



Office of Research Integrity

UNIVERSITY OF COLORADO **BOULDER**

**INSTITUTIONAL REVIEW BOARD**

# IRB Policies

Effective Date: 10 May 2019



# Office of Research Integrity

UNIVERSITY OF COLORADO **BOULDER**

## **INSTITUTIONAL REVIEW BOARD**

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## POLICY: Definitions

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### 1. PURPOSE

- 1.1. This policy establishes definitions followed by the University of Colorado Boulder.

### 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:** An IRB member or consultant has a conflicting interest if any of the following are 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, or patents, trademarks,
  - 2.9.5. 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.



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- 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 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**.
  - 2.22.2. 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).<sup>1</sup>
- 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.

<sup>1</sup> 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 waiver and alteration of consent.



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- 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. **Interaction:** Communication or interpersonal contact between investigator and **Human Subject as Defined by HHS**.
- 2.30. **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.
- 2.31. **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.
  - 2.31.1. 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.
- 2.32. **Meeting Chair:** The IRB member running a convened IRB meeting.
- 2.33. **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
  - 2.33.1. 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 life. 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).
  - 2.33.2. 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.
- 2.34. **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.
- 2.35. **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.
- 2.36. **Non-significant Risk Device:** An investigational device that is not a **Significant Risk Device**.
- 2.37. **Noncompliance:** Failure to follow the regulations or the requirements or determinations of the IRB.



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- 2.38. **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.
- 2.39. **Pregnant Woman:** A woman during the period of time from implantation until delivery.
- 2.40. **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.
- 2.41. **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.
- 2.42. **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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.
- 2.43. **Protocol Deviation:** Failure to follow the IRB approved protocol.
- 2.44. **Regulatory Review:** Review of administrative and regulatory issues unrelated to the regulatory criteria for approval that under the regulations must be determined by a convened IRB or reviewer using the expedited procedure.
- 2.45. **Regulatory Reviewer:** Individual who conducts **Regulatory Review**.
- 2.46. **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.
- 2.47. **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.
- 2.48. **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:
- 2.48.1. Act: The Federal Food, Drug, and Cosmetic Act, as amended (§§201-902, 52 Stat 1040 et. seq., as amended (21 USC 321-392))
- 2.48.2. 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
- 2.49. **Research as Defined by HHS:** A systematic investigation designed to develop or contribute to generalizable knowledge.<sup>2</sup>

<sup>2</sup> 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 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)



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- 2.50. **Restricted:** A status for investigators indicating that new submissions will not be accepted for review.
- 2.51. **Serious Noncompliance: Noncompliance** that adversely affects the rights and welfare of subjects.
  - 2.51.1. For **Human Research** conducted or funded by DOD, **Serious Noncompliance** is failure of a person, group, or institution to act in accordance with this Instruction and its references 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.
- 2.52. **Significant Risk Device:** An investigational device that:
  - 2.52.1. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
  - 2.52.2. 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;
  - 2.52.3. 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
  - 2.52.4. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
- 2.53. **Single Patient Expanded Access:** Treatment with an investigational drug under an IND where the FDA granted an IND pursuant to 21 CFR §312.310
- 2.54. **Suspension of IRB Approval:** Temporary or permanent withdrawal of IRB approval for some or all research procedures short of **Termination of IRB Approval**.
- 2.55. **Termination of IRB Approval:** Withdrawal of IRB approval for all research procedures where the IRB does not anticipate re-opening the study.
- 2.56. **Unanticipated Problems Involving Risks to Subjects or Others:** Information that:
  - 2.56.1. Is unexpected (inconsistent with information previously reviewed by the IRB); and
  - 2.56.2. Indicates that subjects or others are at increased risk of harm because of the research study.
- 2.57. **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, §46.202, §46.303, §46.402
- 3.2. 21 CFR §50, §56.102, §312.3, §812.3

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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.

## POLICY: Abbreviations

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### 1. PURPOSE

- 1.1. This policy establishes abbreviations followed by the University of Colorado Boulder.

