



HRP – 101 – SOP: NASA IRB Serving as IRB of Record

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HRP-101	07/07/2020	v.5	v.4

Purpose

HRP – 101 establishes the process and responsibilities when NASA IRB serves as the IRB of Record.

The process begins when the Institution submits a request to cede review to the NASA IRB as detailed in HRP – 101 – SOP: Establishing Reliance Acknowledgements and submits a request via the eIRB system. The process ends when the study is closed or the Reliance Acknowledgement is Terminated as stated in this policy.

The HHS regulations Common Rule, at 45 CFR 46.103(e), requires that for nonexempt research involving human subjects (or exempt research that requires limited IRB review) that takes place at an institution for which an IRB not operated by that institution exercises oversight, the institution (the Relying Institution) and the organization operating the IRB (the IRB of Record) must document the Relying Institution’s reliance on the IRB for its research oversight. HRP – SOP – 101 describes NASA IRB’s policies and procedures for reliance, including the responsibilities of each entity to ensure compliance with the regulation.

Chapter V – National Aeronautics and Space Administration, of Title 14, Aeronautics and Space, CFR 1230.114 requires that in the conduct of cooperative research project, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with 14 CFR 1230. An institution participating in a cooperative research project may, the approval of the department or agency head, enter into a joint review arrangement and rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication or effort.

Policy

1. It is the policy that the NASA IRB will serve as the IRB of record for all research performed at a NASA center or on NASA property, research involving NASA employees, and/or research including spaceflight human subjects.

2. It is the policy of NASA IRB that the review performed by NASA IRB will meet human subject protection requirements [14 CFR 1230, NPR 7100.1A, HHS 45 CFR 46, and FDA 21 CFR 50, 56, 312, and 812], as applicable.
3. NASA IRB will follow written procedures for reporting its findings and actions to the appropriate officials at the Relying Institution as noted in this policy 'Responsibilities'.
4. It is the policy of NASA IRB that, by signing the Reliance Acknowledgment and ceding review to NASA IRB, the Relying Institution will follow written procedures for reporting and communication as noted in this policy, 'Responsibilities'.

Responsibilities

Responsibilities of ***NASA IRB as the IRB of Record*** include, but are not limited to:

1. Working in collaboration with the point of contact at the Relying Institution to determine and document specific roles and responsibilities for communicating key information with the Relying Institution and the IRB of Record as described within this document.
2. Sending written notification to the study Principal Investigator (PI) of: (i) its decision to approve or disapprove any ceded Research, (ii) any modifications required to secure approval of the Research, and (iii) the date by which renewal of an approval is required.
3. Maintaining all documentation relevant to the research, including but not limited to: NASA IRB submission, protocol review determinations (approvals and disapprovals, stipulations or modifications requests), and NASA IRB meeting minutes.
 - a. Upon reasonable request, providing the Relying Institution with access to relevant records related to the IRB review.
4. Promptly notifying the PI of its findings and actions with respect to any unanticipated problems involving risks to subjects or others (UPIRSOs) or any research-related subject injuries or significant complaints that occurred at a Relying Institution or that occurred at another Relying Institution if such events or actions relate to or may affect the conduct of the Research or the safety, rights, or welfare of subjects participating in the Research at the Relying Institution(s). If the finding of serious and/or continuing noncompliance has a study-wide impact, all Relying Institutions must be notified.
5. Reporting to regulatory agencies and/or sponsors any findings of UPIRSOs, determinations of serious and/or continuing noncompliance, and/or any suspensions or terminations of IRB approval on behalf of all applicable institutions covered by the Reliance Acknowledgement. The NASA IRB will also provide the involved Relying Institutions the opportunity to review and comment on the report before it is sent to federal authorities, such as OHRP, the FDA, or others, as applicable.
6. In the event that a continuing review is submitted after IRB approval for the study expires, or the study expires before the NASA IRB can reapprove the study, notifying the Relying Site from affected sites, in addition to the PI, of the lapse in IRB approval and any applicable corrective action plans.
7. Promptly notifying the PI of any finding of serious and or/continuing noncompliance that may affect the conduct of the research or the safety, rights, or welfare of human subjects.

