Initial Review Submission Form

Use Adobe version 11 or later (Reader or Acrobat)
Asterisked (*) fields are required.

Use this form to request initial IRB approval for a protocol or site.
This is a smart form. Form elements will appear or disappear depending on answers to previous questions.
If your answer does not fit in the space provided, you may refer to and submit separate attachments.
Blank & incomplete answers will result in delayed reviews.

Destination Institutional Review Board (IRB)

*To which WCG IRB is this application being submitted?
If you have questions, please call or email the selected IRB

☐ Aspire IRB (Aspire) (877) 366-5414 email@aspire-irb.com
☐ Copernicus Group IRB (CGIRB) (888) 303-2224, (919) 465-4310 irb@cgirb.com
☐ Hummingbird IRB (HIRB) (855) 447-2123 info@HummingbirdIRB.com
☐ Midlands IRB (MLIRB) (800) 636-4445, (913) 385-1414 info@mlirb.com
☐ New England IRB (NEIRB) (800) 232-9570, (617) 243-3924 info@neirb.com
☐ Western IRB (WIRB) (800) 562-4789 clientservices@wirb.com

Submission Type

*Indicate the type of submission:
☐ New protocol with no Principal Investigator (PI) or site information
☐ Site being added to existing protocol, or change of Principal Investigator (PI)
☐ New protocol and Principal Investigator (PI) (combined submission)

*Is the destination IRB selected above the central IRB for the study?
☐ Yes ☐ No

For clinical use of a Humanitarian Use Device (HUD), Expanded Access, Compassionate Use, and Emergency
Use see separate application forms on the IRB Web site.

Protocol Information

*Protocol title

Protocol version number (if applicable) Sponsor's protocol ID (if applicable)

Protocol version date (if applicable) IRB protocol number (if known)

*Sponsor

Contract Research Organization (CRO) Information

*Is a Contract Research Organization (CRO) involved in the research?
☐ Yes ☐ No

*Contract Research Organization (CRO) name
Federal Funding

*Is this research funded, supported, or conducted by a United States federal department or agency?

- Yes  - No

Because this research is funded, supported, or conducted by a United States federal department or agency, the organizations associated with the research locations are engaged in federal research:

- For each organization involved with the research, submit the following unless already on file with the IRB:
  1. Written documentation of the Federalwide Assurance (FWA)
  2. A Master Services Agreement (MSA) or Institutional Authorization Agreement. (A template agreement is available on the IRB Web site.)

*Select the federal department or agency funding the research:

*Specify the federal department or agency funding the research:

Because the Department of Defense is funding the research:

- Submit:
  1. Completed "Addendum for Department of Defense Funded Research" available on the IRB Web site
  2. The agreement between organizations that specifies the roles and responsibilities of each party.
  3. The specific requirements of research under the Department of Defense Addendum.

Single Review Solution (SRS)

*Is this a submission to WCG’s Single Review Solution (SRS)?

- Yes  - No

*Single Review Solution (SRS) is a WCG service in which the WCG IRBs work together to allow the sponsor and each site to work with WCG IRB of their choice. Contact the IRB if you have questions.*

Clinical Pharmacology Unit Services (CPUS)

*Is this a submission to the Clinical Pharmacology Unit Services (CPUS)?

- Yes  - No

IRB Determinations

*If the IRB determines that the submission does not represent human research or represents research that is exempt from regulation, do you want the IRB to issue an exempt or not human research determination instead of conducting IRB review?

- Yes  - No

*Would you like the IRB to consider whether the research is minimal risk? (Research is minimal risk when the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. In general, studies testing drugs or devices are not minimal risk.)*

- Yes  - No
### Principal Investigator (PI) Information

The IRB usually uses the address in this section in the consent form.

<table>
<thead>
<tr>
<th>Prefix</th>
<th>*First</th>
<th>Middle</th>
<th>*Last</th>
<th>Suffix</th>
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*Email

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<th>*Phone</th>
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Degrees

Mailing address for the above individual:

*Company/Institution/Organization

<table>
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<tr>
<th>*Address Line 1</th>
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</table>

Address Line 2

<table>
<thead>
<tr>
<th>*City</th>
<th>*State</th>
<th>*Postal Code</th>
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</tbody>
</table>

*Province

State or Province

<table>
<thead>
<tr>
<th>*Country</th>
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</tbody>
</table>

☐ Send continuing review forms to this person to be filled out and returned to the IRB

### Contacts

Are there any designated contacts for this research (e.g., Sponsor contact, Contract Research Organization (CRO) contact, Site Management Organization (SMO) contact, study coordinator contact)?

☐ Yes  ☐ No
Initial Review Submission Form  
HRP-212  
Use Adobe version 11 or later (Reader or Acrobat)  
Asterisked (*) fields are required.

Research Contact

Remove this contact

*Contact Type

Prefix  *First  Middle  *Last  Suffix

*Email  *Phone

Degrees

Mailing address for the above individual:

*Company/Institution/Organization

*Address Line 1

Address Line 2

*City  *State  *Postal Code

*Province

State or Province

*Country

☐ Copy this person on IRB correspondence  
☐ Send continuing review forms to this person to be filled out and returned to the IRB

Translated Documents

Documents for subjects must be in language understandable by the subject or the subject’s representative.  
Translated documents must be IRB approved before use.

