**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 |
|  | **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 |
|  | **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.) |
|  | **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) |
|  | **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.) |

**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 |
|  | **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 |
|  | **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](mailto:CIRB-PPL@mail.ad.uab.edu)) and CC your financial staff and the UAB WIRB submissions team ([wirb@uab.edu](mailto:wirb@uab.edu)) |
|  | **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) |

**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 |
|  | **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 |
|  | **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](mailto: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 |
|  | **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.) |