Ascension Wisconsin IRB

Investigator Guidance

IRB Application Sections Reference Guide

This reference guide displays all sections and questions that exist in the electronic IRB application in Mentor. It is intended to be used as a reference for research staff while preparing submissions.

The actual electronic IRB application sections (and questions within each section) presented in Mentor may vary. The sections/questions displayed are dependent on the type of studies and numerous selections made by the research staff during the process of completing the electronic form.

This guide presents all questions, and does not take into account any study specific selections. In addition, some questions listed here may prompt for additional details or uploaded documents; those additional text boxes or upload prompts are not displayed in the reference guide.

Conflict of Interest Questions

Type: Standard

Due Date:

1. fCOIdisclosure	Type: Multiple Choice	Required

Have all Ascension key research personnel completed an fCOI disclosure- as applicable?

All Ascension key research personnel must complete an fCOI disclosure if either of the following is true:

- the study receives any type of funding
- there is a financial COI, regardless of study funding

Options: Yes
No
Not Applicable

2. COI	Type: Multiple Choice	Required

Do any of the key research personnel have a non-financial situation or circumstance that could result in perception of undue influence or impact on professional judgment, or would constitute a potential conflict of interest. (i.e., recruitment a subject(s) that is an employee, colleague or a subordinate of the researcher)

Options: Yes
No

3. NonAffiliated	Type: Multiple Choice	Required

For any key research personnel listed on the IRB application form who are from non-affiliated institution (not employed or otherwise affiliated with Ascension WI), are there any conflicts of interest related to this study that require a management plan and/or has another IRB required a management plan?

Options: Yes
No
N/A No non-affiliate study personnel

4. InstitutionCOI	Type: Multiple Choice	Required

Does Ascension (the institution) have an ownership interest in intellectual property or other conflict related to this study?

Options: Yes
No

Multicenter Studies Questions

Type: Standard

Due Date:

1. Differences	Type: Multiple Choice	Required

Will anything be different at this local site from the multicenter protocol? (i.e., eligibility criteria, not participating in all arms, etc.)

Options: Yes
No

6. MainPI	Type: Multiple Choice	Required

Is any Ascension Wisconsin investigator listed on this study the over-all project director of this multi-center study?

Options: Yes
No

7. NameLocal	Type: Short text	Required

List the name and location of all other centers and investigators.

8. Question 4	Type: Short text	Required

Describe the multi-site management plan for topics relevant to the protection of subjects. (i.e., reporting unanticipated problems, monitoring adverse events, interim analyses, coordination of change, etc.)

9. Question 5	Type: Multiple Choice	Required

Have you or will you request to have any other site rely on the Ascension WI IRB?

Options: Yes
No

Exempt Proposal Questions

Type: Standard

Due Date:

1. Purpose	Type: Short answer	Required

State the purpose and objective(s) of this study.

6. Background	Type: Long answer	Required

Describe the background and significance of this study.

7. Procedures-list	Type: Multiple Choice	Required

Mark any of the following procedures/activities to be done as part of this project:

Options:

- Educational Tests (cognitive, diagnostic, aptitude, achievement)
- Survey and/or Questionnaire
- Interview
- Focus Group
- Benign behavioral interventions (verbal, written, audiovisual recording) from adult subjects who prospectively agree
- Observation of public behavior
- Collection of data, information or documents that already exist (as of today)
- Collection of data, information or documents that will be collected for purposes other than this research study, before secondary use for this study
- Collection of biospecimens that already exist (as of today)
- Collection of biospecimens that will be collected for purposes other than this research study, before secondary use for this study
- Other- describe in the Procedure section

8. Procedures	Type: Long answer	Required

Describe the research procedures used.

9. Question 5	Type: Long answer	Required

Describe the endpoints and statistics.

10. Confidential	Type: Short answer	Required

Describe provisions to protect the privacy of subjects and to maintain the confidentiality of data, including data stroage and transmission (if applicable)

11. Question 6	Type: Multiple Choice	Required

Do you plan to obtain consent from subjects?
Note, informed consent is not required for exempt research. However, depending on the study, it may be appropriate to obtain consent or provide information to subjects. If you do plan to obtain consent, upload the document with the submission.

Options:

- Yes
- No

Subject Recruitment Questions

Type: Standard

Due Date:

1. Describe	Type: Short answer	Required

Describe the specific steps to be used to identify and/or contact prospective subjects/records/tissue. (If applicable, also describe how you have access to lists or records of potential subjects.)

2. Material	Type: Multiple Choice	Required

Will the study use any recruitment materials or documents?

Options:
Yes
No

3. WhatMaterials	Type: Multiple Select	Required

Indicate below what recruitment materials will be used.

