HRP-314 | 3/29/2024

WORKSHEET: Criteria for Approval

The purpose of this worksheet is to provide support for IRB members reviewing research. This worksheet must be used. It does not need to be completed or retained.[[1]](#endnote-2) (LAR = “subject’s Legally Authorized Representative”; subject = participant[[2]](#endnote-3)).

1. General Considerations (Check if “**Yes**” or “**NA**”. All must be checked)

[ ]  The convened IRB (or Designated Reviewer) has, or has obtained through consultation, adequate expertise.

[ ]  For initial review the principal investigator is not Restricted. (“NA if not initial review)**NA:** [ ]

[ ]  Materials are complete.

[ ]  For continuing review, see also Section 4 for additional considerations for these submissions.

☐ For review in which the University of Minnesota is only serving as the Coordinating Center, see also Section 5 for additional considerations.

1. Criteria for Approval (Check if “**Yes**” or “**NA**”. All must be checked) (Applies to initial, continuing, and modifications)

[ ]  Risks to participants are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk.

 Comments: Click or tap here to enter text.

[ ]  Risks to participants are minimized by using procedures already being performed on the participants for diagnostic or treatment purposes. **(“NA” if none) NA:** [ ]

 Comments: Click or tap here to enter text.

[ ]  Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.[[3]](#endnote-4)
Comments: Click or tap here to enter text.

[ ]  Selection of participants is equitable.[[4]](#endnote-5) (Consider the purpose and setting of the research, involvement of vulnerable participants, selection criteria, and recruitment, enrollment, and payment procedures.)

**Relevant Toolkit Documents: HRP-315-WORKSHEET-Advertisements, HRP-316-WORKSHEET-Payments**

 Comments: Click or tap here to enter text.

[ ]  The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.[[5]](#endnote-6)

 **Relevant Toolkit Documents: HRP-335-WORKSHEET-Data and Safety Monitoring**

Comments: Click or tap here to enter text.

[ ]  There are adequate provisions to protect the privacy of participants.[[6]](#endnote-7)

Comments: Click or tap here to enter text.

[ ]  There are adequate provisions to maintain the confidentiality of data.[[7]](#endnote-8)

 Comments: Click or tap here to enter text.

[ ]  Additional safeguards have been included in the study to protect the rights and welfare of participants vulnerable to coercion or undue influence.

 **Relevant Toolkit Documents: HRP-013-SOP-LARs, Children, and Guardians; HRP-334-WORKSHEET-Vulnerable Populations; HRP-412-CHECKLIST-Pregnant Women; HRP-413-CHECKLIST-Non-Viable Neonates; HRP-414-CHECKLIST-Neonates of Uncertain Viability; HRP-415-CHECKLIST-Prisoners; HRP-416-CHECKLIST-Children; HRP-417-CHECKLIST-Adults with Impaired Decision-Making Capacity**

**(“NA” if no vulnerable participants) NA:** [ ]

Comments: Click or tap here to enter text.

[ ]  The informed consent process meets one of these sections or checklists:

[ ]  **Section 6: Consent Process**

[ ]  **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process**

[ ]  **Permanently closed to enrollment**

 Comments: Click or tap here to enter text.

[ ]  The informed consent documentation meets one of these sections, worksheets, or checklists:

[ ]  **Section 7: Long Form**

[ ]  **HRP-317 - WORKSHEET - Short Form**

[ ]  **HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent**

[ ]  **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process**

[ ]  **Section 9: Electronic Consent (eIC)**

[ ]  **Permanently closed to enrollment**

 Comments: Click or tap here to enter text.

[ ]  Additional applicable criteria are met:

**Relevant Toolkit Documents: HRP-315 - WORKSHEET - Advertisements; HRP-316 - WORKSHEET - Payments; HRP-318 - WORKSHEET - Additional Federal Agency Criteria; HRP-412 - CHECKLIST - Pregnant Women; HRP-413 - CHECKLIST - Non-Viable Neonates; HRP-414 - CHECKLIST - Neonates of Uncertain Viability; HRP-415 - CHECKLIST - Prisoners; HRP-416 - CHECKLIST - Children; HRP-417 - CHECKLIST - Cognitively Impaired Adults; HRP-418 - CHECKLIST - Non-Significant Risk Device.**

**(“NA” if none) NA:** [ ]

 Comments: Click or tap here to enter text.

