**INSTRUCTIONS:**

* **Provide information once.** It’s better to refer to earlier items (e.g., “See #...”) than to repeat.
* **If an item does not apply, type “NA.”**
* **If the information is available in a sponsor protocol, grant, investigator brochure, or proposal – for any item marked with an asterisk (\*) – simply reference the title and page numbers of that reference document and upload a copy of the document to eIRB.**
* **Delete instructions as you answer each item.**
* **Use a version number or date in the file name. When you upload the document to eIRB, leave the title field blank so that eIRB uses the file name to label the document.**

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**1. Title**

*Include the full title as listed in eIRB*.

**2. External IRB Review History\***

*If you have submitted this application for review by an external IRB, provide details of the review including the IRB name, study ID, approval status, and IRB contact information*.

**3. Prior Approvals:**

*Describe any approvals that will be obtained prior to commencing the research, including institutional committees, departmental approvals, etc.*

***The approvals below are required PRIOR to submission to the IRB. The IRB will not be able to complete its review without a copy of the approval letter from the committees listed below (if applicable).*** *If this documentation is not included with the IRB submission, the investigator will be notified about missing information during the pre-review process. Review of the study by the IRB will not proceed until this documentation is provided.*

***Conflict of Interest (COI):***

*If any of the individuals involved in the research have a financial interest related to the research, it is necessary that they contact* *COI@umassmed.edu* *to complete the necessary disclosure process. The COI committee is responsible for evaluating the conflict and in conjunction with the PI developing an appropriate mitigation plan.*

*Once approval is received, the IRB application may proceed through the review process as the IRB has final authority to determine whether the conflict and its management plan allow the proposed research to meet criteria for approval.*

***Clinical Engineering Department:***

*All medical devices with power sources regardless of ownership shall be inspected for safety, including grounding and minimal current leakage as necessary, prior to being placed in service. The Clinical Engineering Department Electrical Safety Inspection protocol shall be used as the inspection procedure. All measurements shall meet the NFPA 99, IEC 60601 healthcare standards for electrical safety.*

*Each department that receives new equipment shall notify the Clinical Engineering Department, at 508-334-1111 directly, or through the Materials Management Department, upon delivery of said equipment regardless of the purchase rental, loan, lease, evaluation, or demonstration arrangement. The outside manufacturers/contractors are responsible for the quality and performance of all rented, leased, contracted, or equipment on evaluation.*

*For additional information, please contact Clinical Engineering Department, at 508-334-1111.*

***Biohazardous Agents:***

*• The Institutional Biosafety Committee (IBC) reviews research involving recombinant and synthetic nucleic acids (e.g. human gene transfer studies), infectious agents, and toxins.  It also reviews research involving the processing of and/or experimentation with human blood, secretions, and/or tissues in clinical or basic research laboratories. Studies involving these materials should use the questionnaire at IBC Registration Questionnaire for IRB Protocols*

<http://inside.umassmed.edu/Global/Institutional%20Biosafety%20Committee/IBC%20registration%20questionnaire%20for%20IRB%20protocols_101915.pdf> *(intranet only) to explain why IBC registration is or is not needed. For additional information visit <http://inside.umassmed.edu/Biosafety> (intranet only)*

***Radiation****:*

*• The Radiation Safety Committee (RSC) reviews research with internally administered radioisotopes or external sources of ionizing radiation, which are experimental or protocol driven (i.e., would not normally be required by the subject's medical condition). Studies involving radiation, even when standard of care, should use the “*[Questions for PI](http://inside.umassmed.edu/Radiation/Clinical-Trials/)*” checklist from the Subcommittee on Human Uses (SHU) of the Radiation Safety Committee (RSC) to explain why RSC approval is or is not needed.*

**4. Objectives\***

*Describe the purpose, specific aims, or objectives. State the hypotheses to be tested*.

**5. Background\***

*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 explain how the research will add to existing knowledge*.

