The NASA IRB uses an expedited review process to review studies that meet the categories adopted by the DHHS (Department of Health and Human Services) 45 CFR 46.110 and the FDA (Food and Drug Administration) 21 CFR 46.110 and NASA’s 14 CFR 1230.110 that involve no greater than “minimal risk”.

Expedited review procedures allow the NASA IRB to review and approve studies that meet the criteria within this SOP without convening a meeting of the full NASA IRB.

The purpose of HRP-430 is to describe when the NASA IRB may review new applications, modifications, and continuing review reports by expedited procedures. HRP-430 also describes the requirements for the Expedited Review process.

Policy

1. Expedited review procedures may be carried out by the NASA IRB Chair or by one or more reviewers designated by the Chair from among NASA IRB Members (Prime or Alternate members). Administrative modifications may be carried out by the NASA IRB Office staff.
   a. A NASA IRB Member with a conflicting interest may not participate in an Expedited Review.
2. The NASA IRB Chair, in collaboration with the NASA Office of Research Assurance Manager, will designate a list of NASA IRB Members eligible to conduct Expedited Review of submissions.
   a. The designees must be experienced voting members or alternate members of the NASA IRB.
   b. The NASA IRB Office will maintain a list of designated Expedited reviewers and their areas of expertise.
   c. Selected reviewers will have the qualifications, experience, and knowledge in types of research to be reviewed, as well as be knowledgeable of the requirements to
approve research under expedited review (i.e., CIP certified members or non-CIP certified members who have completed training and demonstrated proficiency).

3. **Eligibility for Expedited Review**: The NASA IRB may review research using Expedited review procedures provided that the following criteria listed in 14CFR1230.110 (b)(1) are met:

   a. The research activities present no more than **minimal risk** to human subjects

   b. All of the procedures fall within the **list of categories** of research published by the Secretary of HHS [and as stated in Appendix 1 of this policy].

   i. The activities on the list should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

   ii. Categories 1-7 pertain to initial, modifications and continuing review

   iii. Categories 8 and 9 pertain to continuing review.

   c. **Minor changes** in previously approved research during the period for which approval is authorized.

   d. Research for which limited IRB review is a condition of exemption under 45CFR46.104(d)(2)(iii), (d)(3)(i)(c), and (d)(7) and (8).

   e. Note: The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of IRB review (expedited or convened).

   f. **Modifications to Research Initially approved by Expedited Review** may be reviewed using expedited procedure provided:

      i. The research continues to meet the Expedited Research Categories **and**

      ii. With the modifications implemented, the research would continue to pose no more than minimal risk

   g. **Modifications to Research Initially Approved by a Convened IRB** may be reviewed by the expedited review process provided:

      i. Modifications do not pose an increased risk to subjects; **and**

      ii. Any additional procedures fall within categories 1-7 of research that may be reviewed using the expedited procedure.

      iii. Modifications constitute a minor change to previously approved research.

      1. **Minor Modifications** (or minor change) is any modification that does not materially affect the assessment of risks and benefits.

      2. Non-material changes will be administratively reviewed as **Administrative Modifications**.

   h. **Annual Expedited Continuing Review** of Approved research: Only research meeting the criteria for Category 8 or 9 of the Expedited Review Categories. All other expedited studies will need to obtain recertification every 5 years.

   i. Research granted exemption but requiring a limited IRB review under the NASA IRB Policy on Exempt Research [SOP finalization TBD - draft form as of 01Sep2020].

4. Expedited Review procedures may **not** be used:

   a. Any study involving human genomic testing
i. NPR 7100 Section 2.2.2 states that all studies involving human genomic testing is categorized as "greater than minimal risk."

b. When identification of the subjects and/or their responses would easily place them at risk of criminal or civil liability or be damaging to the subjects’ reputation, financial standing, employability, etc., unless reasonable and sufficient protections will be implemented so that risks related to invasion of privacy and/or breach of confidentiality are no greater than minimal.

c. For classified research involving human subjects

d. Research subject to FDA regulations: Studies involving randomized use of drugs, devices, or biologics. All such studies are reviewed by the convened IRB.

