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| **IRB of record: UAB IRB** |
|[ ]  **IRB ePortfolio form***Tip:* For funded studies, you will need to provide the OSP and/or University Contracts number  |
|[ ]  **Project Registration Form** **(funded studies only)***Tip:* Include financial staff (contracts/budget) and regulatory staff on this form – anyone who needs the IRB number to complete any startup submissions, including but not limited to OSP, CBR/OnCore/CCTS, etc. |
|[ ]  **IRB ePersonnel form***Tips:** This form should match the Responsible Personnel List (RPL) that is submitted to OSP
* Regardless of type of study or funding, all personnel listed on this form should complete IRB training, ICH GCP training, FCOI training, and FCOI disclosure form for research purposes
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|[ ]  **Protocol Oversight Review Form**\*\*For studies that are reviewed by the O’Neal Comprehensive Cancer Center, the Protocol Review Committee (PRC) Approval Letter is used instead of the PORF.*Tips:* * Different departments use different versions of this form – make sure you have the right one!
* PIs and sub-Is CANNOT sign off on the PORF – it has to be a faculty in the dept/division who is not involved in the study.
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|[ ]  **Drafted assent and/or consent forms**UAB IRB template: <https://www.uab.edu/research/home/irb-forms> |
|[ ]  **Release of Drugs for Human Research Use form**, if applicable*Tip:* This is the Pharmacy release form. IDS Pharmacy and COA Pharmacy will include their quotes when they return this form, so be sure to coordinate with financial administrator/staff  |
|[ ]  **FAP approval letter**, if applicableSubmission form: <https://redcap.dom.uab.edu/surveys/?s=ELDN9LW9YP> *Tip:* Coordinate with financial administrator/staff on the CBR/OCR/CCTS submission form, as this will include the billing review, OnCore calendar build, and request for CRSP/CRU/SPAN/Bionutrition services |
|[ ]  **Radiology Request Quote**, if applicable (UAB only)Submission form: <https://redcap.dom.uab.edu/surveys/?s=PJPANNA439> *Tip:* Coordinate with financial administrator/staff on submission for Research Radiology requests  |
|[ ]  **Release of Pathologic Materials**, if applicable (UAB only)Form: <https://www.uab.edu/research/home/irb-forms> |
|[ ]  **Protocol document**, if available*Tip:* It is highly recommended that a protocol document be available for interventional studies. The Schedule of Events helps immensely when drafting consent forms, the Methods section of the ePortfolio, and the request for billing review/OnCore calendar builds |
|[ ]  **Drug or device information**, if applicable: |
|[ ]  * Investigator Brochure or FDA approved package insert for any drugs that will be used
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|[ ]  * Instructions for Use for any devices that will be used
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|  | * FDA letter for investigational drugs or devices
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|[ ]  **Radiation Safety Approval**, if applicableMore information available here: <https://www.uab.edu/research/home/rsc/rsc-rrsc> Project Registration form: <https://www.uab.edu/research/home/images/RSC/RSC_EHS_Project_Registration_Form_03-09-23.docx>  |
|[ ]  **IBC Approval**, if applicableMore information available here: <https://www.uab.edu/research/home/rsc/rsc-ibc> Project Registration form: <https://www.uab.edu/research/home/images/RSC/RSC_EHS_Project_Registration_Form_03-09-23.docx> |

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| **IRB of Record: WCG IRB** |
|[ ]  **Project Registration Form***Tip:* Include financial staff (contracts/budget) and regulatory staff on this form – anyone who needs the IRB number to complete any startup submissions, including but not limited to OSP, CBR/OnCore/CCTS, etc. |
|[ ]  **Institution Review Form Relying on Outside IRB**Form: <https://www.uab.edu/research/home/irb-forms>*Tip:* You will need to provide the OSP number on this form |
|[ ]  **Drug and Device Information***Tip:* You will need the IND or IDE number of the drug/device, which should be on the protocol document. If not available, request FDA letter from sponsor regulatory contact |
|[ ]  **Protocol Oversight Review Form**\*\*For studies that are reviewed by the O’Neal Comprehensive Cancer Center, the Protocol Review Committee (PRC) Approval Letter is used instead of the PORF.*Tips:* * Different departments use different versions of this form – make sure you have the right one!
* PIs and sub-Is CANNOT sign off on the PORF – it has to be a faculty in the dept/division who is not involved in the study.
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|[ ]  **Protocol document** |
|[ ]  **WCG IRB approved assent and/or consent template(s**) |
|[ ]  **WCG IRB ICF checklist**Form: <https://www.uab.edu/research/home/irb-forms> |
|[ ]  **Billing Information Form** |
|[ ]  **IBC Approval**, if applicableMore information available here: <https://www.uab.edu/research/home/rsc/rsc-ibc> Project Registration form: <https://www.uab.edu/research/home/images/RSC/RSC_EHS_Project_Registration_Form_03-09-23.docx> |
|[ ]  **Release of Drugs for Human Research Use form**, if applicable*Tip:* This is the Pharmacy release form. IDS Pharmacy and COA Pharmacy will include their quotes when they return this form, so be sure to share with financial administrator  |
|[ ]  **FAP approval letter**Submission form: <https://redcap.dom.uab.edu/surveys/?s=ELDN9LW9YP> *Tip:* Coordinate with financial administrator/staff on the CBR/OCR/CCTS submission form, as this will include the billing review, OnCore calendar build, and request for CRSP/CRU/SPAN/Bionutrition services |
|[ ]  **Radiology Request Quote**, if applicable (UAB only)Submission form: <https://redcap.dom.uab.edu/surveys/?s=PJPANNA439> *Tip:* Coordinate with financial administrator/staff on submission for Research Radiology requests (UAB only) |
|[ ]  **Release of Pathologic Materials**, if applicable (UAB only)Form: <https://www.uab.edu/research/home/irb-forms> |
|[ ]  **FDA form 1572** |
|[ ]  **Radiation Safety Approval**, if applicableMore information available here: <https://www.uab.edu/research/home/rsc/rsc-rrsc> Project Registration form: <https://www.uab.edu/research/home/images/RSC/RSC_EHS_Project_Registration_Form_03-09-23.docx> |
|[ ]  **IRB ePersonnel form***Tips:* * This form should match the Responsible Personnel List (RPL) that is submitted to OSP
* All personnel listed on this form should complete IRB training, ICH GCP training, FCOI training, and FCOI disclosure form for research purposes
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|[ ]  **When stamped Institution Review Form is received, proceed to WCG IRB’s submission process**.*Tips:** Do not complete this submission until you have received the stamped Institution Review Form from UAB IRB
* You will need the participant compensation information for this form – request from financial administrator and/or staff negotiating the budget
* Investigator credentials may be required to be uploaded, so have on hand
* Remember to upload the WCG IRB ICF checklist as part of this submission
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| **IRB of record: Advarra/Sterling/Other Academic IRBs** |
|[ ]  **Project Registration Form***Tip:* Include financial staff (contracts/budget) and regulatory staff on this form – anyone who needs the IRB number to complete any startup submissions, including but not limited to OSP, CBR/OnCore/CCTS, etc. |
|[ ]  **Institution Review Form Relying on Outside IRB**Form: <https://www.uab.edu/research/home/irb-forms>*Tip:* You will need to provide the OSP number on this form |
|[ ]  **Reliance agreement***Tips:** Most commercial IRBs (Advarra, Sterling, etc) use SMART IRB reliance platform: <https://reliance.smartirb.org/>
* If the lead site is using an academic IRB, the lead site regulatory contact will provide the reliance documents to you as part of the startup package. Include those documents as part of the submission.
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|[ ]  **Drug and Device Information***Tip:* You will need the IND or IDE number of the drug/device, which should be on the protocol document. If not available, request FDA letter from sponsor regulatory contact |
|[ ]  **Protocol Oversight Review Form**\*\*For studies that are reviewed by the O’Neal Comprehensive Cancer Center, the Protocol Review Committee (PRC) Approval Letter is used instead of the PORF.*Tips:* * Different departments use different versions of this form – make sure you have the right one!
* PIs and sub-Is CANNOT sign off on the PORF – it has to be a faculty in the dept/division who is not involved in the study.
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|[ ]  **Protocol document** |
|[ ]  **IRB approved assent and/or consent template(s)***Tip:* Advarra does not consider the pregnant partner authorization form to be a consent form, so you can use the sponsor’s master template |
|[ ]  **Site drafted assent/and or consent document(s)***Tip:* Insert institutionally-required language from the UAB Boilerplate Consent document (<https://www.uab.edu/research/home/irb-forms>) into the sponsor’s IRB approved template and submit to your regulatory contact for sponsor approval prior to submitting to UAB IRB |
|[ ]  **Lead site IRB approval***Tip:* If using a commercial IRB (Advarra, Sterling, etc) request the initial protocol-level study approval from your regulatory contact. You will also need the current protocol-level IRB approval  |
|[ ]  **Billing Information Form** (for commercial IRBs only) |
|[ ]  **IBC Approval**, if applicableMore information available here: <https://www.uab.edu/research/home/rsc/rsc-ibc> Project Registration form: <https://www.uab.edu/research/home/images/RSC/RSC_EHS_Project_Registration_Form_03-09-23.docx> |
|[ ]  **Release of Drugs for Human Research Use form**, if applicable*Tip:* This is the Pharmacy release form. IDS Pharmacy and COA Pharmacy will include their quotes when they return this form, so be sure to share with financial administrator  |
|[ ]  **FAP approval letter**Submission form: <https://redcap.dom.uab.edu/surveys/?s=ELDN9LW9YP>*Tip:* Coordinate with financial administrator/staff on the CBR/OCR/CCTS submission form, as this will include the billing review, OnCore calendar build, and request for CRSP/CRU/SPAN/Bionutrition services |
|[ ]  **Radiology Request Quote**, if applicable (UAB only)Submission form: <https://redcap.dom.uab.edu/surveys/?s=PJPANNA439> *Tip:* Coordinate with financial administrator/staff on submission for Research Radiology requests (UAB only) |
|[ ]  **Release of Pathologic Materials**, if applicable (UAB only)Form: <https://www.uab.edu/research/home/irb-forms> |
|[ ]  **FDA form 1572** |
|[ ]  **Radiation Safety Approval**, if applicableMore information available here: <https://www.uab.edu/research/home/rsc/rsc-rrsc> Project Registration form: <https://www.uab.edu/research/home/images/RSC/RSC_EHS_Project_Registration_Form_03-09-23.docx> |
|[ ]  **IRB ePersonnel form***Tips:* * This form should match the Responsible Personnel List (RPL) that is submitted to OSP
* All personnel listed on this form should complete IRB training, ICH GCP training, FCOI training, and FCOI disclosure form for research purposes
 |
|[ ]  **When stamped Institution Review Form is received, proceed to the central IRB’s submission process**.*Tips for Advarra/Sterling/commercial IRBs:** Do not complete this submission until you have received the stamped Institution Review Form from UAB IRB
* You will need the participant compensation information for this form – request from financial administrator and/or staff negotiating the budget
* Investigator credentials may be required to be uploaded, so have on hand
* Will need to upload the stamped Institution Review Form and the Received and Noted Letter
 |
|[ ]  **When central IRB approval documents are received, upload site IRB approval and assent/consent forms into IRAP, as per instructions on the Received and Noted Letter.** |