1. Additional Considerations (Check all that apply.)

[ ]  Does the research involve no more than Minimal Risk to participants?

[ ]  For greater than minimal risk research, the scientific assessment requirement is met by:

 [ ]  Local entity

 [ ]  HRPP Facilitated

 [ ]  Federal Funding (Awarded)

 [ ]  Non-Federal Agency

 [ ]  IRB committee (e.g. Pending Funding Awards, Expanded Access Protocols, Protocols that do not qualify for expedited review, etc.)

 For IRB committee led scientific assessment, the IRB must consider the following:

• Is the scientific question reasonable? (e.g. The question is precisely articulated; the research has the potential to provide new and useful knowledge; and the rationale for the proposed research is supported by the literature/background in the protocol.)

• Will the methods described in the protocol answer the question? (e.g. research tests and procedures are appropriate to answer the scientific question; the proposed research measures are valid and reliable or there are methods proposed to establish validity and reliability; the proposed participant population is appropriate; the sample size calculation appears valid and will answer the research question; and the principal investigator is qualified to conduct the research.)

[ ]  Have all issues identified in scientific review been addressed adequately?

 [ ]  Yes [ ]  No [ ]  Not Required for this Study

[ ]  Is there a financial conflict of interest?

 [ ]  Yes [ ]  No

If yes, consider whether the investigator’s relationship to the research creates a bias that might affect the rights and welfare of the human participant of the reliability of the data. See HRP-054 - SOP - IRB Review of Financial Conflicts of Interest for more information.

[ ]  When UMN is serving as the sIRB, consider:

 [ ]  For initial reviews, whether the overall study materials meet criteria for IRB approval and applicable regulatory requirements.

 [ ]  For modifications, whether the changes to the overall study will require additional changes to participating site materials (e.g. consent materials). NOTE: If p-Site materials have to be revised as a result of an overall study modification, the UMN IRB should indicate in the decision that p-Site modification submissions(s) will be required.

[ ]  Does the research require Continuing review? (Note that for FDA, DOJ, or CPSC overseen research, research subject to Pre-2018 Requirements, and single IRB studies, continuing review is required.)

 The research does not require Continuing review if one of the following apply:

[ ]  The research is eligible for expedited review. **(See HRP-313 - WORKSHEET - Expedited Review)[[8]](#endnote-9)**

[ ]  The research in expedited or convened initial review has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or (B) Accessing follow-up clinical data from procedures that participants would undergo as part of clinical care.

Research eligible for expedited review may require continuing review if:[[9]](#endnote-10)

[ ]  Serious or continuing non-compliance determination in the prior year, UPRITSO determinations or other significant findings in the prior year, or studies with additional regulatory oversight (e.g. conflicts of interest, international research setting).

[ ]  Should review take place more often than annually?[[10]](#endnote-11) If so, specify period.

[ ]  A Certificate of Confidentiality applies to this research, and the consent form(s) include the required language. **Relevant Toolkit Documents: HRP-333 - WORKSHEET - Certificate of Confidentiality**

[ ]  Is verification needed from sources other than the investigator that no material changes have occurred since prior review?[[11]](#endnote-12) **(“NA” if initial NA:** [ ] **)**

[ ]  Does information need to be provided to participants because it may affect their willingness to continue participation? **(“NA” if initial NA:** [ ] **)**

1. Primary Reviewer Additional Criteria for Initial Review (Check if **“Yes”** or **“NA”**. All must be checked; may be determined by a primary reviewer)

[ ]  The research has the resources necessary to protect participants. (Time to conduct and complete the research; adequate facilities, participant pool, and medical/psychosocial resources; qualified investigators and research staff; appropriate qualifications for international research.)

Consider requiring the use of the:

[ ] [**Research Participant Brochure**](https://research.umn.edu/units/hrpp/research-participants/resources-research-participants)(e.g., research involving circumstances/dynamics that could increase vulnerability to coercion)

[ ] [**Guidance for Legally Authorized Representatives (LAR) Brochure**](https://research.umn.edu/units/hrpp/research-participants/resources-research-participants)(e.g., GTMR research which includes the involvement of LARs)

[ ] [**Research Participant Contact Cards**](https://research.umn.edu/units/hrpp/education-training/order-print-participant-materials)(e.g., when it is important to increase the likelihood that ER personnel are aware of the research participation)

[ ]  Not necessary for this study.