**6. Inclusion and Exclusion Criteria\***

*Describe the criteria that define who will be included or excluded. If there are sub-groups, label and describe each one. Indicate specifically whether you will include or exclude each of the populations listed below. You may not include these populations in your research unless you include them in your inclusion criteria:*

* *Adults unable to consent* (*adults lacking capacity)*
* *Individuals who are not yet adults (infants, children, teenagers)*
* *Pregnant women*
* *Prisoners*
* *Non-English speaking subjects*

**7. Study-Wide Number of Subjects\***

*If you are part of or are leading a multi-site study, indicate the total number of subjects to be accrued across all sites including UMass Worcester*. *Indicate “NA” unless you are part of a multi-site study in which other PIs conduct the same study at non-UMass Worcester sites.*

**8. Study-Wide Recruitment Methods\***

*Indicate “NA” unless you are part of a multi-site study in which other PIs conduct the same study at non-UMass Worcester sites.*

*If you are part of or are leading a multi-site study, EITHER state that “all recruitment methods are local” OR describe only those methods that are not under the control of the local site (e.g., call centers, national advertisements, sponsor brochures, sponsor retention materials). Describe when, where, and how the study will use these methods. Upload copies of recruitment materials to eIRB. When advertisements are taped for broadcast, provide a link to the final production of the audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording; however, the IRB must review and approve the final audio/video tape.*

**9. Study Timelines\***

*Describe:*

* *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)*

**10. Study Endpoints\***

*Describe:*

* *The primary and secondary outcome measures*
* *Any primary or secondary safety endpoints*

**11. Procedures Involved\***

*Describe and explain the study design starting from the point at which a subject has provided informed consent through any long-term follow-up. Describe:*

* *Any randomization process*
* *All drugs and devices used in the research, the purpose of their use, and their regulatory approval status (e.g., FDA approved/cleared, investigational)*
* *All research procedures being performed and the order in which they are performed, including procedures being performed to monitor subjects for safety or minimize risks*
* *The data to be collected (upload all surveys, instruments, and data collection forms to eIRB)*

*For* ***medical record review****, walk step-by-step through the process of identifying records, accessing data, and recording data. How and where will you search for records? What information, if any, will you download? What information will you record to a data collection sheet? Provide the date range of the charts to be reviewed (e.g., mm/dd/yyyy to mm/dd/yyyy).*

*For instructions on how to conduct an exempt medical record review see:* <http://www.umassmed.edu/ccts/irb/education-and-training/submissionfaq/>

*For the use of a* ***Humanitarian Use Device*** *(HUD) in clinical treatment (not in clinical investigations), provide a description of the device and 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. Upload a copy of the HDE approval order, the product labeling, and the patient information packet that may accompany the HUD to eIRB.*

**12. Data and Specimen Banking\***

*Indicate “NA” unless you will bank data and/or specimens for use in future studies. Consistent with OHRP guidance, all data and specimen banks that maintain direct or indirect subject identifiers require ongoing IRB approval. The IRB recommends anonymizing data and specimens at the earliest opportunity. If you will bank data and/or specimens for use in future studies, describe:*

* *What will be banked*
* *Whether it will be linked to the identity of individual subjects, and if so, how*
* *Where it will be stored*
* *How long it will be stored*
* *Who will have direct access*
* *How access is restricted*
* *When direct and indirect identifiers will be destroyed to anonymize the data/specimens*
* *When it will be destroyed in full, if ever*
* *Who will have access upon request*
* *The process by which someone requests access, the approvals required before access is granted, and what will be released*

**13. Data Analysis and Management\***

* *Provide a power analysis and/or support for the sample size proposed for this study.*
* *Describe the data analysis plan, including any statistical procedures*.
* *Describe any procedures that will be used for quality control of collected data.*

**14. Provisions to Monitor the Data to Ensure the Safety of Subjects\***

*A plan to periodically evaluate data for harms and benefits to determine whether subjects remain safe is required when research involves more than Minimal Risk to subjects. Many minimal risk studies also require such provisions, e.g., monitoring responses to questions about suicidality. The plan should be appropriate to the risk and might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor. If no monitoring is required, briefly explain why. Otherwise describe:*

* *What data will be reviewed, including safety data, adverse events, and efficacy data*
* *Who will review the data (e.g., in terms of expertise)*
* *How frequently or at what points data will be reviewed*
* *What statistical tests for analyzing the safety data determine whether harm is occurring*
* *What conditions trigger an immediate suspension of the research (i.e., stopping rules)*
* *For greater than minimal risk studies with no data monitoring committee (DMC) or data safety monitoring board (DSMB): why the proposed level of monitoring is appropriate*
* *The availability of medical or psychological resources that subjects might need as a result of their participation in the research*
* *Upload a copy of the DMC or DSMB charter to eIRB*

**15. Withdrawal of Subjects Without Their Consent\***

*Indicate “NA” unless you may withdraw subjects from the research without their consent. Otherwise, describe the circumstances in which this might happen, any options subjects might have (e.g., stopping some procedures and continuing others, continued data collection from the clinical record), and any procedures for orderly early termination (e.g., weaning off study drugs)*.

