HRPO Protocol Template and Instructions

• Use this template to prepare a document with the information from the following sections.
• If you have a protocol from a study sponsor, include the sponsor protocol in addition to this protocol for review—you may reference study sponsor protocol sections when filling out this form if you clearly indicate the page and paragraph number where the reviewer can easily locate the information from the sponsor protocol.
• Depending on the nature of what you are doing, some sections may not be applicable to your research. If so mark as “NA” and briefly state why it does not apply: **do not delete the sections**. Please keep an electronic copy of this document. You may need to modify this copy when making changes.
• **Include a version number and/or version date** next to the protocol title and in the footer and update with each revision.
• Note: All checklists referenced in this protocol can be found on the HRPO website and in Click under the “IRB” tab, in the “IRB library”. Consult the HRPO staff for more information about these resources. Please delete the italicized instructions in your final protocol document, as applicable.

1) **Protocol Title (Version # and/or Version Date)**
   Include the full protocol title as listed on the application and consent forms. Make sure the title matches on all documents. Include a version number and/or version date.

2) **IRB Review History**
   If you have submitted this protocol for review by an external IRB, provide the details of the review including the IRB name, date of review, and IRB contact information. Upload all related IRB communications in Click under “Supporting Documents”.

3) **Objectives**
   Clearly describe the purpose, specific aims, or objectives of the proposed research. State the hypotheses to be tested.

4) **Background**
   Briefly describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data. Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.
5) **Inclusion and Exclusion Criteria**

Describe how individuals will be screened for eligibility. Describe the criteria that define who will be included and excluded in your final study sample. Indicate if you are targeting any particular populations such as students, veterans, people on probation, a particular ethnic group, or non-English speakers for recruitment. Indicate specifically whether you will include or exclude each of the following special populations:

- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners

6) **Number of Subjects (Recruitment Target)**

State the maximum number of subjects that will be included in the study. Note for chart reviews and tissue banking studies: datasets/tissue samples are considered “subjects”. Describe the target number accordingly.

Note that you may recruit fewer subjects, but over-enrollment (exceeding this number) is a protocol violation that must be reported to HRPO.

If this is a multicenter study, also indicate the total number of subjects to be accrued across all sites.

If applicable, state the number of subjects who need to be screened in order to meet recruitment goals.

7) **Recruitment Methods**

Describe when, where, and how potential subjects will be recruited, including the source of potential subjects.

Describe the methods that will be used to identify potential subjects, including chart review if applicable—this may require waiver of HIPAA authorization for recruitment (see section 28).

If participants will be recruited using a verbal/e-mail announcement of the research, provide a separate recruitment script. Upload all forms of recruitment materials that will be used such as scripts, flyers, or advertisements separately within the Consent Forms and Recruitment Materials page in the Click IRB system.

8) **Study Timelines**

Include:

- The duration of an individual subject’s participation in the study.
- The duration anticipated to enroll all study subjects.
• The estimated date for the investigators to complete this study (complete primary analyses).

9) **Study Endpoints**

Describe any primary or secondary safety endpoints.

10) **Research Setting**

Describe the sites or locations where your research team will conduct the research.

• Identify where research procedures will be performed, including any laboratory sites conducting analytical procedures.
• For research conducted outside of UNM and its affiliates describe:
  • Site-specific regulations or customs affecting the research outside of UNM
  • Local scientific and ethical review structure

11) **Study Methods**

Provide a step-by-step description of all research procedures in chronological order.

Include:

• Procedures performed to minimize the probability or magnitude of risks.
• Whether or not direct identifiers will be collected and maintained for use in this study.
• All drugs and devices used in the research, the purpose of their use (see also section 29). For Humanitarian Use Devices (HUD), provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures.
• Attach all referenced study instruments, such as surveys/questionnaires, scripts, and data collection forms as separate documents.
• Describe any reimbursement/compensation to subjects (amounts and payment schedule). Describe why the proposed amount is reasonable and appropriate for the participant’s time. If course credit is being offered as compensation for student participants, include separate documentation from the department or the department website information, as applicable. **Note: Consult your department official for reporting requirements associated with cash or merchandise cards distributed to research participants.**

(0.05)
12) **List of Appendices**

Provide a comprehensive list of all recruitment materials, study documents, supplements, data collection forms, and or instruments that will be used in your study as indicated in the previous sections.

