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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
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| * 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)
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| * Sponsor’s IRB approval letter
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| * Sponsor’s IRB approved assent/consent template(s)
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| * 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> |