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|  | **Regulatory Start-up – IRB Submission Documents** |
| Protocol / IRB# |  |
| Investigator |  |

ICH GCP Guideline 8.2: Before the Clinical Phase of the Trial Commences <https://ichgcp.net/8-essential-documents-for-the-conduct-of-a-clinical-trial>

**Which IRB are you using?**

* Investigator-initiated, unfunded protocols = UAB IRB
* Investigator-initiated, funded protocols (single site) = UAB IRB
* Federally funded protocols (single site) = UAB IRB
* Federally funded protocols (multisite) = contact lead site’s regulatory contact for confirmation of IRB of record
* Industry sponsorship guidance: <https://www.uab.edu/research/home/industry-sponsored-protocols>

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| **Which IRB Submission Form should I use?** | |
| For submissions going to **UAB IRB**, the main submission form is the IRB ePortfolio form, located in IRAP. | IRAP: <https://irap.uab.edu/>  ePortfolio guidance: <https://www.uab.edu/research/home/irap-training/irb> |
| For submissions going to **any other IRB**, the main submission form is the IRB Institution Review Form. | IRB forms, Section: Outside IRBs: <https://www.uab.edu/research/home/irb-forms> |
| **What other forms are required for initial IRB submission?**  *(This section applicable for* ***UAB IRB and outside IRBs****)* | |
| * IRB Personnel e-form | Located in IRAP <https://irap.uab.edu/> |
| * Protocol Oversight Review Form (PORF)   **OR**   * Protocol Review Committee (PRC) Approval Letter | PORF for all non-Cancer Center studies on IRB Forms page - Departmental Forms: <https://www.uab.edu/research/home/irb-forms>  **OR**  PRC letter for all Cancer Center studies |
| * Protocol |  |
| * Drafted assent/consent form(s) | Consent form templates available on IRB Forms page - , Consent, Assent, HIPAA Authorizations, and Waivers: <https://www.uab.edu/research/home/irb-forms> |
| * Investigator Brochure or package inserts |  |
| * Release of Drugs for Human Research Use (ROD) | ROD forms for UAB and Children’s available on IRB Forms page - Departmental Forms: <https://www.uab.edu/research/home/irb-forms> |
| * FAP approval | CBR/OnCore/CCTS submission form: <https://redcap.dom.uab.edu/surveys/?s=ELDN9LW9YP> |
| * Release of Pathologic Materials, if applicable | Release of Pathologic Materials forms available on IRB Forms page - Departmental Forms: <https://www.uab.edu/research/home/irb-forms> |
| * Radiation Safety approval, if applicable | OHS Project Registration form (RSC, IBC, etc): <https://www.uab.edu/research/home/rsc-forms-and-guides> |
| * Institution Biosafety Committee (IBC) approval, if applicable | OHS Project Registration form (RSC, IBC, etc): <https://www.uab.edu/research/home/rsc-forms-and-guides> |
| **I am submitting to an outside IRB. What additional forms do I need?**  *(This section applicable for* ***outside IRBs****)* | |
| * FDA form 1572 | \*Use the Institution Review Form as a guideline of what forms need to be included, according to which IRB will serve as the IRB of record.  \*Use the IRAP naming conventions when uploading documents into IRAP: <https://www.uab.edu/research/home/irb-irap/irap-naming-conventions> |
| * Lead site IRB approval (non WCG-IRB studies) |
| * Sponsor’s IRB approval letter |
| * Sponsor’s IRB approved assent/consent template(s) |
| * Reliance agreement | Most commonly used reliance platforms:  SMART (<https://reliance.smartirb.org>)  *and*  IREx (<https://www.irbexchange.org/> |
| * Billing Information Form | Industry sponsorship guidance forms: <https://www.uab.edu/research/home/industry-sponsored-protocols> |