13) **Data and Specimen Banking**

If data or specimens will be banked or archived for future use, describe how specimens will be obtained, exactly what data or specimens will be banked, how the specimens/data will be identified/ de-identified and by whom, where the specimens/ data will be stored, how long they will be stored, how the specimens/ data will be accessed, and who will have access to the specimens. List the data to be stored or associated with each specimen. Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens. If biospecimens are being collected, please include a biospecimens attachment with your submission.

14) **Data Management**

Describe the data analysis plan, including any statistical procedures. Describe what format data will be stored in. Describe the steps that will be taken to secure the data (e.g., access procedures, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers, data and consent forms) during storage, use, and transmission. Describe any procedures that will be used for quality control of collected data.

Describe how data and specimens will be handled:

- What information (particularly if it is PHI) will be included in the data collection?
- Will a link between identifiers and data be created; if so, will it be stored separately and where/ for how long? When and how will it be destroyed?
- Who will have access to the data?
- Who is responsible for receipt or transmission of the data?
- Describe if data will be collected, transmitted, and/or stored via the internet.
- Will data be collected via audio/digital recordings? Will the identifiers be removed during transcription? Can participants request portions of the recording to be deleted? Is there a plan for the secure destruction or reuse of recordings?
- Will data be collected on video recordings or via photographs? Will non-consenting individuals be collected? Give plan for secure destruction or reuse of video/digital images/photographs.
• Specify how and where data will be stored/ for how long/ when and how it will be destroyed/ deleted. State specific location(s) where electronic data and paper forms are stored (e.g., PI’s UNM office computer and locked file cabinet). (Note: any identifiable data must be stored/ transported securely via secured drives/ encryption, or equivalent). The information in this section must also be included in the consent.
• If this is a VA study, will medical records be flagged?
• If this is a VA study, will the PI maintain a Master Subject List?

15) **Provisions to Monitor the Data to Ensure the Safety of Subjects**

For all studies considered greater than minimal risk, include a data and safety monitoring plan (DSMP) for reporting data monitoring committee findings to the HRRC and the sponsor.

A DSMP must include:

• The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. Identify the type of monitoring entity and explain how the objectivity of the monitor is assured.
• What data are reviewed, including safety data, adverse events, and efficacy data?
• How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
• The frequency of data collection, including when safety data collection starts.
• All individuals who will review the identifiable data.
• The frequency or periodicity of review of cumulative data.
• The tests and/or standards for analyzing the safety data to determine whether harm is occurring.
• Any conditions that would result in an immediate suspension of the research.
• Plan to report adverse events and unanticipated problems to the monitoring entity and the HRRC.

16) **Withdrawal of Subjects**

Describe the procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection. Describe any conditions in which the investigators would withdraw a subject from the study.

17) **Risks to Subjects**

List the reasonably foreseeable risks, discomforts, hazards, side effects, or inconveniences to the subjects related to participation in the research.
Describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. Note/acknowledge that almost all research involves breach of confidentiality risk. If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable. If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant. If applicable, describe risks to others who are not subjects. Include all these risks in the consent document.

18) Potential Benefits to Subjects
Describe the potential benefits that individual subjects may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Clearly indicate if there is no direct benefit to participating in the study. Include this information in the consent document.

19) Vulnerable Populations
Please provide rationale for including any of the populations listed below. If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

- If the research involves pregnant women, review “CHECKLIST: Pregnant Women (HRP-412)” in the Click IRB Library to ensure that you have provided sufficient information.
- If the research involves neonates of uncertain viability or non-viable neonates, review “CHECKLIST: Neonates (HRP-413)” “CHECKLIST: Neonates of Uncertain Viability (HRP-414)” in the Click IRB Library to ensure that you have provided sufficient information.
- If the research involves prisoners, review “CHECKLIST: Prisoners (HRP-415)” in the Click IRB Library to ensure that you have provided sufficient information.
- If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (children), provide the age range of the children to be enrolled in the research. Describe in what setting the children will participate. Describe if permission will be obtained by the parents and if assent will be obtained from each child participant. Review the “CHECKLIST: Children (HRP-416)” in the Click IRB Library to ensure that you have provided sufficient information. Consult the HRPO website and use the consent and assent templates to generate your consent documents.
- If the research involves cognitively impaired adults, review “CHECKLIST: Cognitively Impaired Adults (HRP-417)” in the Click IRB Library to ensure that you have provided sufficient information.
20) **Multi-Site Research**

