**IRB of record: UAB IRB**

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|[ ]  **Revisions/Amendments: IRB ePortfolio form, Section 4***For use for all changes included but not limited to:** Changes to the protocol
* Changes to drug information
* Changes to device information
* Changes to funding source
* Changes to consent and assent forms
* Changes to data collection forms
* Changes to subject-facing materials
* Changes in study procedures
* Submission of monitor letters

*Tips:** Change the type of application to revision/amendment OR administrative amendment (depending on type of change)
* Complete section 4 of the IRB ePortfolio form with all changes, *as well as* the other relevant sections of the ePortfolio
* Know the study status (open to enrollment, closed to enrollment, in long-term follow-up/data analysis/etc.)
* Know the current and total subject enrollment numbers; if your team utilizes OnCore, these numbers can be found in the CRA console
* For protocols that were started on an HSP form only, use the separate Revision/Amendment e-form instead
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|[ ]  **Continuing Review: IRB ePortfolio form, Section 2***For use when submitting continuing reviews for:** Full board reviews
* Expedited reviews (1 year renewals)

*Tips:** Change the type of application to continuing review
* Have the start date of the protocol and the current IRB expiration date on hand
* Know the study status (open to enrollment, closed to enrollment, in long-term follow-up/data analysis/etc.) and dates of those statuses
* Know the current and total subject enrollment numbers; if your team utilizes OnCore, these numbers can be found in the CRA console
* Know if you need to report demographic information
* For protocols that were started on an HSP form only, use the separate Continuing Review e-form instead
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|[ ]  **ESU Continuing Review: IRB Revision/Amendment e-form**For use when submitting continuing reviews for:* Expedited status update reviews (3 year renewals)

*Tips:** Know the study status (open to enrollment, closed to enrollment, in long-term follow-up/data analysis/etc.)
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|[ ]  **Change in personnel: IRB Personnel e-form***Tips:** Insure all new personnel have completed IRB, ICH GCP, FCOI training and the financial disclosure for research purposes
* Changes in PI also require change memos (relinquishing PI, accepting PI)
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|[ ]  **Promptly Reportable Information: Problem Report e-form***Tips:* * Must be reported within 10 working days of learning of the event, even if only a partial report is available
* Retrieve a copy of AE or SAE CRF(s) from study coordinator, if available
* Know the study status (open to enrollment, closed to enrollment, temporarily suspended, etc.)
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**IRB of record: WCG IRB**

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|[ ]  **Monitor Letters: IRB Revision/Amendment e-form***Tips:** Know the study status (open to enrollment, closed to enrollment, in long-term follow-up/data analysis/etc.)
* Know the current and total subject enrollment numbers; if your team utilizes OnCore, these numbers can be found in the CRA console
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|[ ]  **Continuing Review: WCG IRB Continuing Review Report Form (CRRF)***Tips:** The CRRF will be sent via email to study contacts; if you do not receive the email, you will receive a CRRF transmission notice, where you can log into Connexus and retrieve the CRRF
* Know the study status (open to enrollment, closed to enrollment, in long-term follow-up/data analysis/etc.) and dates of those statuses
* Know the current and total subject enrollment numbers; if your team utilizes OnCore, these numbers can be found in the CRA console
* Upload into WCG IRB Connexus
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|[ ]  **Change in personnel: Responsible Personnel List (RPL)***Tips:** List only those personnel who are being added or removed
* Submit to CIRB via email (CIRB-PPL@mail.ad.uab.edu) and CC your financial staff and the UAB WIRB submissions team (wirb@uab.edu)
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|[ ]  **Promptly Reportable Information, Part 1: WCG IRB PRI form***Tips:** Must be reported within 10 working days of learning of the event, even if only a partial report is available
* Retrieve a copy of AE or SAE CRF(s) from study coordinator, if available
* Know the study status (open to enrollment, closed to enrollment, temporarily suspended, etc.)
* Know if the outcome and any CAPA that will be put in place to prevent future occurrences

**Promptly Reportable Information, Part 2: the Problem Report e-form***Tips:* * If a promptly reportable event happens at our site that meets UAB IRB’s prompt reporting requirements, you must also complete a Problem Report submission in IRAP.
* Must be reported within 10 working days of learning of the event, even if only a partial report is available
* Retrieve a copy of AE or SAE CRF(s) from study coordinator, if available
* Know the study status (open to enrollment, closed to enrollment, temporarily suspended, etc)
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**IRB of record: Advarra/Sterling/Other Academic IRBs**

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|[ ]  **Monitor Letters: IRB Revision/Amendment e-form***Tips:** Know the study status (open to enrollment, closed to enrollment, in long-term follow-up/data analysis/etc.)
* Know the current and total subject enrollment numbers; if your team utilizes OnCore, these numbers can be found in the CRA console
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|[ ]  **Continuing Review: central IRB’s continuing review form***Tips:** Commercial IRBs will have a form to complete on their IRB platform
* Academic IRB/lead site regulatory contacts will reach out with instructions on how to complete continuing review for a relying site
* Know the study status (open to enrollment, closed to enrollment, in long-term follow-up/data analysis/etc.) and dates of those statuses
* Know the current and total subject enrollment numbers; if your team utilizes OnCore, these numbers can be found in the CRA console
* Once you receive the central IRB’s approval documents, upload these into IRAP as a Continuing Review submission type. Only upload the IRB approval letter and consent/assent forms, if applicable – you **do not** have to complete a Continuing Review Form
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|[ ]  **Change in personnel, Part 1: Responsible Personnel List (RPL)***Tips:** List only those personnel who are being added or removed
* Submit to CIRB via email (CIRB-PPL@mail.ad.uab.edu) and CC your financial staff

**Change in personnel, Part 2: IRB Personnel e-form***Tips:** Once you receive the CIRB’s notification of RPL updates, you must revise the IRB personnel listing as well
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|[ ]  **Promptly Reportable Information, Part 1: Central IRB’s PRI form***Tips:** Must be reported within 10 working days of learning of the event, even if only a partial report is available
* Retrieve a copy of AE or SAE CRF(s) from study coordinator, if available
* Know the study status (open to enrollment, closed to enrollment, temporarily suspended, etc.)
* Know if the outcome and any CAPA that will be put in place to prevent future occurrences

**Promptly Reportable Information, Part 2: the Problem Report e-form***Tips:* * If a promptly reportable event happens at our site that meets UAB IRB’s prompt reporting requirements, you must also complete a Problem Report submission in IRAP.
* Must be reported within 10 working days of learning of the event, even if only a partial report is available
* Retrieve a copy of AE or SAE CRF(s) from study coordinator, if available
* Know the study status (open to enrollment, closed to enrollment, temporarily suspended, etc.)
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