all research procedures where the IRB does not anticipate re-opening the study.

2.59. **Unanticipated Problems Involving Risks to Subjects or Others[6]**: Any incident that:

information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions. Public health authority means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

[5] Investigational drug means a drug or biological drug that is used in a clinical investigation.

[6] Unanticipated problem means any incident that a) was unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents, such as the IRB-approved protocol and informed consent document, b) was related or probably related to participation in the research, and c) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.

2.59.1. Was unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents, such as the IRB-approved protocol and informed consent document, and

2.59.2. Was related or probably related to participation in the research, and

2.59.3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.

2.60. **Wards**: **Children** who are cared for and the responsibility of the state or any other agency, institution, or entity.

3. REFERENCES

3.1. 45 CFR §46.102

3.2. 45 CFR §46.202

3.3. 45 CFR §46.303

3.4. 45 CFR §46.402

3.5. 21 CFR §50

3.6. 21 CFR §56.102

3.7. 21 CFR §312.3

3.8. 21 CFR §812

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HRP-002
POLICY: Abbreviations

1. PURPOSE

1.1. This policy establishes abbreviations followed by the CU Boulder Institutional Review Board.

2. POLICY

2.1. AID: United States Agency for International Development

2.2. CGSB: Canadian General Standards Board

2.3. CIA: United States Central Intelligence Agency

2.4. Commerce: United States Department of Commerce

2.5. CGIRB: Copernicus Group IRB

2.6. CPSC: United States Consumer Products Safety Commission

2.7. CRO: Contract Research Organization

2.8. DHS: United States Department of Homeland Security

2.9. DOD: United States Department of Defense

2.10. DOE: United States Department of Energy

2.11. DOJ: United States Department of Justice

2.12. DOT: United States Department of Transportation

2.13. ED: United States Department of Education

2.14. EPA: United States Environmental Protection Agency

2.15. eRA: Electronic Research Administration

2.16. FDA: United States Food and Drug Administration

2.17. FDR: Canadian Food and Drug Regulations

2.18. FERPA: Family Educational Rights and Privacy Act

2.19. FWA: Federalwide Assurance

2.20. HDE: Humanitarian Device Exemption

2.21. HHS: United States Department of Health and Human Services

2.22. HIPAA: Health Insurance Portability and Accountability Act

2.23. HRPP: Human Research Protection Program

2.24. HUD: Humanitarian Use Device

2.25. ICH-GCP: International Council on Harmonisation – Good Clinical Practice

2.26. IDE: Investigational Device Exemption

2.27. IND: Investigational New Drug

2.28. IRB: Institutional Review Board

2.29. LAR: **Legally Authorized Representative**

2.30. NASA: National Aeronautics and Space Administration

2.31. NSF: United States National Science Foundation

2.32. NSR: **Non-significant Risk Device**

2.33. OHRP: Office of Human Research Protections

2.34. OSTP: United States Office of Science Technology and Policy

2.35. PIPEDA: Personal Information Protection and Electronic Documents Act

2.36. PPRA: Protection of Pupil Rights Amendment

2.37. REB: Research Ethics Board

2.38. SOP: Standard Operating Procedure

2.39. SR: **Significant Risk Device**

2.40. SRO: Site Management Organization

2.41. SSA: United States Social Security Administration

2.42. TCPS: Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

2.43. US: United States

2.44. USDA: Department of Agriculture

2.45. WIRB: Western IRB

2.46. VA: Veterans Affairs

3. REFERENCES

3.1. None.

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HRP-003
POLICY: Designations

1. PURPOSE

1.1. This policy establishes designations [of] CU Boulder officials responsible for the oversight and operation of the Human Research Protection Program.

2. POLICY

2.1. **Institutional Official**: Vice Chancellor for Research & Innovation.

2.2. **Organizational Official**: Associate Vice Chancellor for Research Integrity & Compliance.

2.3. **Designee**: Person who has been selected to perform a specific role or duty.

3. REFERENCES

3.1. None.

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HRP-010
POLICY: Human Research Protection Program

1. PURPOSE

1.1. This policy establishes CU Boulder's Human Research Protection Program (HRPP) and its commitment to protect the rights and welfare of human subjects.

2. POLICY

2.1. Scope.

2.1.1. The HRPP applies to:

2.1.1.1. All **Human Research** which engages CU Boulder as defined by "WORKSHEET: Engagement (HRP-422)."

2.1.1.2. All **Human Research** submitted to the IRB for review.

2.1.2. **Human Research** may not commence until IRB approved.

2.1.3. Activities that are not **Human Research** do not require IRB review and approval.

2.1.4. Questions about whether an activity (such as classroom research, quality improvement, case reports, program evaluation, or surveillance activities) represents **Human Research** should be directed to the IRB. The IRB provides written determinations in response to written requests.

2.1.5. Questions about whether an organization is engaged in **Human Research** should be directed to the IRB. The IRB provides written determinations in response to written requests.

2.1.6. After a study is completed CU Boulder does not consider the return of results to former subjects to be **Human Research**.

2.2. Ethical Principles.

2.2.1. CU Boulder follows the ethical principles described in the report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" also known as "The Belmont Report." (see Section 3, References).

2.2.2. CU Boulder applies these ethical principles to all **Human Research** regardless of funding support or geographic location.

2.2.2.1. Policies and Procedures applied to research conducted domestically are applied to international research.

2.2.3. The following categories of individuals are expected to abide by these ethical requirements:

2.2.3.1. Investigators (whether professional or student).

2.2.3.2. Research staff.

2.2.3.3. IRB members, IRB Chairs, and IRB Co-Chairs.

2.2.3.4. HRPP staff members.

2.2.3.5. Institutional Official, Organizational Official and their Designees.

2.2.3.6. Employees and agents of CU Boulder.

2.2.4. **Clinical Trials** should be conducted in accordance with the ethical principles in the Belmont Report that have their origin in the Declaration of Helsinki and are consistent with good clinical practice and the applicable regulatory requirements.

2.3. Legal Requirements.

2.3.1. For **Human Research as Defined by HHS** conducted, supported, or otherwise subject to regulations by a Federal department or agency who is a signatory of the Common Rule, CU Boulder applies 45 CFR §46 Subpart A and all other regulations of that agency relevant to the protection of human subjects.

2.3.1.1. CU Boulder applies **Pre-2018 Requirements** to all **Human Research as Defined by HHS** initially approved, waived per 45 CFR §46.101(i), or determined exempt before January 21, 2019.

2.3.1.2. CU Boulder applies **2018 Requirements** to all **Human Research as Defined by HHS** conducted or supported by a federal department that is a signatory to the 2018 Common Rule initially approved, waived per 45 CFR §46.101(i), or determined exempt on or after January 21, 2019.

2.3.1.3. CU Boulder applies **Pre-2018 Requirements** to all **Human Research as Defined by HHS** conducted or supported by a federal department that is not a signatory to the 2018 Common Rule.

2.3.1.4. CU Boulder applies all subparts of 45 CFR §46 to **Human Research as Defined by HHS** conducted or supported by DHS, HHS, or VA.

2.3.1.5. CU Boulder applies 10 USC 980, DOD Instruction 3216.02, OPNAVINST 5300.8B, and SECNAVINST 3900.39D to **Human Research as Defined by HHS** conducted or supported by DOD.

2.3.1.6. CU Boulder applies DOE Order 443.1A and "Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with the Department of Energy (DOE) Requirements" to **Human Research as Defined by HHS** conducted or supported by DOE.

2.3.1.7. CU Boulder applies 28 CFR §22 and 28 CFR §512 to **Human Research as Defined by HHS** conducted or supported by DOJ.

2.3.1.8. CU Boulder applies 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98, 34 CFR §99, and 34 CFR §356 to **Human Research as Defined by HHS** conducted or supported by ED.

2.3.1.9. CU Boulder applies 40 CFR §26 and EPA Order 1000.17 Change A1 to **Human Research as Defined by HHS** conducted or supported by EPA, or where the results of the **Human Research** are to be submitted to EPA.

2.3.2. For **Human Research as Defined by FDA**, CU Boulder applies 21 CFR §50 and §56.

2.3.3. For research involving a **Clinical Trial** of a drug or device, CU Boulder commits to apply the "International Conference on Harmonisation – Good Clinical Practice E6." (ICH-GCP), to the extent that it is consistent with FDA regulations.

2.3.4. For research conducted in other countries, CU Boulder applies all policies applied to research conducted domestically, including:

2.3.4.1. Confirming the qualifications of investigators for conducting the research.

2.3.4.2. Conducting initial review, continuing review, and review of Amendments to previously approved research.

2.3.4.3. Handling of complaints, **Noncompliance**, and **Unanticipated Problems Involving Risks to Subjects or Others**.

2.3.4.4. Consent process and other language issues.

2.3.4.5. Ensuring all necessary approvals are met.

2.3.4.6. Coordination and communication with local IRBs.

2.3.5. When the laws of a local jurisdiction encompass activities not included in the definition of **Human Research**, CU Boulder complies with those laws.

2.3.6. CU Boulder prohibits payments to professionals in exchange for referrals of potential subjects ("finder's fees").

2.3.7. This IRB reviews payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") and does not allow them unless the possibility of coercion and undue influence is minimized.

2.4. Components of the HRPP.

2.4.1. Institutional Official:

2.4.1.1. The **Institutional Official** is the leader of the HRPP.

2.4.1.2. The **Institutional Official** (or **Designee**) is authorized to:

2.4.1.2.1. Allocate HRPP resources.

2.4.1.2.2. Appoint and remove IRB members, IRB Chairs, and IRB Co-Chairs.

2.4.1.2.3. Bind HRPP policies on CU Boulder.

2.4.1.2.4. Determine what IRBs CU Boulder will rely upon.

2.4.1.2.5. Disapprove, suspend, or terminate **Human Research**.

2.4.1.2.6. Hire and fire IRB staff members.

2.4.1.2.7. Limit or condition privileges to conduct **Human Research**.

2.4.1.2.8. Determine that information represents **Serious Noncompliance**, **Continuing Noncompliance**, an **Unanticipated Problem Involving Risks to Subjects or Others**, a **Suspension of IRB Approval**, or a **Termination of IRB Approval**.

2.4.1.2.9. Initiate corrective actions towards employees/agents of CU Boulder related to **Serious Noncompliance** or **Continuing Noncompliance**.

2.4.1.2.10. Sign **Reliance Agreements**, or designate a signatory for such agreements.

2.4.1.3. The **Institutional Official** (or **Designee**) is responsible to:

2.4.1.3.1. Oversee the HRPP.

2.4.1.3.2. Ensure the independence of the review process.

2.4.1.3.3. Ensure that complaints and allegations regarding the HRPP are appropriately handled.

2.4.1.3.4. Ensure that the HRPP has sufficient resources, including IRBs, appropriate for the volume and types of **Human Research** reviewed, so that reviews are accomplished in a thorough and timely manner.

2.4.1.3.5. Establish a culture of compliance with HRPP requirements.

2.4.1.3.6. Investigate allegations and correct findings of undue influence on the **Human Research** review process.

2.4.1.3.7. Investigate and correct systemic problems related to the HRPP.

2.4.1.3.8. Periodically review HRPP policies and procedures.

2.4.1.3.9. Periodically review HRPP resources.

2.4.1.3.10. Review and sign federal assurances (FWA) and addenda.

2.4.2. All employees and agents of CU Boulder:

2.4.2.1. All employees and agents of CU Boulder are responsible to:

2.4.2.1.1. Be aware of this policy.

2.4.2.1.2. Be aware of the definition of **Human Research** and determine whether an activity is **Human Research**.

2.4.2.1.3. Consult the IRB when there is uncertainty about whether an activity is **Human Research**.

2.4.2.1.4. Not conduct **Human Research** without IRB approval.

2.4.2.1.5. Report allegations of undue influence related to the HRPP.

2.4.2.1.6. Report **Allegations of Noncompliance** or **Findings of Noncompliance**.

2.4.3. IRB members and HRPP staff members.

2.4.3.1. IRB members, IRB Chairs, IRB Co-Chairs, and HRPP staff members are responsible to:

2.4.3.1.1. Follow HRPP policies and procedures.

2.4.3.1.2. Undergo initial training, including training on specific federal agency requirements when such research is reviewed.

2.4.3.1.3. Participate in continuing education activities at least annually, including training on specific federal agency requirements when such research is reviewed.

2.4.3.1.4. Respond to contacts from research participants or others.

2.4.3.1.5. Ensure contacts from participants or others are reported to the IRB when required by the IRB's written procedures.

2.4.3.1.6. Ensure research submitted to an external IRB meets local requirements.

2.4.3.1.7. Ensure research approved by an external IRB has all local approvals before being conducted.

2.4.3.2. IRB Chairs are authorized to suspend **Human Research**.

2.4.3.3. IRB members and HRPP staff members ultimately report to the **Institutional Official** for HRPP issues.

2.4.4. IRB.

2.4.4.1. The IRB has the authority:

2.4.4.1.1. To approve, require modifications to secure approval, and disapprove all **Human Research** activities overseen and conducted by CU Boulder.

2.4.4.1.2. To suspend or terminate approval of **Human Research** not being conducted in accordance with HRPP requirements or that had been associated with unexpected serious harm to participants.

2.4.4.1.3. To observe, or have a third party observe, the consent process and the conduct of the **Human Research**.

2.4.4.1.4. Determine whether an activity is **Human Research**.

2.4.4.1.5. Determine whether CU Boulder is engaged in **Human Research**.

2.4.4.1.6. To decide whether financial interests **Related to the Research** and the management, if any, allow approval of the **Human Research**.

2.4.4.1.7. To review allegations of **Noncompliance** to make recommendations to the **Institutional Official** regarding **Serious** or **Continuing Noncompliance**.

2.4.4.2. CU Boulder cannot approve **Human Research** that the IRB has not approved.

2.4.5. Investigators and research staff ultimately report to the **Institutional Official** or **Designee** for HRPP issues and are to follow the obligations described in "POLICY: Investigator Obligations (HRP-070)."

2.4.6. The Office of University Counsel works with the **Institutional Official** on HRPP issues and is responsible to:

2.4.6.1. Determine who is a **Legally Authorized Representative**, **Child**, and **Guardian**.

2.4.6.2. Provide legal advice related to the HRPP to the **Institutional Official**, IRB, and investigators.

2.4.6.3. Determine who is an agent for purposes of engagement.

2.4.6.4. Identify relevant state and international laws.

2.4.6.5. Provide legal advice to address conflicts among applicable laws.

2.4.7. Office of Contracts and Grants works on HRPP issues at the request of the **Institutional Official**.

2.5. **Reliance Agreements**.

2.5.1. For federally funded research that must follow **2018 Requirements** (with the exception of exempt research for which IRB oversight is not required by regulation) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB must document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy.

2.5.2. For non-federally funded research, and research under **Pre-2018 Requirements**, that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB must document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy.

2.5.3. CU Boulder may rely upon the IRB of another organization provided a **Reliance Agreement** is in place and the following is true:

2.5.3.1. CU Boulder is engaged in **Human Research** solely because it receives funding directly from a Federal department or agency.

2.5.4. Upon request or when required by law, CU Boulder will execute a **Reliance Agreement** with a relying organization, which documents respective authorities, roles, responsibilities, and communication between the CU Boulder IRB and the relying organization.

2.5.5. External organizations relying on CU Boulder's IRB can expect CU Boulder's IRB to do the following and when CU Boulder relies on an external IRB, CU Boulder expects the IRB to do the following:

2.5.5.1. Determine whether an activity is **Human Research**.

2.5.5.2. Determine whether **Human Research** engages CU Boulder.

2.5.5.3. Determine which persons are considered engaged (agents) in the **Human Research**.

2.5.5.4. Assure all IRB members, IRB Chairs and Co-Chairs are trained in accordance with applicable IRB SOPs.

2.5.5.5. Evaluate scientific or scholarly validity of proposed research.

2.5.5.6. For **Clinical Trials**, assure ICH-GCP guidelines are met, to the extent that it is consistent with FDA regulations including whether the available non-clinical and clinical information on an investigational product is adequate to support the **Clinical Trial**.

2.5.5.7. Identify any relevant local, state, or international requirements related to **Human Research**.

2.5.5.8. Make contact information for the IRB available to current and former subjects.

2.5.5.9. Explain to subjects how to contact someone independent of the investigator for questions, concerns, complaints, or subject rights, or to offer input.

2.5.5.10. Assure individuals with knowledge of community-based participatory research attend meetings where such research is reviewed.

2.5.5.11. Evaluate **Unanticipated Problems Involving Risks to Subjects or Others**, **Noncompliance**, **Serious Noncompliance** and **Continuing Noncompliance**, including when necessary to conduct an audit.

2.5.5.12. Determine whether each **Allegation of Noncompliance** has a basis in fact and whether each incident of **Noncompliance** is serious or continuing, including when necessary to conduct an audit.