If this is a multi-site study where you are the lead investigator and plan to use the UNM HRRC as the central IRB of record, describe the processes to ensure communication among sites, such as:

- All sites have the most current version of the protocol, consent documents, and HIPAA authorization.
- All required approvals have been obtained at each site (including approval by the site’s IRB of record).
- All modifications have been communicated to sites, and approved (including approval by the site’s IRB of record) before the modification is implemented.
- All engaged participating sites will safeguard data as required by local information security policies.
- All local site investigators conduct the study appropriately.
- All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

Describe the method for communicating to engage participating sites:

- Adverse events
- Interim results
- The closure of a study

21) **Community-Based Participatory Research/Field Research**

If you are doing this type of research, describe involvement of the community in the design and conduct of the research. Please include information regarding the approval of research at collaborating sites (for example Albuquerque Public Schools (APS), tribal communities); note that these sites may require approval by local boards and explain how/when these approvals will be considered in collaboration with UNM approvals.

**Study Personnel**

Describe the qualifications of the researcher. Provide a description of the context of cultural norms or local laws and differences with U.S. culture with respect to research autonomy of individual groups, consent, recruitment, age of majority, if parental consent is required, etc. Include explanation of what cultural sensitivities will be required to conduct this study (attach documentation if necessary). Explain the researcher’s ability to speak, read, and write the language of the potential participants.

Describe if the researcher has the knowledge or expertise of the local or state laws that may have an impact on this research. Explain (provide documentation) if the researcher was invited into the community. If not
invited, then describe how the researcher will have culturally appropriate access to the community.

**Location**

Describe research locale and how the research setting was chosen.

**Informed Consent**

Describe the consenting procedure in this research setting/culture. Explain how you will assess responses to your research project (i.e. how the participants feel about your writing about them, publishing, taking photos, etc.). Will you consult with the participants before you publish?

**Procedures**

Describe your understanding of how the community will perceive the collection of data/samples. Describe the anticipated impact to the community. Describe plans for dissemination to the community. Will follow-up with the participants be necessary after data/sample collection? If YES, please explain. Will biological samples be collected? If YES, complete all relevant sections of this protocol template.

22) **Sharing of Results with Subjects/Incidental Findings**

Will you share results with study participants? If so, describe how results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject’s primary care physicians). If not, provide clear and adequate justification for not providing actionable findings to subjects. Consult the HRPO consent template/consent generator for information regarding reporting of incidental findings.

23) **Resources Available**

Describe the qualifications of the PI and study staff (training, experience, oversight) as required to perform the research.

Describe other resources available to conduct the research:

- Feasibility of your recruitment plan/access to potential recruits
- Facilities
- Availability of all resources that subjects might require as a result of participation in human research. Include contact information, where applicable.
- If CTSC resources are being accessed, the signed CTSC resources attachment must be uploaded on the CTSC Submission page in Click IRB.
24) **Prior Approvals/Attachments Requiring Signatures**

Describe any approvals that will be obtained prior to commencing the research. (e.g., school, external sites, funding agency, laboratory, radiation safety, or biosafety approval). Upload the required Departmental Review Form signed by your department chair (or authorized designee if the PI is the Department Chair) into Click IRB under “supporting documents”.

Note: If your study interventions include radiation exposures > 100 mREM, include the signed Radiation Safety Attachment and a UNM HSC Radiation Dose Letter. The consent should also include radiation exposure information in the Risks section.

Other documents that require signature include “Biological Specimens” and “Drug Attachment”.

25) **Confidentiality**

Clearly describe procedures for maintenance of confidentiality (reference Section 12, if applicable) including:

- Where/ how and for how long identifiable data will be stored
- How/ when/ by whom (example: an honest broker) identifiable data will be coded/ de-identified and linked to identifiers and how /where link will be maintained.
- Who will have access to the data?