5. Information obtained after the determination and Approval of an Expedited protocol (e.g. an Amendment, Reportable Event (RNI), sponsor notification, or other pertinent information) may possibly disqualify the study from being approved under an expedited review procedure.

a. If the protocol is disqualified from Expedited review, the new information will be reviewed by the NASA IRB Office and IRB Chair or designee and forwarded to the NASA IRB for determination at a convened meeting.

6. Expedited Review of Recruitment materials

a. When advertisements are easily compared to the approved consent document, the IRB chair, or other designated IRB member, may review and approve by expedited means, as provided by 14 CFR 1230.110 (b)(2), HHS 45 CFR 46.110(b)(2) and FDA 21 CFR56.110(b)(2).

b. When the IRB reviewer has doubts or other complicating issues are involved, the advertising will be reviewed by the NASA IRB Chair as the designated reviewer and he/she will make the decision on whether the study is reviewed at a convened meeting of the IRB.

### Procedures

1. Investigators are required to submit a complete application to NASA’s eIRB, including all required supporting documentation.

a. The investigator is responsible for submitting the same materials the convened NASA IRB receives for protocols reviewed by the convened NASA IRB. Submitted research materials must include sufficient detail for the Reviewer to determine whether the study meets criteria for approval.

2. NASA IRB Office

a. The NASA IRB Office will conduct an initial pre-review for completeness of the submission in accordance with NASA IRB SOPs and screen for accuracy.

b. The NASA IRB Office will confirm that a submission is eligible for Expedited review. The NASA IRB Office will consult with senior staff and Office of Research Assurance management, IRB Chairs, and members as needed, particularly with respect to assessments of risks and benefits.

i. The NASA IRB Office will forward the submission to the NASA IRB Chair and/or designee with appropriate expertise for review.
c. The NASA IRB Office aims to respond to the investigator within one week of receipt of the eIRB submission. Depending upon the type of review (i.e., initial, amendment, continuation) expedited review approval may take from one to three weeks.

3. Authority. An Expedited Review may be performed by the NASA IRB Chair and/or by an experienced NASA IRB member designated by the IRB Chair, based on the member’s area of expertise. Administrative modifications may be performed by the NASA IRB Office Staff.

   a. The Expedited reviewer should, whenever possible and not conflicted, be the NASA Center representative [e.g. Ames, Langley, KSC].
   b. At any time, the Expedited reviewer may request consultation, additional reviewers with expertise, or may refer the item to the full convened IRB.
   c. The assigned reviewer(s) of an Expedited submission may exercise all of the authorities of the full IRB Committee. Except: the reviewer(s) may not disapprove, suspend, or terminate the research.
      i. A research activity may be disapproved only after review by a convened IRB in accordance with the non-expedite procedure set forth in 45 CFR 46.108(b) and 21 CFR 56.108(c) and 14 CFR 1230.108.

4. Determining Eligibility for Expedited Review. The research (or changes to research) is eligible for expedited review if it meets criteria specified in the federal regulations. These are described in Appendix 1 of this SOP and on the Eligibility for Expedited Review of Research form.
   a. The NASA IRB Chair or designee will confirm eligibility for Expedited Review.
   b. The NASA IRB Chair or designee will have access to the materials submitted in the eIRB system including, but not limited to:
      i. The full protocol, application, or a protocol summary containing the relevant information to determine whether the proposed research fulfills the criteria for approval.
      ii. Proposed consent document(s)
      iii. Recruitment materials.
   c. Expedited review must fulfill the requirements of criteria for approval as reviews conducted by a full convened NASA IRB.
      i. The NASA IRB Chair or designee will complete the review applying all applicable approval criteria (e.g. NASA 14CFR1230.111, §1230.116, §1230.117; HHS 45CFR46.111, §46.116, §46.117, and FDA 21CFR56.111, 21CFR50 Subpart B). The reviewer may choose to document on the Approval Criteria Checklist [TBD].
      ii. The requirements for informed consent (or for altering or waiving the requirement for informed consent) apply regardless of whether research is reviewed by the convened IRB or under an expedited procedure.
      iii. The NASA IRB Chair, designated review, and/or additional assigned reviewer provides comments in written form in eIRB.
      ii. If the reviewer finds that the research should not be approved, it must be referred to the full Committee for final determinations.
d. After the NASA IRB Chair or designated reviewer makes the determination that the submission meets the Expedited Review eligibility criteria, and the review of the protocol is complete, the NASA IRB or designee makes one of the following determinations:

   i. The proposed activity is **not research or not human subjects research** and does not require IRB Review.

   ii. The research meets the requirements of **exempt** from IRB Review.

   iii. **Approved** as minimal risk research. Accepted as is, no changes are required. Criteria for Expedited NASA IRB approval are met.