[ ]  The plan for communication among sites is adequate to protect participants. **(“NA” if not a Multi-Site Study where PI is the lead or not initial) NA:** [ ]

[ ]  There are no inconsistencies between the DHHS grant and protocol. **(“NA” if research subject to 2018 Requirements or if there is no DHHS grant.) NA:** [ ]

**Complete remaining items when applicable**

1. Additional Considerations for when the University of Minnesota serves only as the Coordinating Center (Check if “Yes” or “N/A”. All must be checked.)

[ ]  The IRB will review the center’s standard operating procedures and determine whether the operations center or coordinating center has sufficient mechanisms in place to ensure that, where applicable, the following criteria are addressed:

[ ]  Management, data analysis, and data safety and monitoring plan is adequate, given the nature of the research involved;

[ ]  Sample protocols and informed consent documents are developed and distributed to each collaborating institution;

[ ]  Each collaborating institution holds an applicable approved Federal Wide Assurance (FWA);

[ ]  Each protocol is reviewed and approved by the IRB at the collaborating institution prior to the enrollment of participants;

[ ]  Any substantive modification by the collaborating institution of sample consent information related to risks or alternative procedures is appropriately justified; and

[ ]  Informed consent is obtained from each participant in compliance with HHS regulations.

1. Consent Process ­­(Check if “Yes”. All must be checked)

**Relevant Toolkit Documents: HRP-013 - SOP - LARs, Children, and Guardians; HRP-090 - SOP - Consent Process; HRP-416 - CHECKLIST - Children; HRP-417 - CHECKLIST - Adults with Impaired Decision-Making Capacity**

[ ]  The investigator will obtain the legally effective informed consent of the participant or LAR.[[12]](#endnote-13)

[ ]  Dual-Role Consent **(**[ ]  **N/A)**

Dual-role consenting is generally discouraged but determined on a case-by-case basis. The permissibility of a dual-role consent (clinician-investigator) depends on the nature of the research, the vulnerability of the potential participant, and on procedures planned to ensure autonomy. Strategies could include a hybrid model that:

1. Includes both the physician and a more neutral member of the study team and
2. Allows additional time for the patient to consider participation.

[ ]  The circumstances of consent provide the prospective participant or LAR sufficient opportunity to consider whether or not to participate.

[ ]  The circumstances of consent minimize the possibility of coercion or undue influence.

[ ]  Information to be given to the participant or LAR will be in language understandable[[13]](#endnote-14) to the participant or LAR.

[ ]  The prospective participant or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. **(NA if research is subject to Pre-2018 Requirements NA:** [ ] **)**

[ ]  Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. **(NA if research is subject to Pre-2018 Requirements NA:** [ ] **)**

[ ]  Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective participant’s or LAR’s understanding of the reasons why one might or might not want to participate. (NA if research is subject to Pre-2018 Requirements) NA: [ ]

[ ]  There is no exculpatory language[[14]](#endnote-15) through which the participant or LAR is made to waive or appear to waive the participant’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability from negligence.

[ ]  Consent will disclose the elements in **Section 8:** Elements of Consent Disclosure

[ ]  The investigator will follow additional processes when using the Short Form as identified in HRP-317 - WORKSHEET - Short Form Consent Documentation.

1. Long Form of Consent Documentation (Check if “Yes” or “NA”. All must be checked.)

Relevant Toolkit Documents: HRP-013 - SOP - LARs, Children, and Guardians; HRP-091 - SOP - Consent Documentation.

[ ]  The written consent document is accurate, complete, and consistent with the protocol.

[ ]  The written consent document embodies the elements in **Section 8:** Elements of Consent Disclosure

[ ]  The investigator will give either the participant or LAR adequate opportunity to read the consent document before it is signed.

[ ]  The participant or LAR will sign and date the consent document.

[ ]  The person obtaining consent will sign and date the consent document.

[ ]  A copy of the signed and dated consent document will be given to the person signing the document.

[ ]  If there is a LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. **(“NA” if no signature line) NA:** [ ]

[ ]  When a participant or LAR is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the participant or LAR, and that consent was freely given.