Options:
Newspaper/ magazine ads
Radio/TV ads
Scripts (verbal or telephone)
Letters/emails to potential subjects
Letters to healthcare providers
Flyers, Posters, Brochures, etc.
Web site(s)
Other
None

4. Website	Type: Multiple Select	Required

What website(s) will be used for recruitment?

Options:
Clinicaltrials.gov
Ascension WI Clinical Research Department site
Other

5. Posted	Type: Short answer	Required

Describe where recruitment materials will be posted, published or distributed or any other relevant details about how the materials will be used.

6. Letters	Type: Short answer	Required

Describe who will be contacted/receive letters.

7. Access	Type: Short answer	Required

Describe how you have access to the potential subjects contact information. (note, you will need to request a HIPAA waiver in that section since the contact information is being sent outside the institution)

8. Question 8	Type: Multiple Choice	Required

Before a potential subject signs a consent document, are there any screening questions that you need to directly ask the individual to determine eligibility for the study?

Options:
Yes
No

9. Question 9	Type: Multiple Choice	Required

Are there any demographic exclusion criteria?

Options: Yes
No

10. Question 10	Type: Multiple Choice	**Required**

Are there other active studies at your recruitment site that have overlapping eligibility criteria that might generate competition in recruiting subjects?

Options: Yes
No

Pregnant women, fetuses or non-viable neonates Questions

Type: Standard

Due Date:

1. Question 2	Type: Long answer	Required

Explain why the proposed research is scientifically appropriate.
Include descriptions of any pre-clinical and clinical studies that have been conducted and provide data for assessing potential risks to the population included.

Research Involving Pregnant Women or Fetuses

A pregnant woman must be fully informed regarding the foreseeable impact of the research on the fetus or resultant child. In addition, the PI and study staff who have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy or in determining the viability of the fetus. No inducements, monetary or otherwise, will be offered to terminate pregnancy.

Also see: IRB-SOP-906 Special Considerations for Vulnerable Populations

6. Question 1	Type: Multiple Choice	Required

Does this research involve pregnant women or fetuses?

Options: Yes
No

7. Question 3	Type: Multiple Choice

Anticipated risk to the fetus (mark the option that best applies)

Options: Not greater than minimal risk and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means

Greater than minimal risk and the risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus

8. Question 4	Type: Short answer

Provide a rationale for anticipated risk.

9. Question 5	Type: Short answer

Explain why any risk is the least possible for achieving the objectives of the research.

10. Question 6	Type: Multiple Select

Expected benefit of this research to the pregnant woman and/or fetus (mark all that apply)

Options: Research holds out the prospect of a direct benefit to the pregnant woman.

Research holds out the prospect of a direct benefit both to the pregnant woman and the fetus.

There is no prospect of direct benefit for the woman or the fetus, but the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

This research holds out the prospect of a direct benefit solely to the fetus.

This research will involve participants who are pregnant and meet the definition of "children" as defined in the federal regulations (45 CFR 46.402).

Neonates of Uncertain Viability AND/OR Nonviable Neonates

11. Question 7	Type: Multiple Choice	Required

Does the research involve neonates of uncertain viability?

Options: Yes
No

12. Nonviable | Type: Multiple Choice | Required

Does the research involve neonates of nonviable neonates?

Options: Yes
No

13. Question 8 | Type: Short answer

Describe how individuals engaged in the research will have no part in determining the viability of a neonate.
This is a requirement for neonates of uncertain viability and nonviable neonates to be involved in research.

14. Question 10 | Type: Short answer

Explain the procedures that will be used to obtain legally effective informed consent of either parent of the neonate or (if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity) either parent's legally authorized representative will be obtained as required by 45 CFR 46.116 & 117, or state if a waiver of informed consent is being requested.

For neonates of uncertain viability

15. Question 9 | Type: Multiple Choice

Check the appropriate box as it applies to this research:

Options: The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, AND any risk is the least possible for achieving that objective

The main purpose of the research is the development of important biomedical knowledge, which cannot be obtained by other means AND there will be no added risk to the neonate resulting from the research

For non-viable neonates

16. Question 11 | Type: Short answer

Describe how this research meets the following conditions (required for inclusion of nonviable neonates)
- Vital functions of the neonate will not be artificially maintained;
- The research will not terminate the heartbeat or respiration of the neonate;
- There will be no added risk to the neonate resulting from the research; and
- The purpose of the research is to develop important biomedical knowledge that cannot be obtained by other means.

Placenta, dead fetus or fetal material after delivery

17. Question 13 | Type: Multiple Choice | Required

Does this research involve the placenta, dead fetus, or fetal material after delivery?

Options: Yes
No

18. Question 14 | Type: Multiple Select

This research proposes to use the following (check all that apply)

Options: placenta
dead fetus
cells excised from dead fetus
tissue excised from dead fetus
organs excised from dead fetus
macerated fetal material

19. Question 15 | Type: Multiple Choice

Will any information associated with the material identified above be recorded for research purposes in such a manner that

living individuals can be identified, directly or through identifiers linked to those individuals?