   1. When an Expedited Review is used for review of a Minor Modification, as defined in Appendix 3(A), the Designated Reviewer will check ‘mm’ in the eIRB and briefly summarize the modification.

   2. When an Expedited Review is used for an Administrative Modification, as defined in Appendix 3(B), the Designated Reviewer will check ‘other’ in the eIRB and briefly summarize the modification.

   iv. **Contingent Approval (or Approved pending modifications)**. Minor specific changes are required. The NASA IRB Chair/designated reviewer notes the stipulated changes required for approval in eIRB.

   1. Provided the completion of the stipulations can be checked ‘complete’ by the NASA IRB Office, the Modifications do not need to be reviewed by the NASA IRB Chair or designee.

   2. The NASA IRB Chair or designee may request review of the stipulated modifications, in which case the NASA IRB Office will forward to the NASA IRB Chair or designee for final approval.

   v. **Referred for Full Committee Review**. The reviewer may determine that the submission is not expedited. The reviewer may also decide that additional information must be provided by the investigator prior to review by the convened Board.

   1. The Expedited reviewer reserves the authority to refer any study to the Convened NASA IRB for review.

   2. Only the Full Committee may disapprove a study if the criteria for NASA IRB approval are not met.

5. Review Frequency

   a. **Pre-2018 Rule**: For federally-supported research reviewed and approved by Expedited Review procedures on or prior to January 20 2019, the NASA IRB must review ongoing research at least annually, unless the NASA IRB requires more frequent review for a particular protocol.

   i. The NASA IRB may elect, on a study-specific basis, to apply the 2018 Revised Common Rule to studies that were approved prior to January 21, 2019.
1. If NASA IRB elects to apply the 2018 Revised Common Rule to studies approved prior to January 21, 2019, the NASA IRB will send a letter to the PI of qualifying studies notifying them that the study qualifies for No Continuing Review under the Revised Common Rule and that they will be receive an annual reminder prompt via the eIRB.

b. **2018 Revised Common Rule:** Research reviewed and approved by Expedited Review procedures on or after January 21, 2019, unless an Expedited Reviewer determines otherwise, continuing review of research will not be required.

6. **Documentation** will be recorded in the eIRB system.

a. The Expedited Reviewer will document that the study qualifies for Expedited Review, their determination of the level of risk, and the applicable review category(ies) within the eIRB.

b. NASA IRB records for initial and continuing review by the Expedited procedure must include:

   i. Documentation of the risk determination and the specific permissible Expedited Review Category [available within the eIRB].

   ii. That the activity described by the investigator satisfies all criteria for IRB Approval. [NASA IRB-specific Approval Checklist for Reviewers TBD]

   iii. Period of Approval, and that no CR is required, where appropriate

   iv. Determinations required by the regulations including study-specific findings justifying the following determinations:

      1) Approving a procedure which waives or alters the informed consent process;

      2) Approving a procedure which waives the requirement for documentation of consent.

c. Items approved using the Expedited Review procedure are available for Member review at any time in the eIRB system, and are listed on the Agenda as an Addendum for Member review on the NASA IRB agenda.: Initial review, Modifications, New information, and continuing review (where appropriate).

   i. The NASA IRB Agenda and Minutes will reflect the list of Expedited items, major concerns or issues raised during the review and subsequent tactics taken by the reviewer, and the final determination.

c. **Communication with Investigators regarding NASA IRB Actions:**

   i. The NASA IRB Office will provide conditions on NASA IRB Approval Letters to document the applicable expedited review category(ies), approved waiver(s) of informed consent or documentation of consent, and criteria for inclusion of vulnerable subjects in research.