**16. Risks to Subjects\***

*List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Describe the probability, magnitude, duration, and reversibility of the risks, as appropriate. Consider physical, psychological, social, legal, and economic risks. If applicable, indicate procedures that may pose risks that are currently unforeseeable. If applicable, indicate procedures that may pose risks to an embryo or fetus should the subject be pregnant, become pregnant, or impregnate a partner. If applicable, describe risks to others who are not subjects*.

**17. Potential Direct Benefits to Subjects\***

*Indicate “NA” unless there is potential direct benefit to individual subjects from taking part in the research. Describe the probability, magnitude, and duration of the potential direct benefits, as appropriate. Do not include benefits to society or others*.

**18. Vulnerable Populations\***

*If the research involves individuals who are vulnerable to coercion or undue influence, such as individuals from the groups below, explain why they will be included and describe additional safeguards to protect their rights and welfare.*

* ***Students or employees:*** *If enrolling members of these groups, does anyone on the study team teach, supervise, or have the ability to influence a subject’s grades, academic success, or professional advancement? If yes, what additional protections are in place, e.g., to ensure that subjects do not feel unduly influenced to participate?*
* ***Adults unable to consent:***
	+ *How will you determine whether an adult has the capacity to consent?*
	+ *Who will provide permission for the subject to participate? (See* [*HRP-021 POLICY: Legally Authorized Representatives Children and Guardians*](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/)*.)*
	+ *Describe the assent process:*
		- *How will you explain the research so that individuals understand what they are being asked to do?*
		- *How will you obtain the individual’s overt agreement to participate?*
		- *Will you not enroll an individual if there is any sign of unwillingness?*
		- *Are there individuals you will not ask to assent? If yes, which ones and why*?
	+ *If the impairment may be temporary, when and how will you obtain the subject’s later consent?*
	+ *Explain how subjects will be closely monitored*
	+ *Confirm that subjects will be withdrawn from the research if they appear to be unduly distressed.*
	+ *See* [*HRP-414 WORKSHEET: Adults Lacking Capacity*](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/) *to ensure that you have provided sufficient information.*
* ***Subjects who are not yet adults (infants, children, teenagers)****:*
	+ *Indicate whether you will obtain permission from:*
		- *One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child*
		- *Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child*
		- *Individuals other than parents (describe who will be allowed to provide permission and your process to determine their authority to consent to the child’s general medical care)*
	+ *Describe the assent process:*
		- *How will you explain the research so that the children understand what they are being asked to do?*
		- *How will you obtain the child’s overt agreement to participate?*
		- *Confirm you will not enroll a child if there is any sign of unwillingness.*
		- *Are there children you will not ask to assent? If yes, which ones and why?*
	+ *When you obtain assent from children, will it be documented, and if so, how? The IRB allows the person obtaining assent to document assent on the consent form. It does not require assent documents and does not require children to sign them.*
	+ *See* [*HRP-310 CHECKLIST: Children*](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/) *and* [*HRP-311 CHECKLIST: Wards*](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/) *to ensure that you have provided sufficient information.*
* ***Pregnant women:*** *See* [*HRP-305 CHECKLIST: Pregnant Women*](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/) *to ensure that you have provided sufficient information.*
* ***Neonates of uncertain viability or non-viable neonates:*** *See* [*HRP-306 CHECKLIST: Neonates of Uncertain Viability*](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/) *or* [*HRP-307 Checklist: Non-Viable Neonates*](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/) *to ensure that you have provided sufficient information.*

* ***Prisoners:*** *See* [*HRP-308 CHECKLIST: Prisoners*](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/) *or* [*HRP-309 CHECKLIST: Unexpected Incarceration*](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/) *to ensure that you have provided sufficient information.*

**19. Multi-Site Research\***

*Indicate “NA” unless you are part of a multi-site study. If you are part of a multi-site study, indicate whether you are the lead investigator. If you are the lead investigator of a multi-site study, describe the processes to ensure communication among sites, such that:*

* *All sites have the most current version of the protocol, consent document, 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 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 is reported in accordance with local policy.*
* *All sites are informed of problems, interim results, and the study closure*.

**20. Community-Based Participatory Research\***

*Indicate “NA” unless the research is Community-Based Participatory Research as defined below. In that case, describe the involvement of the community in the design and conduct of the research.*

*Definition: “Community-Based Participatory Research” is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-Based Participatory Research begins with a research topic of importance to the community, and aims to combine knowledge with action and to achieve social change to improve health outcomes and eliminate health disparities*.