Options: Yes (individuals are human research subjects; policies and regulations apply)
No

Other Research

20. Question 16 Type: Multiple Choice **Required**

Does this research involve research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, human fetuses, or neonates?
Note, this choice is rarely selected and may require review by the Secretary of the Department of Health and Human Services (DHHS) and posting in the Federal Register for public comments and review.

Options: Yes
No

Children Questions

Type: Standard

Due Date:

1. Question 1 | Type: Multiple Choice | **Required**

Research involving children is limited to the following categories; choose the category that applies to this research.

Options:

Category 1: The proposed research poses no greater than minimal risk to children

Category 2: The proposed research poses greater than minimal risk but the prospect of direct benefit to subjects

Category 3: The proposed research poses greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition.

Category 4: This research not otherwise approvable, but presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children.

6. Question 12 | Type: Multiple Choice | **Required**

Will the study involve minors who are Wards of the State? (includes children placed in foster care)

Additional protections for Wards of the State or any other agency, institution, or entity are outlined in FDA and OHRP regulations and Wisconsin State Law. See the IRB Manual chapter on special procedures required for enrolling Wards of the State in Research. Specific IRB approval is required prior to enrolling Wards in research.
Also see: IRB-SOP-908 Research Involving Children

Options:

Yes

No

Category 1

7. Question 2 | Type: Short answer

Explain why this research poses no greater than minimal risk to children.

8. Question 3 | Type: Short answer

Explain how adequate provisions are made for soliciting the assent of the children and the permission of their parents or legal guardians or indicate that a waiver of assent and parental/guardian permission has been requested.

Category 2

9. Question 5 | Type: Short answer

Explain why the risk is justified by the anticipated benefit to the child.

10. Question 6 | Type: Short answer

Explain why the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

11. Question 7 | Type: Short answer

Explain how adequate provisions are made for soliciting the assent of the children and the permission of their parents or legal guardians.

Category 3

12. Question 9 | Type: Short answer

Explain why the risk represents a minor increase over minimal risk.

13. Question 10 | Type: Short answer

Explain why the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations.

14. Question 11 Type: Short answer

Explain why the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or conditions.

15. Question 12 Type: Short answer

Explain how adequate provisions are made for soliciting the assent of the children and the permission of their parents or legal guardians.

16. Question 14 Type: Short answer

Explain why the proposed research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

17. WardsCategory Type: Multiple Choice **Required**

Which of the following is true of the research:

Options:

The research presents minimal risk to the Ward(45 CFR 46.404; 21 CFR 50.51).

Research that presents greater than minimal risk with a prospect of direct benefit to the Ward (45 CFR 46.405; 21 CFR 50.52).

Research that presents greater than minimal risk with no prospect of direct benefit but is likely to yield generalizable knowledge

Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children AND is related to the children's status as Wards OR is conducted in schools, camps, hospital, institutions, or similar settings in which the majority of children involved as participants are not Wards.

None of the above apply.

18. Question 14 Type: Short answer **Required**

Provide detailed information about the proposed permission/assent process, as well as the identity and authority of the individuals who will provide permission for the Ward subjects.

Adults with Decisional Impairment/Use of LAR Questions

Type: Standard

Due Date:

1. Why	Type: Short answer	Required

Describe the subject population and why they are/may be unable to provide consent for themselves and require the use of a Legally Authorized Representative (LAR)? (i.e. due to a disorder that affects cognitive or emotional functions, a degenerative disease affecting decision-making capacity, are comatose or otherwise incapacitated, etc.)

6. Question 5	Type: Multiple Choice	Required

Concerning the competency of the participants, check each category that applies:

Options:
- Permanently incompetent to give consent due to cognitive impairment
- Temporarily incompetent to give consent due to medical treatment or illness

7. Question 2	Type: Short answer	Required

Explain why it is necessary to involve persons with a decisional impairment in this research.

8. Question 3	Type: Multiple Choice	Required

Will this research enroll institutionalized adults with a decisional impairment?

Options:
- Yes
- No

9. Question 4	Type: Multiple Choice	Required

Research involving persons with a decisional impairment is limited to the following categories. Choose one category that applies to your study.

Options:

Category 1: Research presenting no greater than minimal risk to the participants.

Category 2: Research involving an intervention or procedure that presents an increase over minimal risk to participants, but which offers the potential for direct individual benefit to the participant and is available only in the context of the research study.

Category 3: Research involving an intervention or procedure that presents an increase over minimal risk to involved participants and which does not have the potential for direct individual benefit, provided that the knowledge sought has direct relevance for understanding or eventually alleviating participants' disorder or condition. Studies of high risk without direct benefit are not permitted.

