**Initial Review Submission Form (HRP-212)**

If your answer does not fit in the space provided, you may refer to and submit separate attachments.

(Handwritten submissions are not accepted.)

***Blank & incomplete answers to required questions will result in delayed reviews.***

**This form contains the following sections:**

* [Submission information: 1](#_Toc189723399)
* [Protocol information: 2](#_Toc189723400)
* [Device Information: (skip this section if the research is not a clinical trial of a device) 3](#_Toc189723401)
* [Drug Information: (skip this section if the research is not a clinical trial of a drug) 4](#_Toc189723402)
* [Change of Principal Investigator 4](#_Toc189723403)
* [Vulnerable Populations: 5](#_Toc189723404)
* [Consent: 5](#_Toc189723405)
* [Consent documentation waiver: 7](#_Toc189723406)
* [Sponsor/CRO Contact Information: 9](#_Toc189723407)
* [Principal Investigator (PI) Information: 11](#_Toc189723408)
* [SMO Information (optional) - In this section list SMO contacts for the IRB to enter into its internal system. 11](#_Toc189723409)
* [Study coordinator(s) (optional) - In this section list contacts for the IRB to enter into its internal system. 13](#_Toc189723410)
* [Subject Payment: 14](#_Toc189723411)
* [Confidentiality: Confidentiality refers to the agreements regarding how data will be managed and used. 14](#_Toc189723412)
* [Site information: 15](#_Toc189723413)
* [Research Location(s): 17](#_Toc189723414)
* [IRB Billing Information 18](#_Toc189723415)
* [Special Instructions: 18](#_Toc189723416)
* [Acknowledgements: 18](#_Toc189723417)
* [NAME OF PERSON COMPLETING THIS FORM: 19](#_Toc189723418)

# Submission information:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Is this submission for a Phase One - Healthy Subject Clinical Trial? | | | Yes | | No | |
|  | Is this study to be processed through IRB+?  (IRB+ provides a premium service for your study with personalized oversight and accelerated processing time.) | | | Yes | | No | |
|  | Protocol title: | | | | | | | |
| Sponsor's protocol ID *(if applicable):* | IRB protocol number/tracking number *(if known):* | | | | | | |
| Sponsor: | | | | | | | |
|  | Indicate the type of submission:  New protocol with no Principal Investigator (PI) or site information  New protocol and Principal Investigator (PI) (combined submission)  Site being added to existing protocol, or change of Principal Investigator (PI) -> [**Skip to question 23 below**](#vuln)**.**  *Note: 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*](https://www.wcgclinical.com/irb-resources/irb-forms/)*.* | | | | | | | |
|  | If WCG 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?  For research to be exempt from regulation, the research must be limited to:   * evaluation of educational methods * surveys/interviews/focus groups * benign behavioral interventions * use/review of specimens/information collected for purposes other than the proposed research * federal demonstration projects * evaluation of taste and food quality   For more information, see 45 CFR 46.104(d) | | Yes | | No | |

# Protocol information:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Multi-site Studies Central IRB:  A multi-site study is when more than one Principal Investigator/site is being recruited for a specific protocol. A central IRB is a single IRB that reviews and monitors research for all sites under the research protocols. If there is more than one Principal Investigator for this research – **has the Sponsor/CRO designated this IRB as the central IRB for most sites or the single IRB for this study?** | Yes | No |
|  | Will subjects be required to pay for the investigational product? If yes, how much? | \*Yes | No |
|  | **\*If yes**, please provide details: | | |
|  | Is this research funded, supported, or conducted by a United States federal department or agency? | \*Yes | No |
|  | **\*If yes**, for each organization involved with the research, submit the following unless already on file with the IRB:   * Written documentation of the Federalwide Assurance (FWA) * An Institutional Authorization Agreement (not necessary if your organization has an MSA with WCG IRB) | | |
|  | **\*If yes,** indicate the federal department or agency funding the research:  If the **Department of Defense** is funding the research, submit:   * Completed "Addendum for Department of Defense Funded Research" available on the IRB Web site * The agreement between organizations that specifies the roles and responsibilities of each party. * The specific requirements of research under the Department of Defense Addendum. * Please note each individual initial review submission will need to include their own form. | | |
|  | Will you or others post the research on ClinicalTrials.gov? | \*Yes | No |
|  | **\*If yes**, 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 |
|  | 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. | | |
|  | Has **another IRB reviewed** this research or site and decided to table, defer, disapprove, suspend, terminate, or decline to approve it?  **\*If yes**, provide a detailed explanation of the previous reviews by other IRBs | \*Yes | No |
|  | Will you or others submit data from this research to the US Environmental Protection Agency (**EPA**)? | Yes | No |
|  | Does this research involve any form of human gene transfer as described in Section III-C of the NIH Guidelines? | Yes | No |
|  | Does this study require an independent **Data Monitoring Committee / Data Safety Monitoring Board**? | \*Yes | No |
|  | **\*If yes**, has a service provider already been selected? | \*Yes | No |
|  | **\*If yes**, provide the name of the service provider: | | |
|  | Does this study require an **Endpoint Adjudication Committee**? | \*Yes | No |
|  | **\*If yes**, has a service provider already been selected? | \*Yes | No |
|  | **\*If yes**, provide the name of the service provider: | | |

