

**Study Start Up Checklist**

|  |  |
| --- | --- |
| **Budget and Contract Finalized** | The UW Office of Sponsored Programs (OSP) negotiates and executes Clinical Trial Agreements (CTA). The contract must be signed by OSP and the PI. [*http://depts.washington.edu/comply/docs/COM-101\_Policy.pdf*](http://depts.washington.edu/comply/docs/COM-101_Policy.pdf)Once you’ve reviewed what the sponsor has sent you, forward the protocol, consent form, draft budget, and CTA to OSP via an eGC1. OSP and CRBB will negotiate the CTA and budget concurrently. This process may take a couple weeks to a couple months. Resources:[*http://www.washington.edu/research/main.php?page=industryAgreements*](http://www.washington.edu/research/main.php?page=industryAgreements)[*http://www.washington.edu/research/main.php?page=agreementGuide*](http://www.washington.edu/research/main.php?page=agreementGuide) |
| NOTES: |
| **Financial Contract of Interest Management Plan** | The UW's Financial Conflict of Interest Policy (GIM-10: [*http://www.washington.edu/research/osp/gim/gim10.html*](http://www.washington.edu/research/osp/gim/gim10.html)) seeks to maintain the appropriate balance among all competing interests that have the potential to produce bias in the design, conduct, or reporting of the research or distort technology transfer transactions. To report a potential financial conflict of interest, use the Financial Interest Disclosure System [*http://www.washington.edu/research/tools/fids/*](http://www.washington.edu/research/tools/fids/)UW Medicine provides additional guidance on financial conflicts of interest to faculty within the School of Medicine: [*http://www.gs.washington.edu/office/facultyresources/policies/conflict.pdf*](http://www.gs.washington.edu/office/facultyresources/policies/conflict.pdf). Check with your department to determine if there are additional requirements for your trial.The UW Office of Sponsored Programs will not sign a Clinical Trials Agreement until the significant financial disclosure has been reviewed and the study has been approved to proceed through a plan to manage or eliminate the financial interest. |
| NOTES: |
| **Budget Number** | Once the research budget and contracting are finalized, OSP will release an eFA (Funding Action) to the Grants and Contracts Accounting Office, and they will issue your research budget number. [*http://www.washington.edu/research/main.php?page=industryAgreements*](http://www.washington.edu/research/main.php?page=industryAgreements)[*http://www.washington.edu/research/main.php?page=industryAgreements*](http://www.washington.edu/research/main.php?page=industryAgreements)[*http://f2.washington.edu/fm/gca/setup-maintain-budget/sets-grant-and-contract-budgets/new-budget-set-grants-and-contracts*](http://f2.washington.edu/fm/gca/setup-maintain-budget/sets-grant-and-contract-budgets/new-budget-set-grants-and-contracts) |
| NOTES: |
| **IRB Approval** | If your funding is through the UW Office of Sponsored programs, you will most likely submit your IRB application materials to the UW IRB.UW members of the Cancer Consortium conducting investigator-initiated oncology studies should send their studies to the Fred Hutchinson Cancer Research Center IRB. For information on whether to submit to the Fred Hutch IRB, go to [*https://www.washington.edu/research/hsd/topics/Cancer+Consortium+IRB+at+the+Fred+Hutchinson+Cancer+Research+Center*](https://www.washington.edu/research/hsd/topics/Cancer%2BConsortium%2BIRB%2Bat%2Bthe%2BFred%2BHutchinson%2BCancer%2BResearch%2BCenter)If you will conduct your study onsite at Seattle Childrens, you may need to submit your research study to Seattle Childrens IRB even if the funding is through the UW.Western Institutional Review Board (WIRB) reviews industry-sponsored and industry-initiated research conducted by UW faculty. For information on how to work with WIRB, go to [*https://www.washington.edu/research/hsd/topics/Western+Institutional+Review+Board+%28WIRB%29*](https://www.washington.edu/research/hsd/topics/Western%2BInstitutional%2BReview%2BBoard%2B%28WIRB%29) |
| NOTES: |
| **SPECIAL ISSUES FOR CLINICAL TRIALS** |
| **Intellectual Property and Commercial Development** | If the trial involves issues of intellectual property such as provision/receipt of research materials to/from other institutions/corporate entities, licensing issues, confidentiality agreements, patents, copyrights, etc., contact UW CoMotion to help you with intellectual property and commercial development issues with your trial. (206) 543-3970, uwcomotion@uw.edu, [*http://comotion.uw.edu/material-transfer-agreements-mta*](http://comotion.uw.edu/material-transfer-agreements-mta)[*http://www.washington.edu/admin/rules/policies/PO/EO36.html#3*](http://www.washington.edu/admin/rules/policies/PO/EO36.html#3) |