10. Question 7	Type: Short answer	Required

Indicate who will perform the assessment to determine whether a potential participant is capable of providing consent or assent and describe his/her qualifications for doing this.

11. Question 6	Type: Short answer	Required

Describe the specific criteria or procedures proposed for evaluating the mental status of prospective subjects to determine whether they are capable of consenting

12. Question 8	Type: Short answer	Required

Explain how the Principal Investigator will identify persons authorized to give legally valid consent on behalf of any individual(s) judged incapable of consenting on their own behalf?

13. Question 9	Type: Multiple Choice	Required

Will assent be obtained if the person with decisional impairment is capable of exercising some judgment concerning the nature of the study?

Options: Yes
No

14. Question 10	Type: Short answer	**Required**

Briefly explain will assent be obtained documented?

Other Vulnerable Populations Questions

Type: Standard

Due Date:

1. Question 1	Type: Multiple Select	Required

What other vulnerable populations do you plan to include in the research?

Options:

Physical Impairment An individual with physical impairment (e.g., visual, hearing, speech) that would prevent normal communication, and who is unable to read and/or sign the informed consent (IC), must have an independent witness present when IC is presented/signed. This person must also sign the IC. An independent witness cannot be involved/ vested in the research.

Non-English Speaking Subjects An IRB approved translated consent document must be used. There must also be a person (impartial translator) who is capable of explaining the study and answering questions in the language of the subject throughout the subject's participation in the study. This person cannot be a family member or friend of the subject.

Life-Threatening Condition/Seriously Debilitating Illness The Investigator must fully explain alternative treatments and that participation in the research may not benefit the individual's medical condition. The Investigator must confirm that the subject understands the information.

Employees Pay special attention to matters of voluntariness, undue inducement, and confidentiality. An employee's decision to participate or withdraw from the study should have no impact on his/her employment status. Measures must be taken to ensure confidentiality of an employee's study-related records.

Nursing Home Residents Wisconsin has a Nursing Home/Long Term Care Facility Bill of Rights of which the PI, study staff, and LAR, if appropriate, must be fully aware.

Other

6. Question 2	Type: Short answer	Required

Explain why it is necessary to include this population in the research.

7. Question 3	Type: Short answer	Required

Describe any additional steps taken to ensure the rights and safety of this group(s).

Informed Consent Questions

Type: Standard

Due Date:

1. Who	Type: Multiple Select	Required

Describe who will be responsible for obtaining consent from subjects:

Options:
- PI
- Sub-I(s)
- Research Coordinator(s)
- Other

6. Where	Type: Multiple Select	Required

Describe the location where the consent discussion will occur:

Options:
- In a private room
- In a group setting
- Over the phone
- Via mail/email/fax
- Via an online eConsent tool
- Other

7. Understanding	Type: Multiple Select	Required

What methods will be used to ensure the subject understands the information provided?

Options:
- Ample time provided for question and answer period.
- Potential subjects are allowed to review the consent document as long as needed, including at home or overnight.
- Subject understanding of the study is assessed following the consenting process and before enrolling into the study.
- All study procedures and risks are carefully explained.
- Medical jargon is not used during the consent discussion.
- Educational tools or other information will be provided.
- Other

8. Undue	Type: Multiple Select	Required

Which mechanisms will be used to minimize potential undue influence? (mark all that apply)

Options:
- If the investigator is also the subject's physician/care provider, the differences between research and standard medical care are carefully explained.
- If the study includes payment to subjects, the payment is not emphasized during the consent discussion.
- Any potential benefit of the study is not overstated during the consent discussion.
- Subjects are informed their decision to/to not participate will not impact their normal medical care.
- Other

9. Question 5	Type: Multiple Select	Required

What methods will be used to ensure effective, ongoing consent and agreement to participate?

Options:
- Subjects are verbally reminded about the research and voluntary participate at each visit
- Subjects are provided with updates throughout the study (e.g. newsletters, reminders)
- For subject populations whose decisional ability may change during the study: Decisional ability is routinely assessed, per clinical standards, and ongoing consent is obtained as needed from the subject or LAR, as appropriate
- For minors: Consent is obtained from the subject at the time the age of majority is reached

Other

Waiver or Alteration of Consent Questions

Type: Standard

Due Date:

1. Waive or alter	Type: Multiple Select	Required

Are you requesting to:

Options:
- Alter some of the required elements in the consent form
- Waive the requirement to obtain consent for the recruitment
- Waive the requirement to obtain consent for the entire study

Describe how the request meets all of the following four conditions:

6. Justify wavier 1	Type: Long answer	Required

The research involves no more than minimal risk to the subjects because:

7. Justify wavier 2	Type: Long answer	Required

The waiver or alteration will not adversely affect the rights and welfare of subjects because:

8. Justify wavier 3	Type: Long answer	Required

The research could not practicably be carried out without the waiver or alteration because: *(Indicate why it is not feasible to get consent.)*

9. Justify waiver 4	Type: Long answer	Required

If appropriate, will subjects be provided with additional pertinent information after participation?