### 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. DHS: United States Department of Homeland Security
- 2.8. DOD: United States Department of Defense
- 2.9. DOE: United States Department of Energy
- 2.10. DOJ: United States Department of Justice
- 2.11. DOT: United States Department of Transportation
- 2.12. ED: United States Department of Education
- 2.13. EPA: United States Environmental Protection Agency
- 2.14. eRA: Electronic Research Administration
- 2.15. FDA: United States Food and Drug Administration
- 2.16. FDR: Canadian Food and Drug Regulations
- 2.17. FERPA: Family Educational Rights and Privacy Act
- 2.18. FWA: Federalwide Assurance
- 2.19. HDE: Humanitarian Device Exemption
- 2.20. HHS: United States Department of Health and Human Services
- 2.21. HIPAA: Health Insurance Portability and Accountability Act
- 2.22. HRPP: Human Research Protection Program
- 2.23. HUD: Humanitarian Use Device
- 2.24. ICH-GCP: International Council on Harmonisation – Good Clinical Practice
- 2.25. IDE: Investigational Device Exemption
- 2.26. IND: Investigational New Drug
- 2.27. IRB: Institutional Review Board
- 2.28. LAR: **Legally Authorized Representative**
- 2.29. NASA: National Aeronautics and Space Administration
- 2.30. NSF: United States National Science Foundation
- 2.31. NSR: Non-significant Risk Device
- 2.32. OHRP: Office of Human Research Protections
- 2.33. OSTP: United States Office of Science Technology and Policy
- 2.34. PIPEDA: Personal Information Protection and Electronic Documents Act
- 2.35. PPRA: Protection of Pupil Rights Amendment
- 2.36. REB: Research Ethics Board
- 2.37. SOP: Standard Operating Procedure
- 2.38. SR: **Significant Risk Device**
- 2.39. SSA: United States Social Security Administration
- 2.40. TCPS: Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans
- 2.41. US: United States
- 2.42. USDA: Department of Agriculture
- 2.43. WIRB: Western IRB
- 2.44. VA: Veterans Affairs

### 3. REFERENCES

- 3.1. None





## POLICY: Designations

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### 1. PURPOSE

- 1.1. This policy establishes designations followed by the University of Colorado Boulder.

### 2. POLICY

- 2.1. **Institutional Official or I.O.:** Vice Chancellor for Research & Innovation
- 2.2. **Organizational Official:** Associate Vice Chancellor for Research Integrity and Compliance
- 2.3. **Designee:** Person who has been selected to perform a specific role or duty

### 3. REFERENCES

- 3.1. None



## POLICY: Human Research Protection Program

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### 1. PURPOSE

- 1.1. This policy establishes the University of Colorado 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 the University of Colorado 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 unless there is uncertainty whether the activity is **Human Research**.

- 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.

#### 2.2. Ethical Principles

- 2.2.1. The University of Colorado 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 Reference 1)

- 2.2.2. The University of Colorado Boulder applies its ethical principles to all **Human Research** regardless of support or geographic location.

- 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 vice-chairs
- 2.2.3.4. HRPP staff members
- 2.2.3.5. Institutional Official
- 2.2.3.6. Employees and agents

- 2.2.4. Clinical trials should be conducted in accordance with the ethical principles in Reference 1 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, the University of Colorado 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. The University of Colorado 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. The University of Colorado Boulder applies **2018 Requirements** to all **Human Research as Defined by HHS** conducted or supported by a



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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. The University of Colorado 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. The University of Colorado 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. The University of Colorado 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. The University of Colorado 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. The University of Colorado 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. The University of Colorado 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. The University of Colorado 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**, the University of Colorado Boulder applies 21 CFR §50 and §56.
- 2.3.3. For research involving a clinical trial of a drug or device, the University of Colorado Boulder commits to apply the “International Conference on Harmonisation – Good Clinical Practice E6.” (ICH-GCP).
- 2.3.4. For research conducted in other countries, the University of Colorado 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**, the University of Colorado Boulder complies with those laws.
- 2.3.6. This University of Colorado 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.