8. Promptly notifying the PI, and relevant Relying Sites, of any suspension or termination of IRB approval for that portion of the research taking place at those Relying Institutions. If the suspension or termination is study-wide, all relying Institutions must be notified.
9. Providing information about suspected research misconduct to the Relying Institution for appropriate investigation and action consistent with institutional policy.
10. Providing acknowledgement of study and site closure to the PI
11. Notifying the PI when other sites are accepted for ceded review and reliance has been authorized (e.g. when more than one site has been approved for Reliance on NASA IRB through a Reliance Acknowledgement for the same research study).
12. Participating in conference calls regarding a study as requested.
13. Providing copies of study-wide IRB-approved materials to the PI.
14. Reporting to Sponsor, Federal Agencies, or Other Oversight Entities: If NASA, as the IRB of Record, determines that it must report information to the Sponsor, OHRP, the FDA and/or other oversight entities, it will notify the Relying Institution within a reasonable time in advance of reporting.
 - a. NASA IRB will share the report with Relying Institution before it is sent to the sponsor/oversight authority and will copy their institutional official(s) and designees.

Responsibilities of Relying Institutions include, but are not limited to:

1. Pre-Review Responsibilities

- a. The relying institution must communicate any local context issues relevant to the research protocol to NASA IRB via the eIRB Submission. The relying institution is specifically responsible for:
 - i. Verifying the completeness and accuracy of the reporting of local considerations to NASA IRB, including requirements of applicable state or local laws, regulations, policies, and ancillary review processes as are relevant to the specific study or studies ceded to NASA IRB.
 - ii. Ensuring organizational compliance with all HRPP. For example, if the Relying Institution requires approval by other internal review committees prior to IRB or Ethics Committee approval (e.g. Institutional Biosafety, Radiation Safety), the Relying Institution must include that information and approval letters in the IRB application.
 - iii. Providing information about local restrictions, stipulations, and/or requested substitutions to informed consent documents to NASA IRB for its approval, including institution-specific language (such as the relying institution's standard injury compensation language).
- b. The relying institution should maintain a formal system for checking local context responses prior to sending the Submission through the eIRB.
- c. The relying institution will ensure that research personnel are appropriately qualified and meet NASA IRB standards for eligibility to conduct research, including but not limited to human subjects protection training and collection and maintenance of conflict of interest disclosure forms and management plans.

2. General Responsibilities

- a. Any institutions or organizations engaged in research where NASA IRB serves as the IRB of Record must have an IRB Reliance Acknowledgement with NASA IRB and standard operating procedures for research in place which NASA IRB may request at any time. The Reliance Acknowledgement specifies the institutional party to which the delegation of duties and responsibilities described in this policy apply.
- b. All research involving human subjects at the relying institution must follow one or more of the below regulations, policies, and/or procedures.
 - i. Federal Regulations (14 CFR 1230, NPR 7100.1A, 45 CFR 46, 160, 164 and 21 CFR 50, 56 at minimum.), where relevant, tribal law passed by the official governing body of an American Indian or Alaska Native tribe. Additional federal regulations may apply based on the study design and study funding agency.
 - ii. State and local regulations
 - iii. Institutional Policies
 - iv. ICH-GCP (E6) (as applicable)
 - v. NASA IRB Policies
- c. All relying institutions must comply with the local policies and bylaws of their institution, including, where appropriate, obtaining appropriate departmental approvals, fulfilling training and education requirements, and maintaining open communication regarding protocol requirements within applicable departments.
- d. For all federally funded research, the relying institution will maintain an OHRP-approved FWA and notify NASA IRB promptly in writing of any suspension, restriction, termination, or expiration of said FWA.