*Will you need translated documents or approval of translated documents?

☐ Yes  ☐ No

Because you have indicated that you need translated documents:

Submit a completed “Translation Request” form available on the IRB Web Site
Billing Information

*Use billing information provided by the Sponsor or Contract research organization (CRO)?
○ Yes  ○ No

*How should we send invoices to the billing contact?
○ Printed mail  ○ Email

Mail stop/cost center *(if applicable)*  Purchase order number (PO#) *(if applicable)*  sIRB code *(if applicable)*

*Is the person to whom we should send invoices listed above as a contact?*
○ Yes  ○ No or unsure

*Name of the person to whom we should send invoices*

Provide contact information for the person to whom we should send invoices:

Prefix  *First*  Middle  *Last*  Suffix

*Email  *Phone

Degrees

Mailing address for the above individual:

*Company/Institution/Organization

*Address Line 1

Address Line 2

*City  *State  *Postal Code

*Province

State or Province

*Country
Initial Review Submission Form
HRP-212

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Countries Where the IRB Will Have Oversight

<table>
<thead>
<tr>
<th>Country</th>
<th>*Estimated total number of sites, including sites not reviewed by a WCG IRB</th>
<th>*Estimated number of central sites to be reviewed by a WCG IRB</th>
<th>*Estimated number of institutional sites to be reviewed by a WCG IRB</th>
</tr>
</thead>
</table>

Study Information Estimates

<table>
<thead>
<tr>
<th>Phase</th>
<th>*Estimated study duration</th>
<th>*Projected month in which PI submissions will begin</th>
<th>*Estimated period over which PIs will submit</th>
</tr>
</thead>
</table>

Safety Reporting

*Who will submit IND safety reports to the IRB? (e.g., MedWatch, SUSAR, CIOMS)

- N/A
- Sponsor
- CRO
- PIs
- Other
*Specify: ____________________________

Clinical Trial Information

*Will you or others post the research on ClinicalTrials.gov?

- Yes
- No

*ClinicalTrials.gov Identifier

*Will you or others submit data from this research to the US Food and Drug Administration (FDA) or hold data from this research for inspection by the FDA?

- Yes
- No

*Is the research a clinical trial of a drug?

- Yes
- No

*Is the research a clinical trial of a device?

- Yes
- No
Drug

*Are you conducting the research under an Investigational New Drug Application (IND)?

- Yes
- No

*IND #  

*Drug Name(s)  

*The IRB should use the Investigator Brochure(s) that:

- Is on-line
- Is submitted with this application
- The IRB has on file

If the IRB has an Investigator Brochure on file that is more current than the one posted on-line or submitted with this application, the IRB will review the research using the more current Investigator Brochure on file.

Because you have indicated that the Investigator's Brochure is being submitted with this application:

Submit the Investigator's Brochure(s) for the investigational drug(s).

*Provide the Internet addresses that link to the Investigator Brochure(s):

*Does the investigator hold the IND?

- Yes
- No

Because you have indicated that the Principal Investigator (PI) holds the IND:

Submit information from FDA documenting the IND number.
**Device**

*Are you conducting the research under an Investigational Device Exemption (IDE)?

○ Yes ○ No

*IDE # | *Device name(s) |
| --- | --- |

*The IRB should use the product labeling for the investigational device(s) that:

○ Is online

○ Is submitted with this application

○ The IRB has on file

*If the IRB has product labeling on file that is more current than the one posted online or submitted with this application, the IRB will review the research using the more current product labeling on file.*

Because you have indicated that the product labeling is being submitted with this application:

⚠️ Submit the product labeling for the investigational device(s).

*Provide the Internet addresses that link to the product labeling for the investigational device(s):*


*Are you conducting the research under the Abbreviated IDE (NSR) requirements?*

○ Yes ○ No

*Device name(s) |
| --- |

*Have you submitted this device to FDA for an SR/NSR determination?*

○ Yes ○ No

Because you have indicated that the research is being conducted under the Abbreviated IDE (NSR) requirements:

⚠️ Submit a brief explanation of why the device is not a significant risk device.

*Are you conducting the research to evaluate an FDA-approved device?*

○ Yes ○ No

*For each device, list the device name and indicate how it was FDA approved (Premarket Approval/PMA, Premarket Notification 510(k), Humanitarian Device Exempt/HDE, or Class I/II Exemption), if known, and provide the PMA number, 510(k) number, HDE number, or Class I/II regulatory reference, if known:*


*Does the investigator hold the IDE?*

○ Yes ○ No

⚠️ Because you have indicated that the Principal Investigator (PI) holds the IDE:

Submit information from FDA documenting the IDE number.
**Vulnerable Populations**

*Will the research involve subjects who are adults unable to consent?*
- [ ] Yes
- [ X ] No

*Will the research involve subjects who are children?*
- [ ] Yes
- [ ] No

  *Will the research involve children who are wards of the state?*
  - [ ] Yes
  - [ ] No

  *Will the research involve non-viable neonates?*
  - [ ] Yes
  - [ ] No

  By submitting this form, I confirm that:
  - Individuals engaged in the research will have NO part in determining the viability of a neonate.
  - Vital functions of the neonate will NOT be artificially maintained.
  - The research will NOT terminate the heartbeat or respiration of the neonate.