|  |  |
| --- | --- |
|  | This research is for a clinical trial of a... (select all that apply):  Device  Drug  Other – Describe: |

# Device Information: (skip this section if the research is not a clinical trial of a device)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Are you conducting the research under an Investigation Device Exemption (IDE)?  **\*If no**, **go to** [**question 19**](#Abbreviated_IDE) | Yes | \*No |
|  | If under an IDE:  IDE#:  Device Name: | | |
|  | The IRB should use the product labeling for the Investigational device(s) that is:  Available on-line - Provide the Internet addresses that link to the product labeling for the investigational devices(s):  Submitted with this application - **Submit the product labeling for the investigational devices(s)**.  On file already with WCG IRB | | |
|  | Does the investigator hold the IDE?  **\*If yes,** submit information from FDA documenting the IDE number. | \*Yes | No |
|  | Are you conducting the research under the **Abbreviated IDE (Non-Significant Risk [NSR])** requirements?  **\*If yes,** device name: | \*Yes | No |
|  | Have you submitted this device to FDA for an SR/NSR (significant risk/non-significant risk) determination?  **\*If yes**, submit documentation of FDA's SR/NSR determination.  **\*\*If no**, submit a brief explanation of why the device is not a significant risk device. | \*Yes | \*\*No |
|  | Are you conducting the research to evaluate an FDA-approved device? | \*Yes | No |
|  | **\*If yes**, 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: | | |

# Drug Information: (skip this section if the research is not a clinical trial of a drug)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Are you conducting the research under an Investigational New Drug Application (IND)?  **\*If no**, **go to** [**question 22**](#not_IND) | Yes | \*No |
|  | If under an IND:  IND#:  Drug Name(s): | | |
|  | The IRB should use the investigator brochure that is:  Available on-line - Provide the Internet addresses that link to the investigator brochure:  Submitted with this application - **Submit the investigator brochure(s) for the investigational drug(s)**.  On file already with WCG IRB | | |
|  | Does the investigator hold the IND?  **\*If yes,** submit information from FDA documenting the IND number. | \*Yes | No |
|  | If not under an IND, select one:  IND Exempt: Marketed Drug with no change in risk  IND Exempt: Non-drug research (food, dietary supplement, infant formula, or substance Generally Recognized As Safe [GRAS])  HCT/P  In Vitro Diagnostic Biologic Product  Radioactive drugs being used to assess physiology  Placebo  Cold Isotope  Bioequivalence Study | | |

# Change of Principal Investigator

|  |  |  |  |
| --- | --- | --- | --- |
|  | Is the Principal Investigator (PI) taking over oversight from another PI? | \*Yes | No |
|  | **\*If yes,**   * **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. | | |
|  | **\*If yes**,   * Name and contact information for the current investigator: * Date previous PI leaving/left: * Effective date of the transfer: * Number of subjects currently enrolled: * Reason for the transfer:   **Note:** Report any unreported information that required reporting per IRB '[POLICY: Prompt Reporting Requirements](https://www.wcgclinical.com/wp-content/uploads/2020/08/IRB.POL_.HRP_.071-Prompt-Reporting-Requirements_v4.0_website.pdf)' by creating a separate submission for a "Promptly Reportable Disclosure". For more information on what is required to be reported view the HRP-070 and HRP-071 Policy resources located at <https://www.wcgclinical.com/irb-resources/additional-irb-resources/>. | | |
|  | Has the previous PI already left?  **\*If yes,**   * Who provided oversight during the previous PI's absence?: * Report any subject safety concerns during the previous PI's absence as outlined in the note above. | \*Yes | No |