2.5.5.13. Manage **Unanticipated Problems Involving Risks to Subjects or Others**, **Noncompliance**, **Serious Noncompliance** and **Continuing Noncompliance**, **Suspension of IRB Approval,** and **Termination of IRB Approval**.

2.5.5.14. When appropriate, collaborate with CU Boulder HRPP to manage **Unanticipated Problems Involving Risks to Subjects or Others**, **Noncompliance**, **Serious Noncompliance** and **Continuing Noncompliance**, **Suspension of IRB Approval,** and **Termination of IRB Approval**.

2.5.5.15. Notify the FDA of any **Unanticipated Problems Involving Risks to Subjects or Others**, **Serious Noncompliance** and **Continuing Noncompliance**, **Suspension of IRB Approval,** and **Termination of IRB Approval**.

2.5.5.16. Collaborate with CU Boulder HRPP to notify regulatory agencies other than the FDA of any **Unanticipated Problems Involving Risks to Subjects or Others**, **Serious Noncompliance** and **Continuing Noncompliance**, **Suspension of IRB Approval,** and **Termination of IRB Approval**.

2.5.5.17. Conduct independent IRB review to manage organizational conflict of interest **Related to the Research**.

2.5.5.17.1. The relying organization is responsible to identify organizational conflicts of interests.

2.5.5.18. Identify financial conflicts of interest of investigators and research staff and upon request, review and incorporate the relying organization's management plan.

2.5.5.19. Evaluate and confirm test articles have appropriate regulatory approval (e.g., IND or IDE, meet exemption requirements).

2.5.5.19.1. The relying organization is responsible to have and follow written policies and procedures to ensure that the handling of investigational or unlicensed test articles conforms to legal and regulatory requirements.

2.5.5.20. Evaluate and permit **Emergency Uses** of test articles and assure uses follow FDA requirements.

2.5.5.21. Assure that **Emergency Uses** of test articles are not considered **Human Research as Defined by HHS** and prohibit use of data obtained from an **Emergency Use** for **Human Research as Defined by HHS**.

2.5.5.22. Assure investigators and research staff are trained on DOD requirements when research is DOD-regulated, note the potential for additional training, and the possibility of DOD oversight of the educational program.

2.5.5.23. Assure that IRB members, IRB Chairs and Co-Chairs are trained in accordance with applicable IRB SOPs on DOD requirements when research is DOD-regulated.

2.5.5.24. Evaluate DOD research for scientific merit.

2.5.5.25. For DOD research, determine that the investigator has permission to conduct research in that country by certification or local ethics review.

2.5.5.26. For DOD research, determine that the investigator will follow all local laws, regulations, customs, and practices.

2.5.5.27. Assure the IRB consent meets the requirements of DOD Instruction 3216.02 when reviewing non-exempt classified DOD research.

2.5.5.28. Report **Serious** or **Continuing Noncompliance** of DOD research to the DOD human research protection officer.

2.5.5.29. Assure all DOE requirements of 10 CFR 745 and DOE Order 443.1.B. are met.

2.5.5.30. Assure all DOJ requirements of 28 CFR 22 and 512 are met.

2.5.5.31. Evaluate DOJ research to assure there is an adequate research design and it contributes to the advancement of knowledge about corrections.

2.5.5.32. Assure all ED requirements of 34 CFR 98, 99 and 356 are met.

2.5.5.33. Assure EPA requirements of 40 CFR 26 and EPA Order 1000.17 Change A1 are met, and to flag research that collects data intended to be submitted to EPA as subject to EPA regulations.

2.5.5.34. Provide equivalent protections for participants in non-funded research.

2.5.5.35. Ensuring concordance between any applicable grant in the IRB application, when required by regulators.

2.5.5.36. Assure that investigators and research staff are appropriately trained.

2.5.5.37. For international research:

2.5.5.37.1. Ensure appropriate expertise and knowledge of the country(ies) either through IRB members or consultants.

2.5.5.37.2. Ensure knowledge of local laws.

2.5.5.37.3. Ensure knowledge of cultural context.

2.5.5.37.4. Confirm the qualifications of the researchers and research staff for conducting research in that country.

2.5.5.38. Conduct initial review, continuing review, and review of amendments to previously approved research.

2.5.5.39. Conduct post-approval monitoring.

2.5.5.40. Handle complaints, **Noncompliance**, and **Unanticipated Problems Involving Risk to Participants or Others**.

2.5.5.41. Manage consent process and document and other language issues.

2.5.5.42. Coordinate and communicate with local IRBs when appropriate.

2.5.5.43. Should the relying organization terminate reliance on the IRB, the IRB will continue oversight of active studies until closure or a mutually agreed-upon transfer of the studies.

2.6. Written Procedures.

2.6.1. CU Boulder makes written materials describing the HRPP available to all members of CU Boulder through its Website at https://www.colorado.edu/researchinnovation/irb.

2.6.2. CU Boulder makes written materials describing the HRPP available to sponsors, CROs, and investigators upon request when those materials apply to the requestor.

2.6.3. When written materials are changed, CU Boulder communicates to affected individuals through one or more of the following actions:

2.6.3.1. Email communications.

2.6.3.2. Website postings.

2.6.3.3. Direct outreach at organizational meetings.

2.6.3.4. Training.

2.6.3.5. Mentoring.

2.7. Questions, Concerns, and Feedback.

2.7.1. Individuals should address questions, suggestions, concerns, or complaints about the IRB or HRPP, allegations of undue influence, **Allegations of Noncompliance** or **Findings of Noncompliance** orally or in writing to:

Name	Claire Dunne
Title	IRB Program Director
Address	563 UCB Boulder CO, 80309

Email	Claire.dunne@colorado.edu
Phone	303-735-3702

2.7.2. Individuals may also contact the **Organizational Official** at:

Name	Jon Reuter
Title	Associate Vice Chancellor for Research Integrity and Compliance
Address	563 UCB Boulder CO, 80309
Email	Jon.reuter@colorado.edu
Phone	303-735-5809

2.7.3. CU Boulder takes steps to protect employees and agents who report in good faith, from retaliation and harassment. Employees and agents should immediately report such concerns to the **Organizational Official**.

3. REFERENCES

3.1. "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Apr 18, 1979.

3.2. POLICY: Investigator Obligations (HRP-070)

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HRP-020
POLICY: IRB Member Review Expectations

1. PURPOSE

1.1. This policy establishes the expectations of IRB members for IRB reviews.

1.2. For convened IRB meetings, this policy applies to all members who will be present with voting status.

1.3. For review using the expedited procedure, this policy applies to the **Designated Reviewer** who fulfills the role described for the primary reviewer or obtains consultation for this role.

2. POLICY

2.1. Treat all oral and written information obtained as part of the review process as confidential, and do not disclose or use confidential information without prior authorization.

2.2. For each review consider whether you have a **Conflicting Interest**.

2.2.1. Know the definition of **Conflicting Interest**.

2.2.2. If you have a **Conflicting Interest**, inform the chair and/or IRB prior to the review. Do not participate in that review (including discussion or voting) except to provide information requested by the IRB.

2.3. Attend meetings you are committed to attend.

2.3.1. If you cannot attend a meeting you previously committed to attend, immediately notify IRB office staff.

2.4. In advance of the meeting:

2.4.1. Review the submitted materials and previously approved materials as needed.

2.4.2. Consider the criteria in all applicable worksheets and checklists.

2.4.3. If during your review, you:

2.4.3.1. Need answers to questions about the submitted materials, ask the **Meeting Chair** or IRB staff.

2.4.3.2. Need minutes or other information in the IRB record that you cannot access directly, ask the IRB staff.

2.4.3.3. Think one or more criteria for approval are not met, consider what specific and directive changes would make the protocol approvable.

2.4.4. If you are the primary reviewer:

2.4.4.1. Fill out applicable checklists with preliminary judgments as to whether each criterion is met and provide preliminary study-specific findings justifying any determinations.

2.4.4.2. Review all submitted materials for consistency, including the following when they exist:

2.4.4.2.1. The complete protocol, including any previously approved protocol Amendments.

2.4.4.2.2. Investigator brochure.

2.4.4.2.3. The IRB-approved protocol.

2.4.4.2.4. IRB-approved consent document.

2.4.4.3. Prepare to lead the discussion at the meeting.

2.4.5. If you are the **Prisoner** representative and the protocol involves Prisoners as research subjects, determine whether the criteria in "CHECKLIST: Prisoners (HRP-308)" are met, be present when the protocol is reviewed, and provide a review either orally or in writing.

2.4.6. If you are an IRB member with scientific or scholarly expertise, additionally review the submitted materials in enough depth to evaluate whether the materials accurately describe the subject risks, subject benefits, and knowledge to result, whether alternative procedures are consistent with sound research design and could reduce risk, and whether the research design is sound enough to yield the expected knowledge.

2.5. At meetings:

2.5.1. Share your unique input to get all the issues on the table.

2.5.1.1. If you have questions, ask.

2.5.1.2. If you have information that has not been discussed, share it.

2.5.2. Think critically and use the criteria for approval to decide whether to approve research.

2.5.2.1. If you have a concern, problem, or recommended change, be able to base it on the criteria for approval. If you are unsure of the basis, ask.

2.5.2.2. If you think a criterion for approval is not met, say so.

2.5.2.3. If you think the criteria for approval are not met, do not vote for approval.

2.5.3. Make decisions by majority rule, not consensus.

2.5.3.1. Listen and learn from the group but think and vote independently.

2.5.3.2. Know that dissent is healthy and expected.

2.5.3.3. Respect the opinions of others.

2.6. Improve your knowledge over time.

2.6.1. Participate in required and optional continuing education.

2.6.2. Accept constructive feedback.

3. REFERENCES

3.1. None.

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HRP-021
POLICY: Legally Authorized Representatives, Children, and Guardians

1. PURPOSE

1.1. This policy describes how CU Boulder's IRB determines which individuals are:

1.1.1. **Legally Authorized Representatives** (LARs)

1.1.2. **Children**

1.1.3. **Guardians**

2. POLICY

2.1. When research is conducted in Colorado, the IRB must consult with the Office of University Counsel (OUC) to determine whether an individual or entity meets the definition of a **Legally Authorized Representative**.

2.2. For research conducted outside Colorado, the IRB may consult with the OUC to determine whether an individual or entity meets the definition of a **Legally Authorized Representative**.

2.3. When research is conducted in Colorado, individuals under the age of 18 years are generally considered **Children** with certain exceptions. In applicable circumstances, the IRB must consult with the OUC to determine whether an exception to the general definition applies.

2.4. For research conducted outside Colorado, the IRB may consult with the OUC to determine which individuals are **Children**.

2.5. Individuals who can document that they are legally authorized to consent on behalf of the child to general medical care may serve as a **Guardian**. Consult with the OUC regarding any questions concerning the legal sufficiency of the documentation presented.

3. REFERENCES

3.1. None.

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HRP-022
POLICY: End Approval Dates

1. PURPOSE

1.1. This policy describes the calculation of the **End Approval Date**.

2. POLICY

2.1. The following research has no **End Approval Date**:

2.1.1. Research that does not require continuing review because the research does not have to follow Pre 2018 regulations and one of the following is true:

2.1.1.1. The research is eligible for exemption.

2.1.1.2. The research is eligible for expedited review.

2.1.1.3. The research has progressed to the point that it solely involves data analysis and/or accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care, including analysis of **Identifiable Private Information** or **Identifiable Biospecimens**, which are part of the IRB-approved study.

2.1.2. In these cases where an end date is not required, the Institution implements an administrative check-in procedure which is intended to keep the IRB informed of which research projects are still active.

2.2. For all other research:

2.2.1. The **End Approval Date** is:

2.2.1.1. The date the convened IRB made the determination to approve or conditionally approve the research; or

2.2.1.2. The date the **Designated Reviewer** made the determination to approve the research or confirm that the responsive materials met the requirements of a conditional approval.

2.2.2. The Approval Period is the period of approval granted by the convened IRB or **Designated Reviewer** (e.g., 1 year, 6 months, 3 months).

2.2.3. For initial review, the **End Approval Date** is the Approval Date plus the Approval Period minus one day.

2.2.3.1. For example, if the research was approved for 1 year with an Approval Date of April 15, 2025, the **End Approval Date** is April 14, 2026.

2.2.4. For continuing review:

2.2.4.1. The new **End Approval Date** is the Approval Date for the continuing review plus the Approval Period set in the continuing review minus one day.

2.2.5. The new **End Approval Date** is the Approval Date for the continuing review plus the Approval Period set in the continuing review minus one day.

3. REFERENCES

3.1. 21 CFR §56.109(f)

3.2. 45 CFR §46.104

3.3. 45 CFR §46.109(e)

3.4. 45 CFR §46.110

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HRP-023
POLICY: IRB Records

1. PURPOSE

1.1. This policy describes the contents of IRB records. IRB records, as described in this policy, shall be retained in accordance with "SOP: IRB Records Retention (HRP-140)."

2. POLICY

2.1. Documents in a study file are intended to record the history of IRB actions related to the review.

2.2. IRB files are to include:

2.2.1. Study files (as described in 2.3).

2.2.2. IRB meeting minutes.

2.2.2.1. The IRB meeting minutes capture the final determinations made by the convened committee.

2.2.2.1.1. All worksheets and checklists completed by IRB members prior to a convened IRB meeting represent preliminary judgments and are intended to facilitate informed discussion at the meeting. Such worksheets and checklists do not require retention.

2.2.3. A resume or curriculum vitae for each IRB member.

2.2.4. Current and previous versions of IRB member rosters (See POLICY: IRB Roster (HRP-024)).

2.2.5. Current and previous versions of controlled documents.

2.2.6. Correspondence to and from the IRB related to **Human Subjects Research.**

2.2.7. **Reliance Agreements**.

2.3. Study files are to include the following information when it exists:

2.3.1. Submissions to and from the IRB related to the study.

2.3.2. Protocols or research plans.

2.3.3. Investigator brochure.

2.3.4. Scientific evaluations, when provided by an entity other than the IRB.

2.3.5. Recruitment materials.

2.3.6. Consent documents.

2.3.7. Progress reports submitted by investigators.

2.3.8. Reports of injuries to subjects.

2.3.9. Reports of complaints about the research study.

2.3.10. Records of continuing review activities.

2.3.11. Data and safety monitoring reports.

2.3.12. Amendments.

2.3.13. **Unanticipated Problems Involving Risks to Subjects or Others**.

2.3.14. Documentation of **Noncompliance**.

2.3.15. Significant new findings and statements about them provided to subjects.

2.3.16. For initial and continuing review by the expedited procedure:

2.3.16.1. The specific permissible category for expedited review.

2.3.16.2. Description of action taken by the **Designated Reviewer**.

2.3.16.3. Any findings required by law.

2.3.16.4. If continuing review not required by the regulations, but the **Designated Reviewer** determined that continuing review was required, the **Designated Reviewer's** rationale for that determination.

2.3.17. If the **Designated Reviewer** determines that research falls into one or more categories allowing review using the expedited procedure, but is more than **Minimal Risk**, the **Designated Reviewer's** rationale for that determination.

2.3.18. For exemption determinations, the specific category of exemption.

2.3.19. Required determinations and study-specific findings supporting those determinations for research involving (except when documented in minutes for convened board determinations):

2.3.19.1. Waiver or alteration of the consent process.

2.3.19.2. Waiver of written documentation of informed consent.

2.3.19.3. **Pregnant Women**.

2.3.19.4. **Neonates of Uncertain Viability**.

2.3.19.5. **Nonviable Neonates**.

2.3.19.6. **Prisoners**.

2.3.19.7. **Children**.

2.3.19.8. **Wards**.

2.3.19.9. **Significant Risk Device/Non-significant Risk Device** determinations, which will only be made by the convened board.

2.3.20. For each study's initial and continuing review, the frequency for the next continuing review or that continuing review is not required.

2.4. Records for FDA-regulated research are to be accessible for inspection and copying by authorized representatives of FDA at reasonable times and in a reasonable manner.

2.5. Records for research conducted, supported, or otherwise subject to regulation by a Federal department or agency are to be accessible for inspection and copying by authorized representatives at reasonable times and in a reasonable manner.

2.5.1. Records maintained that document compliance or **Noncompliance** with Department of Defense (DOD) regulations shall be made accessible for inspection and copying by representatives of the DOD at reasonable times and in a reasonable manner as determined by the supporting DOD component.

2.6. Upon request, CU Boulder makes IRB records available on request provided they are relevant to the requester. Such records may be excerpted and/or redacted to comply with CU Boulder obligations to maintain confidentiality.