26) **Provisions to Protect the Privacy of Subjects**

Privacy refers to the study participant and provisions for making them feel at ease and in control of with whom they interact (e.g., the prevention of ‘eavesdropping’ or observation by non-study team members). Describe the steps that will be taken to protect subjects’ privacy including privacy protections during recruitment, consent, and data collection. Indicate how the research team is permitted to access any sources of information about the subjects. If PHI is being collected, HIPAA authorization is required unless a waiver is granted (see Section 28).

27) **Compensation for Research-Related Injury**

Provide a plan to present participants with compensation for research-related injury. If the participant is responsible for seeking their own form of care due to research-related injury, describe how that will be communicated and what options are available to participants.
28) **Economic Burden to Subjects**

*Describe any costs that subjects may be responsible for because of participation in the research. Clearly stipulate what procedures are standard of care and what procedures are research-related in the table below. Please place an X in the box for the responsible party for each procedure involved.*

- List any costs to participants (or their 3rd party payer); include any charges for study procedures, visits, or drug/devices. Ensure that the cost section of the consent form reflects the costs that are covered by the sponsor and the costs for which the participant (or 3rd party payer) are responsible.

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- List any other costs to participants not already described above.

- Will participants be charged for the costs of an investigational drug/device/intervention?

- Explain who will be responsible for paying for treatment of adverse events.

Note: If sponsor will be responsible for treatment of research related injury, submit a copy of the Clinical Trials Agreement (CTA) for review.
Consent Process (including waiver request for HIPAA, waiver of HIPAA for recruitment only, Waiver of Informed Consent, and Alteration of Informed Consent)

Consent

Use the UNM HSC consent generator or one of the consent templates available on the HRPO website/in the Click IRB library. Attach consent documents as fully editable Word documents (please do not submit protected consent documents). Remove all footers and footer formatting from your consent documents.

If you will obtain consent verbally, attach a consent script. If you will be obtaining consent via an on-line survey, please use the survey cover letter consent template on the HRPO website and include your e-mail script with your submission. If this study is collecting and/or storing tissue samples include a Tissue Banking Consent Form.

Fully describe the consenting process including:

- Where the consent process will take place and provisions for privacy
- Waiting periods between informing the prospective subject and obtaining the consent
- Processes to ensure ongoing consent throughout the study
- Any procedure/testing for ensuring that the consent is understood by the participants

Waiver or Alteration of Informed Consent: Review the “CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)” in the Click IRB Library to ensure you have provided sufficient information for the HRRC to make these determinations.

If you are requesting alteration or waiver of informed consent, please address the following items:

- Research is NOT FDA-regulated
- Research does NOT involve non-viable neonates.
- How does the research meet criteria for minimal risk?
- The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- The research could NOT be practicably carried out without the waiver or alteration.
- If the research is to be conducted by or subject to the approval of state and local government officials, please state.
If the research is designed to study, evaluate or examine one or more of the following, please state and explain:

- Public benefit or service programs
- Procedures for obtaining benefits or services under those programs
- Potential changes in or alternatives to those programs/procedures
- Potential changes in methods or levels of payment for benefits or services under those programs

Waiver of Written Documentation of Consent: Review the “CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)” in the Click IRB library to ensure you have provided sufficient information for the IRB to make these determinations.

If you are requesting a waiver of consent documentation, please address the following:

- The written script to be provided orally and assurance that any written information contains all required elements of informed consent.
- How does the research meet criteria for minimal risk?
- A statement that the research is NOT FDA regulated.
- State if the consent would be the only record linking the subject and the research data and would therefore represent the principal risk of harm resulting from a breach of confidentiality.

HIPAA Authorization

If you are collecting PHI, please include a detailed list of all identifiers that will be a part of the study data. Provide justification for use of the PHI being collected. If you will you be obtaining HIPAA authorization for collection of PHI, provide a current HIPAA form. Please consult the HRPO website for current HIPAA authorization forms and for Consent/HIPAA combination forms. Specific UNM HIPAA language must be used. Clearly state that you will be using either a HIPAA form OR that the consent document includes a HIPAA section.

