**Promptly Reportable Information (PRI) Form
(HRP-204)**

Use this form to notify the IRB of promptly reportable new information. WCG IRB’s policy for prompt reporting is available in the IRB section of the [WCG Clinical website](https://www.wcgclinical.com/irb-resources/additional-irb-resources/) [here](https://www.wcgclinical.com/wp-content/uploads/2020/08/IRB.POL_.HRP_.071-Prompt-Reporting-Requirements_v4.0_website.pdf).

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):* |
| Sponsor:  |

# VA Research?

|  |  |  |
| --- | --- | --- |
| Is this report **related to Veterans Affairs (VA) research**? (E.g., at a VA site or VA-sponsored)**\*If yes -** Additional instructions for VA research:* If you are submitting a local SAE that is both unanticipated and related to the research, select "New or increased risk" in the next section.
* If you are submitting a serious problem that is both unanticipated and related to the research, select "New or increased risk" in the next section.
* Any apparent serious or continuing noncompliance with IRB or other human research protection requirements, select "Allegation of noncompliance or finding of noncompliance" in the next section.
* If you are submitting a suspension or termination of VA research by, or at the direction of, any entity external to the facility, select "Suspension or premature termination by the sponsor, investigator, or institution" in the next section.
* If you are submitting a HIPAA privacy rule deficiencies or data security issue, select "Breach of confidentiality" in the next section.

**Note that if you must also report the items listed in the next section, even if they do not fall into any of the above categories.** | \*Yes*[ ]*  | No*[ ]*  |

# Principal Investigator (PI) Information *(if applicable)*:

|  |
| --- |
| PI Name:       |

# What category best describes this problem? Most items below must be reported within 5 days. WCG IRB’s policy for prompt reporting is available in the IRB section of the [WCG Clinical website](https://www.wcgclinical.com/irb-resources/additional-irb-resources/) [here](https://www.wcgclinical.com/wp-content/uploads/2020/08/IRB.POL_.HRP_.071-Prompt-Reporting-Requirements_v4.0_website.pdf).

# 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*:

## [ ]  Audit, inspection or inquiry by a federal agency

|  |  |
| --- | --- |
|  | * Because you are submitting information that requires prompt reporting to the IRB, submit copies of all related reports and correspondence.
 |
|  | What is the date you learned of this problem?      |
|  | What was the date of occurrence? (if known)       |
|  | What is the date reported to sponsor? (if applicable)      |
|  | Describe the problem:      |
|  | Describe actions already taken to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Describe planned actions to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Were one or more subjects harmed or placed at risk because of this problem?**\*If yes**, describe the harms and risk experienced by subject because of this problem**:**       | \*Yes[ ]  | No[ ]  |
|  | Will the protocol or consent form be changed because of this report?**\*If yes,** describe changes to protocol or consent form, including the timeline for these changes to be made:     **\*\*If no,** justify:      | \*Yes[ ]  | \*\*No[ ]  |
|  | Was the audit/inspection targeted to a study approved by this IRB? | Yes[ ]  | \*\*No[ ]  |
|  | Provide the dates of the audit/inspection including the beginning and end dates: (For Health Canada inspections, provide the rating received.) |

## [ ]  Written report from a federal agency (e.g., FDA Form 483)

|  |  |
| --- | --- |
|  | * Because you are submitting information that requires prompt reporting to the IRB, submit copies of all related reports and correspondence.
* Because you are reporting a report from a federal agency:Submit a copy of the written report. (e.g. FDA Form 482 and 483, site's response to the 483, FDA letter responding to the site, EIR Summary, FDA WARNING Letter, Health Canada Inspection Notice, Health Canada Exit Notice)
 |
|  | What is the date you learned of this problem?      |
|  | What was the date of occurrence? (if known)       |
|  | What is the date reported to sponsor? (if applicable)      |
|  | Describe the problem:      |
|  | Describe actions already taken to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Describe planned actions to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Were one or more subjects harmed or placed at risk because of this problem?**\*If yes**, describe the harms and risk experienced by subject because of this problem**:**       | \*Yes[ ]  | No[ ]  |
|  | Will the protocol or consent form be changed because of this report?**\*If yes,** describe changes to protocol or consent form, including the timeline for these changes to be made:     **\*\*If no,** justify:      | \*Yes[ ]  | \*\*No[ ]  |

## [ ]  State medical board action or hospital medical staff action

|  |  |
| --- | --- |
|  | * Because you are submitting information that requires prompt reporting to the IRB, submit copies of all related reports and correspondence.
* Submit documentation of medical license status. (e.g. a current or suspended medical license, a physician profile, or a physician profile indicating a disciplinary or non-disciplinary action)
 |
|  | What is the date you learned of this problem?      |
|  | What was the date of occurrence? (if known)       |
|  | What is the date reported to sponsor? (if applicable)      |
|  | Describe the problem:      |
|  | Describe actions already taken to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Describe planned actions to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Were one or more subjects harmed or placed at risk because of this problem?**\*If yes**, describe the harms and risk experienced by subject because of this problem**:**       | \*Yes[ ]  | No[ ]  |
|  | Will the protocol or consent form be changed because of this report?**\*If yes,** describe changes to protocol or consent form, including the timeline for these changes to be made:     **\*\*If no,** justify:      | \*Yes[ ]  | \*\*No[ ]  |

## [ ]  Allegation of noncompliance or finding of noncompliance

|  |  |
| --- | --- |
|  | * Because you are submitting information that requires prompt reporting to the IRB, submit copies of all related reports and correspondence.
 |
|  | Does this report involve one or more specific subjects? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, Provide the research **identification code(s)** of the involved subject(s) **and the status of that subject** (e.g., no longer enrolled, enrolled but research limited to follow-up, research interventions continuing)**:**       |
|  | Were one or more subjects harmed or placed at risk because of this problem? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, describe the harms and risk experienced by subject because of this problem:      |
|  | What was the date of occurrence? (if known)       |
|  | What is the date reported to sponsor? (if applicable)      |
|  | Describe the problem:      |
|  | Describe actions already taken to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Describe planned actions to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Will the protocol or consent form be changed because of this report?**\*If yes,** describe changes to protocol or consent form, including the timeline for these changes to be made:     **\*\*If no,** justify:      | \*Yes[ ]  | \*\*No[ ]  |

## [ ]  Suspension or premature termination by the sponsor, investigator, or institution

|  |  |
| --- | --- |
|  | * Because you are submitting information that requires prompt reporting to the IRB, submit copies of all related reports and correspondence.
 |
|  | Does this report involve one or more specific subjects? | \*Yes[ ]  | No[ ]  |
| 2.1 | **\*If yes**, Provide the research **identification code(s)** of the involved subject(s) **and the status of the subject(s)** (e.g., no longer enrolled, enrolled but research limited to follow-up, research interventions continuing)**:**       |
|  | Were one or more subjects harmed or placed at risk because of this problem? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, describe the harms and risk experienced by subject because of this problem:      |
|  | What is the date you learned of this problem?      |
|  | What was the date of occurrence? (if known)       |
|  | What is the date reported to sponsor? (if applicable)      |
|  | Describe the problem:      |
|  | Describe actions already taken to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Describe planned actions to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Will the protocol or consent form be changed because of this report?**\*If yes,** describe changes to protocol or consent form, including the timeline for these changes to be made:     **\*\*If no,** justify:      | \*Yes[ ]  | \*\*No[ ]  |

## [ ]  Incarceration of a subject in a research study not approved to involve prisoners

|  |  |
| --- | --- |
|  | * Because you are submitting information that requires prompt reporting to the IRB, submit copies of all related reports and correspondence.
 |
|  | Provide the research **identification code(s)** of the involved subject(s) **and the status of that subject** (e.g., no longer enrolled, enrolled but research limited to follow-up, research interventions continuing)**:**       |
|  | What is the date you learned of this problem?      |
|  | What was the date of occurrence? (if known)       |
|  | What is the date reported to sponsor? (if applicable)      |
|  | Describe the problem:      |
|  | Is it in the subject's best interest to continue in the research while incarcerated? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, will parole boards take into account a prisoner's participation in this research when making decisions regarding parole? | Yes[ ]  | No[ ]  |
|  | Will the subject be informed in advance that continuing to participate in this research will have no effect on his/her parole? | Yes[ ]  | No[ ]  |
|  | Describe the subject's current and expected incarceration: |
|  | Describe the research procedures, including data collection, that need to take place during incarceration: |

## [ ]  New or increased risk

|  |  |
| --- | --- |
|  | * Because you are submitting information that requires prompt reporting to the IRB, submit copies of all related reports and correspondence.
 |
|  | Please provide the PI’s assessment of the relationship to the research and the potential impact on the health of the subject(s):      [ ]  Not related/unlikely related but the Sponsor/CRO/monitor requires reporting |
|  | Does this report involve one or more specific subjects? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, provide the research **identification code(s)** of the involved subject(s) **and the status of that subject** (e.g., no longer enrolled, enrolled but research limited to follow-up, research interventions continuing)**:**  | \*Yes[ ]  | No[ ]  |
|  | What is the date you learned of this problem?      |
|  | What was the date of occurrence? (if known)       |
|  | What is the date reported to sponsor? (if applicable)      |
|  | Describe the problem:      |
|  | Describe actions already taken to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Describe planned actions to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Will the protocol or consent form be changed because of this report?**\*If yes,** describe changes to protocol or consent form, including the timeline for these changes to be made:     **\*\*If no,** justify:      | \*Yes[ ]  | \*\*No[ ]  |

## [ ]  Unanticipated adverse device effect (Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.)

|  |  |
| --- | --- |
|  | * Because you are submitting information that requires prompt reporting to the IRB, submit copies of all related reports and correspondence.
 |
|  | Please provide the PI’s assessment of the relationship to the research and the potential impact on the health of the subject:      [ ]  Not related/unlikely related but the Sponsor/CRO/monitor requires reporting |
|  | Does this report involve one or more specific subjects? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, Provide the research **identification code(s)** of the involved subject(s) **and the status of that subject** (e.g., no longer enrolled, enrolled but research limited to follow-up, research interventions continuing)**:**       |
|  | **\*If yes**, were one or more subjects harmed or placed at risk because of this problem? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, describe the harms and risk experienced by subject because of this problem:      |
|  | What is the date you learned of this problem?      |
|  | What was the date of occurrence? (if known)       |
|  | What is the date reported to sponsor? (if applicable)      |
|  | Describe the problem:      |
|  | Describe actions already taken to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Describe planned actions to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Will the protocol or consent form be changed because of this report?**\*If yes,** describe changes to protocol or consent form, including the timeline for these changes to be made:     **\*\*If no,** justify:      | \*Yes[ ]  | \*\*No[ ]  |

## [ ]  Protocol deviation that harmed a subject or placed subject at risk of harm

|  |  |
| --- | --- |
|  | * Because you are submitting information that requires prompt reporting to the IRB, submit copies of all related reports and correspondence.
 |
|  | Does this report involve one or more specific subjects? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, Provide the research **identification code(s)** of the involved subject(s) **and the status of that subject** (e.g., no longer enrolled, enrolled but research limited to follow-up, research interventions continuing)**:**       |
|  | What is the date you learned of this problem?      |
|  | What was the date of occurrence? (if known)       |
|  | What is the date reported to sponsor? (if applicable)      |
|  | Describe the problem:      |
|  | Describe actions already taken to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Describe planned actions to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Will the protocol or consent form be changed because of this report?**\*If yes,** describe changes to protocol or consent form, including the timeline for these changes to be made:     **\*\*If no,** justify:      | \*Yes[ ]  | \*\*No[ ]  |

## [ ]  Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject

|  |  |
| --- | --- |
|  | * Because you are submitting information that requires prompt reporting to the IRB, submit copies of all related reports and correspondence.
 |
|  | Does this report involve one or more specific subjects? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, Provide the research **identification code(s)** of the involved subject(s) **and the status of that subject** (e.g., no longer enrolled, enrolled but research limited to follow-up, research interventions continuing)**:**       |
|  | Were one or more subjects harmed because of this problem? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, describe the harms experienced by the subject(s) because of this problem:      |
|  | Describe the problem:      |
|  | What is the date you learned of this problem?      |
|  | What was the date of occurrence? (if known)       |
|  | What is the date reported to sponsor? (if applicable)      |
|  | Describe actions already taken to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Describe planned actions to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Will the protocol or consent form be changed because of this report?**\*If yes,** describe changes to protocol or consent form, including the timeline for these changes to be made:     **\*\*If no,** justify:      | \*Yes[ ]  | \*\*No[ ]  |

## [ ]  Breach of confidentiality

|  |  |
| --- | --- |
|  | * Because you are submitting information that requires prompt reporting to the IRB, submit copies of all related reports and correspondence.
 |
|  | Does this report involve one or more specific subjects? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, Provide the research **identification code(s)** of the involved subject(s) **and the status of that subject** (e.g., no longer enrolled, enrolled but research limited to follow-up, research interventions continuing)**:**       |
|  | Were one or more subjects harmed or placed at risk because of this problem? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, describe the harms and risk experienced by subject because of this problem:      |
|  | What is the date you learned of this problem?      |
|  | What was the date of occurrence? (if known)       |
|  | What is the date reported to sponsor? (if applicable)      |
|  | Describe the problem:      |
|  | Describe actions already taken to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Describe planned actions to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Will the protocol or consent form be changed because of this report?**\*If yes,** describe changes to protocol or consent form, including the timeline for these changes to be made:     **\*\*If no,** justify:      | \*Yes[ ]  | \*\*No[ ]  |
|  | Was the breach of confidentiality reported to the affected subjects?      | Yes[ ]  | No[ ]  |

## [ ]  Subject complaint that cannot be resolved by the research team

|  |  |
| --- | --- |
|  | * Because you are submitting information that requires prompt reporting to the IRB, submit copies of all related reports and correspondence.
 |
|  | Provide the research **identification code(s)** of the involved subject(s) **and the status of that subject** (e.g., no longer enrolled, enrolled but research limited to follow-up, research interventions continuing)**:**       |
|  | What is the date you learned of this problem?      |
|  | What was the date of occurrence? (if known)       |
|  | What is the date reported to sponsor? (if applicable)      |
|  | Describe the problem:      |
|  | Describe actions already taken to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Describe planned actions to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Will the protocol or consent form be changed because of this report?**\*If yes,** describe changes to protocol or consent form, including the timeline for these changes to be made:     **\*\*If no,** justify:      | \*Yes[ ]  | \*\*No[ ]  |

## [ ]  Adverse event or IND safety report that requires a change to the protocol or consent

|  |  |
| --- | --- |
|  | * Because you are submitting information that requires prompt reporting to the IRB, submit copies of all related reports and correspondence.
 |
|  | Does this report involve one or more specific subjects? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, Provide the research **identification code(s)** of the involved subject(s) **and the status of that subject** (e.g., no longer enrolled, enrolled but research limited to follow-up, research interventions continuing)**:**       |
|  | Were one or more subjects harmed or placed at risk because of this problem? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, describe the harms and risk experienced by subject because of this problem:      |
|  | Please provide the PI’s assessment of the relationship to the research and the potential impact on the health of the subject:       |
|  | What is the date you learned of this problem?      |
|  | What was the date of occurrence? (if known)       |
|  | What is the date reported to sponsor? (if applicable)      |
|  | Describe the problem:      |
|  | Describe actions already taken to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Describe planned actions to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Will the protocol or consent form be changed because of this report?**\*If yes,** describe changes to protocol or consent form, including the timeline for these changes to be made:     **\*\*If no,** justify:      | \*Yes[ ]  | \*\*No[ ]  |

## [ ]  Information NOT listed above where the sponsor/CRO/monitor has directed a report to the IRB

|  |  |  |  |
| --- | --- | --- | --- |
|  | Does this report involve one or more specific subjects? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, Provide the research **identification code(s)** of the involved subject(s) **and the status of that subject** (e.g., no longer enrolled, enrolled but research limited to follow-up, research interventions continuing)**:**       |
|  | Were one or more subjects harmed or placed at risk because of this problem? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, describe the harms and risk experienced by subject because of this problem:      |
|  | What is the date you learned of this problem?      |
|  | What was the date of occurrence? (if known)       |
|  | What is the date reported to sponsor? (if applicable)      |
|  | Describe the problem:      |
|  | Describe actions already taken to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Describe planned actions to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Will the protocol or consent form be changed because of this report?**\*If yes,** describe changes to protocol or consent form, including the timeline for these changes to be made:     **\*\*If no,** justify:      | \*Yes[ ]  | \*\*No[ ]  |

## [ ]  Change in financial interest disclosure

|  |  |
| --- | --- |
|  | Because there are individuals with unreported financial interests related to this research, complete and submit a "[Financial Interest Disclosure Form](https://www.wcgclinical.com/wp-content/uploads/2020/08/HRP-216.doc)" with this submission. If this disclosure changes, you are required to update this information within 5 business days. |

## [ ]  Other

|  |  |
| --- | --- |
|  | Describe the problem:      |
|  | Does this report involve one or more specific subjects? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, Provide the research **identification code(s)** of the involved subject(s) **and the status of that subject** (e.g., no longer enrolled, enrolled but research limited to follow-up, research interventions continuing)**:**       |
|  | Were one or more subjects harmed or placed at risk because of this problem? | \*Yes[ ]  | No[ ]  |
|  | **\*If yes**, describe the harms and risk experienced by subject because of this problem:      |
|  | What is the date you learned of this problem?      |
|  | What was the date of occurrence? (if known)       |
|  | What is the date reported to sponsor? (if applicable)      |
|  | Describe actions already taken to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
|  | Describe planned actions to mitigate harm, correct the problem, prevent a recurrence: (if none, justify.)      |
| 1. .
 | Will the protocol or consent form be changed because of this report?**\*If yes,** describe changes to protocol or consent form, including the timeline for these changes to be made:     **\*\*If no,** justify:      | \*Yes[ ]  | \*\*No[ ]  |

# If you do not see your problem type listed above, it does not require prompt reporting to the IRB.

# 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.

# 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  |