3. Research Review and Oversight Responsibilities

- a. The relying institution will ensure research personnel are notified of their responsibilities when conducting research pursuant to a Reliance Acknowledgement and this SOP.
- b. A relying institution may perform local review of all studies requesting reliance on NASA IRB, as complies with relying institution policies.
 - i. Research may be disapproved by officials of the relying organization, but they may not approve the research if it has not been approved by NASA IRB when NASA is serving as the IRB of Record.
- c. The relying institution will conduct post-approval monitoring in addition to, or in cooperation with, the NASA IRB.
- d. The relying institution will ensure that the research team is conducting research and recruiting potential research participants in accordance with NASA IRB-approved protocol, procedures, and documents.
- e. The relying institution will maintain, implement, or have access to a human subjects research quality assurance/quality improvement process or other monitoring program

to accept subject complaints, conduct for-cause and not-for-cause audits, and report results to the relying institution research team and to NASA IRB.

- f. The relying institution retains responsibility for investigating allegations of research misconduct of its investigators and for taking appropriate action consistent with institutional policy.
- g. The relying institution and its researchers acknowledge that they are primarily responsible for safeguarding the rights and welfare of each research participant, and that the participant's rights and welfare must take precedence over the goals and requirements of the research.
- h. NASA IRB will review issues of privacy and confidentiality in accordance with the Privacy Act of 1974 to ensure protections of Protected Health Information (PHI).
 - i. If the Relying Institution is a covered entity responsible for HIPAA-compliant research, the NASA IRB will defer to the Relying Institutions SOPs on meeting those provisions (including, but not limited to authorizations, notices of decedent research, and Limited Data Set with Data Use Agreements)

4. PI Responsibilities

- a. Promptly report to the NASA IRB, the following information in accordance with NASA IRB policies and procedures and as specified on the NASA IRB website, including but not limited to:
 - i. Any changes in funding or personnel
 - ii. Potential Conflicts of Interest, including institutional and potential financial interests, that could affect or be affected by the research
 - iii. Changes or modifications to approved research protocol, including the research plan, consent process and form, and/or methods of recruitment
 - iv. Continuing review progress reports
 - v. Protocol Violations
 - vi. Subject injuries related to the research, or significant complaints that could impact the conduct of the research.
 - vii. Significant complaints are defined as those that cannot be resolved by the study team and a) suggest an increased or unexpected new risk or harm or b) change the risk/ benefit ratio of the Research. Other complaints should be reported in accordance with the NASA IRB's policies and procedures.
 - viii. UPIRSOs
 - ix. Any potential noncompliance that occurs in relation to the Research
 - x. Reports of Serious or Continuing Noncompliance
- b. When more than one site has been approved for Reliance on NASA IRB through a Reliance Acknowledgement for the same research study, the PI must:
 - i. Promptly respond to questions or requests for information from other Investigators and/or study teams at Relying Institutions or the Relying IRB.
 - ii. Provide NASA IRB contact information and NASA IRB policies to the Site Investigators.
 - iii. Provide documentation of study-wide IRB determinations to Relying Sites.

- iv. Provide other Relying Sites with the NASA IRB-approved versions of all study-wide documents (e.g., consent and authorization forms, protocol, recruitment materials).
- v. Provide updated copies of the modified versions of study-wide IRB-approved materials to Relying Sites in a timely manner.
- vi. Provide access, upon request, to study records for audit by the Relying Institution, the NASA IRB, and other regulatory or monitoring entities.
- vii. Follow all requirements of the Relying Institution with regard to ceded review, such as ensuring administrative requirements for documenting ceded review have been met before study activation occurs at a Relying Institution.
- viii. Obtain and collate study-wide information for continuing review and submitting to NASA IRB.
- ix. Provide NASA with a closure request form and verifying closure of all sites when a study is closed.
- x. Participate in conference calls regarding a study as requested.