   ii. The Approval Notice will also contain all regulatory determinations including the IRB approval period, the list of funding sources for the research, in addition to the PI and study identifying information and other information as needed.
Definitions

Administrative Modifications: Non-material changes to research-related documentation, previously approved by the NASA IRB, do not require NASA IRB review and only require acknowledgement of receipt by the NASA IRB. The changes will not affect the conduct of the research. [see Appendix 3 for examples]

FDA (Food and Drug Administration)-Regulated Research: The US FDA regulates clinical studies conducted on drugs, biologics, devices, diagnostics, and in some cases dietary supplements and food additives. All such research studies must be conducted in accordance with FDA requirements for the protection of human subjects and IRBs, regardless of funding source (21CFR50 and 56). When FDA regulated test articles are used in research at NASA and funded by another agency, more than one set of regulations may apply. For example, clinical trials involving FDA-regulated test articles that are supported by NASA (or the DHHS), may fall under the jurisdiction of both the FDA and the DHHS. Such trials must comply with the FDA and the DHHS Office for Human Research Protections (OHRP). Where regulations differ, NASA IRB will apply the stricter regulation.

Full Committee Review: reviews conducted at convened meetings at which IRB membership requirements [14CFR1230.107] are met and a quorum consisting of the majority of the members of the IRB is present.

Minimal Risk [14CFR1230.102(j): the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine or psychological examinations or tests.

Minimal Risk for Prisoners: 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. The regulations further state that the IRB must find that the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers [45 CFR 46.305(a)(3)]. If Subpart C does not apply, the IRB may use an equivalent definition of minimal risk for prisoners. [45 CFR 46.303(d)]

Minimal Risk for Research Involving the Department of Defense (funding, subjects, facilities, resources). Per DoD regulations, the phrase “ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” must not be interpreted to include the inherent risks certain categories of subjects face in their daily life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated 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).

Minor Change (or Minor Modification): Minor changes may be reviewed by the expedited process rather than a convened IRB. Based on reference 7, a minor change [see Appendix 3 for examples]:
1. Neither meaningfully increases risk, nor meaningfully decreases benefit, when considered in light of any changes proposed to mitigate risk and improve benefit,
2. Does not meaningfully decrease scientific merit, and

4. Does not adversely affect the assessment of the research with respect to the criteria for approval described in 14CFR1230.111.

References

NASA
1. 14 CFR 1230.110
2. NPR 7100.1B

DHHS Regulations
3. Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research: 45 CFR 46.110
4. Criteria for IRB Approval of Research: 45 CFR 46.111
7. SACHRP Advisory Committee, Recommendations to OHRP regarding definition of a minor change in research under 45CFR46 and 21CFR56; July 20, 2011.

FDA Regulations and Guidance
7. Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research: 21 CFR 56.110
10. AAHRPP Elements: II.2.F
11. AAHRPP Tip Sheet 17: Review of Research by the Expedited Procedure

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Appendix 1: OHRP Expedited Review Categories

Category 1 – Drugs or devices which do not require an IND or IDE

Clinical studies of drugs and medical devices only when either condition (a) or (b) is met:

a. Research on drugs for which an investigational new drug application (IND, 21 CFR 312) is not required. Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.

b. Research on medical devices for which (i) an investigational device exemption application (IDE, 21 CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2 – Blood Samples

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50ml or 3ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Category 3 – Specimens collected prospectively and by non-invasive means

Prospective collection of bio-specimens for research purposes by noninvasive means.

Examples:

a. Hair and nail clippings in a non-disfiguring manner;

b. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

c. Permanent teeth if routine patient care indicates a need for extraction;

d. Excreta and external secretions (including sweat);

e. Un-cannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;

f. Placenta removed at delivery;

g. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

h. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

i. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; or

j. Sputum collected after saline mist nebulization.

Category 4 – Data

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). Examples include:

a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
b. Weighing or testing sensory acuity;
c. Magnetic resonance imaging;
d. Electrocardiography; electroencephalography, thermography detection of naturally occurring radioactivity, electoretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
e. Moderate exercise, muscular strength testing, body composition assessment and flexibility testing where appropriate given the age, weight, and health of the individual.