*Will the research involve neonates of uncertain viability?*
- [ ] Yes
- [ ] No

  By submitting this form, I confirm that:
  - Individuals engaged in the research will have NO part in determining the viability of a neonate.

*Will the research involve subjects who are prisoners?*
- [ ] Yes
- [ ] No

  By submitting this form, I confirm that:
  - Parole boards will NOT take into account a prisoner's participation in the research in making decisions regarding parole.

*Will the research involve subjects who are pregnant or follow subjects who become pregnant while on study?*
- [ ] Yes
- [ ] No

  By submitting this form, I confirm that:
  - NO inducements, monetary or otherwise, will be offered to terminate a pregnancy.
  - Individuals engaged in the research will have NO part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
  - Individuals engaged in the research will have NO part in determining the viability of a neonate.

**Other Populations**

*Will the research involve subjects with limited English skills?*
- [ ] Yes
- [ ] No

*Will the research involve institutionalized subjects?*
- [ ] Yes
- [ ] No

*Will the research involve subjects who are students or employees of the investigators?*
- [ ] Yes
- [ ] No

**Environmental Protection Agency (EPA) Oversight**

*Will you or others submit data from this research to the US Environmental Protection Agency (EPA)?*
- [ ] Yes
- [ ] No
Human Gene Transfer

*Does this research involve any form of human gene transfer as described in Section III-C of the NIH Guidelines?
○ Yes  ○ No

Institutional Services

*Will you conduct this research through an organization that has a contract or Master Services Agreement (MSA) to use Western IRB (WIRB) for IRB services?
○ Yes  ○ No

Name of organization relying on WIRB *(if known)*

WIRB Institution # of organization relying on WIRB *(if known)*

Principal Investigator (PI) Transfer

*Is the Principal Investigator (PI) taking over oversight from another PI?
○ Yes  ○ No

Because you have indicated that the Principal Investigator (PI) is taking over oversight from another PI:

Submit written permission from the sponsor to take oversight of this research. If the research is investigator-initiated, submit written permission from the Principal Investigator (PI) from whom you are taking oversight.

*Date previous PI left  *Effective date of the transfer  *Number of subjects currently enrolled

*Provide the name and contact information for the previous investigator:

*Describe:
● The reason for the transfer
● Who provided oversight during the previous PI’s absence
● Any subject safety concerns during the previous PI’s absence
● Any unreported information that required reporting per IRB "POLICY: Prompt Reporting Requirements"

Report any unreported information that required reporting per IRB "POLICY: Prompt Reporting Requirements" using the "Promptly Reportable Information Form." The policy and the form are on the IRB Web Site.
### Principal Investigator (PI) Specialty

*Is the Principal Investigator (PI) a physician?*
- [ ] Yes
- [ ] No

*National Provider Identifier (NPI) #*

Look up NPI# at [https://npiregistry.cms.hhs.gov](https://npiregistry.cms.hhs.gov)

*What are the demographics of the PI's patient/subject population?*
- [ ] Children
- [ ] Adults
- [ ] Both

**What are the specialties of the site?**

*Primary specialty*

*Specify:*

*Secondary specialty*

*Specify:*

*Which therapeutic area represents the majority of the PI's research:*

*Specify:*

*What is the name of the disease/condition represented by the majority of the PI's patient/subject population?*

### Principal Investigator (PI) Licensure

*Does the Principal Investigator have a medical license?*
- [ ] Yes
- [ ] No

*Are all medical licenses on file with the IRB?*
- [ ] Yes
- [ ] No

Because the Principal Investigator (PI) has a medical license:

⚠️ Submit copies of all current medical licenses showing the issuing authority, license number, and expiration date.
Principal Investigator (PI) Experience

*How many years has the PI conducted human research? (Enter 0 if less than 1 year)
*How many years has the PI conducted clinical trials? (Enter 0 if less than 1 year)
*What percentage of the PI's time is devoted to conducting clinical trials? (%)
*How many clinical trials has the PI previously been a PI or Sub-investigator?
*How many clinical trials is the PI currently conducting?
*Among the clinical trials that the PI is currently conducting, how many are open to enrollment?