3. REFERENCES

3.1. 21 CFR §56.115

3.2. 45 CFR §46.115

3.3. SOP: IRB Records Retention (HRP-140)

3.4. POLICY: IRB Roster (HRP-024)

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HRP-024
POLICY: IRB Roster

1. PURPOSE

1.1. This policy describes the information recorded in IRB rosters.

2. POLICY

2.1. Note on the IRB roster:

2.1.1. The IRB registration number.

2.1.2. The IRB registration name.

2.1.3. Any restrictions on the IRB's scope.

2.1.4. Effective date of the roster.

2.1.5. In the IRB was deactivated, a note to that effect.

2.2. For each IRB member record:

2.2.1. Name.

2.2.2. Earned Degrees.

2.2.3. Gender.

2.2.4. Scientific Status.

2.2.4.1. Whether the IRB member has primary interests in scientific or non-scientific areas: S (Scientific) or NS (Non-scientific).

2.2.5. Representative Capacity:

2.2.5.1. Populations about whom the IRB member is knowledgeable or experienced. (e.g., **Children**, **Prisoners**)

2.2.5.2. If the member represents the general perspective of subjects, note this.

2.2.6. Indications of Experience:

2.2.6.1. Brief description that describes the IRB member's chief anticipated contributions to IRB deliberations, such as profession, certifications, licensure, IRB experience, research experience, or life experience.

2.2.7. Relationship to CU Boulder:

2.2.7.1. Description of any relationship between the IRB member and CU Boulder.

2.2.8. Affiliation Status:

2.2.8.1. Whether the IRB member or an **Immediate Family** member of the IRB member has a relationship with CU Boulder: Affiliated or Non-affiliated.

2.2.8.2. Note that an IRB member may have no relationship to CU Boulder, but the IRB member may be affiliated because an **Immediate Family** member may have a relationship with CU Boulder.

2.2.9. Office:

2.2.9.1. Whether the IRB member is an IRB Chair, IRB Co-Chair, or other appointed office.

2.2.10. Membership Status:

2.2.10.1. Whether the IRB member is a regular member or an alternate member.

2.2.11. Alternates For:

2.2.11.1. If the member is an alternate member, the class of IRB members for whom the member can serve as alternate.

2.2.12. **Designated Reviewer**:

2.2.12.1. Whether the member is a **Designated Reviewer**

3. REFERENCES

3.1. 21 CFR §56.115(a)(5)

3.2. 21 CFR 56.107(d)

3.3. 45 CFR §46.107(a)

3.4. 45 CFR 46.107(d)

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HRP-050
POLICY: States and Transitions

1. PURPOSE

1.1. This policy establishes the states and transitions of studies.

2. POLICY

2.1. A submission is a packet of materials submitted to the IRB. CU Boulder provides an Electronic Research Administration (eRA) submission system. Normally only submissions using the eRA system will be accepted for review.

2.2. The following are allowable submissions:

2.2.1. Initial.

2.2.2. Continuing.

2.2.3. Check-in.

2.2.4. Amendment.

2.2.5. Event Reporting/New Information.

2.2.6. Final Report.

2.3. A study consists of one or more submissions.

2.3.1. A study may have the following states:

Study State	Meaning
Submitted	• An initial submission creates a new study
Determined Not Human Subjects Research	• Study is not **Human Research** • No HRPP oversight is required
Determined Human Research Not Engaged	• Study is **Human Research** • No HRPP oversight is required.
Approved	• Study is **Human Research** • HRPP oversight required • Review determined that the study could proceed
Suspended	• Study is **Human Research** • HRPP oversight required • Prior review determined that the study could proceed • More recent review instituted a **Suspension of IRB Approval**
Terminated	• Study is **Human Research** • HRPP oversight required • Prior review determined that the study could proceed • More recent review instituted a **Termination of IRB Approval**

Expired	• Study is **Human Research** • HRPP oversight required • Prior review determined that the study could proceed • Approval Period passed without continuing review or administrative check-in has not been received
Closed	• Study was **Human Research** • HRPP oversight was required • Prior review determined that the study could proceed • Study meets criteria for closure, or it has been administratively closed by the IRB

2.3.2. A study may change between non- **Human Research** and **Human Research** states. For example, a study might initially be determined to be not **Human Research** and with an Amendment become **Human Research**.

2.4. Review actions on a submission are:

Action	Meaning
Not Human Research	The activity does not meet the organizational definition of **Human Research**.
Human Research Not Engaged	The activity meets the organizational definition of **Human Research,** but the site is not engaged
Exempt	See "SOP: Non-Committee Review Conduct (HRP-104)"
Approve	See "SOP: Non-Committee Review Conduct (HRP-104)" See "SOP: Committee Review Conduct (HRP-106)"
Incomplete	Returned to PI to complete submission requirements
Modifications Required to Secure Approval	Changes required to the submission to allow approval See "SOP: Non-Committee Review Conduct (HRP-104)" See "SOP: Committee Review Conduct (HRP-106)"
Defer	See "SOP: Committee Review Conduct (HRP-106)"
Disapprove	See "SOP: Committee Review Conduct (HRP-106)"
Suspend	See "SOP: Committee Review Conduct (HRP-106)"
Lift Suspension	See "SOP: Committee Review Conduct (HRP-106)"
Terminate	See "SOP: Committee Review Conduct (HRP-106)"
Acknowledge	Submitted item does not require regulatory review

2.5. Administrative actions on a study are:

Action	Meaning
Expire	Approval Period passed without continuing review
Close	Study meets criteria for closure

2.6. Table 1 lists the allowable submissions based on the study's state prior to a submission.

3. REFERENCES

3.1. None.

3.2. Table 1: Allowable submission types by current state of study

Table shows allowable submissions X= allowed		Current State of the Study							
		Submitted	**Determined Not Human Research**	**Determined Human Research Not Engaged**	**Approved**	**Suspended**	**Terminated**	**Expired**	**Closed**
Submission Type	**Initial**	**X**							
	Continuing				**X**	**X**		**X**	
	Check-in				**X**	**X**		**X**	**X**
	Amendment		**X**	**X**	**X**	**X**	**X**	**X**	**X**
	Reportable Event/New Information		**X**	**X**	**X**	**X**	**X**	**X**	**X**
	Final Report				**x**	**x**	**x**	**x**	

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HRP-070
POLICY: Investigator Obligations

1. PURPOSE

1.1. Al This policy describes the obligations of investigators conducting **Human Research** overseen by CU Boulder.

2. POLICY

2.1. Do not commence research until you have the IRB approval letter and have obtained all other required approvals, such as radiation safety approval, biosafety approval, and approvals of departments, sponsors, or hosts that require approval of the use of their resources or access.

2.1.1. If there are any questions about whether you are conducting **Human Research**, contact the IRB before commencing the study.

2.2. Comply with all requirements and determinations of the IRB.

2.3. Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment and space.

2.4. Ensure that all research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.

2.5. Personally conduct or supervise the research.

2.6. Conduct the research in accordance with the relevant current protocol approved by the IRB.

2.7. Protect the rights, safety, and welfare of subjects involved in the research.

2.8. Submit proposed modifications to the IRB in an Amendment prior to their implementation.

2.8.1. Do not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.

2.9. Submit continuing reviews or check-ins as required by the IRB.

2.10. Submit a Final Review form to close research (end the IRB's oversight) when all the following are true:

2.10.1. The protocol is permanently closed to enrollment.

2.10.2. All subjects have completed all protocol related **Interventions** and **Interactions**.

2.10.3. No additional **Identifiable Private Information** about the subjects is being obtained.

2.10.4. The analysis of private **Identifiable Information** is completed.

2.11. If research reaches its **Expiration Date**, without a continuing review or final report stop all research activities and immediately contact the IRB.

2.12. Promptly report to the IRB the information items listed in "POLICY: Prompt Reporting Requirements (HRP-071)."

2.13. Do not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees").

2.14. Do not accept payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.

2.15. For studies regulated by a federal department or agency, follow any additional obligations, as applicable.

2.16. For studies where ICH-GCP compliance is required, follow additional the obligations in "INVESTIGATOR GUIDANCE: Additional ICH-GCP Obligations (HRP-816)."

2.17. When required by the IRB, ensure that consent, permission, and assent are obtained and documented in accordance with the relevant current protocol as approved by the IRB.

2.18. Retain research records (including signed consent documents) for the greater of:

2.18.1. Three years after completion of the research

2.18.2. For drug studies conducted under an IND, two years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until two years after the investigation is discontinued and FDA is notified.

2.18.3. For device studies conducted under an IDE or abbreviated IDE, two years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

2.18.4. The retention period required by the sponsor

2.18.5. The retention period required by local, state, or international law.

2.18.5.1. HIPAA requires signed authorizations to be retained for six years from the date signed or the date when it last was in effect, whichever is later.

3. REFERENCES

3.1. 21 CFR §56.103(a)

3.2. 21 CFR §56.108(a)

3.3. 21 CFR §50.20

3.4. 21 CFR §50.25

3.5. 21 CFR §50.27

3.6. 45 CFR §46.116

3.7. 45 CFR §46.117

3.8. FDA Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions – Statement of Investigator (Form FDA 1572)

3.9. CU Boulder IRB Investigator Manual

3.10. POLICY: Prompt Reporting Requirements (HRP-071)

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HRP-071
POLICY: Prompt Reporting Requirements

1. PURPOSE

1.1. This policy describes the information investigators must promptly report to CU Boulder's IRB when the research is subject to oversight by CU Boulder's IRB.

1.2. For research overseen by an IRB other than University of Colorado Boulder's IRB, investigators should follow the requirements of that IRB.

2. POLICY

2.1. Report the following information items to the IRB within 5 business days of becoming aware:

2.1.1. Audit, inspection, or inquiry by a federal agency.

2.1.2. Written report of a federal agency (e.g., FDA Form 483).

2.1.3. State medical board or hospital medical staff actions.

2.1.4. **Allegation of Noncompliance** or **Finding of Noncompliance.**

2.1.5. Suspension or premature termination by the sponsor, investigator, or institution.

2.1.6. Incarceration of a subject in a research study not approved to involve **Prisoners**.

2.1.7. New or increased risk[1].

2.1.8. Unanticipated adverse device effect[2].

2.1.9. **Unanticipated Problems Involving Risks to Subjects or Others** [3].

2.1.10. **Protocol Deviation** that harmed a subject or placed subject at risk of harm.

2.1.11. **Protocol Deviation** due to the action or inaction of the investigator or research staff.

2.1.12. **Protocol Deviation** made without prior IRB approval to eliminate an immediate hazard to a subject.

2.1.13. Breach of confidentiality.

2.1.14. Unresolved subject complaint.

2.1.15. Adverse event or IND safety report that requires a protocol or consent change.

2.1.16. Written report of a study monitor.

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[1] For example, publications indicating a new risk, new risk in an investigator brochure, FDA black box warning, new risk identified in a data safety monitoring report, information or change that adversely affects subject safety, or information or change that adversely affects the conduct of the research.

[2] Unanticipated adverse device effect means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

[3] Unanticipated problem means any incident that a) was unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents, such as the IRB-approved protocol and informed consent document, b) was related or probably related to participation in the research, and c) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.

2.2. When relying on an external IRB report the following information items to the HRPP Office within 5 business days:

2.2.1. Audit, inspection, or inquiry by a federal agency.

2.2.2. Written report of a federal agency (e.g., FDA Form 483).

2.2.3. State medical board or hospital medical staff actions.

2.2.4. Breach of confidentiality.

2.2.5. Written report of a study monitor.

2.3. Information not listed above does not require prompt reporting to CU Boulder's IRB.

3. REFERENCES

3.1. 21 CFR §56.108(b)

3.2. 45 CFR §46.107(a)

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HRP-101
SOP: Intake Review

1. PURPOSE

1.1. This procedure establishes the process to review IRB submissions for administrative and regulatory issues unrelated to the regulatory criteria for approval of **Human Research**.

1.2. This procedure begins when an IRB submission is viewed by office staff.

1.3. This procedure ends when the **Intake Reviewer** has completed the review, returns the submission to the investigator, or an investigator has withdrawn the submission.

2. POLICY

2.1. As part of IRB review, all submissions are reviewed by an **Intake Reviewer**, to:

2.1.1. Identify submissions with missing materials.

2.1.2. Verify current human subjects training documentation for all study personnel.

2.1.3. Verify conflict of interest disclosure to the Office of Conflicts of Interest & Commitment for all study personnel are satisfied.

2.1.4. Assign the submission to the **Designated Reviewer** with the appropriate expertise for review.

3. RESPONSIBILITY

3.1. An **Intake Reviewer or Designated Reviewer** may carry out these procedures and the procedures may be combined with a **Non-Committee Review**.

4. PROCEDURE

4.1. If the submission is a response to Modifications Required or Incomplete, or is an Event Report/New Information:

4.1.1. Assign the submission to the person who issued the Modifications Required or Incomplete letter, or to the **Designated Reviewer** appropriate for the assigned IRB panel to conduct **Non-Committee Review**.

4.2. For all other submission types, complete **Intake Review**.

4.2.1. Ensure the submission is not missing any documents necessary for review.

4.2.2. Verify all personnel listed on the protocol are in compliance with the required human subjects training requirements.

4.2.3. Verify conflict of interest disclosure to the Office of Conflicts of Interest & Commitment has been completed for all personnel listed on the protocol.

5. MATERIALS

5.1. None.

6. REFERENCES

6.1. POLCY: Definitions (HRP-001)

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HRP-102
SOP: Designated Reviewers

1. PURPOSE

1.1. This procedure establishes the process to designate an **Experienced IRB Member** who can conduct **Non-Committee Review** or revoke the responsibilities of a **Designated Reviewer**.

1.2. This procedure begins when IRB Chair considers adding or removing a **Designated Reviewer**.

1.3. This procedure ends when the IRB Chair or Designee notifies IRB staff of a new **Designated Reviewer** or the removal of a **Designated Reviewer**.

2. POLICY

2.1. None.

3. RESPONSIBILITY

3.1. The IRB Chair or Designee carries out these procedures.

4. PROCEDURE

4.1. To add a **Designated Reviewer**:

4.1.1. Review the IRB roster and ensure that the proposed individual is **Experienced IRB Member**.

4.2. To remove a **Designated Reviewer** no criteria need be followed.

4.3. Notify the IRB staff member managing the IRB roster of the decision to add or remove a **Designated Reviewer** and have that IRB staff member update the IRB roster.

4.4. Notify the individual of the decision.

5. MATERIALS

5.1. None.

6. REFERENCES

6.1. 21 CFR §56.110

6.2. 45 CFR §46.110

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HRP-104
SOP: Non-Committee Review Conduct

1. PURPOSE

1.1. This procedure establishes the process to conduct **Non-Committee Review**.

1.2. This procedure begins when a **Designated Reviewer** has been notified to conduct a **Non-Committee Review**.

1.3. This procedure ends when a **Designated Reviewer** has communicated the IRB's findings and actions to the Investigator or has referred the submission for **Committee Review**. Follow "SOP: Post Review (HRP-111)."

1.4. Identify and document the determinations that need to be made to approve research. (For example, waiver of consent, **Children**, **Prisoners**, IND/IDE)

1.5. Identify any relevant local, state, or international requirements

1.6. Arrange for consultation to resolve local, state, or international requirements.

1.7. Identify other special review issues.

1.8. Determine the level of review (**Committee Review** versus **Non-Committee Review**).

1.9. Handle responses to modifications required to secure approval.

2. POLICY

2.1. **Designated Reviewers** are to review the materials submitted in eRA.

2.2. **Designated Reviewers** may not disapprove, suspend, or terminate research.

2.3. Non-exempt research that does not undergo continuing review is considered open until closed by the investigator or administratively closed by the IRB.

3. RESPONSIBILITY

3.1. **Designated Reviewers** carry out these procedures.

4. PROCEDURE

4.1. Consider whether you have a **Conflicting Interest**.

4.1.1. If so, assign the review task to another **Designated Reviewer**.

4.2. Consider whether you have sufficient expertise to review the submission. If you need additional expertise, follow "SOP: Consultation (HRP-110)." Sufficient expertise includes, as applicable for the research:

4.2.1. Scientific or scholarly expertise.

4.2.2. Knowledge of or experience working with vulnerable populations.

4.2.3. Qualification as a **Prisoner** representative.

4.2.4. Knowledge of the country in which the research is conducted.

4.2.5. Medical licensure for FDA-regulated test articles.

4.2.6. Knowledge of federal agency requirements for DOD, DOE, DOJ, ED, EPA, or EPA research.

4.2.7. Concern with the welfare of **Children** with disabilities or individuals with mental disabilities as subjects, if the research is funded by the National Institute on Disability and Rehabilitation Research and purposefully requires inclusion of these subjects.

4.2.8. Knowledge of community based participatory research.

4.3. If the submission is a response to Modifications Required or Incomplete:

4.3.1. Evaluate whether the submitted materials meet the conditions necessary for approval and evaluate if any other changes to the original submission have been made.

