**Initial Review Submission Form – VA Addendum (HRP-290)**

***Asterisked (\*) questions are required.***

Use this form as an addendum to "[HRP-212 Initial Review of Research](https://www.wcgclinical.com/wp-content/uploads/2020/08/HRP-212.pdf)" to request initial IRB approval for a protocol or site conducting VA Research

For assistance, contact Client Care at clientcare@wcgirb.com or 855-818-2289.

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.***

|  |
| --- |
| **\***Protocol title: |
| Sponsor's protocol ID *(if applicable):*  |

|  |
| --- |
| **\***PI full name: |

**Relevance to Veterans:**

|  |  |
| --- | --- |
|  | **\***Describe the relevance of the proposed project to the health or welfare of the Veteran population |

**HIPAA:**

|  |  |
| --- | --- |
|  | **\***Select one:[ ]  The research and site is not subject to HIPAA[ ]  The research and site will use a VA approved stand-alone HIPAA authorization[ ]  The consent form incorporates a HIPAA authorization[ ]  We are requesting a complete waiver of HIPAA authorization |

**Local VA Facility Liaison Contact Information:**

|  |  |
| --- | --- |
|  | **\***Full Name: |
|  | **\***Email: |

**Required Attachments**

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

Submit the following documentation:

* [Initial Review Submission Form (HRP-212)](https://www.wcgclinical.com/wp-content/uploads/2020/08/HRP-212.pdf)
* This form with all questions marked with a **\*** answered
* Documents supporting answers to questions in this form

**Acknowledgements:**

By submitting this form, I confirm that

* The information within this form is accurate and complete.
* 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:

* Immediately notify the IRB orally upon becoming aware of any local research death that is both unanticipated and related to the research
* Within 5 business days notify the IRB in writing upon becoming aware of:
	+ Any local SAE that is both unanticipated and related to the research
	+ Any serious problem that is both unanticipated and related to the research
	+ Any apparent serious or continuing noncompliance with IRB or other human research protection requirements
	+ Any suspension or termination of VA research by, or at the direction of, any entity external to the facility
	+ Any HIPAA privacy rule deficiencies, including uses and disclosures of PHI for research without legal authority (e.g. without a valid authorization or waiver of authorization), are to be reported in accordance with the requirements included in this section.
* Comply with all applicable VA and other Federal requirements regarding conflict of interest.
* Notify the IRB within 5 business days of any change to information provided on this form.

**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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| --- |
|  \*Printed or Typed Name of Person Completing This Form \*Date  Company & title()  \*Phone number E-mail address (optional) |