Administrative Actions

*Has the Principal Investigator (PI) or any other personnel involved in this research had any of the following that has not been reported to this IRB:
  ● Conviction of a crime
  ● FDA Warning Letter
  ● NIDPOE (Noticed of Initiation of Disqualification Proceedings and Opportunity to Explain)
  ● Suspension or termination by an IRB
  ● Suspension by a federal or governmental agency (such as FDA, HHS, or Health Canada)
  ● OHRP Determination Letter, Health Canada Inspection Letter with observations, or similar
  ● Form FDA 483 in the past 5 years

- OR -

Has the Principal Investigator (PI) or any other personnel involved in this research had any of the following denied, revoked, suspended, reduced, limited, placed on probation, not renewed, relinquished, sanctioned, fined, or subject to disciplinary action that has not been reported to this IRB?
  ● Clinical privileges at any site
  ● DEA licensure
  ● Fellowship/board certification
  ● Medical licensure in any state, nation, or province
  ● Membership on any hospital staff
  ● Prescribing privileges
  ● Professional sanctions including fines and public reprimands
  ● Professional society membership
  ● Research privileges at any site

- OR -

Is there any action or investigation currently pending before any court of law, federal agency, or state licensing board concerning the professional conduct of the Principal Investigator (PI), or any other personnel involved in this research in that individual's capacity as a research investigator or as a clinician that has not been reported to this IRB?
  ○ Yes   ○ No

*List the individual(s) involved and their role(s) in the research:

*Provide the approximate start date(s) of occurrence:
*Name the entity(ies) issuing the action:

*Provide a detailed history and any management or corrective action plan currently in place:

*Are all related documents including resolution steps on file with this IRB?

- [ ] Yes
- [ ] No

Because there are current or past administrative actions where documents are NOT on file with the IRB:

Include in this submission copies of all documents related to the administrative action cited above including a description of the resolution steps.
The IRB does not routinely list addresses in this section in the consent form.

Physical address where subjects will be seen or research will take place:

*Company/Institution/Organization

*Address Line 1

Address Line 2

*City

*State

*Postal Code

*Province

State or Province

*Country

*Which of the following best describes this location's function?
- College/University
- Dialysis Center
- Hospital
- Medical Office
- Nursing Home
- Psychiatric Facility
- Research Clinic
- Other

*Describe the location's function:

Describe any additional resources available at this location that are relevant to this research: (e.g., interpreters, bilingual staff members, counselling services)

The following questions apply to all research locations

Phone numbers for subjects to call for questions or injury

*Daytime phone number

*24 hour phone number

*Do any communities around the above locations(s) have a negative attitude towards the conduct of research?
- Yes
- No

*Describe:
*Does a local IRB have jurisdiction over research over any of the above location? (If this site is covered by a Master Services Agreement (MSA) or is a member of our Global Research Network (GRN), you may check "No")

〇 Yes 〇 No

Because you indicated that another IRB has jurisdiction over one or more locations:

⚠️ Submit a "Reliance Agreement" available on the IRB Web Site for each site subject to local IRB jurisdiction

*Are there any state or local laws that impose additional requirements for research?

〇 Yes 〇 No

*Describe the stricter requirements and cite the law:


*Is the distance between any location and the main location greater than 50 miles (80 kilometers)?

〇 Yes 〇 No

*Explain how the PI will provide adequate oversight of the locations:


Site Management Organization (SMO) Information

*Is a Site Management Organization (SMO) involved with this research site?

〇 Yes 〇 No

*SMO name

Site Enrollment Estimate

*Planned number of subjects to be enrolled locally  

For information only. The IRB will not consider this estimate to be an enrollment limit for the site.

Research Team Information

*Indicate the number of investigators and research staff involved with the conduct this research:

*Physician Sub/Co-investigators

*Other Sub/Co-investigators

*Research Coordinators

*Other research staff
Research Team Training

The Principal Investigator (PI) must ensure that all investigators and research staff undergo training on the ethics and regulations of human subject protections before being involved in the conduct of this research. For clinical research, the Principal Investigator (PI) must ensure that all investigators and research staff undergo training on Good Clinical Practice (GCP).

*Have all investigators and research staff involved with the conduct of this research taken one or more of the following programs and all applicable training programs noted as required?

- ACRP Certified Clinical Investigator Training
- CenterWatch: Protecting Study Volunteers in Research
- Collaborative IRB Training Initiative (CITI)
- DIA Certified Investigator (CCI)
- SOCRA Clinical Research Professional (CRP)
- Tri-Council Policy Statement online training (TCPS)
- WCG Academy

☐ Yes  ☐ No

*Describe the training taken:


Prior IRB Review

*Has another IRB reviewed this research or site and decided to table, defer, disapprove, suspend, terminate, or decline to approve it?

☐ Yes  ☐ No

*Provide a detailed explanation of the previous reviews by other IRBs:


IRB Transfer

*Are you transferring IRB oversight from another IRB to this IRB?

☐ Yes  ☐ No

Because you have indicated that IRB oversight from another IRB to this IRB:

⚠️ Submit a completed "IRB Transfer" form available on the IRB Web Site along with copies of consent documents approved by the previous IRB

Consent

*Will subjects or their legally authorized representatives provide informed consent to take part in this research?

☐ Yes  ☐ No

Consent Waiver

*Explain why you are not obtaining consent:


Consent Setting

*Indicate the setting of the consent process:

- Private room
- Over the phone
- On-line
- Open Ward
- Waiting room
- Emergency setting
- Group setting
- In public
- Other or a combination of the above

*Provide additional information describing and justifying the consent setting:


Legally Authorized Representatives

*Will the research involve obtaining consent from legally authorized representatives (LARs)?