5. Responsibilities of all Relying Institutions

- a. Follow all requirements of their home institution with regard to ceded review, such as ensuring other reviews or sign-offs required by the institution have been completed before a study is activated.
- b. Promptly respond to questions or requests for information from NASA IRB and, when applicable, the PI (or designee) through the communication mechanism(s) established by the Reliance Acknowledgement and this SOP.
- c. Participate in conference calls regarding a study as requested by NASA IRB.
- d. Work with the PI, when applicable, and the other reliance points of contact from their home institution, as applicable, to incorporate site-specific required language into the consent template to be used at their institution.
- e. Provide the sponsored programs office or institutional official at their institution with documentation that IRB oversight for a study has been ceded to and approved by an IRB external to their home institution.
- f. Provide the reliance point of contact from their home institution with information regarding local Site Investigator or other Relying Site personnel changes.
- g. Provide, upon request, access to study records for audit by the local institution, NASA IRB, and other regulatory or monitoring entities.
- h. **Reporting Requirements**- The relying institution agrees to facilitate NASA IRB's responsibility for initial and continued review, record keeping, and reporting requirements. All information requested or required by NASA IRB will be reported in a timely manner
 - i. The relying institution will notify NASA IRB of any legal request (e.g. subpoena, open records request) connected to the study and reasonable assist with investigations and response to such requests as mutually determined to be lawful and appropriate.

1. The relying institution will also notify NASA IRB of audits (including findings and corrective actions), communications with regulatory agencies, and findings of research misconduct.
- ii. The relying institution will provide cooperation with and necessary reports for any audit or investigation of any matter related to the research study for which NASA IRB is serving as the IRB of Record.
- iii. All financial **Conflicts of Interest** (COIs) must be reported to NASA IRB.
 1. If the relying institution has a Public Health Service (PHS)-compliant conflict of interest policy, it must comply with all aspects of that policy.
 2. NASA IRB requires that all relying institutions and research personnel comply with NASA IRB's COI policies in addition to any local conflict of interest requirements.
 3. Investigators must report, to their institution, any changes in conflict of interest (COI) disclosures and resulting changes in COI management plans related to the research (i.e., the specific study or studies ceded to the NASA IRB).

Procedures

1. The PI or Relying Institution must submit a request for Reliance Acknowledgement
 - a. Establish NASA IRB as the IRB of Record as specified in HRP – 100 – SOP: Establishing Reliance Acknowledgements.
 - b. Post Approval Reporting
 - i. After NASA IRB has approved the protocol, the following information must be reported to and approved (as applicable) by NASA IRB in accordance with NASA IRB's SOPs, as specified on the NASA IRB website (including, but not limited to):
 1. Any change to an approved research protocol, including research plan, consent process and form, and/or methods of subject recruitment
 2. PI changes
 3. Protocol Violations
 4. Reports of serious or continuing noncompliance
 5. Unanticipated Problems Involving Risks to Subjects or Others
 6. Potential conflicts of interest, including institutional and potential financial interests, that could affect or be affected by the research
 7. Continuing Review
 8. Any other NASA – IRB specific reporting requirements
 - ii. Reporting to Sponsor, Federal Agencies, or Other Oversight Entities: If NASA, as the IRB of Record, determines that it must report information to the Sponsor, OHRP, the FDA and/or other oversight entities, it will notify the Relying Institution within a reasonable time in advance of reporting.

1. NASA IRB will share the report with Relying Institution before it is sent to the sponsor/oversight authority and will copy their institutional official(s) and designees.
2. Termination of the Reliance Acknowledgement
 - a. Either NASA IRB or Relying Institution may unilaterally terminate the Acknowledgement by providing thirty (30) calendar days written notice.
 - b. The Acknowledgement may be terminated in its entirety only upon the mutual agreement of all then-participating institutions. For clarity, termination of a participating site from the Acknowledgement will not terminate the Acknowledgement with respect to the remaining participating sites and institutions.
 - c. Participation in the Acknowledgement will terminate immediately in the event of and as of the effective date of any suspension, restriction, termination, or expiration of NASA's FWA; and in the event and as of the effective date of any failure of its IRB to remain registered with OHRP.
 - d. Termination of the Acknowledgement shall not affect NASA IRB's obligations under 45 CFR 46.109(e) and 21 CFR § 56.109(f) to continue review of NASA-funded research projects that occur on NASA property and/or involve NASA-related research subjects.
 - e. In the event of Termination of the Acknowledgement, NASA IRB will work with the Relying Institution involved in the Termination to determine the effect of such Termination on any research and associated research activities being conducted under the Acknowledgement at the time of Termination.
 - f. NASA IRB, as the IRB of Record will, when possible and appropriate, provide continued oversight for ongoing research for the reasonable time necessary to appropriately transfer oversight of the research to another IRB of Record.
 - g. Termination of the Acknowledgement shall be in writing and state, at a minimum, (1) the reason for Termination, (2) the effects of the Termination on any research activities, (3) any possible risks associated with Terminating the agreement when research remains open with the IRB of Record, and (4) plans for continued oversight of active research during the transfer of the reviewing IRB.