# Vulnerable Populations:

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Select all populations your research will involve, if any.**  **Leave all boxes unchecked if none apply.**  Subjects who are adults unable to consent  Subjects who are children  Children who are wards of the state  Non-viable neonates. *By selecting this box, you 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.*  Neonates of uncertain viability. *By selecting this box, you confirm that individuals engaged in the research will have NO part in determining the viability of a neonate.*  Subjects who are prisoners. *By selecting this box, you confirm that parole boards will NOT take into account a prisoner's participation in the research in making decisions regarding parole*  Subjects who are pregnant at enrollment. *By selecting this box, you 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.*  Subjects who become pregnant while on study. *By selecting this box, you confirm 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.* | | |
|  | Will the research involve subjects who are students or employees of the investigators? | Yes | No |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Are you **transferring IRB oversight** from another IRB to this IRB?  **\*If yes**, submit a completed ["IRB Transfer" form](https://www.wcgclinical.com/wp-content/uploads/2020/08/IRB-Transfer-Cover-Letter-Checklist-Summary-v-01-12-2024.doc) available on the [WCG Web Site](https://www.wcgclinical.com/irb-resources/irb-forms/) along with copies of consent documents approved by the previous IRB | \*Yes | No |

# Consent:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Will subjects or their representatives provide informed consent to take part in this research?  **\*If no** –   * Explain why you are not obtaining consent: * By submitting this form, you affirm that the research will exclude individuals who were asked to provide broad consent per 45 CFR §46.104(d)(7) for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens being used in this research, and refused to consent. * **Skip to** [**question 34**](#hipaa_waiver)**.** | Yes | \*No |
|  | Indicate the setting of the consent process:  Private room  Waiting room\*  Over the phone\*  On-line\*  Open Ward\*  Emergency setting\*  Group setting\*  In public\*  Other\*. Describe: | | |
|  | \*For all locations selected above that are not “private room”, provide additional information describing and justifying the consent setting: | | |
|  | 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, not enroll the prospective subject.* * *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 to not 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 |
|  | **\*If no,** describe your process of consent: | | |
|  | Would you like WCG to maintain a Protocol-Level Template Consent Form?  **\*If yes**, submit the Sponsor’s Template Consent Form | \*Yes | No |
|  | Will subjects or their representatives sign a written consent form?  **\*\*If no**, skip to section on [consent documentation waiver](#doc_waiver) below. | \*Yes | \*\*No |
|  | **\*If yes,** how will signatures be obtained?  Wet Ink  Electronic\*  Both\* | | |
|  | **\*If electronic (or “both”)**, is the signature documentation on the online consent form FDA Part 11 compliant as a legal signature (for more information see FDA Part 11, Electronic Records; Electronic Signatures - Scope and Application)?  **\*If no,** provide more information regarding the status of the platform used to collect electronic signatures: | Yes | \*No |
|  | 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 providing 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 |
|  | **\*If no**, describe your process for written documentation of consent: | | |

# Consent documentation waiver:

|  |  |  |  |
| --- | --- | --- | --- |
|  | If subjects or their representatives will not sign a written consent form: will you use a script or information sheet to provide consent information to subjects or their representatives?  **\*If no**, describe your plan to provide consent information to subjects or their representatives: | Yes | \*No |
|  | HIPAA Waiver of Authorization:  *Clinical investigators need to assess if they are a covered entity as defined by the Office for Civil Rights. All PIs who are covered entities must have HIPAA Authorization language for potential participants for study-related medical records to be available for review by the sponsor, CRO, IRB, and regulatory bodies. For your studies under the approval of WCG IRB, your HIPAA authorization language must be submitted to and be approved prior to its use.*  *WCG IRB will review research materials to determine how the privacy and confidentiality of participants' personal health information is protected in accordance with applicable laws and regulations. The burden of HIPAA compliance rests with the covered entity.*  *Researchers who are covered entities and do not wish to request a waiver, may satisfy the HIPAA requirement for authorization by choosing one of the following alternative methods:*   * *Obtain a HIPAA compliant signed authorization from the research participant using a stand-alone document that the covered entity has created; or* * *Incorporate the HIPAA language into the ICF and submit to WCG IRB for review in accordance with applicable laws; or* * *Attach an addendum that contains the HIPAA language to the ICF and submit to WCG IRB for review in accordance with applicable laws.*   *WCG IRB will review authorization language upon the request of a covered entity. If the authorization language is embedded in the research consent document, then the IRB must review it. If the authorization language is separate from the research consent document, then the covered entity may determine whether or not to submit the language for IRB review. WCG IRB will review separate authorization documents upon request.*  Indicate which of the following HIPAA waivers, if any, you are requesting::   * None * Full Waiver (complete the questions below) * Partial waiver of authorization for access to records for subject recruitment or screening (complete the questions below) * Partial waiver of authorization for waiver of signing an authorization form (complete the questions below) | | |
|  | For requests for approval of a HIPAA waiver, 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: | | |