Waiver of Documentation of Consent Questions

Type: Standard

Due Date:

1. Justify waiver 1 Type: Multiple Choice

Indicate which of the following applies. (Select one)

Options:

The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. NOTE: A waiver of documentation of consent can only be granted for FDA regulated research if this justification applies.

The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. (Note: If this category is chosen, include copies of a consent form and/or parental permission form for subjects who want written documentation linking them to the research.)

6. Justify waiver 2 Type: Multiple Choice

What materials will be used to inform potential subjects about the research?

Options:

A letter accompanying a questionnaire

Verbal script

Other

HIPAA Questions

Type: Standard

Due Date:

1. Health Informaiton	Type: Multiple Choice	Required

Will you access or use <u>health information</u> for this project?

Options: Yes
No

6. Indentifiers	Type: Multiple Choice	Required

Are any identifiers attached to the health information?
If you will be looking at a medical record for screening, recruitment or for conducting the research, check "Yes".

Options: Yes
No
N/A no health information used

7. Prep-Research-1	Type: Multiple Choice	Required

<u>For screening and recruitment,</u> will Ascension Wisconsin Investigators or research staff review protected health information (PHI) <u>*before*</u> an authorization form is signed?

Options: Yes
No

8. Prep-Research-2	Type: Multiple Choice	Required

<u>For screening and recruitment *before*</u> an authorization is signed, are the following true:

- The sole purpose of the review of PHI is to aid in the recruitment of research subjects for this study.
- Only PHI that is reasonably necessary to accomplish recruitment will be used.
- PHI that is abstracted during the screening/recruitment review <u>*will not be shared*</u> outside of the study team or Ascension Wisconsin.

Options: Yes, ALL of the above are true
No, not all of the above apply
N/A no health information used

9. Research PHI	Type: Multiple Select	Required

<u>For the research study,</u> which of the following apply (mark all that apply):

Options: A signed HIPAA Authorization will be obtained and documented as part of the consent process. *Complete and upload a study specific HIPAA Authorization form (English, Spanish, Hmong, contact the IRB if other languages are needed).*

Will request to waive or alter the HIPAA authorization requirement.

Will request to use a limited data set in this research, which consists of only the following identifiers: town, city, zip code, dates and/or ages. *Complete and upload a data use agreement.*

N/A no health information used for this research

HIPAA Waiver Questions

Type: Standard

Due Date:

1. Waiver	Type: Multiple Select	Required

What type of waiver is requested for this project? (select all that apply)

Options:

Waive the requirement to obtain HIPAA Authorization for all of the research

Partial Waiver of HIPAA Authorization (i.e. recruitment activities that are not "preparatory to research" activities. For example, disclosing PHI outside of Ascension Wisconsin for the purpose of contacting/ recruiting.)

Alteration of HIPAA Authorization (i.e. omitting some required elements. For example, not requiring a signed authorization for a survey where the PI obtains verbal consent)

N/A not requesting a waiver (i.e will get a signed HIPAA authorization or aren't accessing, using or disclosing PHI for research)

6. Source	Type: Short text	Required

Describe the source(s) of PHI.

7. LmtDataSet	Type: Multiple Select	Required

Will you be accessing, using and/or recording any ot the following in association with health information for the purposes of this study? (Check all that apply)

Options:

Names

Social security numbers

Telephone number, email address or other unique contact information

Account number information such as medical record number, health plan beneficiary numbers or Certificate/license numbers

Internet Protocol (IP) addresses or other unique online identifiers such as avatars or URLs

Device identifiers or serial numbers

Full face (or comparable) photographic images

Biometric identifiers (like finger a voice recording)

Any geographic subdivisions smaller than a State (including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code) if according to the current publicly available data from the Bureau of the Census: 1) When all zip codes with the same three initial digits are combined, there are > 20,000 people; and 2) Initial 3 digits of zip code for geographic units containing 20,000 or fewer people changed to 000.

Any elements of dates (except year) directly related to an individual, including: birth date, admission date, discharge date, date of death.

All ages over 89 or elements of dates (including year) indicative of such age (except when ages/ elements are aggregated into a single category of age 90 or older)

Any other unique identifying number, characteristic, or code

Link to identifiers (a code/key kept separate from data linking participants' identifier(s) to a code in the data set)

No, I'm not accessing, using or collecting any of these identifiers

8. Risk	Type: Multiple Select	Required

Explain how the proposed use of the participants' PHI presents no more than minimal risk to the privacy of the individual.

Options:

Information will not be disclosed unless stripped of all identifiers

Data will be coded prior to disclosures (identifiers stored separately with a key to re-identify data)

Research team members will sign a Confidentiality Agreement (upload template with the submission)

Other

9. Destroy	Type: Multiple Choice	Required

When will identifiers be destroyed?