- Yes
- No

*How you will determine the capacity of cognitively impaired subjects:


*How will you verify who constitutes an LAR in the legal jurisdiction where the research is conducted?

- Legal counsel
- Institutional policy
- State/provincial/local law
- Other

*How will you verify who is an LAR in the legal jurisdiction where the research is conducted:


Consent Process

*Will the research team do all the following?

- Give the person providing informed consent as much time as they need to decide.
- If the person providing informed consent needs more time than is allowed by the research design, do not enroll the prospective subject.
- Evaluate whether the person providing informed consent is experiencing time pressure to decide, and stop enrolling prospective subjects if they need more time than allowed by the research design.
- Evaluate whether the person providing informed consent is experiencing time pressure to decide, and if so, do not enroll the prospective subject, even if the person providing informed consent agrees to be in the research.
- Ensure there is no threat of harm or adverse consequences to the prospective subject for a decision not to take part in the research.
- Stop the informed consent process once the person providing consent indicates that he or she does not want to take part in the research.
- Evaluate whether the person providing informed consent is being coerced or unduly influenced by others to take part in the research, and if so, not enroll the prospective subject, even if the person providing informed consent agrees to be in the research.
- Communicate in the preferred language of the person providing informed consent.
- Adapt the presentation of the information to the subject's capacities in terms of intelligence, rationality, maturity and language.
- Invite and answer questions from the person providing informed consent.
- Evaluate whether the person providing informed consent understands the information provided, and not enroll a prospective subject who does not understand, even if that person providing informed consent agrees to be in the research.
- Ensure that no information is provided to the prospective subject or the person providing informed consent that is made to waive or appear to waive any of the prospective subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
- Communicate to the person providing informed consent all the information in the consent document or script approved by the IRB.
- Not enroll a prospective subject when the person obtaining informed consent is unwilling to listen to or consider the information, even if the person providing informed consent agrees to be in the research.

☐ Yes  ☐ No

*Describe your process of consent:

Consent Documentation

*Will subjects or their legally authorized representatives (LARs) sign a written consent form?

☐ Yes  ☐ No

Consent Documentation Waiver

*Will you use a script or information sheet to provide consent information to subjects or their LARs?

☐ Yes  ☐ No

*Describe your plan to provide consent information to subjects or their LARs:
Consent Form Processing

*Does your organization have pre-approved consent language on file with the IRB?

○ Yes  ○ No

*Indicate how you want us to process consent forms:

○ The IRB should apply the pre-approved consent language to the IRB-approved template, or if not available, to the sponsor's most recent template. *(If you include a consent form with this submission, the IRB will not use it if there is a template on file.)*

○ The IRB should review the attached forms that have the pre-approved consent language tracked (red-lined) onto the IRB-approved template.

○ The IRB should review the attached forms that have the pre-approved consent language tracked (red-lined) onto the sponsor's most recent template

○ The IRB should add site-specific contact language to the currently approved template. *(If you include a consent form with this submission, the IRB will not use it if there is a template on file.)*

○ Other

*Describe:

Consent Documentation Process

*Will the research team do all the following?

● The investigator will give the person providing consent adequate opportunity to read the consent document before it is signed and dated

● The consent document will be signed and dated by the person providing consent

● The consent document will be signed and dated by the person obtaining consent

● A signed and dated copy of the consent document will be given to the person providing consent

● For a clinical trial: If the person proving consent cannot read, an individual who is independent of the trial, who cannot be unfairly influenced by people involved with the trial (*"impartial witness"*) will be present during the entire informed consent discussion and will sign and date the consent document to attest that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the person providing consent.

○ Yes  ○ No

*Describe your process for written documentation of consent:

HIPAA Waiver of Authorization

*What type of waiver of HIPAA authorization, if any, are you requesting?

○ Full waiver of authorization

○ Partial waiver of authorization for access to records for subject recruitment or screening

○ Partial waiver of authorization for waiver of signing an authorization form

○ None
By submitting this form, I confirm that:
- The research team will comply with HIPAA to secure the protected health information.
- The research team will use, reuse, or disclose protected health information only as allowed by HIPAA.

*Describe or list the identifiers planned to be used or disclosed?

*Explain why access to the protected health information is necessary:

*Describe the plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, or justify their retention:

*Explain why the research could not practicably be conducted without the waiver:

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

**Subject Payment Policy**

*Will you allow payments to subjects for participation?
- Yes  
- No

*Are sites required to follow the same amount and timing of payments?
- Yes  
- No

*Provide subject payment language using one of the methods described below:
- I have already incorporated subject payment language into documents submitted with this application
- I will provide subject payment information in this form for the IRB to incorporate into submitted documents

*List the submitted documents that include payment language:

Provide the word-for-word subject payment language to include in each consent document or script:
## Subject Payment Information

**Delete this payment description**

*Title or description of document to modify: (e.g., Main consent document, sub-study consent document)*

*Enter the word-for-word subject payment language to include in this document: (Describe the amount per milestone and the timing of payments)*