Definitions

Cooperative Research: those projects covered by this policy that involve more than one institution.

Department or agency head [14 CFR 1230.102]: the head of any federal department or agency and any other officer or employee of any departments or agency to whom authority has been delegate.

Engaged: NASA is considered engaged in research when NASA's *employees or agents* obtain:

- (1) data about the subjects of the research through intervention or interaction with them,
or
- (2) identifiable private information about the subjects or research, or
- (3) the informed consent of human subjects for the research

and analog and parabolic flight studies funded by NASA.

Institution [14 CFR 1230.102]: any public or private entity or agency (including federal, states, and other agencies).

IRB of Record: The “Reviewing IRB” to which authority for IRB review and oversight has been ceded by the Relying IRB or Relying Site for an instance of research specified in the RA.

Key Personnel: Those involved in the conduct of human subject research in which the persons engaged are in direct contact with research participants consenting and/or collecting data, and/or have access to private and identifiable research data.

Noncompliance: Failure to follow the regulations, or the requirements or determinations of the IRB. Noncompliance is defined as a violation of any federal, state, or local regulation that governs human research; any institutional policy on human research; any deviation from the protocol approved by the IRB or stipulations imposed by the IRB as a condition of approval.

- i. In the case of research funded or conducted by the Department of Defense (DOD), Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) instruction 3216.02, its references, or applicable requirements.

Principal Investigator (PI): The NASA PI or PI that is responsible for coordination with the NASA IRB or the IRB of Record for all of the research sites.

Reliance Acknowledgement (RA): An agreement or ‘acknowledgement’ entered in to by two or more institutions engaged in human subject research that permits one or more institutions to cede IRB review to another IRB. The signed acknowledgement permit a single IRB to review human subject research activities for more than one site and documents respective authorities, roles, responsibilities, and communication between an organization providing the ethical review and a participating organization relying on a reviewing IRB.

Relying IRB: The local IRB an institution or organization that has ceded IRB review to another IRB to provide IRB review and oversight for a specific study or set of studies.

Relying Site (Relying Institution): The research site(s) at an institution or organization that has ceded IRB review to another IRB to provide IRB review and oversight for a specific study or set of studies.

Significant Complaints: a complaint that may adversely impact a participant or potential participant’s safety, rights, or welfare and/or one that requires a change to the study protocol or consent form.

Site Investigator (Local Investigator): The investigator at one of the sites where the study is occurring and is responsible to PI.

Unanticipated Problem Involving Risks to Subjects or Others (UPIRSO): Any information that is (1) unanticipated, (2) related to the research, and (3) indicates that subjects or others are at increased risk of harm.

- j. For Department of Defense (DOD) research the term Unanticipated Problem Involving Risks to Subjects or Others includes any incident, experience, or outcome that meets ALL three of the following conditions
 - i. Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied.

- ii. Is related or possibly related to participation in the research (in this Instruction, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).
- iii. Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

References

NASA

- 1. 14 CFR 1230.114
- 2. NPR 7100.1A

DHHS Regulations

- 3. 45 CFR 46.103(e), 46.114

FDA Regulations and Guidance

- 4. 21 CFR 50, 56, 312, and 812

Other

- 5. ICH-GCP (E6)
- 6. NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

AAHRPP

- 7. AAHRPP Tip Sheet 24: Single IRB or EC Review

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