Options: At the earliest possible opportunity consistent with the research
Identifiers will be retained indefinitely

10. Practicable	Type: Short text	**Required**

Explain why the research could not practicably be conducted without the waiver of authorization.

11. NeedPHI	Type: Short text	**Required**

Explain why the research could not practicably be conducted without access to and use of protected health information.

Procedures, Risks and Benefits Questions

Type: Standard

Due Date:

1. Question 3	Type: Multiple Select	Required

Does the study involve any of the following interventions? (mark all that apply)

Options:
- Administration of drugs, chemicals, or biological agents (approved or unapproved)
- Administration of medical device (approved or unapproved)
- Any surgical procedure(s)
- Administration of physical stimuli
- Administration of Recombinant Synthetic Nucleic Acid Molecules, Toxins or Infectious Agents
- N/A the research does not include any of the above

6. Question 14	Type: Short answer	Required

Describe the nature and degree of the risk or potential harm for any interventions marked above.

7. Question 15	Type: Short answer	Required

Describe the precautions that will be taken to minimize the risk to subjects for any interventions marked above.

8. Question 4	Type: Multiple Select	Required

Does the study involve any of the following tests or procedures? (mark all that apply)

Options:
- Direct interaction with subject(s)
- Use of private records (i.e. medical, educational)
- Biological Specimens (i.e. blood, tissue)
- Exposure to Radioisotopes or other sources of ionizing radiation (including X-rays) done for research purposes only
- MRI, CT or other images done for research purposes only
- N/A the research does not include any of the above

9. Question 4	Type: Multiple Select	Required

What precautions will be used to ensure subject privacy is protected? (select all that apply)

Options:
- The collection of sensitive information is limited to the amount necessary to achieve the aims of the research; no unneeded sensitive information is being collected
- Research intervention is conducted in a private room
- Use of drapes or other barriers for subjects who are required to disrobe
- Consent will be obtained prior to taking any photographs or audio/video recordings
- Other

10. Question 19	Type: Multiple Select	Required

Indicate type of human biological specimens used in this research.

Options:
- Blood
- Tissue
- Spinal Fluid
- Other

11. Question 20	Type: Multiple Select	Required

Indicate the source of the specimens.

Options:
- Existing clinical specimens
- Prospective collection of excess clinical specimens

Existing research specimens
Prospective collection of specimens research purposes
Other sources

12. Question 21 Type: Multiple Select **Required**

Indicate the type testing that will be done on the specimens. (mark all that apply)

Options:
Safety evaluations
Pharmacokinetic analysis
Biomarkers
Genetic testing (i.e. pharmacogenetics, genetic testing, whole genome sequencing, etc.)
Other

13. Question 23 Type: Multiple Select **Required**

What identifiers will be on the samples?

Options:
No identifiers (no one can identify a subject from any information recorded for the research)
Indirect identifiers (unique code which could be used by the source to identify a subject)
Direct identifiers (marked with identifier such as name, date of birth, medical record, etc.)

14. Question 24 Type: Short answer **Required**

Describe how specimens are stored? (include who, where, safeguards in place to protect subjects)

15. Question 25 Type: Short answer **Required**

What will happen to the specimen(s) when the research testing is completed?

16. Question 30 Type: Short answer **Required**

Describe the research-related procedure(s) involving exposure to radiation. Include an explaination of how this differs from how a patient would be treated outside of the study.

17. Question 9 Type: Multiple Choice **Required**

Will MRIs or other imaging be conducted by staff who have not been previously trained following standard processes and procedures for use and safety?

Options:
Yes
No

18. Question 10 Type: Multiple Choice **Required**

Will subjects who are pregnant, under 18 years old or have implanted devices, be included?

Options:
Yes
No

19. Question 12 Type: Multiple Choice **Required**

Is contrast used as part of the research specific scans?

Options:
Yes
No

20. Question 5 Type: Multiple Select **Required**

Does the study involve any of the following interventions or interactions? (mark all that apply)

Options: Manipulation of psychological or social variables (social isolation, psychological stresses)

Any probing for personal or sensitive information in surveys or interviews

Presentation of materials which subjects might consider sensitive, offensive, threatening or degrading

Use of deceptive techniques

N/A the research does not include any of the above

21. Question 26 Type: Short text **Required**

Describe the nature and degree of the risk or potential harm for any interventions or interactions marked above.

22. Question 27 Type: Short answer **Required**

Describe the precautions that will be taken to minimize the risk to subjects for any interventions or interactions marked above.

23. Question 6 Type: Multiple Choice **Required**

Does the research intervention involve treatment or therapy?

Options: Yes

No

24. Question 7 Type: Short answer **Required**

How would subjects be treated in a non-investigational setting? Describe treatment considered to be standard care, any alternatives (drugs or other therapies) that might be used.