# Sponsor/CRO Contact Information:

In this section list contacts for the IRB to enter into its internal system. These contacts should be individuals who can answer questions the IRB staff may have about the research. These contacts will be listed on Certificates of Action in the cc section and will also receive notifications from the IRB’s internal system, including the Continuing Review Report Forms that the system generates each year.

|  |  |
| --- | --- |
|  | **Sponsor** **Contact** Name:       **or**  NA/not known  Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code)        This is a sponsor contact for all Principal Investigators under this research |
|  | **Optional**:  **Sponsor Contact** **#2** Name:  Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code)        This is a sponsor contact for all Principal Investigators under this research |
|  | **Optional:**  **Sponsor Contact** **#3** Name:  Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code)        This is a sponsor contact for all Principal Investigators under this research |
|  | **Optional:**  **Sponsor Contact** **#4** Name:  Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code)        This is a sponsor contact for all Principal Investigators under this research |
|  | **Optional:**  **Sponsor Contact** **#5** Name:  Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code)        This is a sponsor contact for all Principal Investigators under this research |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Is a **CRO** involved in the research?  **\*If yes, CRO company name:** | \*Yes | No |
|  | **CRO Contact Name**:  Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code)        This is a CRO contact for all Principal Investigators under this research | | |
|  | **Optional**:  **CRO Contact #2 Name**:  Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code)        This is a CRO contact for all Principal Investigators under this research | | |
|  | **Optional**:  **CRO Contact #3 Name**:  Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code)        This is a CRO contact for all Principal Investigators under this research | | |
|  | **Optional**:  **CRO Contact #4 Name**:  Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code)        This is a CRO contact for all Principal Investigators under this research | | |
|  | **Optional**:  **CRO Contact #5 Name**:  Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code)        This is a CRO contact for all Principal Investigators under this research | | |

*If you’d like more contacts added than space is available for here, please add them to the Special Instructions field at the end of this form.*

# Principal Investigator (PI) Information:

|  |  |  |  |
| --- | --- | --- | --- |
|  | PI Name:  PI Degree(s):  PI Company Name:  PI Mailing Address: (street, city, state, postal code)        PI Phone:  PI E-mail: | | |
|  | Is the Principal Investigator (PI) a physician?  **\*If yes:**  Specialty:  National Provider Identifier (NPI) #:       (Look up NPI# at <https://npiregistry.cms.hhs.gov>) | \*Yes | No |
|  | Does the Principal Investigator have a medical license? | \*Yes | No |
|  | Are all medical licenses on file with the IRB?  **\*If no**, submit copies of all current medical licenses showing the issuing authority, license number, and expiration date. | \*Yes | No |

# SMO Information (optional) - In this section list SMO contacts for the IRB to enter into its internal system.

These contacts should be individuals who can answer questions the IRB staff may have about the research. These contacts will be listed on Certificates of Action in the cc section and will also receive notifications from the IRB’s internal system, including the Continuing Review Report Forms that the system generates each year.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Is a Site Management Organization (SMO) involved with this research site?  **\*If yes,** SMO Name: | \*Yes | No |
|  | **SMO Contact Name**:       **or**  NA  Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code) | | |
|  | **Optional:**  **SMO Contact #2** Name:        Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code) | | |
|  | **Optional:**  **SMO Contact #3** Name:        Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code) | | |
|  | **Optional:**  **SMO Contact #4** Name:        Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code) | | |
|  | **Optional:**  **SMO Contact #5** Name:        Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code) | | |

*If you’d like more contacts added than space is available for here, please add them to the Special Instructions field at the end of this form.*

