

**Study Implementation Checklist**

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| **IDENTIFY AND ENROLL ELIGIBLE PARTICIPANTS** | |
| **Pre-screen Records to Identify Eligible Participants** | If you are using Epic or ORCA to identify possible subjects to approach for research, you should have IRB approval of a Waiver of HIPAA Authorization (and if the UW is the IRB reviewing the project, a Waiver of Informed Consent also). See the Pre-Study Initiation Checklist sections “IRB Approval” and “Access to UW Electronic Medical Records.”  If you access patient medical information 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/)  [*http://depts.washington.edu/comply/docs/PP\_18.pdf*](http://depts.washington.edu/comply/docs/PP_18.pdf)  [*http://depts.washington.edu/comply/docs/PP\_25.pdf*](http://depts.washington.edu/comply/docs/PP_25.pdf)  It may be helpful to talk with an informatics consultant about extracting data from the medical record.  [*https://www.iths.org/investigators/services/bmi/*](https://www.iths.org/investigators/services/bmi/) |
| NOTES: | |
| **Recruitment and Informed Consent** | Recruitment is often an iterative process. It is a good idea to document the effectiveness of individual recruitment techniques in case they are not working. You can use this data to change course later if needed.  Some funding agencies and industry sponsors require that you submit a list of potential participants screened as part of the recruitment process, along with documentation of why ineligible individuals did not meet study criteria. They may provide you with a screening log to submit, or you may need to create your own ([*https://www.iths.org/investigators/forms-templates/study-document-templates/*](https://www.iths.org/investigators/forms-templates/study-document-templates/)).  Once you’ve confirmed that an individual is interested in learning more about the study, you can proceed to conduct informed consent discussion. You will need to obtain documentation of informed consent as required by the IRB-approved consent procedures. There may be multiple consent and assent forms, along with translated consent forms, depending on the study population. It may be necessary to tailor your consent discussion for each population involved, and to arrange for interpretation services.  Provide copies of the signed consent and HIPAA forms to participants, but keep the originals in your files. Check your IRB approval to see if you described how to file documents that contain participant identifiers, and follow the process as approved. |
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| **Screening to Confirm Eligibility** | Once a participant has provided informed consent for your study, check their information against the eligibility criteria to ensure they continue to qualify to participate in the study. If still eligible, proceed with any protocol-required screening procedures. Once you confirm the participant can continue in the study, you can assign them a study ID code.  If CRBB was involved in finalizing your budget, notify CRBB of subject enrollment (this process is covered in the Epic RES110 course, but questions about how to do this can be directed to [crbb@uw.edu](mailto:crbb@uw.edu))  If you are working with an industry sponsor, you may also need to notify them of enrollment and discuss study invoicing needs with your department fiscal specialist. |
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| **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) |
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| **RESEARCH VISITS AND DATA CAPTURE** | |
| **Study Visits** | Schedule and conduct study visits and research activities per the IRB-approved protocol. Work with service providers and facilities to support intervention and data collection needs (see Pre-Study Initiation Checklist sections “Training/Credentialing,” “Confirm Research Support Services and Facilities,” “Research Instrument Validation and Calibration,” and “Arranging Compensation for Research Participants.”) |
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| **Data Capture** | To complete Case Report Forms (CRFs), capture study visit documentation from participants’ medical records, and evaluation instruments and questionnaires. Enter study data into your data management system, which might be an eCRF or a custom database created in REDCap, Excel, or Access. <https://www.iths.org/investigators/services/bmi/redcap/> |
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| **Specimens** | Many studies include collection and/or analysis of specimens, like blood, urine, and/or tissue. Be sure to follow both protocol and institutional requirements for collecting, processing, shipping, analysis, and storage of study specimens.  [*https://www.ehs.washington.edu/rbs/bbp.shtm*](https://www.ehs.washington.edu/rbs/bbp.shtm)  [*https://www.ehs.washington.edu/eposhiphazmat/*](https://www.ehs.washington.edu/eposhiphazmat/) |