25. Question 8 Type: Multiple Choice **Required**

Is the research-related treatment available to patients without taking part in the research study?

Options: Yes (be sure to mention this as an alternative in the consent form)

No

26. Question 25 Type: Multiple Select **Required**

Could the research result in the identification of any of the following? (mark all that apply)

Options: Identification of previously unknown condition from clinical images done specifically for research (i.e. disease)

Identification of previously unknown condition or disease from clinical tests done specifically for research (i.e. disease, suicidal thoughts, wrong paternity, etc.)

Incidental findings related to investigational tests or procedures

Discovery illegal activity (drug use, domestic violence, child abuse/neglect, etc.)

Other

None

27. Question 26 Type: Multiple Choice **Required**

Will the records or specimens be stored for future unknown research?

Options: Yes

No

28. Question 5 Type: Multiple Select **Required**

What precautions will be used to maintain the confidentiality of identifiable information?

Options: Paper-based records will be kept in a secure location and only be accessible to study personnel.

Computer-based files will be stored on an Ascension server or other secure location and only be made available to personnel involved in the study through the use of access privileges and

passwords.

Records will include indirect identifiers (unique code/key which could be used by the study team to identify a subject)

Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.

As soon as feasible, identifiers will be removed from study-related information.

A Certificate of Confidentiality has been obtained from the NIH.

Audio and/or video recordings of subjects will be transcribed then destroyed to eliminate the ability to identify subjects.

For FDA-regulated research: Electronic source data will be captured, reviewed & retained in accordance with FDA Guidance on Electronic Source Data in Clinical Investigations.

Other

29. BenefitDirect Type: Short answer **Required**

List any anticipated direct benefit to the subject from participation in the research. (If none, state that here and in the consent document)

30. BenefitSociety Type: Short answer **Required**

List any anticipated societal benefits from this research.

31. Question 16 Type: Short answer **Required**

Justify the risk in terms of the potential scientific or societal benefit in relation to the anticipated benefits to subjects.

Investigational Product(s) Questions

Type: Standard

Due Date:

1. DrugBio	Type: Multiple Choice	Required

Does this study include the use of a Drug, Biologic or Dietary Supplement?

Options: Yes
No

6. Device	Type: Multiple Choice	Required

Does this study include the use of a Medical Device?

Options: Yes
No

Type	Type: Multiple Select	Required

What is the regulatory status of the drug(s), biologic(s), or dietary supplement(s) involved? (mark all that apply)

Options: **Product(s) are approved** for marketing (no IND required) and are used according to the approved labeling
Product(s) are approved for marketing (no IND required) but are used **differently** than in the approved labeling
IND is required (FDA Investigational Drug number)
Expanded access or single patient use IND

8. Question 6	Type: Multiple Choice	Required

What is the regulatory status of the medical device(s) involved? (mark all that apply)

Options: **Device is approved** and used according to the approved labeling
Device is approved but used **differently** than the approved labeling
Non-Significant Risk (NSR) Device determination is being requested
Device is exempt from IDE requirements (PMA exempt device, 510(k) cleared)
IDE is required (FDA Investigational Device Exemption number)

9. Question 9	Type: File Upload	Required

Upload the Package Insert for the approved drug.

10. Question 11	Type: File Upload

Upload the instructions for use for the device.

11. Question 10	Type: File Upload

Upload the Investigator brochure for the Investigational drug, biologic or supplement.

12. Supply	Type: Multiple Select	Required

What is the source of the investigational product?

Options: Supplied by sponsor
Other

Product	Type: Multiple Select	Required

How will drugs/biologics/dietary supplements be received, stored, dispensed, tracked and returned/destroyed ?

Options: By an Ascension Pharmacy

By Investigator
Other

14. Question 7	Type: Short answer	Required

Describe the responsible parties and manner of the receipt, tracking and return/destruction of the device?

15. Question 8	Type: Short answer	Required

Describe the the location and manner of storage and access to the device?

Data and Safety Monitoring Plan Questions

Type: Standard

Due Date:

7. plan	Type: Multiple Select	Required

Describe the data safety monitoring plan.

Options:
- Formal external monitoring board
- Monitored by Sponsor (no external board)
- Monitored by PI only
- No formal data and safety monitoring plan
- Other

8. Compliacne	Type: Short answer	Required

Describe the plan for assuring data accuracy and protocol compliance.

Cost and Compensation Questions

Type: Standard

Due Date:

1. SponsorContact	Type: Multiple Choice	Required

Will the subjects bear any costs which are not part of standard of care?

Options: Yes
No

2. Question 2	Type: Multiple Choice	Required

Will compensation be offered to subjects for their participation?