**(“NA” if all participants are able to read) NA:** [ ]

1. Elements of Consent Disclosure[[15]](#endnote-16) (Check if “Yes” or “NA”. All must be checked.

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| Required Elements*(\*Can be omitted if there are none*.)[ ]  The study involves research.[ ]  The purposes of the research.[ ]  The expected duration of the participant’s participation.[ ]  The procedures to be followed.[ ]  Identification of any procedures, which are experimental.\*[ ]  Any reasonably foreseeable risks or discomforts to the participant.\*[ ]  Any benefits to the participant or to others, which may reasonably be expected from the research.*\*[[16]](#endnote-17)*[ ]  Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.*\**[ ]  The extent, if any, to which confidentiality of records identifying the participant will be maintained.*\**[ ]  How to contact the research team for questions, concerns, or complaints about the research.[ ]  How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the participants’ rights; to obtain information; or to offer input.[ ]  Whom to contact in the event of a research-related injury to the participant.[ ]  Participation is voluntary.[ ]  Refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.[ ]  The participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.[ ]  **For studies under the 2018 Rule** (including FDA regulated research approved on or after January 21, 2019): One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:[ ]  A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the LAR, if this might be a possibility; or[ ]  A statement that the participant’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.(NA if research is subject to Pre-2018 Requirements) NA: [ ]  |

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| **Required for More than Minimal Risk Research**[ ]  Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.[ ]  Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. |

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| **Required for Clinical Trials that Follow ICH-GCP**[ ]  The approval of the IRB.[ ]  The probability for random assignment to each treatment.[ ]  The participant's responsibilities.[ ]  When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.[ ]  The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the participant.[ ]  When there is no intended clinical benefit to the participant, a statement to this effect.[ ]  The monitors, auditors, IRB, and regulatory authorities will be granted direct access to the participant's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the participant, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the participant or LAR is authorizing such access.[ ]  If the results of the trial are published, the participant’s identity will remain confidential. |

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| **Required for FDA-Regulated Research[[17]](#endnote-18)**[ ]  The possibility that the Food and Drug Administration may inspect the records and should not state or imply that FDA needs permission from the participant for access to the records[[18]](#endnote-19).[ ]  The data collected on the participant to the point of withdrawal remains part of the study database and may not be removed.[ ]  The investigator should ask a participant who is withdrawing whether the participant wishes to provide further data collection from routine medical care.[[19]](#endnote-20)[ ]  For controlled drug/device trials (except Phase I drug trials) and pediatric device surveillance trials: “A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.” |

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| **Additional Elements of Informed Consent[[20]](#endnote-21)** [ ]  The particular treatment or procedure may involve risks to the participant, which are currently unforeseeable. **NA:** [ ] [ ]  If the participant is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. **NA:** [ ] [ ]  Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent. **NA:** [ ] [ ]  Any additional costs to the participant that may result from participation in the research. **NA:** [ ] [ ]  The consequences of a participant’s decision to withdraw from the research. **NA:** [ ] [ ]  Procedures for orderly termination of participation by the participant. **NA:** [ ] [ ]  Significant new findings developed during the course of the research, which may relate to the participant’s willingness to continue participation will be provided to the participant. **NA:** [ ] [ ]  Approximate number of participants involved in the study. **NA:** [ ] [ ]  Amount and schedule of all payments. **NA:** [ ] [ ]  A statement that the participant’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit. (NA if research is subject to Pre-2018 Requirements **NA:** [ ] )[ ]  A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions. (NA if research is subject to Pre-2018 Requirements **NA:** [ ] )[ ]  For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). (NA if research is subject to Pre-2018 Requirements **NA:** [ ] )[ ]  Any additional information which should be given to participants when in the IRB’s judgement the information would meaningfully add to the protection of the rights and welfare of participants.[[21]](#endnote-22) **NA:** [ ] [ ]  When the study involves genetic testing, a statement that outlines the protections afforded to the participant under the Genetic Information Nondiscrimination Act (GINA). **NA:** [ ]  |

1. Additional Considerations for Electronic Consent (eIC) (Check if “Yes” or “NA”. All must be checked)

[ ]  The eIC process includes all the requirements listed in **Section 6 - Consent Process.**

[ ]  Electronic consent document includes all elements required by HHS and/or FDA regulations (45 CFR 46.116 and 21 CFR 50.25 as applicable). See **Section 8 - Elements of Consent Disclosure**

[ ]  The eIC plan is documented appropriately in the protocol and participants will:

 [ ]  Have enough time to dedicate to the eIC process,

 [ ]  Be informed of approximately how long the process will take, and

 [ ]  Be informed of what information will be presented to them.