4.3.2. If the submitted materials meet the conditions necessary for approval and nothing else in the submission has changed, document that the submission is approved and follow "SOP: Post Review (HRP-111)." Otherwise, process as described in this SOP.

4.4. If the submission meets criteria for closure, close the study, follow "SOP: Post-Review (HRP-111)" and "SOP: Study Closure (HRP-118)" to notify the investigator, and stop further processing. If the study does not meet closure criteria follow "SOP: Study Closure (HRP-118)".

4.5. If the investigator is **Restricted** and the submission satisfies all outstanding delinquent submissions, remove the investigator's **Restricted** status.

4.6. If the investigator is **Restricted** and the submission is an initial submission, notify the investigator of IRB policy to disapprove those submissions.

4.6.1. If the investigator wants to address the **Restricted** status, have the contact provide additional information as appropriate to resolve the issues, or withdraw the submission and resubmit when complete.

4.6.2. If the investigator does not want to address the **Restricted** status, note this and continue processing.

4.7. For initial submission:

4.7.1. Use "WORKSHEET: Regulatory Review (HRP-420)."

4.7.2. Document any **Regulatory Review** findings in eRA.

4.8. For an amendment submission:

4.8.1. Review the **Regulatory Review** findings associated with prior approval(s).

4.8.2. Use "WORKSHEET: Regulatory Review (HRP-420)."

4.8.3. Update **Regulatory Review** findings as needed.

4.8.4. Determine whether the submission includes information that might represent an Unanticipated Problem Involving Risks to Subjects or Others, **Serious Noncompliance**, **Continuing Noncompliance**, **Suspension of IRB Approval**, or **Termination of IRB Approval**.

4.8.4.1. If so, request a new submission for New Information for that part of the submission.

4.9. For continuing review submission:

4.9.1. Review the **Regulatory Review** findings associated with prior approval(s).

4.9.2. Use "WORKSHEET: Regulatory Review (HRP-420)" or equivalent in eRA.

4.9.3. Update **Regulatory Review** findings as needed.

4.9.4. Determine whether the submission includes information that might represent an Unanticipated Problem Involving Risks to Subjects or Others, **Serious Noncompliance**, **Continuing Noncompliance**, **Suspension of IRB Approval**, or **Termination of IRB Approval**.

4.9.4.1. If so, request a new submission for New Information for that part of the submission.

4.10. For reportable event submission:

4.10.1. Review the **Regulatory Review** findings associated with prior approval(s).

4.10.2. Determine whether the submission includes information that might represent an Unanticipated Problem Involving Risks to Subjects or Others, **Serious Noncompliance**, **Continuing Noncompliance**, **Suspension of IRB Approval**, or **Termination of IRB Approval**.

4.10.2.1. If so, refer the submission to **Committee Review**.

4.11. Identify any relevant local, state, or international requirements related to **Human Research**.

4.11.1. Arrange for consultation, if needed to resolve local, state, or international regulatory issues.

4.12. Take one of the following actions:

4.12.1. Determine whether the submission is eligible for **Non-Committee Review** based on risk level and expedited review categories if applicable.

4.12.1.1. If the submission is not eligible for **Non-Committee Review**, refer to the IRB staff member handling the submission for **Committee Review**.

4.12.2. "Not Human Research": The submission does not meet the definition of **Human Research** based on "WORKSHEET: Human Research (HRP-421)."

4.12.3. "Human Research Not Engaged" the submission meets the definition of **Human Research** but does not engage the institution based on "WORKSHEET: Engagement (HRP-422)."

4.12.4. "Exempt": The submission meets the criteria in ""WORKSHEET: Exemption (HRP-423)."

4.12.5. "Approve": The submission meets the criteria "WORKSHEET: Expedited Review (HRP-424)," "WORKSHEET: Criteria for Approval (HRP-400)," and other applicable worksheets and checklists as determined by the **Regulatory Review**.

4.12.6. "Modifications Required": This determination can apply to any submission that requires additional information for a final determination to be made.

4.12.7. ".118 Determination": When a federal funding agency requires IRB approval before the funding agency can release grant monies, and the investigator cannot submit a

complete research proposal, the IRB may provide a preliminary opinion on the proposed research.

4.12.8. "Acknowledge": The IRB wants to confirm that the IRB has reviewed the materials, but an action of "Approve" is not applicable.

4.12.9. "Incomplete": The submission lacks information necessary to adequately review.

4.13. If the determination is to "Approve" or "Modifications Required," document your determination regarding the criteria for approval.

4.14. If the determination is "Modifications Required" or "Incomplete," communicate the required modifications or reasons for the Incomplete to the submission contact for resolution.

4.15. Document in eRA:

4.15.1. The action taken.

4.15.2. If the action is "Exempt," document the category or categories from "WORKSHEET: Exemption (HRP-423)" allowing the exemption.

4.15.3. If the action is "Approve," document:

4.15.3.1. The category or categories in "WORKSHEET: Expedited Review (HRP-424)" allowing review using the expedited procedure.

4.15.3.2. The period of approval (not to exceed one year) or that continuing review is not required.

4.15.3.3. If the research is subject to **Revised Requirements** and you require continuing review even though it is not required by "WORKSHEET: Criteria for Approval (HRP-400)," document the rationale for requiring continuing review.[1]

4.16. If you cannot apply any of the above actions, inform the IRB staff that **Committee Review** is required.

4.16.1. If the reason that you cannot apply any of the above actions is because the research is subject to the **Revised Rule** and falls into a category in "WORKSHEET: Expedited Review (HRP-424)" allowing initial review by the expedited procedure, but involves greater than **Minimal Risk**, document the rationale that the research involves greater than **Minimal Risk**.

5. MATERIALS

5.1. WORKSHEET: Regulatory Review (HRP-420)

5.2. WORKSHEET: Human Research (HRP-421)

5.3. WORKSHEET: Engagement (HRP-422)

5.4. WORKSHEET: Exemption (HRP-423)

5.5. WORKSHEET: Expedited Review (HRP-424)

5.6. WORKSHEET: Criteria for Approval (HRP-400)

[1] When research is FDA-regulated and subject to the **Revised Rule**, the IRB's rationale for requiring continuing review is that the research is FDA-regulated.

6. REFERENCES

6.1. SOP: Post Review (HRP-111)

6.2. SOP: Consultation (HRP-110)

6.3. SOP: Study Closure (HRP-118)

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HRP-105
SOP: Committee Review Preparation

1. PURPOSE

1.1. This procedure establishes the process to prepare for an IRB meeting.

1.2. This procedure begins when meeting preparation commences.

1.3. This procedure ends when IRB members attending the meeting have been notified of the agenda and their assignments.

2. POLICY

2.1. CU Boulder places limits on the number of items on the agenda of an IRB meeting. The workloads are determined by IRB staff and members on a per IRB panel basis. The limits are based on the complexity of agenda items at a typical meeting and the time available to meet. Limits are adjusted as needed by IRB staff and members.

3. RESPONSIBILITY

3.1. IRB staff carry out these procedures.

4. PROCEDURE

4.1. Confirm which IRB members (regular, alternate, IRB Chairs, and IRB Co-Chairs) will be present at the meeting.

4.2. Prepare an agenda, which includes convened review items and expedited review actions taken since the last agenda.

4.3. Assign IRB member(s) as primary reviewers to present each convened review item.

4.4. Ensure that at least one IRB member with relevant scientific/scholarly expertise will be present for each agenda item.

4.4.1. If an IRB member with relevant scientific/scholarly expertise is not available, follow “SOP: Consultation (HRP-110)” to obtain a consultant.

4.5. Ensure that the meeting will be appropriately convened based on “WORKSHEET: Quorum (HRP-431).”

4.6. If the meeting will not meet the quorum requirements, make arrangements to meet quorum requirements or notify the IRB Program Director or IRB Chair.

4.7. Ensure that all IRB members are provided or have access to the materials in “POLICY: IRB Member Review Expectations (HRP-020)”at least 48 hours before meetings, unless an exception is cleared by an IRB Chair or Designee.

5. MATERIALS

5.1. WORKSHEET: Quorum (HRP-431)

6. REFERENCES

6.1. SOP: Consultation (HRP-110)

6.2. POLICY: IRB Member Review Expectations (HRP-020)

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HRP-106
SOP: Committee Review Conduct

1. PURPOSE

1.1. This procedure establishes the process for conducting an IRB meeting.

1.2. This procedure begins when the meeting is called to order.

1.3. This procedure ends when the meeting is adjourned.

2. POLICY

2.1. The **Meeting Chair** is responsible to:

2.1.1. Lead the IRB meeting.

2.1.2. Facilitate IRB review.

2.1.3. Ensure this SOP is followed.

2.1.4. Monitor the IRB's decisions for consistency.

2.1.5. Ensure that IRB members are free to participate in discussions.

2.1.6. Ensure that IRB members attending by teleconference can actively and equally participate in all discussions.

2.1.7. Vote as an IRB member.

2.2. The **Meeting Chair** is expected to:

2.2.1. Help IRB members meet their expectations in “POLICY: IRB Member Review Expectations (HRP-020).”

2.2.2. Encourage IRB members to:

2.2.2.1. Ask questions.

2.2.2.2. Speak their minds at every protocol review.

2.2.2.3. Share information that has not been discussed.

2.2.2.4. Listen and learn from the group.

2.2.2.5. Respect dissenting opinions.

2.2.2.6. Think and vote independently.

2.2.3. Mentor and guide IRB members to use the criteria for approval in WORKSHEET: Criteria for Approval (HRP-400) by:

2.2.3.1. Facilitating IRB members’ understanding of the research to the degree sufficient to apply the criteria for approval.

2.2.3.2. Having IRB members base concerns, problems, and recommended modifications on the criteria for approval.

2.2.3.3. Removing issues from consideration when the **Meeting Chair** and IRB members determine they do not affect the criteria for approval.

2.2.3.4. Obtaining assistance when the **Meeting Chair** and IRB members are uncertain whether an issue affects the criteria for approval.

2.2.3.5. Framing difficult or controverted issues in terms of the criterion that is the basis of the controversy.

2.2.3.6. Taking votes on the criterion for approval that is the basis for a controversy, if after sufficient discussion a controverted issue remains unresolved.

2.2.3.7. Reminding IRB members who believe that one or more criteria for approval voted are not met that they should not vote for approval.

2.2.3.8. Supporting dissent based on the criteria for approval.

2.2.4. Encourage IRB member engagement by:

2.2.4.1. Reinforcing IRB member expectations.

2.2.4.2. Encouraging IRB members to use their unique perspective to contribute to IRB deliberations.

2.2.4.3. Caring about each IRB member as a person.

2.2.4.4. Encouraging IRB members to continue to develop their review skills.

2.2.4.5. Ensuring opinions of IRB members count.

2.2.4.6. Communicating the mission of CU Boulder IRB to protect subjects.

2.3. IRB members are responsible for understanding the definition of **Conflicting Interest** and for timely self-identifying their **Conflicting Interests**.

2.4. The **Meeting Chair** may help IRB staff determine that certain IRB members have voting status and others have non-voting status.

2.4.1. The number of IRB members with voting status is not greater than the number of regular IRB members on the IRB roster.

2.4.2. During the meeting the **Meeting Chair** may change who has voting status and who has non-voting status.

2.4.3. The **Meeting Chair** is responsible for notifying the IRB staff at the meeting of any change in IRB members' voting status.

2.5. All IRB members who are part of the quorum may vote.

2.6. Ad hoc substitutes may not serve as IRB members.

2.7. Absent IRB members may submit written comments but may not vote.

2.8. Consultants may not vote.

2.9. Observers may attend meetings, but:

2.9.1. May not participate in IRB deliberations unless requested by the IRB to serve as a consultant.

2.9.2. May not vote.

2.9.3. Must agree to maintain the confidentiality of the IRB proceedings.

2.10. When a protocol is ambiguous, the IRB may resolve the ambiguity by obtaining written information from the sponsor or investigator in advance of the meeting as an alternative to contingent approval. IRB members must be made aware of this information, either orally or in writing.

3. RESPONSIBILITY

3.1. **Meeting Chairs** carry out these procedures.

4. PROCEDURE

4.1. Call the meeting to order.

4.2. Review and approve minutes from previous meeting.

4.3. Ask whether anyone has a **Conflicting Interest** related to any agenda item.

4.4. For each study review:

4.4.1. If there are individuals (either IRB members or consultants) with a **Conflicting Interest** related to an agenda item:

4.4.1.1. IRB members may ask questions of those individuals.

4.4.1.2. If physically present, ask those individuals to leave the room.

4.4.1.3. If present by teleconference, set the conference equipment to block communications or ask the member to leave the call during the review.

4.4.2. If the study is eligible for **Non-Committee Review**, the IRB can take no action and have the item reviewed by **Non-Committee Review**.

4.4.3. Take no action on the item when notified by an IRB staff member that quorum requirements are not met[1] or when there is insufficient time.

4.4.3.1. Move the item to another meeting.

4.4.4. If one or more consultants are involved:

4.4.4.1. Inform the IRB members of any **Conflicting Interest**.

4.4.4.2. Have the consultants present at the meetings discuss their findings.

4.4.5. For each primary reviewer:

4.4.5.1. Review relevant findings of **Regulatory Review** and **Regulatory Review** contingencies.

4.4.5.2. For a review related to an **Unanticipated Problem Involving Risks to Subjects or Others**, **Serious Noncompliance**, **Continuing Noncompliance**, **Suspension of IRB Approval**, or **Termination of IRB Approval** have the IRB determine whether any of these apply, and if so, lead the IRB members through a discussion of “WORKSHEET: New Information (HRP-411).”

[1] If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored. If required members (e.g. non-scientific) leave the room and quorum is lost votes cannot be taken until the quorum is restored, even if half of the members are still present.

4.4.5.3. Lead the IRB through a discussion of the criteria in applicable worksheets.

4.4.5.4. When a checklist is applicable, discuss the checklist determinations and study-specific findings supporting those determinations.

4.4.5.5. Summarize the IRB's consensus.

4.4.6. Ensure any additional concerns from committee members are raised and discussed.

4.4.7. Request a motion from the Primary Reviewer for one of the following:

4.4.7.1. "Approve": When the IRB determines that the research meets or still meets the criteria for approval.

4.4.7.1.1. For initial and continuing review, include in the motion, the level of risk (**Minimal Risk** or greater than **Minimal Risk**), and either that continuing review is not required, or the period of continuing review (not to exceed one year).

4.4.7.1.2. If the research is subject to **2018 Requirements** and continuing review is not required by "WORKSHEET: Criteria for Approval (HRP-400)," but the IRB requires continuing review, provide the IRB's rationale for requiring continuing review.

4.4.7.1.3. Document that the criteria for approval are met or still met.

4.4.7.2. "Conditionally Approve with Modifications Required to Secure Approval": When the IRB determines that the research will meet or still meets the criteria for approval with minor or prescriptive changes or requirements that can be verified without considering the criteria for approval.

4.4.7.2.1. For initial and continuing review, include in the motion, the level of risk (**Minimal Risk** or greater than **Minimal Risk**), and either that continuing review is not required, or the period of continuing review (not to exceed one year).

4.4.7.2.2. If the research is subject to **2018 Requirements** and continuing review is not required by "WORKSHEET: Criteria for Approval (HRP-400)," but the IRB requires continuing review, provide the IRB's rationale for requiring continuing review.

4.4.7.2.3. Summarize the IRB's required modifications and reasons.

4.4.7.2.4. Document that if the conditions are satisfied, the criteria for approval will be met or are still met.

4.4.7.3. "Defer": When the IRB determines that the initial, continuing, or modification submission does not meet the criteria for approval and does not meet the criteria for "Disapprove."

4.4.7.3.1. Summarize the IRB's reasons and recommendations, if any.

4.4.7.4. "Disapprove": The initial, continuing, or modification submission does not meet the criteria for approval and the IRB considers the research to have extensive deficiencies.

4.4.7.4.1. Summarize the IRB's reasons and recommendations, if any.

4.4.7.5. "Suspend": When the IRB determines that based on new information the previously approved research no longer meets the criteria for approval, or some research activities meet the criteria for approval, or the IRB has recommendations that may make the research meet the criteria for approval.

4.4.7.5.1. Include in the motion: Which research activities must stop or be modified.

4.4.7.5.2. If the research in its entirety no longer meets the regulatory criteria for approval, include in the motion: Stop all research procedures (except as noted below) and stop enrollment

4.4.7.5.3. If stopping research will adversely affect the best interests of currently enrolled subjects, include in the motion: Which subjects can continue and what procedures can be performed

4.4.7.5.4. Lead the IRB members through a discussion of "WORKSHEET: New Information (HRP-411)" to consider additional actions.

4.4.7.5.5. Summarize the IRB's reasons and recommendations.

4.4.7.6. "Terminate": When the IRB determines that based on new information the previously approved research no longer meets the criteria for approval and the IRB has no recommendations to make the research approvable.