# Study coordinator(s) (optional) - In this section list contacts for the IRB to enter into its internal system.

These contacts should be individuals who can answer questions the IRB staff may have about the research. These contacts will be listed on Certificates of Action in the cc section and will also receive notifications from the IRB’s internal system, including the Continuing Review Report Forms that the system generates each year.

|  |  |
| --- | --- |
|  | **Study Coordinator** Name:       **or**  NA  Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code) |
|  | **Optional:**  **Study coordinator #2** Name:        Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code) |
|  | **Optional:**  **Study coordinator #3** Name:        Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code) |
|  | **Optional:**  **Study coordinator #4** Name:        Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code) |
|  | **Optional:**  **Study coordinator #5** Name:        Phone:  E-mail:  Mailing Address (optional): (street, city, state, postal code) |

*If you’d like more contacts added than space is available for here, please add them to the Special Instructions field at the end of this form.*

# Subject Payment:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Will subjects be paid for participation?  *(this includes any monetary payments for traveling/parking/transportation/meal reimbursements, etc.; not strictly payment for participation)*  **\*If yes, provide the details below.** | \*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. List the submitted documents that include payment language:  OR  Below is the payment information for the IRB to incorporate into consent forms:   * Include any monetary payments for participation, including traveling/parking/transportation/meal reimbursements, etc. * Provide the word-for-word subject payment language to include in each consent document or script, OR if you are following the sponsor's IRB-approved template, provide the amount for each fill-in blank and whether to include any optional language. * Enter the word-for-word subject payment language to include in this document. Include both:   + **The amount per milestone** (e.g., amount per visit, amount at completion) and   + **When** payments are made (e.g., at each visit, monthly, quarterly, at completion)     **If you will have multiple consent forms with different payment language, please list the payment language for each additional consent form**:  Name of consent document:  Payment information:  Name of consent document:  Payment information:  Name of consent document:  Payment information: | | |
|  | Daytime phone number for subjects to call for questions or injury: | | |
|  | 24 hour phone number for subjects to call for questions or injury (required for drug, device studies): | | |

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

|  |  |  |  |
| --- | --- | --- | --- |
|  | Will you be subject to and in compliance with HIPAA?  **If yes,** please skip to next section.  **\*If no, please answer the questions below.** | Yes | \*No |
|  | Will the research be covered by a Certificate of Confidentiality (COC)? | Yes | No |
|  | Will you maintain paper records and electronic equipment containing confidential information in a physically secure location?  **\*If no**, explain: | Yes | \*No |
|  | Will staff be trained on confidentiality procedures?  **\*If no**, explain: | Yes | \*No |
|  | Will you limit access to confidentiality data on a need to know basis?  **\*If no**, explain: | Yes | \*No |
|  | Will you remove identifiers as soon as feasible?  **\*If no**, explain: | Yes | \*No |
|  | Will you encrypt confidential data stored electronically? This includes data on a 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)?  **\*If no**, explain: | Yes | \*No |
|  | Will you encrypt confidential data transmitted over the Internet (including email)?  **\*If no**, explain: | Yes | \*No |
|  | Describe any additional procedures to protect confidentiality: (e.g., confidentiality agreements, coding): | | |

# Site information:

|  |  |  |  |
| --- | --- | --- | --- |
|  | 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?  **\*If no**, describe what procedures will be followed to protect the privacy of subjects: | Yes | \*No |
|  | Will you conduct this research through an organization that has a contract or Master Services Agreement (MSA) to use WCG IRB for IRB Services? | \*Yes | No |
|  | **\*If yes**,   * Name of organization relying on WCG IRB (if known): * WCG IRB Institution # of organization relying on WCG IRB (if known): | | |
|  | Site Enrollment Estimate (*WCG IRB will not consider this estimate to be an enrollment limit for the site*.) What is the planned number of subjects to be enrolled locally? | | |
|  | 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:  Principal Investigator (PI) Experience: | | |
|  | 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? | | |
|  | 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 any entity that is sponsoring the research, or an entity that is manufacturing the product or service being tested, not reported to this IRB in previous submissions for this protocol?   * Any remuneration from the entity in the previous twelve months that exceeds $5,000, when aggregated for the individual and their immediate family * Any equity interest in the entity * Any intellectual property rights and interests * Any governance or executive relationship with the entity | \*Yes | No |
|  | **\*If yes,** complete and submit the Financial Interest Disclosure Form available [here](https://www.wcgclinical.com/wp-content/uploads/2020/08/HRP-216.doc) for each individual with a reportable interest. | | |
|  | The Principal Investigator and Research Study Staff are required to have human subjects protections training.  Please select all trainings that the investigator and research staff have undergone from the below list.  *If you have completed a different training not listed, please describe the training and confirm it included human subject protections training.*  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  WCG InvestigatorSpace® Training  Human Research Protection Foundational Training (OHRP)  Other – Describe: | | |
|  | 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:   * 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 |
|  | **\*If yes**, 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?  **\*If no**, include in this submission copies of all documents related to the administrative action cited above including a description of the resolution steps. | Yes | \*No |