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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** 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 vice-chairs
- 2.4.1.2.3. Bind HRPP policies on the University of Colorado Boulder
- 2.4.1.2.4. Determine what IRBs the University of Colorado 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 Organizational Official 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 the University of Colorado Boulder:

2.4.2.1. All employees and agents of the University of Colorado 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**.
- 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**.



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- 2.4.3. IRB members and HRPP staff members
  - 2.4.3.1. IRB members, IRB chairs, IRB vice-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 (e.g., DOD) 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 (e.g., DOD) when such research is reviewed.
    - 2.4.3.1.4. Respond to contacts from 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 members and HRPP staff members ultimately report to the **Organizational 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 the University of Colorado 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 the University of Colorado 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**.
  - 2.4.4.2. The University of Colorado Boulder cannot approve **Human Research** that the IRB has not approved.
- 2.4.5. Investigators and research staff ultimately report to the **Organizational Official** 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 **Organizational 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 **Organizational 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. Resolve conflicts among applicable laws



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2.4.7. Office of Contracts and Grants works with the **Organizational Official** on HRPP issues.

**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. The University of Colorado 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. The University of Colorado 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, the University of Colorado Boulder will execute a Reliance Agreement with a relying organization, which documents respective authorities, roles, responsibilities, and communication between this University of Colorado Boulder and the relying organization.

2.5.5. External organizations relying on the University of Colorado Boulder's IRB can expect the University of Colorado Boulder's IRB to do the following and when the University of Colorado Boulder relies on an external IRB the University of Colorado 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 the University of Colorado 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 Vice 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, 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 and manage **Unanticipated Problems Involving Risks to Subjects or Others, Noncompliance, Serious Noncompliance** and



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- 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 the University of Colorado Boulder 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 the University of Colorado Boulder 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 a test articles and assure uses follow FDA requirements.
- 2.5.5.21. Assure that emergency uses of a 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 Vice 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.



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- 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 has the requirements of DOD Instruction 3216.02 when reviewing non-exempt classified DOD research.
- 2.5.5.28. Report serious or continuing noncompliance with 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. The University of Colorado Boulder makes written materials describing the HRPP available to all members of the University of Colorado Boulder through its Website at <https://www.colorado.edu/researchinnovation/irb>.
- 2.6.2. The University of Colorado 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, the University of Colorado 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





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2.7. Questions, Concerns, and Feedback

- 2.7.1. Individuals should address questions, suggestions, concerns, or complaints about the IRB or human research protection program; allegations of undue influence, **Allegations of Noncompliance** or **Findings of Noncompliance** orally or in writing to:

<p><b>Name</b> Claire Dunne  <b>Title</b> IRB Program Director  <b>Street</b> 3100 Marine Street  <b>City, State ZIP</b> Boulder, CO 80309  <b>Email:</b> Claire.dunne@colorado.edu  <b>Phone:</b> 303-735-3702</p>
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- 2.7.2. Individuals may also contact the Organizational Official at:

<p><b>Name</b> Joseph Rosse  <b>Title</b> Associate Vice Chancellor for Research Integrity and Compliance  <b>Street</b> 3100 Marine Street  <b>City, State ZIP</b> Boulder, CO 80309  <b>Email:</b> Joseph.Rosse@colorado.edu  <b>Phone:</b> 303-735-3702</p>
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- 2.7.3. The University of Colorado Boulder takes steps to protect employees and agents who report in good faith, from retaliation and harassment and should immediately report such concerns to the **Organizational Official**.

**3. REFERENCES**

“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.



## POLICY: IRB Member Review Expectations

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### 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 roles described for the primary presenter, and the scientific/scholarly reviewer, or obtains consultation for these roles.

### 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**, 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 as directed in (See Table 1 in REFERENCES).
  - 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 **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 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



## POLICY: IRB Member Review Expectations

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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 a question, ask.