Waiver of HIPAA authorization: Review the “CHECKLIST: HIPAA Waiver of Authorization (HRP-441)” in the Click IRB library to ensure you have provided sufficient information for the IRB to make these determinations.

If you are requesting a waiver of HIPAA or a waiver of HIPAA for recruitment purposes only, please address all of the following items:
• Explain how the use of PHI involves no more than minimal risk to the privacy of the research subjects based on one of the following:
  • Describe an adequate plan to protect the PHI.
  • Describe an adequate plan to destroy PHI at the earliest opportunity, unless there is a reason to retain it (please justify).
  • Provide assurance that PHI will not be re-used or disclosed inappropriately.
  • Justification that waiver will not adversely affect rights of participants.
  • Justification that research could not be practicably carried out without waiver.
  • Provide a comprehensive list of PHI being collected under the waiver.
  • Steps that will be taken to minimize the possibility of coercion or undue influence.
  • Steps that will be taken to ensure the subjects’ understanding.

Non-English Speaking Subjects

• Indicate what language(s) other than English is/are the primary language(s) of prospective subjects or representatives.
• If ≥ 25% of subjects are expected to be non-English speakers, describe the process to ensure that the oral and written information provided to those subjects will be in the appropriate language. Indicate the language(s) that will be used by those obtaining consent. Consult the HRPO website for short-form consents.

Planned Emergency Research Consents

If the research involves a waiver of the consent process for planned emergency research, please review the “CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)” in the Click IRB library to ensure you have provided sufficient information for the IRB to make these determinations.

Cognitively Impaired Adults/Adults Unable to Consent/Use of a Legally Authorized Representative (LAR)

• Describe the process to determine whether an individual is capable of consent.
• Describe how the participant’s decisional capacity will be assessed/documented and by whom.
• Describe how the participant’s decisional capacity will be assessed as the study proceeds in order to evaluate any deterioration in the participant’s level of capacity to consent.

• Will the participant’s decisional capacity be assessed as the study proceeds in order to evaluate any improvement in the participant’s level of consent capacity?

• List the individuals from whom permission will be obtained (e.g. close relative, legal guardian, legally authorized representative appointed in a medical durable power of attorney) and describe the process for assent of these research participants.

• Describe how this authority to provide consent will be confirmed.

• For HUD use, provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.

30) Drugs or Devices

List and describe the use of all drugs, biologics, devices, and/or radiopharmaceuticals being used in this study. If the research involves drugs or devices and is investigator-initiated, indicate whether the results will be reported to FDA.

Drugs: Please respond to all questions in this section and include a completed and signed Drug Attachment form.

• Are the products to be used approved by the FDA for the proposed purpose? YES or NO

If YES, indicate that all drugs will be sent to/ stored in/ dispensed under the supervision of a licensed pharmacist.

  ▪ If a licensed pharmacist is not being used, provide a detailed description of drug storage, accountability and procedures including the name and title of the person who will be labeling and dispensing medications and their qualifications.
  
  If NO, indicate if an IND application been submitted for this research.

If the study involves marketed drugs and an IND has not been obtained, please respond to all of the following (YES/ NO and explain your response):

  ▪ The investigation is NOT intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor
intended to be used to support any other significant change in the labeling for the drug: YES/NO/ explain your response.

- If the drug undergoing investigation is lawfully marketed as a prescription drug product, the investigation is NOT intended to support a significant change in the advertising of the product: YES/NO: explain your response.

- The investigation does NOT involve a route of administration or dosing regimen or use in a patient population or other factor that significantly increases risk (or decreases acceptability of risk) associated with the use of the drug product: YES/NO/ explain your response.

- The investigation is conducted in compliance and with the requirements set forth in 21 CFR part 50 (Informed Consent); and the investigation is conducted in compliance with the requirements of 21 CFR 312.7 (restrictions on promotion and charging for investigational drugs): YES/NO: explain your response.

Medical Devices: Please respond to all questions in this section.

Provide the name of the medical device (FDA approved or not approved) where the safety or effectiveness of the device is being evaluated, and describe its use in the study.