| NOTES: |
| **IDE Studies** | If the trial involves testing an investigational device under the FDA’s Investigational Device Exemption (IDE), you will need to work with CRBB and UW Medicine Compliance to identify the expected reimbursement for the device and device-related treatment. [*https://depts.washington.edu/crbb/IDE\_Implementation.html*](https://depts.washington.edu/crbb/IDE_Implementation.html)[*http://depts.washington.edu/comply/compliance-programs/research-compliance/investigational-device-exemption-ide/*](http://depts.washington.edu/comply/compliance-programs/research-compliance/investigational-device-exemption-ide/)If the IDE study includes services related to the device and or implant/removal at UWMC, contact INVESTIGATIONAL IMPLANT AND DEVICE COMMITTEE Ellie Sun, Interim Program Manager of Surgical Services (206) 598-1771, elliesun@uw.edu If the IDE study includes services related to the device and or implant/removal at HMC, contact HMC SURGICAL COUNCIL COMMITTEE Ketra Hayes, Assistant Administrator of Surgical Services (206) 744-8094, kmhayes@uw.edu |
| **Medicare Approval and Pre-Authorization** | UW Medicine requires advance local or national Medicare approval in order to submit claims for research participants enrolled in trials testing investigational devices under the FDA’s Investigational Device Exception (IDE). Medicare approval is not required if the trial will cover all costs to participants, or if a trial is exempt from the FDA IDE regulations. **You should contact UW Medicine Compliance early in the start-up process of your IDE study to prepare the application for permission to bill Medicare:** (206) 543-3098, comply@uw.edu |
| NOTES: |
| **Radiation – Imaging and Radioactive Materials** | If the trial includes use of any type of radiation (x-rays, nuclear medicine, radiation therapy, etc.), you must apply for an Authorization to Use Radiation on Human Subjects from the UW Radiation Safety Office. [*http://www.ehs.washington.edu/rso/*](http://www.ehs.washington.edu/rso/)[*http://www.ehs.washington.edu/forms/rso/rsoform.shtm*](http://www.ehs.washington.edu/forms/rso/rsoform.shtm) |
| NOTES: |
| **Recombinant DNA and Human Gene Therapy** | Trials involving human gene transfer or recombinant DNA based vaccines must be reviewed and approved by the UW’s Institutional Biosafety Committee (IBC) prior to enrolling patients. All human gene transfer trials must be reviewed by the NIH Recombinant DNA Advisory Committee prior to approval by the UW IBC. [*http://www.ehs.washington.edu/rbsresplan/ibc.shtm*](http://www.ehs.washington.edu/rbsresplan/ibc.shtm) |
| NOTES: |
| **Stem Cells** | The UW Embryonic Stem Cell Research Oversight Committee (ESCRO) reviews and approves research involving human embryonic stem cells (hESC). The ESCRO Committee review ensures that both institutional and public concerns regarding sensitive ethical, legal, scientific, and policy issues unique to hESC research are addressed. If your trial involves stem cells, contact ESCRO. [*http://www.washington.edu/research/escro/*](http://www.washington.edu/research/escro/) |
| NOTES: |
| **Vertebrae Animal Research** | If the trial has an animal research component, you will need oversight by the UW Institutional Animal Care and Use Committee: [*http://oaw.washington.edu/*](http://oaw.washington.edu/). Contact UW Comparative Medicine for additional resources: [*http://depts.washington.edu/compmed/*](http://depts.washington.edu/compmed/) |
| NOTES: |
| **TRAINING/CREDENTIALING** |
| **Human Subjects Protections and GCP Training** | There is no institutional-wide requirement for human subjects training at the University of Washington. However, many sponsors, funding agencies, UW departments, and collaborating institutions require that all members of the research team have completed a standard training course on the protecting human subjects in research. The Collaborative Institutional Training Initiative (CITI) web-based training meets the Human Subjects Protection and Good Clinical Practice (GCP) requirements of most industry sponsors, and there may be sponsor-mandated renewal periods (repeat courses every 2-3 years). To take a course on the CITI website, you must register for an account and then affiliate yourself with the UW (you may need to manually add the GCP module onto your CITI training dashboard). [*http://www.washington.edu/research/hsd/courses/*](http://www.washington.edu/research/hsd/courses/) |
| **Clinical Trial Policy Training** | CRBB provides Clinical Trial Policy Training to ensure that all UW Medicine faculty have a uniform knowledge of the regulations governing clinical research and that they understand the internal processes that have been implemented in order to maintain compliance in clinical research billing. [*https://depts.washington.edu/crbb/Training\_CTP.shtml*](https://depts.washington.edu/crbb/Training_CTP.shtml)Research support staff may also need to complete the CRBB modules within the UW Medicine Clinical Research Staff Training Program (CRB1, CRB2, CRB3). *https://depts.washington.edu/crbb/Training\_CRS\_req.shtml*  |
| **HIPAA Training** | UW employees who are involved with research conducted with UW Medicine facilities must complete “HIPAA Online Training” and sign the “UW Medicine Privacy, Confidentiality and Information Security Agreement” within the first 30 days of the individual’s first day as a member of the research team. [*http://depts.washington.edu/comply/training-programs/hipaa-privacy-and-information-security-training/*](http://depts.washington.edu/comply/training-programs/hipaa-privacy-and-information-security-training/) |
| **Epic Training** | For trials that utilize UW Medicine clinical facilities, investigators (or their designees) are required to use Epic scheduling software to enter research subject enrollment status information and to forward study-related admission notifications to the UW Clinical Research Budget and Billing office. To do this work, members of the research team need to complete Epic training and obtain access to Epic. To register for the Epic classroom training course, RES110: Epic Research Participant Enrollment: [*https://depts.washington.edu/erctrain/Classes.html*](https://depts.washington.edu/erctrain/Classes.html)[*https://services.uwmedicine.org/oip/form/newAccount.jsp*](https://services.uwmedicine.org/oip/form/newAccount.jsp) |
| **Clinical Research Billing for Research Procedures** | There are complex federal and private payer rules that govern the conditions under which clinical services, items and tests associated with a research study can be billed to study sponsors, study subjects and/or their insurers. Research teams are required to use Epic to accurately bill for research procedures. Accurate research billing depends on planning and collaboration between the research team and a wide variety of individuals and offices before, during and after the study is initiated. [*https://depts.washington.edu/comply/policies-procedures/#research-billing-compliance-policies*](https://depts.washington.edu/comply/policies-procedures/#research-billing-compliance-policies)Other resources:[*https://depts.washington.edu/crbb/Research\_Patient\_Linking.shtml*](https://depts.washington.edu/crbb/Research_Patient_Linking.shtml)*,* [*https://depts.washington.edu/crbb/EPIC\_Tools.shtml*](https://depts.washington.edu/crbb/EPIC_Tools.shtml) |
| **Bloodborne Pathogens** | If members of the research team have a potential for exposure to human blood and its components, human tissue, all human cell lines, human source materials, as well as medications derived from blood (e.g., immune globulins, albumin) and other potentially infectious materials, your research team IS required to comply with the UW's Bloodborne Pathogens Program (one hour annual online training). [*https://www.ehs.washington.edu/rbs/bbp.shtm*](https://www.ehs.washington.edu/rbs/bbp.shtm)  |
| **Radiation Safety Training** | Members of your research team may need to complete radiation safety training or review “Radiation Safety Training for Ancillary Personnel” annually. [*https://www.ehs.washington.edu/rsotrain/ancillary\_rad\_safety.shtm*](https://www.ehs.washington.edu/rsotrain/ancillary_rad_safety.shtm)[*https://www.ehs.washington.edu/rsotrain/radclass.shtm*](https://www.ehs.washington.edu/rsotrain/radclass.shtm) |
| **Shipping Biohazards** | If your research team will package and ship specimens via land, air, or sea, all team members must be trained and certified to ship hazardous materials (4-hr course repeated every 2 years). There are prescriptive requirements for packaging and labeling of hazardous materials and for the associated documentation used in the event of an emergency. There are fines for lack of certification and improper packaging and, worse, a chance for loss of life and property. [*https://www.ehs.washington.edu/eposhiphazmat/*](https://www.ehs.washington.edu/eposhiphazmat/) |
| **UWMC Credentialing** | The UWMC credentialing process ensures that individuals including research staff (specifically, personnel other than physicians, Nurse Practitioners, and Physician’s Assistants) who interact with patients at UWMC are competent to practice in their role and have current immunizations to ensure the safety of the patients. Some credentialing documents must be updated annually in your records. [*http://www.uwmedicine.org/uw-medical-center/credentialing*](http://www.uwmedicine.org/uw-medical-center/credentialing)  |
| NOTES: |
| **PRE-STUDY PREPARATION** |
| **Confirm Research Support Services and Facilities** | Based on your final budget and contract, contact the supporting departments who will be involved with the trial to let them know you are ready to begin. This might include:* ITHS CLINICAL RESEARCH CENTER [*https://www.iths.org/investigators/units/crc/*](https://www.iths.org/investigators/units/crc/)
* IDS PHARMACY [*https://depts.washington.edu/drugsvcs/home/content/investigational-drug-service-ids*](https://depts.washington.edu/drugsvcs/home/content/investigational-drug-service-ids)
* **You will need to create template MD orders for IDS pharmacy.**
* HMC (206) 744-5448 hmcids@u.washington.edu
* UWMC (206) 598-6054, uwmcids@u.washington.edu
* UW LABORATORY MEDICINE [*http://depts.washington.edu/labweb/*](http://depts.washington.edu/labweb/), (206) 598-6131, lmofficesupport@uw.edu
* Research Testing Services [*http://depts.washington.edu/labweb/Research/index.htm*](http://depts.washington.edu/labweb/Research/index.htm), (206) 616-8979, rts@uw.edu
* **You will need to obtain RTS requisition forms from RTS prior to study initiation.**
* UW DEPARTMENT OF PATHOLOGY [*http://www.pathology.washington.edu/research/request/*](http://www.pathology.washington.edu/research/request/)
* UW DEPARTMENT OF RADIOLOGY RESEARCH PROGRAM [*http://www.rad.washington.edu/research/research-services*](http://www.rad.washington.edu/research/research-services)
 |
| NOTES: |
| **Site Initiation Visit** | Many industry sponsors/CROs conduct a Site Initiation Visit (SIV) to prepare and set up a research site, conduct protocol training, and ensure the Principal Investigator (PI) fully understands all trial responsibilities. The visit usually occurs after the site has completed all regulatory requirements, including IRB approval, but prior to recruiting participants. The sponsor/CRO will want to meet with the PI and as many members of the research team as possible. The sponsor/CRO may ask to meet with representatives from supporting departments (pharmacy, radiology, lab medicine, etc.).Topics of discussion during the site initiation visit include:* PI responsibilities
* PI and research team qualifications
* Study objectives, eligibility criteria, recruitment, and procedures
* Space requirements, availability of a secure area to store investigational drug or devices, availability of required equipment
* Lab manual, specimen processing, and shipping
* Regulations and Good Clinical Practice (GCP) guidelines, informed consent requirements, IRB obligations, adverse event reporting, drug accountability, source documentation, and records retention (regulatory documents and study file organization)
* Data forms review (Case Report Forms, or CRFs), including electronic data entry
 |
| NOTES: |
| **Access to UW Electronic Medical Records** | If you will use the UW’s electronic medical record systems (ORCA and Epic) to identify eligible patients or capture clinical data about participants, you’ll need to request ORCA and Epic access for necessary research staff from User Access Administration: [*https://info.medical.washington.edu/online/support\_Forms/new-account.aspx*](https://info.medical.washington.edu/online/support_Forms/new-account.aspx)If you access PHI for research purposes under an IRB-approved HIPAA waiver, you must record and submit records of the dates and purposes of these disclosures to UW Medicine Compliance via the UW Medicine Disclosure Accounting online database. [*http://depts.washington.edu/comply/compliance-programs/hipaa-program/accounting-of-disclosures/*](http://depts.washington.edu/comply/compliance-programs/hipaa-program/accounting-of-disclosures/) |
| NOTES: |
| **Laboratory Medicine and Research Testing Services** | If results of testing performed by UW Lab Medicine will be part of data capture, you must maintain copies of CLIA and CAP certifications. [*http://depts.washington.edu/labweb/AboutLM/Accred/*](http://depts.washington.edu/labweb/AboutLM/Accred/)You must also maintain a list of lab normal ranges for clinical tests included in your data, easily accessible via MINDscape.Lab Medicine is also the home department for Research Testing Services, which coordinates and provides research-related phlebotomy, CLIA-licensed testing, research-only testing, processing, and limited specimen storage. RTS provides paper Requisition Forms that must accompany all samples delivered to UW Labry Medicine for phlebotomy/processing/testing. [*http://depts.washington.edu/labweb/Research/index.htm*](http://depts.washington.edu/labweb/Research/index.htm) |
| NOTES: |
| **Research Instrument Validation and Calibration** | Scientific Instruments supports over 18,000 pieces of patient care, laboratory, and research equipment with UW system. Their records can be used to document compliance with TJC, CAP, CLEA, AABB, FDA, CMS, or other accrediting agencies requirements for equipment maintenance. [*https://depts.washington.edu/hsasf/scientific-instruments/*](https://depts.washington.edu/hsasf/scientific-instruments/)  |
| NOTES: |
| **Arranging Compensation for Research Participants** | Trials often offer compensation to research participants to encourage and appreciate the time and effort involved in participation. Payments or travel/parking reimbursements to research subjects must be approved by the IRB as part of the research activities. You may need to work with your department to identify specific procedures for compensation of research participants. Resources:* HSD: <http://www.washington.edu/research/hsd/docs/1271>
* UW Procurement: <https://f2.washington.edu/fm/ps/how-to-pay/research-subjects/>
* UW Transportation (parking): <http://www.washington.edu/facilities/transportation/park-dept#1>
 |
| NOTES: |
| **Register on [participatein](http://www.participateinresearch.org)****[research.org](http://www.participateinresearch.org)** | UW researchers can post their trials to [www.participateinresearch.org](http://www.participateinresearch.org), so potential volunteers can search for studies that apply to them. |
| NOTES: |
| **Create Study Database** | For investigator-initiated studies, many researchers set up custom study databases to centralize data entry optimized for analysis. You might choose to use Microsoft Excel or Access, or REDCap. [*https://www.iths.org/investigators/services/bmi/redcap/*](https://www.iths.org/investigators/services/bmi/redcap/)[*https://www.iths.org/investigators/services/bmi/redcap/redcap-training/*](https://www.iths.org/investigators/services/bmi/redcap/redcap-training/)  |
|  |
| **Register on** [**clinicaltrials.gov**](http://www.clinicaltrials.gov) | Certain types of interventional clinical research studies are required to be listed on ClinicalTrials.gov, but all researchers may post their study to ClinicalTrials.gov (even observational studies). Resources: * <http://www.washington.edu/research/hsd/docs/1113>
* <https://clinicaltrials.gov/ct2/manage-recs>
 |
| NOTES: |
| **Set Up the Study Binder** | Regulatory binders help research teams organize their files, maintain regulatory compliance, and adhere to Good Clinical Practice (GCP) standards for record keeping practices for research involving human subjects. Most sponsors/CROs will provide the organizational forms and supplies they require you to maintain throughout the trial. See ICH GCP guidance, E6, section 8 “Essential Documents for the Conduct of a Clinical Trial” [*http://www.fda.gov/downloads/Drugs/guidances/ucm073122.pdf*](http://www.fda.gov/downloads/Drugs/guidances/ucm073122.pdf)Sample ITHS forms: <https://www.iths.org/investigators/forms-templates/study-document-templates/>  |
| NOTES: |
| **Do a Walk Through** | To make sure you are prepared to conduct the trial, do a walk-through of the research procedures before you schedule the first visit:* Confirm pre-screening steps in Epic and ORCA
* Create visit packets that contain your recruitment, consent, and data collection resources you will use when approaching participants
* Role play a recruitment conversation using the recruitment script
* Pretend to schedule a study visit
* Role play an informed consent discussion
* Walk from the place where you’ll meet the participant to the visit location(s)
* Make sure you have everything you need at the visit location(s): lab kits, MD orders, pharmacy communication, lab requisition slips, data collection forms, laptop to access eCRFs/regulatory docs, equipment calibrated and in working order, mailing/shipping containers
* Review data collection forms (CRFs) and confirm access to electronic data entry system
 |
| NOTES: |