**Change In Research Form (HRP-201)**

Use this form to request IRB approval for a modification to approved research.

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

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

# Identifying Information:

|  |  |
| --- | --- |
| Protocol title: | |
| Sponsor's protocol ID *(if applicable):* | IRB protocol number/tracking number *(if known):* |
| Protocol version date *(if applicable):* | Protocol version number *(if applicable)*: |
| Sponsor: | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | Is this submission for a Phase One - Healthy Subject Clinical Trial? | Yes | No |
|  | Who is submitting?  Sponsor or Contract Research Organization (CRO)  Site Management Organization (SMO)  Site | | |
|  | Does this update apply to all sites?  Yes  No, this is only applicable to select investigator(s) – List investigator(s):  No, review for the study only | | |

**Select the type(s) of request(s) you’d like to make – The sections are collapsed by default, click the arrow next to the heading to expand or collapse each heading:**

## Protocol revision, amendment, or administrative letter:

If you are submitting a revised protocol, providing a red-lined version with changes tracked in addition to the clean version will expedite processing.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Required elements for this type of change:   * Rationale for the change * Summary of changes and/or redline of changes   Provide a summary of and a rationale for the changes, or indicate the submitted documents that include this information: | | |
|  | Are you submitting a modified or new consent form related to the protocol revision/amendment/administrative letter?  **\*If yes, complete the consent form section below.** | \*Yes | No |

## Consent Form:

If there is a change of mailing address or phone number of a PI or other contact related to a change in address of a research location, check "Change address of a research location" in the "Submitted Changes" section and follow directions in that section. Otherwise, submit a "Contact Change" form with this application.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Type of change:  Addition of new consent form(s)  Revision of currently IRB-approved consent forms  Both additional and revision | | |
|  | I confirm that my requested changes have been tracked onto the most recent WCG IRB-Approved Consent Form in Word format. I understand that failure to provide the required documentation will result in a hold and delayed review. | | |
|  | If you have a preference for which subjects you want to re-consent (e.g., subjects on study drug, future subjects, all subjects), describe your preference here and provide your rationale.   * Preference: * Rationale: | | |
|  | Will you need translated documents or approval of translated documents? | Yes | No |

## Investigator’s Brochure (Drug or Device Brochure):

Please note, when WCG IRB receives an updated drug brochure, DSMB reports, or related prescribing information, WCG IRB will automatically process for all investigator sites (the ensuing "approved" action indicates that the IRB has the document on file for the research).

|  |  |
| --- | --- |
|  | Select one (or both) of the following as applicable:  The Investigator’s Brochure (Drug or Device Brochure) was previously submitted  The Investigator’s Brochure (Drug or Device Brochure) is attached to this submission |

## Planned protocol deviation:

|  |  |
| --- | --- |
|  | Because you are requesting approval of a planned protocol deviation, **i**ndicate the parties that are in agreement with the planned protocol deviation (e.g., PI, sponsor, medical monitor) and **submit correspondence that documents the agreement of the involved parties** with the planned protocol deviation: |
|  | Latest date the protocol deviation can be approved: |
|  | Describe the planned protocol deviation: |
|  | Explain why the action you want to take is inconsistent with the protocol: |
|  | Provide the rationale for the planned deviation: |

## Recruitment methods:

|  |  |
| --- | --- |
|  | Describe the changes to the currently approved recruitment plans: |

## Subject materials (Advertisements, scripts, recruitment materials, retention materials, diaries, ID cards, etc.):

|  |  |  |  |
| --- | --- | --- | --- |
|  | Type of change:  Addition of new subject materials  Revision of previously IRB-approved subject materials  Both additional and revision | | |
|  | Will you need translated documents or approval of translated documents? | Yes | No |

## Subject Payment:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Will you pay subjects for participation?  (this includes any monetary payments such as traveling/parking/transportation/meal reimbursements etc.; not strictly just 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: | | |

## Phone Numbers for Subjects:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Daytime Phone Number:  24 Hour Phone Number: | | |
|  | Are the phone numbers listed on consent forms being updated at this time?  **\*If yes, complete the consent form section in this form above.** | \*Yes | No |

## HIPAA Waiver(s):

|  |  |
| --- | --- |
|  | Please complete and submit the appropriate HIPAA waiver form(s):   * [Full Waiver](https://www.wcgclinical.com/wp-content/uploads/2020/08/HIPAA_WAIVER-FULL-1.doc) * [Partial Waiver](https://www.wcgclinical.com/wp-content/uploads/2020/08/HIPAA_PARTIAL_WAIVER-1.doc) |

## Financial Interest Disclosure:

|  |  |
| --- | --- |
|  | Please complete and submit the Financial Interest Disclosure Form available [here](https://www.wcgclinical.com/wp-content/uploads/2020/08/HRP-216.doc). |

## Adding or Removing Research Personnel:

Warning: A Change to Investigator is the only type of personnel change you are required to report to the IRB. To make this type of change submit a completed initial review submission form for the new PI.

The Principal Investigator is responsible for ensuring training of new personnel as described in the Initial Review Application Form.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Do any of the personnel changes require additional financial interest disclosures?  **\*If yes, complete the** c**omplete and submit the Financial Interest Disclosure Form available** [**here**](https://www.wcgclinical.com/wp-content/uploads/2020/08/HRP-216.doc)**.** | \*Yes | No |
|  | Do any of these personnel changes need to be applied to the consent form? (WCG IRB does not require sub-investigators or other study personnel be listed in the consent form)  **\*If yes, complete the consent form section in this form above.** | \*Yes | No |

## Research Location Change:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | What type of site change does this concern?  Additional site  or  Relocated site (change address of an approved research location): The site submitted in this form replaces the site located at: *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*.  This change is effective as of date: *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*.  or  Inactivate one or more sites:  Physical address of location(s) to inactivate: *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  This change is effective as of date: *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*.  or  This is a new mailing address | | | |
|  | **Site:**  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): | | | |
|  | **Daytime phone number for subjects to call for questions or injury**:  () | | | |
|  | **24 hour phone number for subjects to call for questions or injury**:  () | | | |
|  | 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 |

## Translation Request:

|  |  |
| --- | --- |
|  | Please complete and submit the Translation Request Submission Form available [here](https://www.wcgclinical.com/wp-content/uploads/2020/08/HRP-230.doc). |

## Change in email address or phone number of a research contact who receives emails or phone calls directly from IRB staff:

|  |  |
| --- | --- |
|  | If the changes you are submitting with this form are solely related to a new or updated email addresses or phone numbers of research contacts, **STOP**. Do NOT submit this Change in Research form – instead, submit a standalone [Contact Information Update Form](https://www.wcgclinical.com/wp-content/uploads/2020/07/HRP-202.doc) instead and WCG IRB will make the change to its records at no charge.  Contacts provided in the Contact Information Update Form will be included in general e-mail correspondence sent directly from IRB staff to individuals/groups when applicable.  To also provide them with the appropriate level of access in Connexus, please follow the necessary steps as outlined in our User Management Quick Reference Guide available [here](https://connexus.wcgirb.com/resources).  Note: If you submit a Contact Information Update Form with a Change in Research form and no other changes, you will be charged for a modification. |

## Other:

|  |  |
| --- | --- |
|  | Use this section to submit any change that is not listed above (and is not considered [Promptly Reportable Information](https://www.wcgclinical.com/wp-content/uploads/2024/06/PRI_HRP-204.docx)) which may require submission to WCG IRB, for example: Data Safety Monitoring Board or Committee reports, requests for approval of an alternative consent process, etc.  Describe the requested change/review request: |

# 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.
* ***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***.

# 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 (optional) |