4.4.7.6.1. Lead the IRB members through a discussion of "WORKSHEET: New Information (HRP-411)" to consider additional actions.

4.4.7.6.2. Summarize the IRB's reasons.

4.4.7.7. "Lift Suspension": When the IRB determines that based on a modification submission or new information the previously suspended research meets the criteria for approval.

4.4.7.8. "Tabled": The research will be removed from the meeting agenda.

4.4.7.9. ".118 Determination": When a federal funding agency requires IRB approval before the funding agency can release grant monies, and the investigator cannot submit a complete research proposal, the IRB may provide a preliminary opinion on the proposed research.

4.4.7.10. "Acknowledge": The IRB wants to confirm that the IRB has reviewed the materials, but an action of "Approve" is not applicable.

4.4.8. Ensure that the IRB staff member taking minutes has recorded the IRB's actions, required modifications, reasons, recommendations, determinations, summary of controverted issues, and findings.

4.4.9. Call for a vote of IRB members "For," "Against," or "Abstaining." If more than half the IRB members present vote "For," the motion is approved.

4.4.9.1. Treat a tie vote to approve a motion for "Approve" or "Modifications Required to Secure Approval" as an IRB decision of "Defer."

4.5. Have individuals with a **Conflicting Interest** rejoin the meeting.

4.6. Adjourn the meeting when there is no further business or when notified by an IRB staff member that quorum for all remaining agenda items cannot be met.

4.6.1. If there are remaining agenda items, move them to another meeting.

5. MATERIALS

5.1. WORKSHEET: Criteria for Approval (HRP-400)

5.2. WORKSHEET: New Information (HRP-411)

6. REFERENCES

6.1. 21 CFR §56.109

6.2. 45 CFR §46.109

6.3. OHRP Guidance on IRB Approval of Research with Conditions

6.4. POLICY: IRB Member Review Expectations (HRP-020)

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HRP-107
SOP: Committee Review Quorum Monitoring

1. PURPOSE

1.1. This procedure establishes the process to monitor an IRB meeting for quorum and expertise.

1.2. This procedure begins when the meeting is called to order.

1.3. This procedure ends when the meeting is adjourned.

2. POLICY

2.1. None.

3. RESPONSIBILITY

3.1. IRB staff members carry out these procedures based on "WORKSHEET: Quorum (HRP-431)."

4. PROCEDURE

4.1. Before the meeting is called to order, ensure that the meeting will be appropriately convened considering the items on the agenda and anticipated attendance for each item.

4.2. When members anticipated to be present leave the meeting, ensure the remainder of the meeting will be appropriately convened considering the items on the agenda and anticipated attendance for each item.

4.3. Determine whether the meeting is appropriately convened before review of each agenda item that has special quorum requirements not anticipated at the beginning of the meeting.

4.4. When evaluating quorum do not count IRB members with a **Conflicting Interest**.

4.5. Notify the Meeting Chair when quorum requirements are not met and ensure the meeting is paused until quorum is reestablished.

5. MATERIALS

5.1. WORKSHEET: Quorum (HRP-431)

6. REFERENCES

6.1. None.

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HRP-108
SOP: Minutes

1. PURPOSE

1.1. This procedure establishes the process to take IRB minutes.

1.2. This procedure begins when the meeting is called to order.

1.3. This procedure ends when the minutes are finalized.

2. POLICY

2.1. None.

3. RESPONSIBILITY

3.1. IRB staff members and/or the IRB Chair carry out these procedures.

4. PROCEDURE

4.1. Use the current minutes template to record minutes.

4.2. At the beginning of the minutes:

4.2.1. Record the following information on IRB members present at any time during the meeting and having voting status at least once during the meeting[1]:

4.2.1.1. Name.

4.2.1.2. Status[2].

4.2.1.3. Whether the IRB member is an alternate.

4.2.1.4. Whether the IRB member attended by teleconference.

4.2.2. Record the following information on individuals present at any time during the meeting who never have voting status:[3]

4.2.2.1. Name.

4.2.2.2. Role.

4.3. If IRB members are present by teleconference, indicate whether they received all pertinent material before the meeting and could actively and equally participate in all discussions.

4.4. Record the time the meeting is called to order.

4.5. For each item related to specific research:

4.5.1. Record the type of review[4].

[1] If an IRB member has non-voting status for the entire meeting, list as an "Others Present."
[2] For example: IRB Chair, IRB Co-Chair, scientific member, non-scientific member, unaffiliated member
[3] This may include IRB members who are present for the meeting but never vote, consultants, non-IRB members, IRB staff, etc.
[4] For example: Initial, continuing, modification, event report/new information, study, site

4.5.2. Record relevant information about the research:

4.5.2.1. Title.

4.5.2.2. Principal investigator.

4.5.2.3. IRB number.

4.5.2.4. Funding

4.5.3. When needed for clarity, summarize previous IRB actions.

4.5.4. If any item is not acted upon, record the reason.[5]

4.5.5. If a consultant provided an oral report, summarize the key information provided.

4.5.6. If there were any controverted issues, (IRB members expressed a difference of opinion), summarize the issue, label as a controverted issue, and summarize the resolution, if any.

4.5.6.1. If there were no controverted issues, record this.

4.5.7. Record the motion.

4.5.7.1. For a motion of "Approve" or "Modifications Required to Secure Approval" related to an initial or continuing review submission record:

4.5.7.1.1. The period of approval or that continuing review is not required.

4.5.7.1.2. If continuing review is not required by "WORKSHEET: Criteria for Approval (HRP-400)" but the IRB requires continuing review, document the rationale for requiring continuing review.

4.5.7.1.3. Whether the risk is **Minimal Risk** or greater than **Minimal Risk**.

4.5.7.1.4. Any required checklist determinations along with study-specific findings supporting those determinations.

4.5.7.1.5. Any rationale for any **Non-significant Risk Device** or **Significant Risk Device** determination.

4.5.7.1.6. The IRB's determination regarding the criteria for approval.

4.5.7.2. For a motion of "Modifications Required to Secure Approval," record the IRB's modifications required to secure approval and the reasons for those modifications.

4.5.7.3. For a motion of "Defer," record the IRB's reasons and recommendations if any.

4.5.7.4. For a motion of "Disapprove," record the IRB's reasons.

4.5.7.5. For a motion of "Suspend," record the specific activities suspended and the IRB's recommendations, if any.

4.5.7.6. For a motion of "Lift Suspension," no other information needs to be recorded.

[5] For example: Loss of all non-scientific members, missing expertise, meeting ended early due to fire alarm

4.5.7.7. For a motion of "Terminate," record the IRB's reasons.

4.5.7.8. For a motion of .118 Determination, no other information needs to be recorded.

4.5.7.9. For a motion of "Acknowledge," no other information needs to be recorded.

4.5.7.10. For a motion of "Tabled," record the IRB's reasons.

4.5.8. Record the vote as the numbers:

4.5.8.1. For": Voting for the motion.

4.5.8.2. "Against": Voting against the motion.

4.5.8.3. "Abstain": Present for the vote but not voting "For" or "Against."

4.5.8.4. "Absent": Not present for reasons other than a **Conflicting Interest.**

4.5.8.4.1. Record the names of absent members (members in attendance at the meeting but absent from the room for the vote).

4.5.8.5. "Recused": Not present for discussion and not voting due to a **Conflicting Interest**.

4.5.8.5.1. Record the names of recused members.

4.5.8.6. Record the names of alternate members substituting for members present at the meeting but not in voting status.

4.5.8.7. Record the Non-Voting Status: Present at the meeting but not in voting status (in voting status for some items but not in voting status for all items).

4.5.8.7.1. Record the names of members present in non-voting status.

4.5.8.8. Record the time the meeting is adjourned.

4.5.8.9. Provide the minutes to the IRB Program Director and **Meeting Chair** for review.

4.5.8.10. Provide a draft copy of the minutes to IRB members for review and approval at the next convened meeting.

4.5.8.11. Provide the approved minutes to the IRB members.

4.5.8.12. Provide approved minutes to the **Institutional Official** or **Designe**e.

5. MATERIALS

5.1. WORKSHEET: Criteria for Approval (HRP-400)

6. REFERENCES

6.1. 21 CFR §56.115(a)(2)

6.2. 45 CFR §46.115(a)(2)

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HRP-109
SOP: Not Otherwise Approvable Research

1. PURPOSE

1.1. This procedure establishes the process for the organization to review research that is not otherwise approvable, but because the research is not subject to regulatory approval no government agency will conduct a review of this research to determine whether it can be approved.

1.2. This procedure begins when the **convened** IRB determines that research falls into a not otherwise approvable category.

1.3. This procedure ends when the IRB is informed of the **Institutional Official**'s decision.

2. POLICY

2.1. None.

3. RESPONSIBILITY

3.1. The **Institutional Official** or carries out these procedures.

4. PROCEDURE

4.1. Research in this category that is not federally funded and does not involve FDA-regulated products will be reviewed by a special panel convened by the **Institutional Official** to make the determinations that would otherwise be made by HHS or FDA when evaluating research in this category.

4.2. Determine whether to review the research.

4.2.1. If a determination is made not to review the research, inform the IRB and take no further action under this SOP.

4.3. Identify a panel of five or more experts in pertinent disciplines (e.g., science, medicine, education, ethics, and law) and relevant subject advocates willing to serve on a public panel.

4.3.1. Determine whether any panel member has a **Conflicting Interest**.

4.3.2. Do not use panel members with a **Conflicting Interest**.

4.4. Provide panel members with all information reviewed by the convened IRB.

4.5. Ask panel members to provide individual written recommendations.

4.6. Set a date for a meeting.

4.7. Conduct the meeting:

4.8. After the meeting, have each panel member write an independent recommendation for one of the following:

4.8.1. The research should proceed because it falls into an approvable research category on "CHECKLIST: Nonviable Neonates (HRP-307)," "CHECKLIST: Neonates of Uncertain Viability (HRP-306)," or "CHECKLIST: Children (HRP-310)."

4.8.2. The research does not meet any of the above criteria but should proceed because the following criteria are met:

4.8.2.1. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of **Children** or pregnant women, **Fetuses**, or **Neonates**.

4.8.2.2. The research will be conducted in accordance with sound ethical principles.

4.8.2.3. Adequate provisions are made for soliciting the assent of **Children**, the permission of their parents or **Guardians**, and the consent of subjects, as required by "WORKSHEET: Criteria for Approval (HRP-400)," "CHECKLIST: Nonviable Neonates (HRP-307)," "CHECKLIST: Neonates of Uncertain Viability (HRP-306)," or "CHECKLIST: Children (HRP-310)."

4.8.3. The research with modifications should proceed under one of the above criteria.

4.8.4. The research should not proceed.

4.9. Review the panel report and make one of these recommendations:

4.9.1. Approve the research as submitted.

4.9.2. Approve the research with modifications.

4.9.3. Disapprove the research.

4.10. Inform the IRB and the investigator of the recommendation.

4.10.1. Place the study on the agenda of a convened IRB.

5. MATERIALS

5.1. CHECKLIST: Nonviable Neonates (HRP-307)

5.2. CHECKLIST: Neonates of Uncertain Viability (HRP-306)

5.3. CHECKLIST: Children (HRP-310)

5.4. WORKSHEET: Criteria for Approval (HRP-400)

6. REFERENCES

6.1. 21 CFR §50.54

6.2. 45 CFR §46.207

6.3. 45 CFR §46.407

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HRP-110
SOP: Consultation

1. PURPOSE

1.1. This procedure establishes the process to obtain consultation.

1.2. This procedure begins when the IRB requires competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB.

1.3. This procedure ends when the IRB is informed of the consultation findings.

2. POLICY

2.1. N The relying organization is responsible to identify organizational conflicts of interests.one.

3. RESPONSIBILITY

3.1. For **Committee Review**, IRB staff members carry out these procedures.

3.2. For **Non-Committee Review**, the **Designated Reviewer** carries out these procedures.

4. PROCEDURE

4.1. Identify a consultant with the required expertise who can provide a review. Identify individuals as follows:

4.1.1. IRB members

4.1.2. University Employees

4.1.3. External consultants

4.2. Contact the consultant and determine availability for review.

4.3. Determine whether the consultant has a **Conflicting Interest**.

4.3.1. If so, inform the **Meeting Chair** or the **Designated Reviewer**. Do not use consultants with a **Conflicting Interest**.

4.4. Obtain the agreement of the consultant to maintain confidentiality of information provided.

4.5. Use “POLICY: IRB Member Review Expectations (HRP-020)” to determine which documents to make available to the consultant so the IRB can obtain the additional expertise needed, and make these documents available to the consultant. If the additional expertise needed does not require review of any materials, no materials need be provided.

4.6. For **Committee Review**:

4.6.1. If the consultant provided a written report, make the report available to the IRB members attending the meeting.

4.6.2. If the consultant did not provide a written report, invite the consultant to the IRB meeting.

4.6.3. If requested by the IRB, invite the consultant to the IRB meeting.

4.7. For **Non-Committee Review**:

4.7.1. Obtain the written information from the consultant.

4.7.2. Document information received with the name of the consultant.

5. MATERIALS

5.1. None.

6. REFERENCES

6.1. 21 CFR §56.107(f)

6.2. 45 CFR §46.107

6.3. POLICY: IRB Member Review Expectations (HRP-020)

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HRP-111
SOP: Post Review

1. PURPOSE

1.1. This procedure establishes the process to communicate the IRB's findings and actions.

1.2. This procedure begins when the convened IRB or **Designated Reviewer** has completed a review.

1.3. This procedure ends when the IRB or **Designated Reviewer** communicates its findings and actions.

2. POLICY

2.1. CU Boulder does not need to directly report to a regulatory agency, if the agency has been notified by alternate mechanisms.

2.2. OHRP does not require organizations to report **Unanticipated Problems Involving Risks to Subjects or Others**, **Serious Noncompliance**, and **Continuing Noncompliance** when unrelated to the local context.

3. RESPONSIBILITY

3.1. IRB staff members carry out these procedures.

4. PROCEDURE

4.1. For initial and Continuing Review, where determined that Continuing Review is required:

4.1.1. Calculate the **End Approval Date** following "POLICY: End Approval Date (HRP-022)".

4.2. Update any newly approved consent document with the approval date.

4.3. Complete the applicable notification for the actions described in Table 1 below using the appropriate template(s) or, when necessary, draft a unique notification.

4.4. Within 30 days of a decision by the IRB or **Designated Reviewer** send the notification to:

4.4.1. The investigator

4.4.2. Study contact

4.4.3. The DOD component[1] when the research involving human subjects is DOD-supported and the notification involves any of the following:

4.4.3.1. Significant changes to the research protocol are approved by the IRB, as a result of the IRB continuing review or amendment.

4.4.3.2. A change in the IRB used to review and approve the research to a different IRB.

[1] Send to the Human Research Protections Officer (HRPO) of the DOD component, which is the individual who is delegated the responsibilities as defined in paragraph 48 CFR §252.235. There may be more than one HRPO in a DOD Component. Some DOD Components may use a different title for the person(s) with the defined responsibilities.

4.4.3.3. Communication from any Federal department or agency or national organization informing CU Boulder that any part of its HRPP is under investigation for cause.

4.4.4. Other individuals or organizations determined to be appropriate by the IRB Program Director, IRB Chair, **Organizational Official.**

4.5. The following individuals or entities must receive notification from CU Boulder or the institution where the research is being conducted when the notification involves **Unanticipated Problems Involving Risks to Subjects or Others**, **Serious Noncompliance**, **Continuing Noncompliance**, **Suspension of IRB Approval**, or **Termination of IRB Approval**:

4.5.1. **Institutional Official**.

4.5.2. Sponsor or Contract Research Organization, when the research is sponsored.

4.5.3. Site Management Organization or equivalent, when the research is reviewed on behalf of such an organization.

4.5.4. Agency (e.g., DOD, EPA, FDA, HHS, VA), when the research is subject to regulation by that agency and the agency requires reporting.

4.5.5. Additional contacts, as required by any relevant agreement.

4.5.6. The local research ethics committee or equivalent, when the research is international or collaborative research involving collaboration with a local research ethics committee or equivalent.

4.5.7. Other individuals or organizations determined to be appropriate by the IRB Program Director, IRB Chair, or **Institutional Official**, such as:

4.5.7.1. Office responsible for oversight of the grant or contract.

4.5.7.2. Legal Counsel.

4.5.7.3. Risk Management.

4.5.7.4. Privacy Officer, when the information involves unauthorized use, loss, or disclosure of individually **Identifiable Information**.