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| **MAINTAIN REGULATORY AND FINANCIAL RECORDS** | |
| **Problem Reports (Deviations and Adverse Events)** | Carefully identify, document, resolve and report any problems that occur throughout the study. IRBs, FDA, and funding agencies each have specific timelines and guidelines for reporting these events, so check with your contacts to understand your responsibilities. They may provide you with an adverse event tracking log to submit, or you may need to create your own ([*https://www.iths.org/investigators/forms-templates/study-document-templates/*](https://www.iths.org/investigators/forms-templates/study-document-templates/)). |
| NOTES: | |
| **Submit Protocol Amendments** | If you need to make changes to your study after you obtain initial IRB approval, you will need to submit a request to modify, or amend, your study to the IRB in advance of initiating the change. If you are working on an industry trial, confirm with the sponsor whether they will submit changes for you.  If you are conducting an investigator-initiated study and have a protocol, be sure to update this document with any applicable changes throughout the study (and change the version number and date with each revision). If you are conducting an investigator-initiated IND or IDE study, check with your FDA contact to determine if they also need to approve the protocol change.  If the changes will impact the study budget, you may need to contact CRBB to re-negotiate budget and OSP to re-negotiate contract. [*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) |
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| **Submit Progress Reports** | You will receive the expiration date for your IRB approval at the time of your initial approval, and with each subsequent continuing approval. This date will vary based on the study. Prior to your IRB approval expiration date, you will need to submit a continuing review report to the IRB. Follow the IRB’s procedures for submitting the progress report within their stated timeframe. [*https://www.washington.edu/research/hsd/docs/1720*](https://www.washington.edu/research/hsd/docs/1720)  If you are conducting an investigator-initiated IND or IDE study, check with your FDA contact to find out their requirements for Progress Report contents and timelines. [*http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.64*](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.64)  Check with your funding agency about their annual reporting requirements (for example, NIH requires reporting race/ethnicity stats for enrolled participants). |
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| **Monitoring Study Records** | If you are working with industry, or if you are acting as a sponsor-investigator on an investigator-initiated IND or IDE study, you will need to participate in monitoring visits throughout the study. This may be done in-person or remotely. If you have a data management center reviewing study data, be sure to prioritize quick turnarounds for data queries.  If your study does not have external monitoring, it is good practice to periodically review the data and regulatory records to ensure you are capturing data as planned and meeting your regulatory responsibilities. It may be helpful to consult an ITHS research monitor. [*https://www.iths.org/investigators/services/regulatory-monitoring/*](https://www.iths.org/investigators/services/regulatory-monitoring/)  It may be helpful to talk with a biostatistician about conducting interim data analysis. [*https://www.iths.org/investigators/services/cbs/*](https://www.iths.org/investigators/services/cbs/)  If your study includes a DSMB, understand their scope of work (usually in a charter, which you may receive a copy of) and meeting schedule, along with your role in providing information or responding to their inquiries. |
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| **Monitor the Budget** | Balancing costs, spending and budgetary allowances at least monthly is paramount to staying on track. If you are working with an industry sponsor, your final Clinical Trials Agreement (CTA) will specify what should be invoiced to the sponsor. Submit invoices to the sponsor within the timeframes outlined in the CTA. If you are working with a funding agency, check with the UW Office of Sponsored Programs and/or your department’s grants manager about budget spending restrictions, and for information on no-cost extensions. UW OFFICE OF SPONSORED PROGRAMS (206) 543-4043, [osp@uw.edu](mailto:osp@uw.edu) |
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| **Complete Refresher Trainings on Human Subjects Protections and GCP** | Many funding agencies/sponsors have requirements to complete human subject protections and/or Good Clinical Practice refresher training. Check with your sponsor about expected time frames. [*http://www.washington.edu/research/hsd/courses/*](http://www.washington.edu/research/hsd/courses/) |
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