## Subject Payment

*Will you pay subjects for participation?*

- [ ] Yes
- [ ] No

*Provide subject payment language using one of the methods described below:*

- [ ] I have already incorporated subject payment language into documents submitted with this application
- [ ] I will provide subject payment information in this form for the IRB to incorporate into submitted documents

*List the submitted documents that include payment language:

Provide the word-for-word subject payment language to include in each consent document or script:

## Subject Payment Information

**Delete this payment description**

*Title or description of document to modify: (e.g., Main consent document, sub-study consent document)*

*Enter the word-for-word subject payment language to include in this document: (Describe the amount per milestone and the timing of payments)*
Secondary Research

*Select one:

- There is a possibility that identifiers might be removed from the identifiable private information or identifiable biospecimens, and after such removal, the information or biospecimens may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

- Subject information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

- The research does NOT involve the collection of identifiable private information or identifiable biospecimens.

Alternatives

*If a subject decides not to take part in the research are there any alternative procedures or courses of treatment that might be advantageous to the subject?

- Yes
- No

*List those alternatives and provide a brief description of each:

Confidentiality

Confidentiality refers to the agreements regarding how data will be managed and used.

*Will you comply with HIPAA?

- Yes
- No

*Will the research be covered by a Certificate of Confidentiality (COC)?

- Yes
- No

Methods to Maintain Confidentiality

*Will you maintain paper records and electronic equipment containing confidential information in a physically secure location?

- Yes
- No

*Will staff be trained on confidentiality procedures?

- Yes
- No

*Will you limit access to confidential data on a need to know basis?

- Yes
- No

*Will you remove identifiers as soon as feasible?

- Yes
- No

*Will you encrypt confidential data stored electronically? This includes data on desktop computers, servers, mobile devices (e.g., laptops, netbooks, tablets, cell phones), and on removable media (e.g., USB drives, removable hard drives, CD, DVD)?

- Yes
- No

*Will you encrypt confidential data transmitted over the Internet (including email)?

- Yes
- No
*Provide an explanation for each "NO" answer:


**Additional Methods to Maintain Confidentiality**

Describe any additional procedures to protect confidentiality: *(e.g., confidentiality agreements, coding)*


**Subject Privacy**

*Privacy refers to persons’ interest in controlling the access of others to themselves, such as the ability to control who sees them, hears them, touches them, and has access to their private information. Additional privacy interests include the time and place where individuals provide information, the nature of the information provided by the individuals, the nature of the individual’s experiences during the trial, and who receives and can use the information.*

*Will you or others perform procedures in a private setting?*

- Yes
- No

*Describe what procedures will be followed to protect the privacy of subjects:*


**Financial Interest Disclosure**

*The following question applies to financial interests that have not been previously reported to this IRB:*

*Does the Principal Investigator (PI), the PI's immediate family, or any other research personnel or their immediate families, have any of the following financial interests in an entity that is sponsoring the research, or an entity that is manufacturing the product or service being tested?*

- Any remuneration from the entity in the previous twelve months that exceeds $5,000, when aggregated for the individual and their immediate family. *(Remuneration includes salary and any payment for services not otherwise identified as salary, such as consulting fees, honoraria, or paid authorship)*
- Any equity interest in the entity. *(Equity interest includes any stock, stock option, or other ownership interest)*
- Any intellectual property rights and interests *(e.g., patents, copyrights)*
- Any governance or executive relationship with the entity *(e.g., board of director, CEO)*

- Yes
- No

Because there are individuals with unreported financial interests related to this research, complete a "Financial Interest Disclosure Form" on the IRB Web Site:

Include in this submission a completed "Financial Interest Disclosure Form" for each individual with unreported financial interests. The form is available on the IRB Web Site. If this disclosure changes, you are required to update this information within 5 business days.
Recruitment Bonuses

*Will the Principal Investigator (PI) or research team be offered recruitment bonuses? *(extra payments tied to the rate or timing of recruitment or enrollment)*

☐ Yes  ☐ No

Because you indicated that the Principal Investigator (PI) or research team will be offered recruitment bonuses: *(extra payments tied to the rate or timing of recruitment or enrollment)*

Submit a Recruitment Bonus Financial Disclosure Form along with any sponsor correspondence or materials describing the recruitment bonus program, or a copy of the budget for the research.

Subject Recruitment

*Will you or others recruit subjects for this research?*

☐ Yes  ☐ No

*Will all recruited subjects be individuals with whom the Principal Investigator (PI) has an existing relationship?*

☐ Yes  ☐ No

Select all recruitment methods. *(Scripts and advertisements must be IRB-approved before use)*

☐ In person  ☐ Database of individuals who agreed to be contacted

☐ Physician to physician referrals  ☐ Print advertisements

☐ Internet advertisements  ☐ Radio or television advertisements

☐ Telephone screening scripts  ☐ Site initiated communication

☐ Call center initiated communication

*Will you or others recruit subjects for this research using methods not listed above?*

☐ Yes  ☐ No

Describe the other methods you or others will use to recruit subjects for this research:


Canadian Research

Because you have indicated that the research will take place in Canada:

Submit a completed "Canadian Supplement" form available on the IRB Web Site

International Research

Because you indicated that research would be conducted outside of the United States and Canada, complete the following sections:
Country:

*Are there any laws in this country regarding human subject research? Include laws related to:
  ● IRB/ethics committee review
  ● Local IRB/ethics committee review
  ● Government approval
  ● Obtaining informed consent
  ● Compensation of subjects who are injured while taking part in research
  ● Involvement of vulnerable populations (e.g., indigenous persons, children, pregnant women, and cognitively impaired individuals) in research
  ○ Yes  ○ No

*Describe:


*Are there factors in this country that may affect the ethical acceptability or conduct of this research, such as socioeconomic conditions, ethnic diversity, or religious beliefs?
  ○ Yes  ○ No

*Describe


*Does the population in this country have a negative attitude towards the conduct of human subject research?
  ○ Yes  ○ No

*Describe:


*Are there any professional or medical ethics codes that govern the conduct of researchers in this country?
  ○ Yes  ○ No

*Describe:


*Is the approval of governmental agencies or officials required to conduct research in this country?
  ○ Yes  ○ No

*Describe:


*Will a local IRB or ethics committee review this research in this country?
  ○ Yes  ○ No

*Name of IRB or Ethics Committee
*Describe the arrangements for local oversight of the research:

*Contact information for the IRB or Ethics Committee chair or representative

Prefix  *First  Middle  *Last  Suffix

*Email  *Phone

Degrees

Mailing address for the above individual:

*Company/Institution/Organization

*Address Line 1

Address Line 2

*City  *State  *Postal Code

*Province

State or Province

*Country

☐ Copy this person on IRB correspondence

☐ Send continuing review forms to this person to be filled out and returned to the IRB

**Required Submission Materials for Protocol Only Submission**

To avoid processing delays, remove security/password protection from all submitted documents.

Submit the following documentation:

- This form with all questions marked with a * answered
- Final protocol (or most recent version with any applicable amendments)
- Supporting documents
- All information intended to be seen or heard by subjects, including:
  - Consent documents (in Microsoft Word compatible format)
  - Information sheets (in Microsoft Word compatible format)
  - Advertisements and recruitment scripts (Advertisements and recruitment materials and changes to advertisements and recruitment materials must be IRB approved before their use)
Initial Review Submission Form
HRP-212

Use Adobe version 11 or later (Reader or Acrobat)
Asterisked (*) fields are required.

Required Submission Materials for Site Only Submission

To avoid processing delays, remove security/password protection from all submitted documents.

Submit the following documentation:

- This form with all questions marked with a * answered
- Advertisements and recruitment scripts specific to your site (Advertisements and recruitment materials and changes to advertisements and recruitment materials must be IRB approved before their use)
- Curriculum vitae for the Principal Investigator (PI), if a current one is not already on file with the IRB

Required Submission Materials for Protocol and Site Submission

To avoid processing delays, remove security/password protection from all submitted documents.

Submit the following documentation:

- This form with all questions marked with a * answered
- Final protocol (or most recent version with any applicable amendments)
- Supporting documents
- All information intended to be seen or heard by subjects, including:
  - Consent documents (in Microsoft Word compatible format)
  - Information sheets (in Microsoft Word compatible format)
  - Advertisements and recruitment scripts (Advertisements and recruitment materials and changes to advertisements and recruitment materials must be IRB approved before their use)
- Curriculum vitae for the Principal Investigator (PI), if a current one is not already on file with the IRB

Additional Submission Materials Based on Previous Answers

Based on previous answers, include the following additional documentation with this submission:

Reason

For each organization involved with the research, submit the following unless already on file with the IRB:

1. Written documentation of the Federalwide Assurance (FWA)
2. A Master Services Agreement (MSA) or Institutional Authorization Agreement. (A template agreement is available on the IRB Web site.)

Submit:

1. Completed "Addendum for Department of Defense Funded Research" available on the IRB Web site
2. The agreement between organizations that specifies the roles and responsibilities of each party.
3. The specific requirements of research under the Department of Defense Addendum.

Because this research is funded, supported, or conducted by a United States federal department or agency, the organizations associated with the research locations are engaged in federal research:

Because the Department of Defense is funding the research:

Submit a completed "Translation Request" form available on the IRB Web Site

Because you have indicated that you need translated documents:

Submit the Investigator's Brochure(s) for the investigational drug(s).