4.5.7.5. Information Security Officer, when the information involves violations of information security requirements.

4.5.8. Make any newly approved consent documents, scripts, or assent documents available to the investigator.

5. MATERIALS

5.1. None.

6. REFERENCES

6.1. 21 CFR §50.54

6.2. 45 CFR §46.207

6.3. 45 CFR §46.407

6.4. 21 CFR §50.24(e)

6.5. 21 CFR §56.109(e)

6.6. DOD Instruction 3216.02 November 8, 2011

6.7. POLICY: End Approval Date (HRP-022)

6.8. Table 1

Notification	Template
Approve - From convened IRB review	Convened IRB Approval
Approve - From **Non-Committee Review**	Approval – Expedited
Exempt	Exempt Determination
Closure	Closure
Incomplete Submission	Incomplete (specific-situation templates also available)
Modifications Required to Secure Approval - From convened IRB review	Convened IRB Modifications Required
Modifications Required to secure Approval	Modifications Required
Modifications Required to Determine Not Human Research	Modifications Required to Secure Determination
Defer	Deferral
Acknowledgment of oversight conducted by another institution under a **Reliance Agreement**	IRB Authorization Agreement
Disapprove	Disapproval
Expired	Expiration notice generated in Reminders and Notifications screen of eRA
Not Human Research	Not Human Research Determination
Suspend	Suspension
Terminate	Termination
Notification of Tabled study	Tabled template
Reportable Event determined to be: • **Continuing Noncompliance** • **Serious Noncompliance** • **Suspension of IRB Approval** • **Termination of IRB Approval** • **Unanticipated Problems Involving Risks to Subjects or Others**	Event Reporting Template
Reportable Event determined to be **Non-compliance** that is neither serious nor continuing	Event Reporting Template
Determination of Preliminary Approval for research anticipated to include human subjects determination under 45 CFR §46.118	118 Determination

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HRP-112
SOP: New Information

1. PURPOSE

1.1. This procedure establishes the process to manage new information.

1.2. This procedure begins when the IRB receives information (regardless of whether the information is reportable), a formal event report, or receives reportable new information as part of another submission type.

1.3. This procedure ends when the information item is determined not to represent a problem that requires management, is managed administratively, or referred to the convened IRB for review.

2. POLICY

2.1. All decisions that information represents **Serious Noncompliance**, **Continuing Noncompliance**, an **Unanticipated Problems Involving Risks to Subjects or Others**, a **Suspension of IRB Approval**, or a **Termination of IRB Approval** are to be confirmed by the **Institutional Official** or **Designee**.

3. RESPONSIBILITY

3.1. The **Designated Reviewer** and/or IRB Chair carry out these procedures.

3.2. An IRB Chair or **Designated Reviewer** follows this SOP before placing an item of new information on the IRB agenda.

4. PROCEDURE

4.1. Ask the following six questions.

4.1.1. Does the information represent an **Allegation of Noncompliance**? If yes:

4.1.1.1. Evaluate the **Allegation of Noncompliance** to determine whether there is a basis in fact.

4.1.1.2. If the final determination is that the **Allegation of Noncompliance** has a basis in fact, then this represents **Noncompliance**.

4.1.2. Does the information represent **Noncompliance**? If yes:

4.1.2.1. Refer Allegations of **Noncompliance** to the IRB Program Director or IRB Chair to complete this procedure.

4.1.2.2. Evaluate the **Noncompliance** to determine whether it is **Serious Noncompliance** or **Continuing Noncompliance**.

4.1.3. Does the information represent **Serious Noncompliance**?

4.1.4. Does the information represent **Continuing Noncompliance**?

4.1.5. Does the information represent an **Unanticipated Problem Involving Risks to Subjects or Others**?

4.1.6. Does the information represent a **Suspension of IRB Approval** or a **Termination of IRB Approval**?

4.2. If the answers to all six questions above are "no":

4.2.1. Respond as needed to any complaint, query, or input.

4.2.2. Follow any other applicable SOPs.

4.2.3. If an acknowledgment is expected, follow "SOP: Post Review (HRP-111)" to notify the investigator.

4.2.4. No further action is required under this SOP.

4.3. If any of the answers are "yes" or are uncertain, the information represents a possible reportable event, continue with the following steps:

4.3.1. Consider whether any immediate actions might be necessary (seek guidance from persons with expertise in the area when necessary) to protect the rights and welfare of current or future subjects while additional information is gathered.

4.3.1.1. If so, take those actions, notify the institution, sponsor, CRO, or SMO, as applicable, and notify the **Institutional Official**.

4.3.2. Consider whether immediate notification of the institution, sponsor, CRO, or SMO might be appropriate.

4.3.2.1. If so, notify the institution, sponsor, CRO, or SMO, as applicable, and notify the **Institutional Official**.

4.3.3. If more information is needed, contact the investigator to gather new information.

4.3.4. If the information represents **Noncompliance** that is neither **Serious Noncompliance**, nor **Continuing Noncompliance**, evaluate any submitted corrective action.

4.3.4.1. If the corrective action plan is insufficient, contact the investigator to develop a sufficient correction action plan.

4.3.4.1.1. If the investigator is unable to develop a sufficient corrective action, consider the **Noncompliance** to be **Continuing Noncompliance**.

4.3.4.2. If the research team develops a sufficient corrective action, follow "SOP: Post Review (HRP-111)" to notify the investigator.

4.3.5. If the information represents possible **Serious Noncompliance**, **Continuing Noncompliance**, an **Unanticipated Problem Involving Risks to Subjects or Others**, a **Suspension of IRB Approval**, or a **Termination of IRB Approval**:

4.3.5.1. Notify the **Institutional Official**.

4.3.5.2. Bring the information to the attention of an IRB Chair or IRB Co-Chair for consideration of whether any immediate actions are necessary to protect the rights and welfare of subjects in advance of the meeting.

4.3.5.3. Send for **Committee Review** for final determination and review of corrective action plan.

4.4. If any of the questions listed in Section 4.1 of this SOP cannot be answered, in this SOP then follow "SOP: Investigations (HRP-117)."

5. MATERIALS

5.1. WORKSHEET: New Information (HRP-411)

6. REFERENCES

6.1. 45 CFR §46.108

6.2. 21 CFR §56.108

6.3. SOP: Post Review (HRP-111)

6.4. SOP: Investigations (HRP-117)

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HRP-113
SOP: Unexpected Incarceration

1. PURPOSE

1.1. This procedure establishes the process to manage unexpected incarcerations of subjects.

1.2. This procedure begins when an IRB receives information that a subject in a study not approved for involvement of **Prisoners** as subjects has been incarcerated.

1.3. This procedure ends when all actions have been taken to protect the rights and welfare of the subject prior to **Committee Review**.

2. POLICY

2.1. None.

3. RESPONSIBILITY

3.1. IRB staff members carry out these procedures or ensure they are carried out by other personnel.

4. PROCEDURE

4.1. Confirm that the subject meets the definition of a **Prisone**r.

4.1.1. If not, take no further action.

4.2. Determine whether any research procedures need to take place while the subject is a **Prisoner**.

4.2.1. If none, confirm that the investigator will not perform any research procedures until the subject is no longer a **Prisoner** and take no further action.

4.3. Determine whether it is feasible for the subject to remain in the research.

4.3.1. If it is not feasible for the subject to remain in the research, have the investigator withdraw the subject. Consider the risks associated with terminating participation in the research, and implement actions as needed to protect the subject's rights and welfare, such as alternative treatment or expanded access.

4.4. Determine whether it is in the subject's best interests to remain in the research.

4.4.1. If it is not in the subject's best interest to remain in the research, have the investigator withdraw the subject. Consider the risks associated with terminating participation in the research, and implement actions as needed to protect the subject's rights and welfare, such as alternative treatment or expanded access.

4.5. If feasible for the subject to remain in the research and in the subject's best interests to remain in the research:

4.5.1. Keep the subject enrolled in the research

4.5.2. Use "CHECKLIST: Unexpected Incarceration (HRP-309)"

4.5.3. Assign to agenda for **Committee Review**.

5. MATERIALS

5.1. CHECKLIST: Unexpected Incarceration (HRP-309)

6. REFERENCES

6.1. DOD Instruction 3216.02 November 8, 2011

6.2. OHRP Guidance: Prisoner Research - FAQs

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HRP-114
SOP: Suspension or Termination by the Organization

1. PURPOSE

1.1. This procedure establishes the process to institute a **Suspension of IRB Approval** or **Termination of IRB Approval** outside of a convened IRB meeting.

1.2. This procedure begins when an authorized individual institutes a **Suspension of IRB Approval** or **Termination of IRB Approval**.

1.3. This procedure ends when the authorized individual has notified the IRB staff.

2. POLICY

2.1. The officials authorized by "POLICY: Human Research Protection Program (HRP-010)" to institute a **Suspension of IRB Approval** or **Termination of IRB Approval** may take these actions when in their opinion the rights and welfare of subjects may be at risk before action can be taken through **Committee Review**.

3. RESPONSIBILITY

3.1. The **Institutional Official** carries out these procedures.

4. PROCEDURE

4.1. Notify the investigator in writing of the **Suspension of IRB Approval** or **Termination of IRB Approval** and the reasons for the action.

4.2. Ask the investigator for a list of currently enrolled subjects and their level of involvement in the research (e.g., active **Interventio**n or long-term follow-up).

4.3. Consider whether the rights and welfare of currently enrolled subjects may be adversely affected. If so, consider the following actions:

4.3.1. Transfer subjects to another investigator.

4.3.2. Require clinical care outside the research.

4.3.3. Allow continuation of some research activities under the supervision of an independent monitor.

4.3.4. Require follow-up of subjects.

4.3.5. Require adverse events or outcomes to be reported to the IRB.

4.3.6. Notify current subjects.

4.3.7. Other actions.

4.4. Notify the IRB staff member handling the protocol of the action to place on the agenda of a convened IRB meeting.

4.5. Notify agency (e.g., DOD, EPA, FDA, HHS, VA), when the research is subject to regulation by that agency and the agency requires reporting.

4.6. Notify any additional contacts, as required by any relevant agreement.

4.7. Notify other individuals or organizations determined to be appropriate by the IRB Program Director, IRB Chair, or Organizational Official, such as:

4.7.1. Office responsible for oversight of the grant or contract.

4.7.2. Legal Counsel.

4.7.3. Risk Management.

4.7.4. Privacy Officer, when the information involves unauthorized use, loss, or disclosure of individually **Identifiable Information**.

4.7.5. Information Security Officer, when the information involves violations of information security requirements.

5. MATERIALS

5.1. None.

6. REFERENCES

6.1. 21 CFR §56.108

6.2. 21 CFR §56.113

6.3. 45 CFR §46.103 (**Pre-2018 Requirements**)

6.4. 45 CFR §46.108

6.5. 45 CFR §46.113

6.6. POLICY: Human Research Protection Program (HRP-010)

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HRP-116
SOP: Inquiries/Complaints

1. PURPOSE

1.1. This procedure establishes the process to manage inquiries/complaints received by the IRB. Inquiries/complaints may be submitted by subjects or individuals not enrolled in the research and can be submitted anonymously.

1.2. This procedure begins when the IRB Program Director or Designee is made aware of a inquiry/complaint.

1.3. This procedure ends when the IRB Program Director or Designee has successfully resolved inquiry/ complaint, determined the inquiry/complaint falls under “SOP: New Information (HRP 112)”, or does not fall under IRB purview.

2. POLICY

2.1. All inquiries/complaints are referred to the IRB Program Director, including complaints reported by the site/sponsor via a continuing review form or reportable event form or other method.

2.2. An inquiry or complaint includes an inquiry or complaint by a third party on behalf of another individual. This individual is referred to as the complainant in this SOP.

2.3. Initial reviews of new inquiries/complaints are to be completed within 2 business days of receipt.

2.4. Complainants are to be contacted within 3 business days of receipt of their inquiry/complaint, if possible.

2.5. Ask for guidance from appropriate IRB members, managers, staff, and University legal counsel as needed.

3. RESPONSIBILITY

3.1. The IRB Program Director or Designee performs these procedures.

4. PROCEDURE

4.1. If the call or email is concerning a complaint, follow the process outlined below, but if the contact is just a simple inquiry from a subject/subject’s representative, it is acceptable to respond to the inquiry and consider the issue resolved.

4.2. Verify that the complaint is not a duplicate.

4.3. Create a new complaint record and record on-going progress and resolution in the record, including association of any documents received, such as e-mails or faxes.

4.4. Contact the complainant, if possible, to discuss the reported issue.

4.4.1. Inform the complainant of the role of the IRB and ask the complainant what their expectation is for the IRB to assist in resolving concern.

4.4.2. As appropriate, gather information as necessary from the complainant, e.g., subject number, e-mail address, cell phone number, work number, etc.

4.4.3. Ask the complainant for permission to contact the site on their behalf.

4.4.4. Ask the complainant if his or her name can be used when the site is contacted.

4.4.5. Ask whether the complainant wishes to be advised when contact has been made with the site and the sponsor/contract research organization (and institution, if applicable), and the anticipated next steps.

4.5. Assess the situation and identify any possible past reported complaints associated with the same research staff and or site to determine if there is a pattern of reported complaints.

4.6. If permitted by the complainant, contact the site.

4.6.1. Outline the nature of the call.

4.6.2. Explain that the sponsor/contract research organization will likely be appraised of the call.

4.7. Notify the sponsor/contract research organization of the complaint.

4.8. If the study has dual or split IRB oversight, notify the other IRB that a subject complaint has been received.

4.9. If the investigator is at an institution for which CU Boulder is providing IRB services, notify the institution's contact.

4.10. If the institution, sponsor/contract research organization, or other third parties authorized by the Organizational Official ask for a copy of the complaint, provide a copy and redact **Private Information** unless authorized by the complainant and requested by the requestor.

4.11. Follow "SOP: New Information (HRP-112)."

4.12. Work with the involved individuals to resolve the complaint.

4.12.1. If the complaint cannot be resolved due to inaction of an involved individual, consider the complaint to be **Continuing Noncompliance** and follow "SOP: New Information (HRP-112)."

4.13. If requested by the complainant, advise the complainant when contact has been made with the site and the sponsor/CRO (and institution, if applicable), and the anticipated next steps.

4.14. If appropriate, ask the sponsor/CRO (and institution, if applicable) to keep the IRB informed of steps being taken to resolve the complaint.

4.15. If the complaint remains unresolved, review every 15 business days and record any actions taken or reasons why the complaint remains open.

4.15.1. If the complaint remains unresolved for 30 days, discuss with the appropriate IRB manager how to proceed.

4.16. If appropriate, draft a written response to the complainant and other appropriate parties.

4.16.1. Consider the privacy issues involved and the wishes of the complainant, CRO, and sponsor.

4.16.2. When appropriate, draft separate responses to the investigator, sponsor/CRO, and institution (when applicable) following resolution of the complaint.

5. MATERIALS

5.1. None.

6. REFERENCES

6.1. SOP: New Information (HRP-112)

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HRP-117
SOP: Investigations

1. PURPOSE

1.1. This procedure establishes the process to conduct investigations.

1.2. The process begins when the IRB staff members and chair cannot answer a question required by "SOP: New Information (HRP-112)."

1.3. The process ends when the investigation is complete, and the answer has been provided to the **Institutional Official** or **Designee**.

2. POLICY

2.1. None.

3. RESPONSIBILITY

3.1. The **Institutional Official** or **Designee**:

3.1.1. Appoints the members of the investigative committee based on the expertise and background needed to answer the question.

3.1.2. Appoints a chair of the investigative committee.

3.1.3. Charges the investigative committee with the question to be answered.

3.1.4. Charges the investigative committee with a deadline.

3.2. The investigative committee, under the IRB Chair's leadership, conducts the procedures described in Section 4 below. Investigative committee members make their decisions based on a preponderance of the evidence.

3.3. Investigative committee decisions are made by majority vote.

3.4. Individuals being interviewed may have an advisor present. However, the advisor cannot address the investigative committee. The investigative committee by a vote of the majority may exclude the advisor when in the opinion of the investigative committee that person's presence is disruptive.

3.5. The Organizational Official may refer the investigation to the Standing Committee on Research Misconduct (SCRM) in lieu of steps 4.1-4.4.

4. PROCEDURE

4.1. Notify the investigator that an investigation is being conducted, the question to be answered, and the time frame for completion.

4.2. Determine what information to gather and what individuals to interview.

4.3. Gather information and interview individuals.

4.4. Repeat information gathering and interviews until a decision can be made.

4.5. The investigative committee provides a written report of the investigative committee's decision to the **Institutional Official** or **Designee**.

5. MATERIALS

5.1. None.

6. REFERENCES

6.1. University of Colorado Administrative Policy Statement# 1007: Misconduct in Research, Scholarship, and Creative Activities

6.2. SOP: New Information (HRP-112)

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HRP-118
SOP: Study Closure

1. PURPOSE

1.1. This procedure establishes the process to close a study protocol.

1.2. The process begins when the IRB receives a submission requesting study closure.

1.3. The process ends when the investigator has been notified the study has been closed.

2. POLICY

2.1. None.

3. RESPONSIBILITY

3.1. IRB staff members carry out these procedures.

4. PROCEDURE

4.1. If the submission indicates the study is not ready to be closed per "WORKSHEET: Closure Criteria (HRP-413)," contact the investigator. Offer the investigator the opportunity to revise the submission or provide additional information.