[ ]  The PI has a plan for ensuring that the eIC process allows participants the opportunity to consider whether or not to participate and to ask questions about the study before signing the eIC document and ask questions about the study at any time during the participant’s involvement in the research.

[ ]  The date of the electronic signature will be captured.

**(NA if waiver of documentation of consent is requested and justified) NA:** [ ]

[ ]  The individual signing the eIC (i.e. the participant, LAR, or parent(s)/guardian(s)) will be given a copy of the written informed consent form (by e-mail or print)

**(NA if waiver of documentation of consent is requested and justified) NA:** [ ]

[ ]  Questions or methods to gauge participant comprehension of key study elements are clearly defined in the informed consent procedures.

[ ]  Electronic consent process includes age-appropriate materials to facilitate comprehension.

[ ]  Electronic consent process is suitable to the study population or procedures are outlined to accommodate participant’s needs.

[ ]  Electronic consent document/process allows participants to proceed forward or backward or pause for review later.

[ ]  Measures are present to ensure that participants have access to all of the consent related materials, including hyperlinks or other external documents.

[ ]  Plans are adequate to maintain external hyperlinks or documents and participant access to these documents throughout the lifespan of the study until completion are detailed in the informed consent procedures.

[ ]  The informed consent process outlines in detail how any included documents will be utilized.

[ ]  Measures are present to ensure that the identity of the signer and the integrity of the data can be verified when consent is not witnessed by the study team.

[ ]  For FDA-Regulated Clinical Trials including children as research participants, if the parent or guardian initially documents the child’s assent, procedures are in place to verify the child’s identify and assent when the child initially presents to the investigator.

**(NA if the research is not a FDA-Regulated Clinical Trial) NA:** [ ]

[ ]  For FDA-Regulated research, additional criteria must be met to comply with Part 11 (21 CFR part 11) (NA if the research is not a FDA-Regulated Clinical Trial [ ] ):

[ ]  The PI will use the University of Minnesota’s e-Consent Part 11 compliant REDCap module.

[ ]  The PI has a plan for verifying the identity of the participant if the consent is not obtained in-person (such as a pass-code process).

[ ]  All versions of the participant’s consent forms will be maintained within the project’s “vault” or platform. NOTE: UMN REDCap eIC module meets this requirement.

[ ]  The eIC form will be accessible either electronically, in paper, or static format to the Quality Assurance Program or IRB upon request.

**Guidance for IRB Decisions: Defer or Require Modifications to Secure Approval**

**OHRP REGULATIONS FOR FEDERALLY-FUNDED STUDIES**

Criteria for IRB approval of research: 45 CFR 46.111(a), (b)

**FDA REGULATIONS FOR DRUG, BIOLOGIC, AND DEVICE STUDIES**

Criteria for IRB approval of research: 21 CFR 56.111(a), (b), (c)

**MAKING IRB DECISIONS: Refer to IRB Member Manual, UMN HRP-100**

**A) Circumstances that preclude the IRB from approving research (deferral)**

 The IRB should defer a research study when the IRB: (a) is unable to make determinations required for approval at 45 CFR 46.111 and/or 21 CFR 56.111 and, if applicable, relevant subparts (B, C or D); and (b) is unable to specify modifications to the research protocol that if made would allow the IRB to make these required determinations.

 Deferral will require another round of review by the convened IRB.

**The IRB stipulates that the PI:**

1. & 2. Provide a justification.

Examples:

* Provide a justification for using a placebo and withholding currently available treatment for a serious medical condition for participants assigned to the control group.
* Provide a justification for enrolling children in the research and an explanation of how the research would satisfy the requirements of subpart D, 45 CFR part 46.

3. Revise the study hypothesis and, accordingly, the study design.

Examples:

* A study is methodologically flawed to the point that no meaningful or reliable information will result.
* The IRB cannot verify that the study design will answer the research questions.
* The protocol describes switching from continuous to pulsed DBS. Expand on the rationale for this switch and the acceptability of the risks associated with the switch and if this is within the approved indicated use of the device.
* The IRB requests that you build in a plan to assess the potential for cardiac events into the research such as conducting an EKG for participants, a review of cardiac history for the previous 6 months, or a note from participants’ physicians that they have no known cardiac issues.
* A testable hypothesis is not clearly stated. Please include a testable hypothesis; e.g., the frequency of self-reported infusion-related reactions is not different between trastuzumab and the drug described in the study.