**21. Sharing of Research Results with Subjects\***

*Indicate whether or not you will share research results (e.g., study results or research results for individual subjects, such as results of investigational diagnostic tests, genetic tests, or incidental findings) with subjects or others (e.g., the subject’s primary care physicians). If research results will be shared, describe when and how*.

**22. Setting**

*Describe the sites or locations where your research team will identify and recruit potential subjects, perform research procedures, and conduct data entry and analysis. Describe any necessary facilities (e.g., access to private rooms, operating suites). Describe the composition and involvement of any community advisory board. If you are conducting research outside of UMass-Worcester, describe any site-specific regulations or customs affecting the research and any local scientific and ethical review*.

**23. Resources Available**

*Describe study personnel.*

* *Do not list people by name. Provided new personnel meet a description in the approved study plan, the PI can add study staff by updating the Project Personnel tab in eIRB (or using the Non-UMass Personnel List, if appropriate) instead of obtaining prior IRB review and approval for a Modification to the study plan.*
* *List each study staff role (e.g., PI, co-investigator, research assistant, research coordinator). Be sure the roles match the roles on the Project Personnel tab in eIRB.*
* *Describe the responsibilities for each role.*
* *Describe the qualifications required to serve in each role (e.g., training, including training by the PI; experience; oversight). When applicable, describe knowledge of the local study sites, culture, and society.*
* *Describe the time the PI and staff will devote to conducting and completing the research.*
* *If the PI is a student, resident, fellow, or other trainee, confirm a faculty advisor has been appointed to oversee the conduct of the research.*

*Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions. If appropriate, describe plans to notify and educate floor personnel (e.g., units, head nurses, floor nurses) about the study, its procedures, who to contact, etc*.

**24. Local Recruitment Methods**

*Justify the feasibility of recruiting the required number of suitable subjects within the given recruitment period. For example, how many potential subjects do you have access to? What percentage of them do you need to recruit?*

*Describe when, where, and how potential subjects will be identified and recruited. If recruiting in a clinical setting, will clinical staff ask potential subjects if it’s ok for study staff to approach? If recruiting by mail, will letters come from the subject’s clinician or clinic head?*

*Describe how individuals will be screened for eligibility. Will any identifiers be recorded? If so, when will identifiers be de-linked from the data and when will identifiers be completely destroyed? Be sure to address individuals who enroll and individuals who turn out to be ineligible or who decline to participate.*

*Upload copies of recruitment materials, including flyers, emails, letters, phone scripts, etc., to eIRB. For advertisements, upload the final copy of printed advertisements. When advertisements are taped for broadcast, provide a link to the final production of the audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording; however, the IRB must review and approve the final audio/video tape.*

*Describe the amount, method, and timing of any payments to subjects*.

**25. Local Number of Subjects**

*Indicate the total number of subjects to be accrued locally. If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., the number of subjects excluding screen failures and later withdrawals).*

**26. Confidentiality**

*Describe the data and/or specimens. For example:*

* *What types of data will exist? Will they be in hard copy or electronic format?*
* *Will they be anonymous, coded, or have direct identifiers?*

*Describe the steps that will be taken to secure data and/or specimens during data collection, storage, use, and transmission. For example:*

* *Which staff roles will be responsible for their receipt or transmission?*
* *How will they be collected and transported?*
* *Where and how will they be stored?*
* *How long will they be stored?*
* *Will any portable devices (e.g., laptops, thumb drives) be used?*
* *Which staff roles will have access?*
* *How will you limit access?*
* *Will staff undergo any special training or require special authorizations?*
* *Will you implement electronic controls, such as password protection? Encryption?*
* *Will you use physical controls, such as locked offices?*
* *If data or specimens are coded, how will you store the key that links the code to subject identifiers separately from the data and specimens?*
* *When and how will you securely destroy identifiers to anonymize data?*
* *When and how will you securely destroy the data and specimens in full?*
* *Have you obtained or will you seek a* [*Certificate of Confidentiality*](http://grants.nih.gov/grants/policy/coc/index.htm)*?*

**27. Provisions to Protect the Privacy Interests of Subjects**

*Describe the steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. For example, will procedures be conducted in a private setting? Will you use drapes or other barriers for subjects who are required to disrobe? Is the collection of sensitive information about subjects limited to the information that is necessary to conduct the research? Will subjects be told that they can skip any question they wish?*

*If the research team will access protected health information for research purposes, address the use of any HIPAA waiver of authorization or HIPAA authorization. Upload copies of these documents to eIRB*.