4.1.1. If the investigator will revise the submission, have the investigator resubmit and stop processing the current submission.

4.2. If the investigator will not revise the submission, continue processing:

4.2.1. Assign a **Designated Reviewer** with appropriate expertise from the list of **Designated Reviewers**.

4.2.2. Ensure that the **Designated Reviewer** is provided or has access to the materials in "POLICY: IRB Member Review Expectations (HRP-020)."

4.2.3. Notify the **Designated Reviewer**.

4.3. If the study is ready to be closed:

4.3.1. Update study information in eRA

4.3.2. Within 30 days send the notification of closure to:

4.3.2.1. The investigator.

4.3.2.2. Study contacts.

4.3.2.3. Other individuals or organizations determined to be appropriate by the IRB Director, IRB Chair, or **Organizational Official**.

5. MATERIALS

5.1. WORKSHEET: Closure Criteria (HRP-413)

6. REFERENCES

6.1. POLICY: IRB Member Review Expectations (HRP-020)

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HRP-120
SOP: Conflict of Interest

1. PURPOSE

1.1. This procedure establishes the process to evaluate academic/researcher conflicts of interest as they relate to **Human Research**.

1.2. This procedure begins at the point of a protocol's submission where academic/researcher conflicts of interest requirements are reviewed.

1.3. This procedure ends when the IRB requirements regarding academic/researcher conflicts of interest have been satisfied, or the submission has been declined/withdrawn.

2. POLICY

2.1. All university affiliated personnel who engage in the design, conduct or reporting of research are required to disclose conflicts of interest on an annual basis and with interval changes.

2.2. Per federal regulation and in accordance with campus policy, academic/researcher conflicts of interest must be disclosed and managed prior to engaging in human subjects research.

2.3. Reporting requirements pertaining to university affiliations such as job titles and student categories are specified in the Boulder campus academic/researcher Conflicts of Interest & Commitment policy.

2.4. Training and ongoing education requirements are specified in the Boulder campus academic/researcher Conflicts of Interest & Commitment policy.

3. RESPONSIBILITY

3.1. The IRB staff verify, prior to the Approval of any research involving human subjects, that academic/researcher conflicts of interest have been disclosed, and when required by the Office of Conflicts of Interest & Commitment, a management plan has been executed.

4. PROCEDURE

4.1. The IRB staff will verify investigators have completed the appropriate reporting as described above.

4.2. Check submissions for declared conflict of interest, and if so, ensure COI management plan has been provided to the IRB for review.

5. MATERIALS

5.1. None.

6. REFERENCES

6.1. 42 CFR Part50, Subpart F

6.2. 45 CFR Part 94

6.3. University of Colorado Boulder Conflicts of Interest & Commitment policy

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HRP-121
SOP: Restricted Investigators

1. PURPOSE

1.1. This procedure establishes the process to make an investigator **Restricted**.

1.2. The process begins when the IRB receives a submission that warrants restriction.

1.3. The process ends when the investigator is removed from the **Restricted** list.

2. POLICY

2.1. None.

3. RESPONSIBILITY

3.1. The convened Board carry out these procedures.

4. PROCEDURE

4.1. If an investigator repeatedly fails to follow IRB guidance, the IRB has the option to add the investigator to a **Restricted** list.

4.1.1. At a convened meeting the IRB determines the investigator should be added to the **Restricted** investigator list, identifies the reason(s) for the restriction, and identifies requirements for removal from the list.

4.2. The investigator will be notified by an IRB staff member that they are **Restricted**, the reason for the restriction and what is required to have them removed from the list.

4.3. The investigator may not submit a new research study until they have been removed from the **Restricted** list.

5. MATERIALS

5.1. None.

6. REFERENCES

6.1. None.

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HRP-122
SOP: Undue Influence of the HRPP

1. PURPOSE

1.1. This procedure establishes the process to manage allegations of undue influence of the HRPP.

1.2. This procedure begins when the **Institutional Official** learns of an allegation of undue influence of the HRPP.

1.3. This procedure ends when any undue influence of the HRPP has been mitigated.

2. POLICY

2.1. Individuals responsible for business development may not serve as IRB members and may not be involved in daily operations of the review process and may not discuss business development with IRB members.

2.2. Staff may explain written procedures to individuals involved in the review process.

2.3. Individuals in CU Boulder may not:

2.3.1. Provide information beyond an explanation of written procedures that might influence or appear to influence the review process determinations made as part of the criteria for approval.

2.3.2. Communicate CU Boulder's financial issues regarding specific protocols to individuals responsible for the review process.

2.3.3. Answer questions about CU Boulder's business issues posed by individuals responsible for the review process where the answers might influence or appear to influence review decisions.

2.4. When the IRB does not follow written procedures, CU Boulder can require the IRB to re-review the submission and disapprove research approved by the IRB.

2.5. All individuals in CU Boulder are required to ensure that allegations of undue influence of the HRPP or review process are reported to the **Institutional Official** within 5 days of becoming aware of the allegation.

2.6. If the **Institutional Official** is the source of the undue influence, this issue will be reported to the **Organizational Official**.

3. RESPONSIBILITY

3.1. The **Institutional Official** carries out these procedures or ensures that others carry them out.

4. PROCEDURE

4.1. Gather information to determine the veracity of the allegation using discretion regarding the most efficient and effective methods. Methods to gather information can include, but are not limited to:

4.1.1. Interviews of individuals inside and outside CU Boulder.

4.1.2. Review of records inside and outside CU Boulder.

4.1.3. Consultation with internal or external entities.

4.2. If the report has no basis in fact, take no further action under this SOP.

4.3. Take appropriate steps to eliminate the undue influence using discretion regarding the most efficient and effective methods. Steps may include, but are not limited to:

4.3.1. No action.

4.3.2. Verbal counseling.

4.3.3. Education.

4.3.4. Reassignment of duties.

4.3.5. Termination of employment.

4.4. Document the findings and actions, if any, related to undue influence of the IRB.

4.5. Consider whether the research should be re-reviewed by the IRB.

5. MATERIALS

5.1. None.

6. REFERENCES

6.1. 21 CFR §56.109

6.2. 21 CFR §56.112

6.3. 21 CFR §56.113

6.4. 45 CFR §46.109

6.5. 45 CFR §46.112

6.6. 45 CFR §46.113

6.7. POLICY: Human Research Protection Program (HRP-010)

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HRP-130
SOP: IRB Formation

1. PURPOSE

1.1. This procedure establishes the process to form an IRB.

1.2. This procedure begins when the **Institutional Official** has decided to form a new IRB.

1.3. This procedure ends when the new IRB has been formed and duly registered with OHRP.

2. POLICY

2.1. CU Boulder maintains a roster of IRBs at CU Boulder.

3. RESPONSIBILITY

3.1. The **Institutional Official** carries out these procedures.

4. PROCEDURE

4.1. For external IRBs:

4.1.1. Ensure that the IRB meets the criteria in “POLICY: Human Research Protection Program (HRP-010)”.

4.1.2. Arrange for an agreement or contract and file the agreement or contract.

4.1.3. Update the roster of IRBs.

4.2. For internal IRBs:

4.2.1. Select at least five individuals to serve as IRB members and an IRB Chair. One or more IRB Co-Chairs may be designated.

4.2.2. Follow “SOP: IRB Member Addition (HRP-132)” for each IRB member.

4.2.3. Use “WORKSHEET: IRB Composition (HRP-430)” to evaluate whether the IRB is appropriately constituted.

4.2.3.1. Revise the membership as needed.

4.2.4. Complete a new IRB roster.

4.2.5. Register the IRB at http://ohrp.cit.nih.gov/efile/ before the IRB convenes.

5. MATERIALS

5.1. WORKSHEET: IRB Composition (HRP-430)

6. REFERENCES

6.1. 21 CFR §56.106

6.2. 21 CFR §56.107

6.3. 45 CFR §46.107

6.4. 45 CFR §46 Subpart E

6.5. POLICY: Human Research Protection Program (HRP-010)

6.6. SOP: IRB Member Addition (HRP-132)

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HRP-131
SOP: IRB Deactivation

1. PURPOSE

1.1. This procedure establishes the process to deactivate an IRB.

1.2. This procedure begins when the **Institutional Official** or **Designee** has decided to deactivate an existing IRB.

1.3. This procedure ends when the IRB has been deactivated.

2. POLICY

2.1. CU Boulder maintains a roster of IRBs for CU Boulder.

3. RESPONSIBILITY

3.1. The **Institutional Official** or **Designee** carries out these procedures.

4. PROCEDURE

4.1. Ensure that no active protocols are under review by the IRB to be deactivated.

4.2. For external IRBs:

4.2.1. If an agreement or contract is in place, follow the termination terms of that agreement.

4.2.2. Update the roster of IRBs.

4.3. For internal IRBs:

4.3.1. Notify each IRB member. For each IRB member who will no longer serve as an IRB member prepare and send a thank you letter signed by the Organizational Official.

4.3.2. Update the IRB roster to indicate the IRB is deactivated.

4.4. Unregister the IRB at http://ohrp.cit.nih.gov/efile/ within 30 days.

5. MATERIALS

5.1. None.

6. REFERENCES

6.1. 21 CFR §56.106

6.2. 21 CFR §56.107

6.3. 45 CFR §46.107

6.4. 45 CFR §46 Subpart E

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HRP-132
SOP: IRB Member Addition

1. PURPOSE

1.1. This procedure establishes the process to add an IRB member to an IRB.

1.2. This procedure begins when a potential IRB member has been identified.

1.3. This procedure ends when the individual is not offered IRB membership, or the member has been added and the IRB's registration has been updated.

2. POLICY

2.1. IRB members will be selected based on qualifications, education, experience, and having a positive attitude toward board membership.

2.2. The IRB Chair should normally be an IRB member who is a respected individual with knowledge of research ethics, regulations, guidance, and IRB policies and procedures.

2.3. IRB Chairs and Co-Chairs:

2.3.1. Discharge the IRB Chair's responsibilities when the IRB Chair is unable to do so.

2.3.2. Discharge the responsibilities assigned by the IRB Chair.

2.3.3. Assist in the operation of the IRB.

3. RESPONSIBILITY

3.1. The **Institutional Official** or Designee carries out these procedures.

4. PROCEDURE

4.1. Obtain a copy of the individual's résumé or curriculum vitae.

4.2. Provide the résumé or curriculum vitae to the **Institutional Official** or **Designee** for review.

4.3. If the **Institutional Official** or **Designee** agrees that the background of the potential member is a good fit with the current membership of the IRB, telephone or in-person interviews will be conducted with the Organizational Official or Designee. The potential IRB member may also attend and observe an IRB meeting.

4.4. At the completion of the appropriate interviews, the Designee will notify the **Institutional Official** or **Designee** that the interviews have been conducted and make a recommendation with regard to having the potential IRB member begin IRB member training.

4.5. Upon successful completion or verification of training, the IRB Program Director notifies the **Institutional Official** or **Designee** that the individual has completed training and assesses whether they have completed the training in a satisfactory manner to be appointed as a board member.

4.6. If the training has been satisfactory and the **Institutional Official** or **Designee** agrees, appoint the IRB member, and update the IRB roster. If the training has not been satisfactory, the IRB Chair and/or the IRB Program Director and **Institutional Official** or **Designee** will either agree

on a plan for additional training, or will decline to offer IRB membership to the potential IRB member.

4.7. Obtain information from the individual to complete the roster.

4.8. Use “WORKSHEET: IRB Composition (HRP-430)” to evaluate whether the IRB is appropriately constituted.

4.9. Revise the membership as needed.

4.10. If the new member is a chair, update the IRB’s registration at http://ohrp.cit.nih.gov/efile/ within -90 days.

5. MATERIALS

5.1. WORKSHEET: IRB Composition (HRP-430)

6. REFERENCES

6.1. 21 CFR §56.106

6.2. 21 CFR §56.107

6.3. 45 CFR §46.107

6.4. 45 CFR §46 Subpart E

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HRP-133
SOP: IRB Member Removal

1. PURPOSE

1.1. This procedure establishes the process to designate or remove individuals from the list of IRB members who can review and approve exempt **Human Research**.

1.2. This procedure begins when IRB Program Director considers adding or removing an individual designated to review and approve exempt **Human Research**.

1.3. This procedure ends when the IRB Program Director notifies IRB staff of a new individual designated to review and approve exempt **Human Research** or the removal of a previously designated individual.

2. POLICY

2.1. The **Institutional Official** or **Designee** is responsible for deciding whether to remove an IRB member.

3. RESPONSIBILITY

3.1. The **Institutional Official** or **Designee** carry out these procedures.

4. PROCEDURE

4.1. Update the IRB roster.

4.1.1. Use “WORKSHEET: IRB Composition (HRP-430)” to evaluate whether the IRB is appropriately constituted.

4.1.2. Revise the membership as needed.

4.2. Notify the IRB member.

4.3. If the IRB member will no longer serve as an IRB member prepare and send a thank you letter signed by the **Institutional Official** or **Designee**.

4.4. If the removed member was a chair, update the IRB’s registration at http://ohrp.cit.nih.gov/efile/ within 90 days.

5. MATERIALS

5.1. WORKSHEET: IRB Composition (HRP-430)

6. REFERENCES

6.1. 21 CFR §56.106

6.2. 21 CFR §56.107

6.3. 45 CFR §46.107

6.4. 45 CFR §46 Subpart E

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HRP-134
SOP: Designated Exempt Reviewers

1. PURPOSE

1.1. This procedure establishes the process to designate or remove individuals from the list of IRB members who can review and approve exempt **Human Research**.

1.2. This procedure begins when IRB Program Director considers adding or removing an individual designated to review and approve exempt **Human Research**.

1.3. This procedure ends when the IRB Program Director notifies IRB staff of a new individual designated to review and approve exempt **Human Research** or the removal of a previously designated individual.

2. POLICY

2.1. CU Boulder may designate one or more individuals to review and approve exempt **Human Research**.

2.2. Individuals designated to review and approve exempt **Human Research** do not need to be IRB members.

2.3. All **Designated Reviewers** may review and approve exempt **Human Research**.

3. RESPONSIBILITY

3.1. The IRB Program Director carries out these procedures.

3.2. The IRB Program Director maintains a list of individuals designated to review and approve exempt **Human Research**.

4. PROCEDURE

4.1. To designate an individual to review and approve exempt **Human Research**:

4.1.1. Train the individual to approve exempt **Human Research** in one or more categories using the following documents.

4.1.1.1. POLICY: IRB Records (HRP-023).

4.1.1.2. SOP: Designated Exempt Review Conduct (HRP-135).

4.1.1.3. WORKSHEET: Human Research (HRP-421).

4.1.1.4. WORKSHEET: Exemptions (HRP-423) modified to limit the exemption category or categories to those authorized.

4.1.1.5. POLICY: Investigator Obligations (HRP-070).

4.1.1.6. POLICY: Prompt Reporting Requirements (HRP-071).

4.1.2. Notify the IRB Program Director to update the list of individuals designated to review and approve exempt **Human Research** to include the name of the individual.

4.2. To remove an individual's designation to review and approve exempt **Human Research**:

4.2.1. Notify the IRB Program Director to update the list of individuals designated to review and approve exempt **Human Research** to remove the name of the individual.

4.3. Inform the individual that he or she may no longer review and approve exempt **Human Research**.

5. MATERIALS

5.1. WORKSHEET: Human Research (HRP-421)

5.2. WORKSHEET: Exemptions (HRP-423)

6. REFERENCES

6.1. 45 CFR §46.104

6.2. POLICY: IRB Records (HRP-023)

6.3. SOP: Designated Exempt Review Conduct (HRP-135)

6.4. POLICY: Investigator Obligations (HRP-070)

6.5. POLICY: Prompt Reporting Requirements (HRP-071)

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HRP-135
SOP: Designated Exempt Review Conduct

1. PURPOSE

1.1. This procedure establishes the process for an individual designated to review and approve exempt **Human Research** h to conduct such a review.

1.2. This procedure begins when an individual designated to review and approve exempt **Human Research** has received a research proposal.

1.3. This procedure ends when the reviewer has either:

1.3.1. Approved the proposal as exempt **Human Research**.

1.3.2. Referred the proposal to a **Designated Reviewer** if they are not a **Designated Reviewer**.

2. POLICY

2.1. All **Human Research** conducted under the auspices of CU Boulder including exempt research, must be submitted to the IRB for review and approval.