- Has an Investigational Device Exemption (IDE) application been submitted to the FDA? (YES or NO)

If YES: provide the sponsor name, address and the IDE number and indicate which documentation is attached to verify the IDE: (FDA letter, sponsor letter, IDE# on the sponsor protocol, or other)

If NO IDE application has been submitted: Your study which uses a medical device in the context of a clinical study protocol may require the submission of an IDE to the FDA. To determine if an IDE is required, please answer the following questions.

The device meets the requirements for an abbreviated IDE if all of the following are TRUE. Please articulate responses to all of the following:

- The device is not banned
- The device is not a significant risk device (HRRC determination is required)
• The sponsor or investigator will label the device in accordance with 21CFR812.5
• The sponsor or investigator will comply with the requirements of 21CFR812.46 with respect to monitoring investigations
• The sponsor or investigator will maintain research records required under 21CFR812.140 (b) and (5) and make the reports required under 21CFR812.150 (b) (1) through (3) and (5) through (10).
• The sponsor or investigator will ensure that participating investigators maintain the records required by 21CFR812.140 (a)(3)(i) and make the reports required under 21CFR812.150(a) (1) (2) (5) and (7).
• The sponsor or investigator will comply with the prohibitions in 21CFR812.7 against promotion and other practices.
Please complete the section below to determine if an IDE is required:

- Is the device FDA-approved for marketing and is it being used or investigated in accordance with its labeling (YES or NO)
- Is the device a diagnostic device? (YES or NO)

If YES, please articulate each of the following:

- The sponsor will comply with applicable requirements in 21 CFR809.10
- The device is non-invasive
- The device does not require an invasive sampling procedure that presents significant risk
- The device does not by design or intention introduce energy into the subject
- The device is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure
- Is the device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution?
- Is the device testing for the purpose of determining safety and effectiveness?
- Is the device a custom device as defined in 21CFR812.3(b)?

If all responses to the questions in this section are NO; an IDE is required. Please see:  www.fda.gov/cdrh/devadvice/ide/application.shtml

Provide a detailed description of device storage and accountability procedures:

- Where will the device be shipped within UNM?
- Where will the device be stored?
- Who will have access to the device?
- What security safeguards are in place to ensure proper accountability, access and storage of the device?
- If the device is experimental, will it be labeled “Investigational Use Only”?
- Who will be responsible for:
  - Device accountability
  - Labeling/ dispensing
  - State the qualifications of this person
Describe how the investigational device is controlled, and how accidental use outside of approved research will be avoided.

Non-Significant Risk Determination Section

Complete this section if you are using a device which does not have an IDE# and the use of the device in this study poses only non-significant risk, in your opinion:

- Is the device intended as an implant (≥30 days)?
- Is the device for use supporting or sustaining human life?
- Is the device for a use of substantial importance in diagnosing, curing, mitigating or treating disease or preventing impairment of human health?
- Does the use of the device present a potential for serious risk to health, safety or welfare of the subjects?

If responses to all of the questions in this section are NO, this is a non-significant risk device.

Explain why the use of the device in this study poses non-significant risk, and attach any other supporting information. In addition, explain whether the sponsor, the FDA or any other oversight organization has already made a risk determination for the device.

Humanitarian Use Device (HUD):

Provide name of the HUD, date of HUD designation, and device manufacturer/sponsor.

Provide the following information:
- What is the disease or condition the device is intended to treat?
- Provide a description of the device, including the implantation (if applicable) and use of the device.
- Describe the marketing history of the device, including a summary of existing pre-clinical studies, clinical investigations, and experiences with the device.
- Specify who will be responsible for the receipt and tracking of the HUD.
- Describe the contraindications, warnings, and precautions for use of the device.
- Describe the alternatives (practices and procedures) that are available to treat or diagnose the patient’s disease or condition.
- Describe the process you will use to inform patients that the HUD is a device authorized under federal law; however, the effectiveness of the device for a specific indication has not been demonstrated. (e.g. do you propose to use consent/brochure/labeling document from the sponsor)
Consult with the HRPO staff regarding other reporting requirements for HUD submissions

Remember to save the completed protocol as a Word document so that if changes are required, you can submit them as track changes with a new version number and/or version date.

Please review the IRB Submission Checklist in the IRB Library to ensure you have all required documents for your IRB submission.