**28. Compensation for Research-Related Injury**

*Describe the available compensation in the event of research-related injury. For industry-sponsored research at UMMS, the sponsor is typically responsible for coverage in accordance with the Clinical Trial Agreement. Please contact Meg Johnson, Director of Clinical Research, if you are unsure. For all other research, indicate whether funds have been set aside*.

**29. Economic Burden to Subjects**

*Describe any costs for which subjects may be responsible because of participation in the research*.

**30. Consent Process**

*If you will be obtaining informed consent:*

* *Explain how you will ensure that all study staff are familiar with and will follow* [*HRP-802 INVESTIGATOR GUIDANCE: Informed Consent*](http://www.umassmed.edu/ccts/irb/investigator-guidance/)*.*
* *Describe where the consent process will take place.*
* *Describe any waiting period between recruiting the subject and obtaining consent such that subjects have sufficient time to consider whether or not to participate.*
* *Describe any process to ensure ongoing consent.*

*If you will be obtaining informed consent from* ***non-English speaking subjects****:*

* *Explain whether you will use a translated consent form or a short form.*
* *If you will translate the consent form, indicate the languages.*
* *If you will use a short form, provide a justification for not translating the consent form and confirm that the short form will have UMMS IRB approval.*
* *Describe how you will provide oral and written information to these subjects in a language they understand.*

*If you will not be obtaining informed consent, required information will not be disclosed, or the research involves deception, explain how the study meets regulatory criteria (a) through (c) and confirm (d):*

1. *The research involves no more than Minimal Risk to the subjects.*
2. *The waiver or alteration will NOT adversely affect the rights and welfare of the subjects.*
3. *The research could NOT practicably be carried out without the waiver or alteration.*
4. *Confirm that in the event it becomes appropriate to provide subjects with additional pertinent information after participation, you will seek the guidance of the IRB.*

*In some cases, different criteria apply. Please see* [*HRP-300 CHECKLIST: Waiver of Consent HHS*](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/)*,* [*HRP-301 CHECKLIST: Waiver of Consent Emergency Research*](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/)*, or for FDA-regulated research* [*HRP-302 CHECKLIST: Waiver of Consent Leftover Specimens*](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/) *to ensure you have provided sufficient information for the IRB to determine that the research is eligible for a waiver or alteration of the consent process.*

*For the use of* ***Humanitarian Use Devices*** *(HUD) in clinical treatment (not in clinical investigations), the IRB does not require an informed consent document. 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. Most HUDs include a patient information packet that should be given to patients before the procedure whenever possible.*

*Upload copies of any consent forms, assent forms, fact sheets, or patient information packets to eIRB*.

**31. Process to Document Consent in Writing**

*Indicate whether you will or will not document consent in writing. If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. If you will document consent in writing, explain how you will ensure that all study staff are familiar with and will follow* [*HRP-803 INVESTIGATOR GUIDANCE: Documentation of Informed Consent*](http://www.umassmed.edu/research/irb/sop/).

**32. Drugs or Devices**

*If the research involves drugs or devices, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and only by authorized investigators*.

*If a drug is investigational (has an IND) or a device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:*

* *Identify the holder of the IND/IDE/Abbreviated IDE.*
* *Explain the procedures followed to comply with FDA sponsor requirements for the following:*

|  |  |
| --- | --- |
|  | ***Applicable to:*** |
| ***FDA Regulation*** | ***IND Studies*** | ***IDE studies*** | ***Abbreviated IDE studies*** |
| *21 CFR 11* | *X* | *X* |  |
| *21 CFR 54* | *X* | *X* |  |
| *21 CFR 210* | *X* |  |  |
| *21 CFR 211* | *X* |  |  |
| *21 CFR 312* | *X* |  |  |
| *21 CFR 812* |  | *X* | *X* |
| *21 CFR 820* |  | *X* |  |

*If an investigational drug is IND exempt, identify the relevant category from* [*HRP-425 WORKSHEET: Drugs*](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/) *and explain how the investigational drug meets each criterion in that category.*

*If an investigational device is IDE exempt, identify the relevant category from* [*HRP-426 WORKSHEET: Devices*](http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/) *and explain how the investigational device meets each criterion in that category*.

*For a claim of abbreviated IDE (non-significant risk device study), upload the sponsor’s justification of its determination.*