2.2. Individuals designated to review and approve exempt **Human Research** are to:

2.2.1. Maintain the records required by this SOP for three years after the last reviewer action or after withdrawal by the investigator.

3. RESPONSIBILITY

3.1. Individuals designated to review and approve exempt **Human Research** carry out these procedures.

4. PROCEDURE

4.1. Review submitted materials in eRA.

4.2. Determine whether the project is **Human Research**.

4.2.1. Use “WORKSHEET: Human Research (HRP-421).”

4.2.2. If the project is not or may not be **Human Research**, refer the submission to a **Designated Reviewer**.

4.3. If the project is **Human Research**, determine whether the project can be approved as exempt **Human Research** by using “WORKSHEET: Exemptions (HRP-423).”

4.3.1. If unsure whether the project is exempt **Human Research**, refer the submission to a **Designated Reviewer**.

4.3.2. If not approvable as exempt **Human Research**, request that the investigator modify the project to meet exemption criteria or refer the submission to a **Designated Reviewer**.

4.3.3. Exemptions 7 and 8 of the revised New Common Rule will not be used by CU Boulder; rather such activities will be reviewed under the expedited review procedure.

4.3.4. The IRB can decide to review an exempt study by expedited review.

4.4. File the records required by “POLICY: IRB Records (HRP-023).”

5. MATERIALS

5.1. WORKSHEET: Human Research (HRP-421)

5.2. WORKSHEET: Exemptions (HRP-423)

6. REFERENCES

6.1. 45 CFR 46.104

6.2. POLICY: IRB Records (HRP-023)

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HRP-140
SOP: IRB Records Retention

1. PURPOSE

1.1. This procedure establishes the process to retain IRB records.

1.2. This procedure begins at least every three months.

1.3. This procedure ends when all records that are no longer required to be retained are destroyed.

2. POLICY

2.1. Study files designated by legal counsel as being on “legal hold” are not to be destroyed until the legal hold is removed.

2.2. Study files relating to research requiring continuing review which has not been conducted are retained for at least 3 years after the last IRB action.

2.3. Study files relating to research requiring continuing review which has been conducted are retained for at least 3 years after completion of the research, regardless of whether there was subject enrollment.

2.4. Study files relating to research not requiring continuing review are retained for at least 3 years after the last IRB action.

2.5. Incomplete study files that were never finalized and sent to **Committee Review** or **Non-Committee Review** are retained for at least 3 years after the last IRB action.

2.6. The following documents are retained indefinitely:

2.6.1. IRB meeting minutes.

2.6.2. A resume or curriculum vitae for each IRB member.

2.6.3. Current and previous versions of IRB member rosters.

2.6.4. Current and previous versions of controlled documents.

3. RESPONSIBILITY

3.1. IRB staff members carry out these procedures.

4. PROCEDURE

4.1. Identify the study files that can be destroyed.

4.1.1. Omit destruction of records on a legal hold.

4.1.2. Previously approved studies requiring continuing review: Three years after the date on which all research sites overseen by CU Boulder’s IRB have been completed either through closure, **Termination of IRB Approval**, disapproval, or lapse of approval.

4.1.3. Research never approved and research not requiring continuing review: Three years after the last IRB action or after withdrawal by the investigator.

4.2. Shred paper documents and dispose the shredded materials securely.

4.3. Electronic documents stored in the eRA system will be kept indefinitely or until eRA is no longer utilized at CU Boulder.

5. MATERIALS

5.1. None.

6. REFERENCES

6.1. 21 CFR §56.115

6.2. 45 CFR §46.115

6.3. HRP-023 POLICY: IRB Records

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HRP-141
SOP: Annual and Periodic Tasks

1. PURPOSE

1.1. This procedure establishes the process to conduct annual tasks and tasks carried out less frequently than annually related to the HRPP.

1.2. This procedure begins every year in July for annual tasks and as needed for other tasks.

1.3. This procedure ends when evaluations and corrective actions are completed.

2. POLICY

2.1. In order to ensure an effective and compliant HRPP, the UCB conducts periodic self-assessment and continuous improvement practices in connection with IRB and related activities.

2.2. In order to enhance the understanding of subjects, prospective subjects, and communities the CU Boulder IRB makes subject information available on the CU Boulder IRB Web site.

3. RESPONSIBILITY

3.1. The **Institutional Official** delegates individuals to carry out these procedures.

4. PROCEDURE

4.1. Obtain updated résumés or curricula vitae from each IRB member and IRB staff member every 3 years (or confirmation that the existing one is still accurate).

4.2. Evaluate in consultation with the IRB Chair and IRB Program Director as appropriate:

4.2.1. General performance of the HRPP, such as:

4.2.1.1. Feedback from investigators, research staff, sponsors, and subjects.

4.2.1.2. Results of regulatory audits.

4.2.1.3. Results of continuous improvement activities.

4.2.1.4. New requirements.

4.2.1.5. Compliance with policies and procedures.

4.2.1.6. Compliance with regulatory requirements.

4.2.1.7. Status of action items from previous reviews.

4.2.2. HRPP resources for:

4.2.2.1. Space.

4.2.2.2. Personnel.

4.2.2.3. HRPP educational program.

4.2.2.4. Legal counsel.

4.2.2.5. Conflicts of interests.

4.2.2.6. Quality improvement.

4.2.3. Submission metrics for **Committee Review** and **Non-Committee Review**.

4.2.4. Whether the number of IRBs is appropriate for the volume and types of research reviewed.

4.2.5. Whether the composition of IRBs meets the requirements in "WORKSHEET: IRB Composition (HRP-430)."

4.2.6. Whether the IRB and organizational registrations have been appropriately updated.

4.2.7. The knowledge and performance of each IRB member, IRB Chair, IRB Co-Chair, and IRB staff member.

4.2.7.1. Consult with the IRB Chair on the performance of IRB members and IRB staff members.

4.2.8. Whether IRB members, IRB Chairs, IRB Co-Chairs, and IRB staff members have completed required training.

4.2.9. Review a sample of minutes of the previous year for compliance with "SOP: Minutes (HRP-108)".

4.3. Provide a copy of the evaluation to the **Institutional Official.**

4.4. Take actions as needed to:

4.4.1. Reallocate HRPP resources.

4.4.2. Modify the number of IRBs.

4.4.3. Modify the composition of IRBs.

4.4.4. Remove individuals with persistent knowledge and performance gaps.

4.4.5. Correct knowledge and performance gaps of individuals.

4.4.6. Arrange for individuals to take missing training.

4.4.7. Modify the IRB improvement plan.

4.5. Update IRB registrations as required at http://ohrp.cit.nih.gov/efile/.

4.6. Update organizational registrations as required at http://ohrp.cit.nih.gov/efile/FwaRenew.aspx.

5. MATERIALS

5.1. WORKSHEET: IRB Composition (HRP-430)

5.2. Participant Brochure

6. REFERENCES

6.1. 21 CFR §56.106

6.2. 21 CFR §56.107

6.3. 45 CFR §46.107

6.4. 45 CFR §46 Subpart E

6.5. SOP: Minutes (HRP-108)

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HRP-143
SOP: Weekly and Daily Tasks

1. PURPOSE

1.1. This procedure establishes the process to conduct weekly and daily tasks of the IRB.

1.2. This procedure begins the first business day of the week for weekly tasks and each business day for daily tasks.

1.3. This procedure ends when notifications are complete.

2. POLICY

2.1. Notifications required by this SOP are to be provided in writing.

3. RESPONSIBILITY

3.1. IRB staff members carry out these procedures. With systems that can perform these functions automatically, this function may be used.

4. PROCEDURE

4.1. Daily check for protocols that require continuing review reached their **End Approval Date** 3 months ago and move them to Administratively Closed status.

4.2. Daily check for protocols that have expired due to lack of continuing review.

4.2.1. Send out TEMPLATE LETTER: Expiration Notice informing the investigator the study is expired, and all research activities must stop, new subjects may not be enrolled, and the continuing review progress report must be submitted as soon as possible.

4.3. Daily check for protocols that do not require continuing review that have reached their **End Approval Date**.

4.3.1. Send out TEMPLATE LETTER: Check-in Not Received notice informing the investigator that the IRB requires confirmation that the study is active.

4.4. Currently there are no Weekly tasks.

5. MATERIALS

5.1. None.

6. REFERENCES

6.1. None.

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HRP-144
SOP: Meeting Scheduling

1. PURPOSE

1.1. This procedure establishes the process to schedule convened IRB meetings.

1.2. The process begins when additional meetings need to be scheduled.

1.3. The process ends when sufficient meetings are scheduled.

2. POLICY

2.1. CU Boulder may convene unscheduled meetings to deal with urgent issues that the IRB cannot address in a scheduled meeting, provided members are given timely notification and a justification for convening the unscheduled meeting.

3. RESPONSIBILITY

3.1. IRB staff members carry out these procedures.

4. PROCEDURE

4.1. Create a schedule of meetings at least one month in advance.

4.2. Make the schedule available to IRB members and investigators.

4.3. Notify the following individuals of the updated schedule:

4.3.1. IRB members

4.3.2. Organizational Official

4.4. Notify committee members of an added unscheduled meeting with sufficient notice to adequately review materials.

5. MATERIALS

5.1. None.

6. REFERENCES

6.1. None.

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HRP-180
SOP: Emergency and Compassionate Uses

1. GENERAL INFORMATION

1.1. The CU Boulder campus does not carry out activities that involve emergency or **Compassionate Uses** of a drug or biologic. If this situation changes, then the CU Boulder IRB will put into place appropriate procedures before the use of such drugs or biologics occurs. "HRP-180 SOP: Emergency and Compassionate Uses" serves as a placeholder should the need for these procedures arise.

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HRP-181
SOP: Appeal of IRB Decisions/Determinations

1. PURPOSE

1.1. This procedure establishes the appeal process to conduct a re-review of an IRB decision to disapprove, suspend, or terminate research.

1.2. This procedure begins when an appeal is received by the IRB office.

1.3. This procedure ends when the IRB makes a decision on the appeal.

2. POLICY

2.1. An investigator may appeal to the IRB for a formal re-review of a disapproval, suspension, or termination decision when an investigator believes that the IRB's decision is due to: inadequate or inaccurate information; or, IRB non-compliance with University of Colorado Boulder IRB Policies and Procedures, state law, or federal regulation.

3. RESPONSIBILITY

3.1. IRB Chairs and IRB Program Director carry out these procedures.

4. PROCEDURE

4.1. An investigator submits an appeal to the IRB due to a belief that the IRB's decision to disapprove, suspend, or terminate research was due to inadequate or inaccurate information or IRB non-compliance with University of Colorado Boulder IRB Policies and Procedures, state law, or federal regulation.

4.1.1. The investigator must make such an appeal in writing to the IRB.

4.1.2. The appeal request consists of sending the IRB Program Director a cover letter outlining the basis for the appeal and documents that support the appeal.

4.1.3. The IRB Program Director reviews the appeal request to determine whether an appeal is appropriate. This may include consultation with the investigator, the IRB Chair, select members of the IRB, or the **Institutional Official**, as needed. The IRB Program Director informs the investigator by email whether the request has been accepted for review.

4.2. The following outlines the process for appeals heard by the convened IRB.

4.2.1. The IRB Chair may hold a closed session of the IRB without the investigator, prior to the appeal portion of the meeting, to establish the key issues and questions to consider.

4.2.2. The researcher is invited to present information and rationale to the IRB.

4.2.3. There is a question-and-answer session with the researcher.

4.2.4. The researcher leaves the meeting room.

4.2.5. The IRB members and other meeting attendees discuss the appeal.

4.2.6. The IRB moves and then votes whether to take one of the following actions:

4.2.6.1. Approve the appeal and modify the original decision;

4.2.6.2. Disapprove the appeal and uphold the original determination; or,

4.2.6.3. Defer the appeal and obtain additional information or consultation in order to make a final decision.

4.3. The IRB's appeal determination, and any other considerations or requirements associated with it, are communicated to the researcher in writing.

4.4. A decision by the IRB to disapprove, suspend, or terminate a project is not subject to reversal by CU Boulder **Institutional Official** or any other officer of CU Boulder, state, or federal government.

4.5. Only one appeal will be allowed on a given matter. The concluding IRB decision of an appeal is final and cannot be appealed.

5. MATERIALS

5.1. None.

6. REFERENCES

6.1. Guidance for IRBs, Clinical Investigators, and Sponsors; IRB Continuing Review after Clinical Investigation Approval; February 2012

6.2. 45 CFR 46.108

6.3. 45 CFR 46.109

6.4. 21 CFR 56.111

6.5. 21 CFR 56.108(a)

6.6. 21 CFR 56.109(f)

6.7. 45 CFR 46.110(b)(2)

6.8. 45 CFR 46.111

6.9. 45 CFR 46.116

6.10. 45 CFR 46.117

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APPENDIX 1: CHECKLISTS

1. GENERAL INFORMATION

1.1. The Checklists at HRP-300-HRP-327 are used when applicable:

1.1.1. During an Expedited review by a designated reviewer. The Checklist will be completed and retained.

1.1.2. Prior to a convened meeting. Any Checklists completed by IRB members prior to a convened IRB meeting represent preliminary judgments and are intended to facilitate informed discussion at the meeting. Such Checklists do not require retention.

1.1.3. Checklists are only used at initial review, or amendment when the research newly involves one of the applicable considerations.

HRP #	CHECKLIST: Title
HRP-300	CHECKLIST: Waiver of Consent
HRP-303	CHECKLIST: Waiver of Documentation of Consent
HRP-305	CHECKLIST: Pregnant Women
HRP-306	CHECKLIST: Neonates of Uncertain Viability
HRP-307	CHECKLIST: Non-Viable Neonates
HRP-308	CHECKLIST: Prisoners
HRP-309	CHECKLIST: Unexpected Incarceration
HRP-310	CHECKLIST: Children
HRP-326	CHECKLIST: Devices
HRP-327	CHECKLIST: Drugs

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APPENIDX 2: WORKSHEETS

1. GENERAL INFORMATION

1.1. The Worksheets at HRP-400-HRP-481 are used to support research review; these documents are not retained.

HRP #	WORKSHEET: Title
HRP-400	WORKSHEET: Criteria for Approval
HRP-405	WORKSHEET: Additional Criteria DOD
HRP-406	WORKSHEET: Additional Criteria DOJ
HRP-407	WORKSHEET: Additional Criteria ED
HRP-408	WORKSHEET: Additional Criteria EPA
HRP-409	WORKSHEET: Additional Criteria DOE
HRP-410	WORKSHEET: Additional Criteria International
HRP-411	WORKSHEET: New Information
HRP-413	WORKSHEET: Closure Criteria
HRP-414	WORKSHEET: Adults Lacking Capacity
HRP-415	WORKSHEET: Consent Disclosures
HRP-420	WORKSHEET: Regulatory Review
HRP-421	WORKSHEET: Human Research
HRP-422	WORKSHEET: Engagement
HRP-423	WORKSHEET: Exemptions
HRP-424	WORKSHEET: Expedited Review
HRP-427	WORKSHEET: HIPAA Authorization
HRP-428	WORKSHEET: HIPAA Waiver of Authorization
HRP-430	WORKSHEET: IRB Composition
HRP-431	WORKSHEET: Quorum
HRP-470	WORKSHEET: External IRB Screening
HRP-480	WORKSHEET: FERPA
HRP-481	WORKSHEET: PPRA

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APPENDIX 3: INVESTIGATOR MANUAL (HRP-910)

HRP-910
Investigator Manual

2. GENERAL INFORMATION

2.1. HRP-910: Investigator Manual is located on the CU Boulder IRB website: https://www.colorado.edu/researchinnovation/media/1487

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APPENDIX 4: CU Boulder Board Member Manual

3. GENERAL INFORMATION

3.1. The Board Member Manual is located on the CU Boulder IRB website: https://www.colorado.edu/researchinnovation/media/1487

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APPENIDX 5: VERSION DOCUMENTATION

Version #	Version Notes:	Effective Date:
3.0	• Complete review and revision of the Policies and Standard Operating Procedures. • Organizational Official (OO) responsibilities have been returned to the Institutional Official (IO) role and will be delegated to the OO outside of this document. • Clarified that all final determinations by the convened board are officially documented in the meeting minutes. • Streamlined the procedures for Expedited review. • HRP-101 SOP Regulatory Review was renamed “Intake Review” and the regulatory-related tasks were moved to HRP-104 SOP: Non-Committee Review Conduct. • HRP-103 SOP: Non-Committee Review Preparation, was deleted and the information included in HRP-104 SOP: Non- Committee Review Conduct. • HRP-142 SOP: Monthly Tasks was deleted and the tasks included in HRP-143 SOP: Weekly and Daily Tasks. • Policies and SOPs are combined into one document for clarity and ease of use. • Worksheets and Checklists have been reformatted to allow easier access and use. • Formatting and minor changes made for clarity.	June 30, 2025

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