4. Provide a description of procedures.

Examples:

* Provide a description of procedures that the control group will undergo.

5. Provide clarifying information needed to assess the risks to participants.

* Clarify whether individuals who have taken aspirin within 14 days prior to enrollment will be excluded from the study because of concerns about the risks of bleeding.

6. Clarify the timing and circumstances under which informed consent will be sought.

* The informed consent process cannot be assessed because insufficient information was provided in the protocol.
* Provide a copy of the telephone script for review.
* The IRB requires that you develop a plan for assessing capacity to consent to research. The plan must include the use of the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) unless you can provide a more appropriate, validated tool in context of the research and population.
* The committee requested an explanation of how participants who do not speak English as their first language will be accommodated so that they may participate in the study. Please identify these languages and submit translated copies of the consent form for review.

7. Provide a plan to reduce risks to participants.

* Implement additional participant monitoring in order to reduce risks to participants, given the number of serious adverse events that have occurred in study participants since the prior IRB review.

**B) Circumstances that permit the IRB to require modifications to secure approval**

 The IRB can require modifications to secure approval when the IRB determines that the study would fulfill the criteria for approval once certain conditions are met. The conditions are specific and limited and further review by the full IRB at a convened meeting would not be necessary.

**The IRB stipulates that the PI:**

1. Confirm specific assumptions or understandings on the part of the IRB.

* Confirm that the research excludes children.
* Confirm that any standard contrast material used in radiological procedures dictated by the research protocol will be limited to agents and dose levels specified by the IRB and submit the revised protocol.

2. Submit additional documentation.

* Submit the certificate of ethics training.
* Provide the endorsement letter(s) from a department chair as required by institutional policy.
* Provide a copy of the approved clinical privileges/hospital staff appointment document in order to confirm that the researcher has approval to perform the procedures (e.g., percutaneous liver biopsies) proposed in the research protocol at the institution where the research is to be conducted.

3. Make precise language changes to protocol or informed consent documents.

* Simplify the description of the study risks.
* Correct minor grammatical and typographical errors in the informed consent document.
* Re-locate in the informed consent document the statement, “You will receive $500 for participating in this study,” from the “Benefits” section of the form to a separate section under the heading “Compensation.”
* Simplify the description of the study risks in the informed consent document to be at an 8th-grade comprehension level.

4. Make substantive changes to protocol or informed consent documents along with clearly stated parameters that the changes must satisfy.