Because you have indicated that the Investigator's Brochure is being submitted with this application:
Submit information from FDA documenting the IND number.  
Because you have indicated that the Principal Investigator (PI) holds the IND:

Submit the product labeling for the investigational devices(s).  
Because you have indicated that the product labeling is being submitted with this application:

Submit documentation of FDA's SR/NSR determination.  
Because you submitted this device to FDA for an SR/NSR determination:

Submit a brief explanation of why the device is not a significant risk device.  
Because you have indicated that the research is being conducted under the Abbreviated IDE (NSR) requirements:

Submit information from FDA documenting the IDE number.  
Because you have indicated that the Principal Investigator (PI) holds the IDE:

Submit written permission from the sponsor to take oversight of this research. If the research is investigator-initiated, submit written permission from the Principal Investigator (PI) from whom you are taking oversight.  
Because you have indicated that the Principal Investigator (PI) is taking over oversight from another PI:

Submit copies of all current medical licenses showing the issuing authority, license number, and expiration date.  
Because the Principal Investigator (PI) has a medical license:

Include in this submission copies of all documents related to the administrative action cited above including a description of the resolution steps.  
Because there are current or past administrative actions where documents are NOT on file with the IRB:

Submit a "Reliance Agreement" available on the IRB Web Site for each site subject to local IRB jurisdiction  
Because you indicated that another IRB has jurisdiction over one or more locations:

Submit a completed "IRB Transfer" form available on the IRB Web Site along with copies of consent documents approved by the previous IRB  
Because you have indicated that IRB oversight from another IRB to this IRB:

Include in this submission a completed "Financial Interest Disclosure Form" for each individual with unreported financial interests. The form is available on the IRB Web Site. If this disclosure changes, you are required to update this information within 5 business days.  
Because there are individuals with unreported financial interests related to this research, complete a "Financial Interest Disclosure Form" on the IRB Web Site:

Submit a Recruitment Bonus Financial Disclosure Form along with any sponsor correspondence or materials describing the recruitment bonus program, or a copy of the budget for the research.  
Because you indicated that the Principal Investigator (PI) or research team will be offered recruitment bonuses: (extra payments tied to the rate or timing of recruitment or enrollment)

Submit a completed "Canadian Supplement" form available on the IRB Web Site  
Because you have indicated that the research will take place in Canada:
Special Instructions

Provide any special instructions or additional relevant information for this submission:

How to Send Your Submission to the IRB and Access IRB-Approved Documents

Submit this form and all supporting documents through the Connexus Web Portal or IRBNet. If you submit documents by email, mail, or facsimile, you may be charged additional administrative fees.

The IRB provides approved documents through the Connexus Web Portal. If you use IRBNet, the IRB also publishes documents into IRBNet.

If you do not use IRBNet, register with the Connexus Web Portal. Contact the IRB for assistance with registering.
Acknowledgement

By submitting this form, I confirm that:

- The information within this form is accurate and complete.
- Sites will have the emergency equipment required by the protocol.
- I am the Principal Investigator (PI) or the PI's designee authorized to submit on behalf of the PI.
- The PI has full awareness of the information within this form.

By submitting this form, I confirm that the investigators conducting this research will:

- Not commence research until receipt of the IRB approval letter.
- Comply with all requirements and determinations of the IRB.
- Protect the rights, safety, and welfare of subjects involved in the research.
- Personally conduct or supervise the research.
- Conduct the research in accordance with the relevant current protocol approved by the IRB.
- Ensure that there are adequate resources to carry out the research safely.
- Ensure that research staff are qualified to perform procedures and duties assigned to them during the research, including completion of human subject protection training.
- Submit proposed modifications to the IRB prior to their implementation.
  - Not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
- Submit continuing review reports when requested by the IRB.
- Submit a closure form to close research (end the IRB's oversight) when:
  - The protocol is permanently closed to enrollment
  - All subjects have completed all protocol related interventions and interactions
  - For research subject to federal oversight other than FDA:
    - No additional identifiable private information about the subjects is being obtained
    - Analysis of private identifiable information is completed
  - If research approval expires, stop all research activities and immediately contact the IRB.
- Promptly report to the IRB the information items listed in the IRB's "Prompt Reporting Requirements" available on the IRB's Web site.
- Not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.")
- Not accept payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.
- When required by the IRB ensure that consent, permission, and assent are obtained and documented in accordance with the relevant current protocol as approved by the IRB.
- Notify the IRB within 5 business days of any change to information provided on this form.

By submitting this form, I confirm that the individual and/or organization agrees to promptly communicate or provide, and where necessary cause each investigator to promptly communicate or provide, the following information relevant to the protection of human subjects to the IRB in a timely manner:

- Upon request of the IRB, a copy of the written plan between sponsor or CRO and site that addresses whether expenses for medical care incurred by human subject research subjects who experience research related injury will be reimbursed, and if so, who is responsible in order to determine consistency with the language in the consent document.
- Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation. Such reports will be provided to the IRB within 5 days.
- Reports from any data monitoring committee, data and safety monitoring board, or data and safety monitoring committee in accordance with the time frame specified in the research protocol.
- Any findings from a closed research when those findings materially affect the safety and medical care of past subjects. Findings will be reported for 2 years after the closure of the research.
Initial Review Submission Form

HRP-212

Use Adobe version 11 or later (Reader or Acrobat)
Asterisked (*) fields are required.

Person Completing This Form

Prefix   *First   Middle   *Last   Suffix

*Email   *Phone

Company/Institution/Organization (optional, but preferred)

Check Submission for Completeness

Click here to check the form for incomplete entries:

Notice

We continually improve our forms. This form will be replaced by an updated version at least 30 days before: 01 Apr 2019
This form cannot be edited after this date. Download the latest version from the IRB Web site before this date.

For IRB use only: