**Request for Waiver of Authorization under HIPAA**

**(HRP-218)**

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:

|  |  |
| --- | --- |
| Sponsor's protocol ID *(if applicable):* | IRB protocol number/tracking number *(if known):* |
| Sponsor: | |
| Investigator Name: | |

# Waiver Information:

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|  | Indicate which of the following HIPAA waivers you are 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   HIPAA Waivers 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.* |
|  | 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: |
|  | 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. |

# Special Instructions:

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| 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.

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| --- |
| Name of Person Completing This Form Date    Company & Title    Phone number E-mail address |