* Ensure that risks to participants are minimized by adding “a history of aspirin use in the past 14 days” to the exclusion criteria.
* Revise the protocol to indicate that informed consent of the prospective participants will be sought by the investigator during an outpatient clinic visit at least one week before the surgery in order to ensure that informed consent will be obtained under circumstances that provide prospective participants with sufficient opportunity to consider whether to participate.
* Revise the protocol to include the precise agents and dose of standard contrast materials used in radiological procedures as specified by the IRB.
* Revise the research protocol to include a description of the type and amount of standard contrast material to be used in the radiological procedures dictated by the research protocol, and designating an IRB member or consultant who is a radiologist to review the revised protocol and ensure that the use of standard contrast material is medically appropriate.
* Revise the research protocol to include a plan for: (a) informing participants about the results of standard clinical tests performed as part of the research protocol (e.g., cardiac function tests), and (b) referring participants for appropriate clinical follow-up.
* Modify the informed consent document to include standard template language used for research involving college psychology students, stating that comparable non-research alternatives for earning extra credit will be offered to students who choose not to participate in the research.
* Add to the informed consent document a description of the risks of a standard chemotherapy drug, where the risks are well described in the research protocol.
1. This document satisfies AAHRPP elements I.1.E, I.1.F, I.7.C, I-9, II.1.E, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.2.I, II.3.A, II.3.B, II.3.C-II.3.C.1, II.3.D, II.3.E, II.3.F, II.3.G, II.4.A, II.4.B, III.1.F [↑](#endnote-ref-2)
2. University of Minnesota uses the term “research participant” in reference to “research subject”. [↑](#endnote-ref-3)
3. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. [↑](#endnote-ref-4)
4. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. [↑](#endnote-ref-5)
5. When the IRB determines that data and safety monitoring is appropriate, the IRB will evaluate the adequacy of those plans by considering such issues as reporting mechanisms, the frequency of the monitoring, the entity that will conduct the monitoring, the specific data to be monitored, procedures for analysis and interpretation of the data, actions to be taken upon specific events or end points, and procedures for communication from the data monitor to the IRB and sites. (AAHRPP Tip Sheet #6, section 5) [↑](#endnote-ref-6)
6. The IRB will consider it appropriate to include adequate provisions to protect the privacy of subjects when there is a reasonable expectation that prospective research subjects will want to control how, and with whom, they interact and communicate, particularly on issues that may be “sensitive” or “private.” The IRB will determine whether there are adequate provisions to protect the privacy of subjects by considering subjects’ potential comfort with the procedures being performed, comfort with the research setting, and comfort with the information being sought. (AAHRPP Tip Sheet #5 section 2b-c) [↑](#endnote-ref-7)
7. The Secretary of HHS will, after consultation with the Office of Management and Budget’s privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data. In the interim, the IRB will consider it appropriate to make adequate provisions to maintain confidentiality of data any time confidentiality is promised by the investigator, or when there are legal/ethical requirements to maintain data confidentiality. The IRB will determine whether there are adequate provisions to maintain the confidentiality of that data based on a review of the procedures that are in place to meet those promises or legal/ethical requirements (e.g. What information is included in the data, how it is stored, how long it will be stored, who will have access to it, and who will be responsible for receiving/transmitting it.) (AAHRPP Tip Sheet #4 section 2b-c) [↑](#endnote-ref-8)
8. For research eligible for expedited review under 8(b) and 9, continuing review is required. [↑](#endnote-ref-9)
9. For expedited review eligible research, documentation regarding continuing review requirement must be included in the Designated Review form in ETHOS. [↑](#endnote-ref-10)
10. Consider nature and level of risks; degree of uncertainty regarding the risks; subject vulnerability; investigator experience; IRB’s experience with investigator or sponsor; projected rate of enrollment; and whether study involves novel procedures. [↑](#endnote-ref-11)
11. Implement when the veracity of the information provided is questioned. [↑](#endnote-ref-12)
12. (LAR = “subject’s Legally Authorized Representative”). Electronic consent (eIC) may be used to either supplement or replace paper-based informed consent processes in order to best address the participant’s needs throughout the course of the study. See Section 9: Electronic Consent (eIC) for additional requirements if the researcher plans to use eIC processes. [↑](#endnote-ref-13)
13. “Understandable” means the information presented to prospective subject is in a language and at a level the subjects can comprehend (including an explanation of scientific and medical terms) *FDA’s Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* <https://www.fda.gov/media/88915/download> [↑](#endnote-ref-14)
14. FDA considers exculpatory language to be language that has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt *FDA’s Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* <https://www.fda.gov/media/88915/download> [↑](#endnote-ref-15)
15. For additional guidance for FDA-regulated research on the elements of consent (including examples and recommendations on language), please see *FDA’s Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* <https://www.fda.gov/media/88915/download> [↑](#endnote-ref-16)
16. If payments, including reimbursement for research-related expenses incurred by subjects due to participation, are provided, the consent process should not identify them as benefits *FDA’s Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* <https://www.fda.gov/media/88915/download> [↑](#endnote-ref-17)
17. The FDA generally recommends against including statements such as "FDA has given permission for the clinical investigation to proceed" or "FDA has approved the clinical investigation” in the informed consent process, because such statements may suggest to subjects that the investigation has FDA’s endorsement. *FDA’s Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* <https://www.fda.gov/media/88915/download> [↑](#endnote-ref-18)
18. *FDA’s Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* <https://www.fda.gov/media/88915/download> [↑](#endnote-ref-19)
19. The University of Minesota recognizes that FDA guidance uses “may” but it is the general expectation that investigators **should** ask. See https://www.fda.gov/media/75138/download [↑](#endnote-ref-20)
20. University of Minnesota IRB recognizes that most studies will require these additional elements of consent. [↑](#endnote-ref-21)
21. 21 CFR 56.109 (b): (b) An IRB shall require that information given to subjects as part of informed consent is in accordance with 50.25. The IRB may require that information, in addition to that specifically mentioned in 50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects. [↑](#endnote-ref-22)