# Research Location(s):

If you need to submit more than one location, please complete the standalone location form for each additional one, available on the [WCG Clinical website](https://www.wcgclinical.com) [**here**](https://www.wcgclinical.com/wp-content/uploads/2024/06/IR_Additional_Sites_Form.docx).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | Site #1:  Name of Research Location:  Physical Address: (street, city, state/province, postal code, country) (must match part 3 of Canadian QIU form, if applicable)    Site number assigned by sponsor (optional): | | | |
|  | | Which of the following best describes this location's function?  Medical Office or Research Clinic  Hospital  College/University or Academic Medical Center  Other (specify): | | | |
|  | | Does a local IRB have jurisdiction over research over any of the above locations? (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")  **\*If yes**, Submit a "Reliance Agreement" [available on the WCG Clinical Web Site](https://www.wcgclinical.com/irb-resources/irb-forms/) for each site subject to local IRB jurisdiction. | | \*Yes | No |
|  | | Describe any additional resources available at this location that are relevant to this research: **(optional)** | | | |
|  | Do any communities around the above location have a negative attitude towards the conduct of research?  **\*If yes**, describe: | | \*Yes | No |
|  | Are there any state or local laws that impose additional requirements for research?  \*If yes, describe the stricter requirements and cite the law: | | \*Yes | No |
|  | Is the distance between any location and the main location greater than 50 miles (80 kilometers)?  **\*If yes**, Explain how the PI will provide adequate oversight of the locations: | \*Yes | No | There is only one site |

# IRB Billing Information

|  |  |
| --- | --- |
|  | All submissions must be accompanied by a completed copy of our [Billing Information Stand-Alone Form](https://www.wcgclinical.com/wp-content/uploads/2021/11/Billing-Information-Stand-alone-Form-v-01-12-2024.docx). Please download a copy, complete it and send it along with your submission.  ***PAYMENT TERMS: Invoices are due net 30 days unless otherwise agreed to in writing. Late payments may be subject to a monthly finance charge of 1.5% of the amount owed from the due date until payment in full. WCG IRB shall be entitled to recover all reasonable attorneys' fees, costs and expenses associated with any efforts to recover payment for overdue invoices.*** |

# Special Instructions:

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

# Acknowledgements:

By submitting this form, I confirm and understand the following acknowledgements.

* The information within the submitted documents is accurate and complete.
* I am authorized to submit on behalf of the sponsor or the PI.

By submitting this form, I confirm that the investigator named in it will:

* Not commence research until receipt of the IRB approval letter.
* Comply with all requirements and determinations of the IRB.
* Have the emergency equipment required by the protocol.
* 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 (within 5 days) report to the IRB the information items listed in the IRB's "[Prompt Reporting Requirements](https://www.wcgclinical.com/wp-content/uploads/2020/08/IRB.POL_.HRP_.071-Prompt-Reporting-Requirements_v4.0_website.pdf)” available on the [WCG’s Web site](https://www.wcgclinical.com/irb-resources/additional-irb-resources/).
* 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”).
* 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, provide 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.
* Provide 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.
* Provide 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.
* Provide any findings from 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.

# NAME OF PERSON COMPLETING THIS FORM:

Please tell us who you are and how we can contact you if we have questions about this form.

|  |  |  |
| --- | --- | --- |
| Printed or Typed Name of Person Completing This Form Date    Company & Title  ()  Phone number E-mail address | | |
| Should the submitter be added as a contact for this research?\*  (\*Contacts may be asked questions about the research by IRB staff, will be listed on Certificates of Action in the cc section and will also receive notifications from the IRB’s internal system, including the Continuing Review Report Forms that the system generates each year.) | Yes | No |