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

2.5.2. We 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 *(see next page)*

## POLICY: IRB Member Review Expectations

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	Initial Review	Review of an Amendment	Continuing Review	Review of Event Reporting (New Information)
3.1.	<ul style="list-style-type: none"> <li>Review the following materials to a depth sufficient to determine whether the criteria in applicable worksheets and checklists are met:</li> </ul>	<ul style="list-style-type: none"> <li>Review the summary of the Amendment.</li> <li>Determine which criteria in applicable worksheets and checklists are affected.</li> <li>Review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:</li> </ul>	<ul style="list-style-type: none"> <li>Review the continuing review progress report and attachments.</li> <li>Determine which criteria in applicable worksheets and checklists are affected.</li> <li>Review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:</li> </ul>	<ul style="list-style-type: none"> <li>Review the event/new information and attachments.</li> <li>Determine which criteria in applicable worksheets and checklists are affected.</li> <li>Review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:</li> </ul>
<b>Review of Research</b>	<ul style="list-style-type: none"> <li>Initial application form(s)</li> <li>Protocol</li> <li>Any consent document(s) and script(s)</li> <li>Any recruitment materials</li> <li>Any reports of consultants</li> <li>Any other information all IRB members were asked to review</li> </ul>	<ul style="list-style-type: none"> <li>Protocol</li> <li>Previously approved Amendments not reflected in the current protocol, or a summary thereof</li> <li>Any consent document(s) and script(s)</li> <li>Any recruitment materials</li> <li>Any reports of consultants</li> <li>Any other information all IRB members were asked to review</li> </ul>	<ul style="list-style-type: none"> <li>Protocol</li> <li>Previously approved Amendments not reflected in the current protocol, or a summary thereof</li> <li>Any consent document(s) and script(s)</li> <li>Any recruitment materials</li> <li>Any reports of consultants</li> <li>Any other information all IRB members were asked to review</li> </ul>	<ul style="list-style-type: none"> <li>Protocol</li> <li>Previously approved Amendments not reflected in the current protocol, or a summary thereof</li> <li>Any consent document(s) and script(s)</li> <li>Any recruitment materials</li> <li>Any reports of consultants</li> <li>Any other information all IRB members were asked to review</li> </ul>

3.2. Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff Humanitarian Device Exemption (HDE) Regulation: Questions and Answers

## **POLICY: Legally Authorized Representatives Children and Guardians**

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### **1. PURPOSE**

- 1.1. This policy describes the University of Colorado Boulder's determination of 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 following individuals are **Legally Authorized Representatives**:
  - 2.1.1. This decision must be made by consulting the Office of University Counsel
- 2.2. For research outside Colorado, the IRB may consult with the Office of University Counsel (OUC) to determine which individuals are **Legally Authorized Representatives**
- 2.3. When research is conducted in Colorado individuals under the age of 18 years are **Children** with the exception of:
  - 2.3.1. This decision must be made by consulting the Office of University Counsel
- 2.4. For research outside Colorado, the IRB may consult with the Office of University Counsel (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**.

### **3. REFERENCES**

- 3.1. None



## POLICY: End Approval Dates

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### 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. Exempt research

2.1.2. Research that does not require continuing review per "WORKSHEET: Criteria for Approval (HRP-400)."

2.2. For all other research:

2.2.1. The 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, 2020, the **End Approval Date** is April 14, 2021.

2.2.4. For continuing review:

2.2.4.1. The new **End Approval Date** is the Approval Date plus the approval period minus one day

2.2.5. For Amendments, the **End Approval Date** is unchanged.

### 3. REFERENCES

3.1. 21 CFR §56.109(f)

3.2. 45 CFR §46.109(e)



## POLICY: IRB Records

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### 1. PURPOSE

- 1.1. This policy describes the contents of IRB records.

### 2. POLICY

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

- 2.2. IRB files are to include:

- 2.2.1. Study files
- 2.2.2. IRB meeting minutes
- 2.2.3. A resume or curriculum vitae for each IRB member
- 2.2.4. Current and previous versions of IRB member rosters
- 2.2.5. Current and previous versions of controlled documents
- 2.2.6. Correspondence to and from the IRB related to human 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. Records of continuing review activities
- 2.3.10. Data and safety monitoring reports
- 2.3.11. Amendments
- 2.3.12. Unanticipated Problems Involving Risks to Subjects or Others**
- 2.3.13. Documentation of Noncompliance**
- 2.3.14. Significant new findings and statements about them provided to subjects
- 2.3.15. For initial and continuing review by the expedited procedure:
  - 2.3.15.1. The specific permissible category
  - 2.3.15.2. Description of action taken by the **Designated Reviewer**
  - 2.3.15.3. Any findings required by law
  - 2.3.15.4. If continuing review not required by "WORKSHEET: Criteria for Approval (HRP-400)", but the **Designated Reviewer** determined that continuing review was required, the **Designated Reviewer's** rationale for that determination
- 2.3.16. If a **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
- 2.3.17. For exemption determinations, the specific category of exemption
- 2.3.18. Required determinations and study-specific findings supporting those determinations for research involving:
  - 2.3.18.1. Waiver or alteration of the consent process
  - 2.3.18.2. Waiver of written documentation of informed consent
  - 2.3.18.3. Pregnant Women**
  - 2.3.18.4. Neonates of Uncertain Viability**
  - 2.3.18.5. Nonviable Neonates**
  - 2.3.18.6. Prisoners**
  - 2.3.18.7. Children**
  - 2.3.18.8. Wards**



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### 2.3.18.9. Significant Risk Device/Non-significant Risk Device determinations

2.3.19. 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, the University of Colorado Boulder makes IRB records available to clients provided they are relevant to the client. Such records may be excerpted and/or redacted to comply with the University of Colorado Boulder obligations to maintain confidentiality.

## 3. REFERENCES

3.1. 21 CFR §56.115

3.2. 45 CFR §46.115





## POLICY: IRB Roster

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### 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. If 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 the University of Colorado Boulder
  - 2.2.7.1. Description of any relationship between the IRB member and the University of Colorado 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 the University of Colorado Boulder: A (Affiliated) or NA (Non-affiliated)
  - 2.2.8.2. Note that an IRB member may have no relationship to the University of Colorado Boulder, but the IRB member may be affiliated because an **Immediate Family** member may have a relationship with the University of Colorado Boulder.
- 2.2.9. Office
  - 2.2.9.1. Whether the IRB member is an IRB chair, IRB vice-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



## POLICY: IRB Roster

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2.2.11.1. If the member is an alternate member, the class of IRB members for whom the member can 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), 56.107(d)
- 3.2. 45 CFR §46.107(a)(2), 46.107(d)



## POLICY: States and Transitions

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### 4. PURPOSE

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

### 5. POLICY

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

5.2. The following are allowable submissions:

- 5.2.1. Initial
- 5.2.2. Continuing
- 5.2.3. Amendment
- 5.2.4. Event Reporting (New Information)

5.3. A study consists of one or more submissions.

5.3.1. A study may have the following states:

State	Meaning
Determined Not Human Research	<ul style="list-style-type: none"> <li>• Study is not human research</li> <li>• No HRPP oversight is required.</li> </ul>
Determined Human Research Not Engaged	<ul style="list-style-type: none"> <li>• Study is human research</li> <li>• No HRPP oversight is required.</li> </ul>
Approved	<ul style="list-style-type: none"> <li>• Study is human research</li> <li>• HRPP oversight required</li> <li>• Review determined that the study could proceed</li> </ul>
Suspended	<ul style="list-style-type: none"> <li>• Study is human research</li> <li>• HRPP oversight required</li> <li>• Prior review determined that the study could proceed</li> <li>• More recent review instituted a <b>Suspension of IRB Approval</b></li> </ul>
Terminated	<ul style="list-style-type: none"> <li>• Study is human research</li> <li>• HRPP oversight required</li> <li>• Prior review determined that the study could proceed</li> <li>• More recent review instituted a <b>Termination of IRB Approval</b></li> </ul>
Expired	<ul style="list-style-type: none"> <li>• Study is human research</li> <li>• HRPP oversight required</li> <li>• Prior review determined that the study could proceed</li> <li>• Approval period passed without continuing review</li> </ul>
Closed	<ul style="list-style-type: none"> <li>• Study was human research</li> <li>• HRPP oversight was required</li> <li>• Prior review determined that the study could proceed</li> <li>• Study meets criteria for closure</li> </ul>

5.3.2. 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.



