New Initial IRB Review Process:
Initial Review Application (IRA) + Abbreviated WRG-HS Application

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https://research.med.cornell.edu/irb

IRB Initial Review Application (IRA): Overview

An IRB-specific tool completed as part of the abbreviated WRG-HS initial application form

Streamlines and focuses the collection of all IRB-required ethical and regulatory information in one place increasing IRB compliance needs

Greatly reduced duplicative collection of information found in the previous WRG-HS application

Resides on the WCM IRB website allow for easier updates with no impact on WRG

3 study-specific versions:

- Biomedical IRA: Used in association with the Therapeutic JCTO Protocol template and/or for studies that will use a device/drug or implement a clinical trial.
- Biorepository IRA: Used for the establishment of a biorepository (storage and maintenance) for potential future use, not testing and research.
- SBER and Records IRA: Used in association with the Observational or Tissue Use/Chart Review JCTO template, the Education Protocol Template, and/or have a study that will conduct social, behavioral, or educational research.
The New Abbreviated WRG-HS Initial Application

Review and Approval

1. Please select the IRB responsible for oversight of this research.

In Question 1, you are now selecting "WCM" as the reviewing IRB. Unless the research is part of a Single IRB arrangement or BRANYplus, please note prior confirmation details on the IRB process and how to start it can be found here.

Question 2 does not appear when WCM is the IRB of Record.

Please note that questions 2 is not appearing due to branching logic based on your answer to question 1.

The New Abbreviated WRG-HS Initial Application, Cont.

- Specimens table is now included as an option
- Links to the new supplemental forms included in Drugs, Biologics, Devices (Specimens) tables
- Upload the IRA form here

Drug Table

<table>
<thead>
<tr>
<th>15.15 Name (generic or trade name)</th>
<th>Neurontin (gabapentin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please complete the DRUGS form linked here and attach.</td>
<td>WCM IRB Research with Drugs.docx 17-Aug-2022 05:03:41 PM</td>
</tr>
</tbody>
</table>

Device Table

<table>
<thead>
<tr>
<th>14.2 Device Name:</th>
<th>AdaptACRT algorithm</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.3Manufacturer:</td>
<td>GSK</td>
</tr>
<tr>
<td>Please complete the WCM IRB Research with Devices.docx Aug-2022 09:01:31 PM</td>
<td></td>
</tr>
</tbody>
</table>

| Please complete the specimen form linked here and attach. | WCM IRB Research with Specimens.docx Aug-2022 08:11:11 PM |

Please upload a copy of the ICH GCP - 7 INVESTIGATOR'S BROCHURE - ICH Investigator's Brochure: GCP.pdf 17-Aug-2022 06:12:28 PM.

9. Please visit WCM IRB Research Application (IRA) site to select and fill in the applicable IRA for your study. Once complete, attach IRB Review Application - Investigator's Brochure.docx 08:11:23 PM.
How does this change streamline the submission process?

**IRAs will now account for information about:**

- General Study Design
- Retrospective and/or Prospective
- Cost, Reimbursement, or Compensation
- Risks and Risk Minimization
- Benefits
- Privacy and Confidentiality
- Informed Consent, Minor Assent, and Parental/Guardian Permission

**WRG-HS's initial application will now ONLY collect:**

- Personnel (WCM/NYP)
- Non-Affiliated (Non-WCM/NYP) Personnel
- Review & Approval
- Sponsors and Entities
- Attachments

**IRA and Abbreviated Initial Walk-Thru**
Other Supplemental Forms

Where do I find the IRAs and the other supplemental forms?

Institutional Review Board

Forms & Applications

IRB Review Application (IRA) Forms
For all new initial applications submitted to New Submissions must be attached to an IRB Review Application (IRA). Please select and fill in the applicable IRB Review Application (IRA) linked below. Once complete, please upload it to IRB as part of your new submission.

- **Biomedical IRA**: Use this IRB Review Application if you have completed the Therapeutic Studies (TS) Protocol template and/or have a study which will use a device/drug or implement a clinical trial.
- **Biospecimen IRA**: This IRB Review Application template is used by the establishment of a biobank for storage and maintenance of potential future use, not testing and research.
- **MRI and Research IRA**: Use this IRB Review Application if you have completed the Non-Therapeutic Studies or Tissue stock/Chart Review (SOC) template, the Education Protocol Template and/or have a study which will use conduct social behavioral, or educational research.

Supplemental Forms
- **Drug Form**: Used for any study involving investigational supplements
- **Device Form**: Used for any study involving medical devices as defined by the FDA
- **Specimen Form**: Used for any study collecting or using human biological specimens for research (e.g., organ tissue, plasma, urine, feces, saliva). This may include specimens collected as part of routine care for use as part of the research. This includes medical waste.
Interim Abbreviated Application/IRA: Initial Application Implementation Efforts

- IRB meets with ITS’ Research Admin team weekly

- Collected feedback from the IRB liaison working group (composed of heavy IRB/WRG-HS users)

- Conducted User Acceptance Testing (UAT) in collaboration with ITS’ RA

- Provides the WCM research community with web-based resources, in-person consultations, and 2x week walkthroughs and training ahead of and post Go Live.
FAQS

Q: Do the IRAs replace the protocol document?
A: No. The IRAs are forms specific to IRB review and determination and do not replace your protocol document. Note that your protocol document is used for other institutional requirements such as PRMC, CTSC, RSC, and/or IBC submissions.

Q: Would I need to use the IRAs if submitting to BRANY via BRANYplus?
A: No, the IRAs and other supplemental forms are to be used for studies where WCM is the reviewing IRB. If using BRANY, or any other external IRB as your reviewing IRB, then you’d continue to complete the corresponding protocol document only.

Q: When does the new requirement go into effect?
A: The IRAs will go live on September 15th, so any record created on or after this date will need to complete the IRAs as part of their submission.

Q: What if I’ve already started my intake/ initial prior to September 15th?
A: If created before September 15th, your record would still show the same sections and not the abbreviated version of it. In terms of the IRA requirement, submissions will be assessed on a case-by-case basis and IRA completion might be requested at the IRB’s discretion.

Q: What if I am not certain which form to use, or have questions about completing it?
A: We invite you to make use of our consultation services, as well as reach out to our IRB listserv team for any further assistance.

Q: Would there be other training sessions available?
A: Yes! Training will also be available on Tuesday, 8/30, Tuesday, 9/6, Friday, 9/9, and lastly Monday, 9/12. Note that registration is required:

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Registration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wednesday 8/24</td>
<td>11:00am–12:00pm</td>
<td>register here</td>
</tr>
<tr>
<td>Thursday 8/25</td>
<td>12:00pm–1:00pm</td>
<td>register here</td>
</tr>
<tr>
<td>Tuesday 9/6</td>
<td>12:00pm–1:00pm</td>
<td>register here</td>
</tr>
<tr>
<td>Friday 9/9</td>
<td>12:00pm–1:00pm</td>
<td>register here</td>
</tr>
<tr>
<td>Monday 9/12</td>
<td>12:00pm–1:00pm</td>
<td>register here</td>
</tr>
</tbody>
</table>

Helpful Resources

Request a Consultation

or

Email:
WCM IRB Office: irb@med.cornell.edu
HRPO team: hrpo@med.cornell.edu
Questions?