Options: Yes
No

Ancillary Reviews Questions

Type: Standard

Due Date:

1. Question 6	Type: Multiple Choice	Required

Is this study supported through the Clinical Research Department? (i.e. an AWRI clinical research coordinator, investigational drug or device)

Options: Yes
No

6. Question 1	Type: Multiple Choice	Required

Is there a research contract, agreement, or grant related to this research?

Options: Yes
No

7. Question 2	Type: Multiple Choice	Required

Is the contract or agreement final? (must be fully negotiated, but does not need to be signed)

Options: NCI cooperative group oncology studies with no study specific agreement
Yes
No (The protocol can NOT be submitted to the IRB until the contract or agreement is final)

9. Question 4	Type: Multiple Choice	Required

Are the following topics included in the contract/agreement?

- Details of subject remuneration.
- Sponsor agrees to provide payment for medical care for research participants with a research-related injury.
- Sponsor will promptly report any findings from monitoring activities that could affect the rights or safety of subjects.
- Sponsor will provide data and safety monitoring reports to the PI and IRB, when appropriate.
- After study closure, the Sponsor will provide any result information that could affect the rights or safety of subjects.
- PI/ Sponsor role in publication/disclosure of results.

Options: Yes
No

10. Question 5	Type: Multiple Choice	Required

Are the details in the contract/agreement regarding the following consistent with the information in the IRB application, consent, and other materials submitted ot the IRB?

- Details of subject remuneration.
- Sponsor agrees to provide payment for medical care for research participants with a research-related injury.
- Sponsor will promptly report any findings from monitoring activities that could affect the rights or safety of subjects.
- Sponsor will provide data and safety monitoring reports to the PI and IRB, when appropriate.
- After study closure, the Sponsor will provide any result information that could affect the rights or safety of subjects.
- PI/ Sponsor role in publication/disclosure of results.

Options: Yes
No

11. Question 7	Type: Multiple Choice	Required

Does the study involve exposure to radiation (including extra images that include radiation) that are specifically done as part of the research (not considered standard care)?

Options: Yes

No

12. Question 8 Type: Multiple Choice **Required**

Will any of the following occur at an Ascension facility as part of this research.

- Research involving recombinant or synthetic nucleic acid molecules or human gene transfer techniques
- Use of biological toxins (including truncated or mutated toxins)
- Research involving identification or culturing of pathogenic organisms (bacteria, viruses, protozoans, fungi) in risk group 2 or above

Options: Yes
No

13. Question 9 Type: Multiple Choice **Required**

Will the protocol include any activities that would need to meet institutional guidelines for marketing/ communications?
(i.e.recruitment material that is part of a news story or video recording done in a hospital)

Options: Yes
No

IRB Reliance on an External IRB Questions

Type: Standard

Due Date:

1. External IRB	Type: Multiple Choice

What IRB are you requesting to serve as the IRB of record?

Options:
- NCI CIRB
- MCW IRB
- Another IRB

Humanitarian Use Device (HUD) Questions

Type: Standard

Due Date:

HUD Details

1. Question 1	Type: Short text	Required

Humanitarian Use Device (HUD) name:

6. Question 3	Type: Short answer	Required

Describe the nature and purpose of the HUD.

7. Question 4	Type: Short answer	Required

Describe the intended use/ clinical indication for the HUD use.

Subject Recruitment

8. Question 5	Type: Short text	Required

Estimated number of patients you expect at this site per year.

9. Question 8	Type: Short answer	Required

Describe how this device will be explained to the patient. Patients should be told that the device is an HUD and that the effectiveness of the device has not been demonstrated.

10. Question 6	Type: Short answer	Required

What financial obligations will the patient incur as a result of receiving this device?

11. Question 7	Type: Short answer	Required

Medicare approval is required prior to use of the device. Describe if/when approval has been or will be obtained.

Risks, Benefits and Alternatives

12. Question 9	Type: Short answer	Required

What are the potential risks/discomforts associated with the procedure?

13. Question 10	Type: Short answer	Required

Explain any available esitmates about the probability, severity, or potential reversibility of specific risks?

14. Question 11	Type: Short answer	Required

What procedures will be used to prevent/minimize any potential risks or discomforts?

15. Question 12	Type: Short answer	Required

Describe the probable benefits of the procedure for patients.

16. Question 13	Type: Short answer	Required

Explain how the potential benefits of the use of the device outweigh the potential risks and how these risks are justified.

17. Question 14	Type: Short answer	Required

What therapeutic alternatives are available to patients? There is always the alternative to choose not to receive a HUD.

18. Question 15 Type: Multiple Choice **Required**

Do any of the physicians listed on this form requesting authorization to use this device have any stock or patent position with the device?

Options: Yes
No

19. Question 16 Type: Multiple Choice **Required**

Did any of the physicians listed on this form requesting authorization to use this device participate in product design or development for this device, or as company director or consultant?

Options: Yes
No