## POLICY: States and Transitions

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5.4. Review actions on a submission are:

Action	Meaning
Not Human Research	<ul style="list-style-type: none"> <li>The activity does not meet the organizational definition of <b>Human Research</b>.)</li> </ul>
Human Research Not Engaged	<ul style="list-style-type: none"> <li>The activity meets the organizational definition of <b>Human Research</b> but the site is not engaged</li> </ul>
Approve	<ul style="list-style-type: none"> <li>See “SOP: Committee Review Conduct (HRP-106)”</li> </ul>
Incomplete	<ul style="list-style-type: none"> <li>Returned to PI to complete submission requirements</li> </ul>
Modifications Required	<ul style="list-style-type: none"> <li>Changes required to the submission to allow approval</li> </ul>
Defer	<ul style="list-style-type: none"> <li>See “SOP: Committee Review Conduct (HRP-106)”</li> </ul>
Disapprove	<ul style="list-style-type: none"> <li>See “SOP: Committee Review Conduct (HRP-106)”</li> </ul>
Suspend	<ul style="list-style-type: none"> <li>See “SOP: Committee Review Conduct (HRP-106)”</li> </ul>
Terminate	<ul style="list-style-type: none"> <li>See “SOP: Committee Review Conduct (HRP-106)”</li> </ul>

5.5. Administrative actions on a study are:

Action	Meaning
Expire	<ul style="list-style-type: none"> <li>Approval period passed without continuing review</li> </ul>
Close	<ul style="list-style-type: none"> <li>Study meets criteria for closure</li> </ul>

5.6. Table 2 lists the allowable submissions based on the study’s state prior to a submission.

## 6. REFERENCES

6.1. None

## POLICY: States and Transitions

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6.2. Table 2: Allowable submissions

Table shows allowable submissions X= allowed		State of the Study							
		Submitted	Determined Not Human Research	Determined Human Research Not Engaged	Approved	Suspended	Terminated	Expired	Closed
Submission Type	<b>Initial</b>	X							
	<b>Continuing</b>				X	X		X	
	<b>Amendment</b>		X	X	X	X	X	X	X
	<b>New Information</b>		X	X	X	X	X	X	X



## POLICY: Investigator Obligations

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### 1. PURPOSE

- 1.1. This policy describes the obligations of investigators conducting **Human Research** overseen by the University of Colorado Boulder.

### 2. POLICY

- 2.1. Do not commence research until you have the IRB approval letter and 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 research involving human subjects, 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 when requested 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. For research subject to federal oversight other than FDA:
    - 2.10.3.1. No additional identifiable private information about the subjects is being obtained
    - 2.10.3.2. The analysis of private identifiable information is completed
- 2.11. If research approval expires, 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.

### 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



Office of Research Integrity  
UNIVERSITY OF COLORADO BOULDER  
INSTITUTIONAL REVIEW BOARD

## **POLICY: Investigator Obligations**

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- 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)



## POLICY: Prompt Reporting Requirements

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### 1. PURPOSE

- 1.1. This policy describes the information to promptly report to the University of Colorado Boulder's IRB when the research is subject to oversight by the University of Colorado 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. GUIDANCE

- 2.1. Report the following information items to the IRB within 5 days:
  - 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<sup>3</sup>
  - 2.1.8. Unanticipated adverse device effect<sup>4</sup>
  - 2.1.9. Protocol deviation that harmed a subject or placed subject at risk of harm
  - 2.1.10. Protocol deviation due to the action or inaction of the investigator or research staff
  - 2.1.11. Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject
  - 2.1.12. Breach of confidentiality
  - 2.1.13. Unresolved subject complaint
  - 2.1.14. Adverse event or IND safety report that requires a protocol or consent change
  - 2.1.15. Written report of a study monitor
- 2.2. When relying on an external IRB report the following information items to the HRPP Office within 5 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 the University of Colorado Boulder's IRB.

### 3. REFERENCES

- 3.1. 21 CFR §56.108(b)
- 3.2. 45 CFR §46.107(a)(4)

<sup>3</sup> 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.

<sup>4</sup> 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.