**Category 5 – Materials (collected retrospectively or prospectively, depending on the circumstance)**
Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

This suggests that Category 5 only covers materials generated for non-research purposes; however, OHRP issued a clarification of the scope of Expedited Category (5) in 2007 at 72 FR60849 stating: “OHRP has concluded that expedited review category 5 was intended to, and should, include research involving existing information or specimens that were previously collected for nonresearch purposes, as well as research involving existing information or specimens that were previously collected for research purposes – provided they were not collected for the currently proposed research.”

*Note that some research in this category may be exempt from the federal regulations or NASA IRB Policy and procedure. This listing refers only to research that is not exempt.*

**Category 6 – Voices, video, digital, or image recordings**
Collection of data from voice, video, digital, or image recordings made for research purposes.

**Category 7 – Individual or group characteristics or behavior; surveys; interviews, etc.**
Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

*Note that some research in this category may be exempt from federal regulations or NASA IRB Policy and procedure. This listing refers only to research that is not exempt.*

**Category 8 – Continuing review of research previously approved by the convened IRB**
Continuing review (i.e., renewal) of research previously approved by the convened IRB as follows:

a. (i) The research is permanently closed to the enrollment of new subjects; and
   (ii) All subjects have completed all research-related interventions; and
   (iii) The research remains active only for long-term follow-up of subjects.
b. No subjects have been enrolled and no additional risks have been identified; or
c. The remaining research activities are limited to data analysis.

**Category 9 – Continuing review of previously approved research not conducted under an IND or IDE**
Continuing review (i.e., renewal) of research previously reviewed and approved by the NASA IRB:
a. The research is not conducted under an investigational new drug application (IND) or investigational device exemption (IDE); and
b. Categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk; and
c. No additional risks have been identified since IRB review at a convened meeting.

Appendix 2: Minimal Risk Procedures

Examples of Minimal Risk Study Procedures:

- Collection of blood samples by venipuncture (within volume limits, defer to NASA Policy updates)
- Collection of data through non-invasive means (excluding studies that require general anesthesia or sedation for research purposes) routinely employed in clinical practice, including MRI, ECG, and ultrasound
- Collection of data from voice, video, digital or image records made for research purposes
- Research on individual or group characteristics or behavior (e.g. focus groups, surveys, interviews)

Examples of Studies that are Not Minimal Risk Procedures:

- Biopsies
- X-rays and DEXA scans
- Procedures in protocols that include investigational drugs or devices
Appendix 3: Administrative and Minor Modifications

A. Administrative Modifications:
   a. Administrative Modifications are submitted in eIRB as a MOD.
   b. Examples of administrative modifications include, but are not limited to:
      i. Research sponsor or funding agency clarification and notification memos;
      ii. CITI training updates
      iii. DSMB or other reports, with recommendations, if no change to the research is recommended;
      iv. Typographical or editorial correction to study documents, including consent forms, recruitment materials, protocols, etc.;
      v. Study closure notifications
      vi. Recategorization of the protocol such as a determination that the activity is not human subjects research

B. Minor Modifications: Proposed modifications (amendments) to research-related activities approved by the convened IRB may be considered to be minor changes provided that they are limited to one or more of the categories below. The reviewer will make the final determination whether the proposed change may be reviewed using expedited procedures as listed below:
   a. Change in appropriately credentialed study personnel;
   b. Change in consent wording that does not increase risk or decrease benefit (e.g. correction of grammatical errors or clarifying statement);
      i. If the consent change might alter the future/current/past subjects’ willingness to participate, the change may require Full Board review (if the study risk is greater than minimal);
   c. Change in category qualifying for exemption or expedited review;
   d. Increase/decrease in subject number (a statistically small change or a change that will not alter the overall premise of the study);
   e. Adding monitoring parameters aimed at enhancing subject safety;
   f. A new media advertisement;
   g. Changes to inclusion or exclusion criteria without increase in risk to subjects;
   h. Changes in the dosage form (e.g. tablet to liquid) but not route of administration;
i. Extending an observational follow-up period (depending on the nature of the procedures, if any, used to collect the observational data);

j. Changes in the number of study visits without increase in risk to subjects; and

k. Change in remuneration (i.e. payments and reimbursement) to subjects.

l. Complement increment mission changes to personnel or data sharing plan