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**Research Feasibility Checklist Template**

***This checklist template provides departments with an outline of the information to consider when assessing study feasibility. Use of this checklist is not required. This document may be customized to suit department needs, or departments may elect to create their own forms to document feasibility assessment.***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Principal Investigator** | | | | | |
| **Name *(Last, First)*** | **Title**  Choose an item. | | | | |
| **Department** | **Email** | | | | |
| **Point of Contact (If other than PI)** | | | | | |
| **Name *(Last, First)*** | **Email** | | | | |
| **Study Details** | | | | | |
| **Title** | | | | | |
| **Anticipated Start Date**  Click or tap to enter a date. | **Anticipated End Date**  Click or tap to enter a date. | | | | |
| **UW Recruitment Goal**  Number of Subjects:     Number of Healthy Volunteers: | | | | | |
| **Department & Scholarly Merit** | | **Yes** | **No** | **Unknown** | **N/A** |
| 1. Is the study meritorious with the potential for peer-reviewed publications and/or external recognition? | |  |  |  |  |
| 1. Is the study aligned with the department’s priorities? | |  |  |  |  |
| 1. Is this study similar to previous studies conducted at the site? | |  |  |  |  |
| * If yes, were these previous studies conducted successfully? | |  |  |  |  |
| 1. Is there an impact on the UW reputation or specific academic interests related to this research? | |  |  |  |  |
| **Fiscal** | | **Yes** | **No** | **Unknown** | **N/A** |
| 1. Is external and/or internal funding sufficient to cover total study budget expenses inclusive of regulatory and non-departmental ancillary program/services? | |  |  |  |  |
| 1. Have you conducted research with this sponsor or funder in the past? | |  |  |  |  |
| 1. Does the clinical trial agreement include problematic terms? | |  |  |  |  |
| 1. Is the study sponsor financially sound? | |  |  |  |  |
| 1. Will the study require insurance reimbursement from government and/or private payers? | |  |  |  |  |
| 1. If the study is cancelled prior to enrollment, will the sponsor pay for pre-study activities (IRB submission, meetings)? | | ☐ | ☐ | ☐ | ☐ |
| **Personnel** | | **Yes** | **No** | **Unknown** | **N/A** |
| 1. Does the investigator possess the qualifications to oversee the study? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will the study procedures be performed by clinical health care system providers/employees? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will all personnel engaged in the study meet the following requirements: 2. appropriate experience, credentials, and training to assure study fidelity, data integrity, and subject safety; 3. sufficient time available to conduct the research based on other commitments; 4. performing study activities commensurate with their job description, practice (or non-practice) limits, and training; and 5. appropriately supervised and monitored? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will any study procedures or evaluations occur outside of regular clinic or unit hours? | | ☐ | ☐ | ☐ | ☐ |
| * If yes, will clinical health care system providers/employees be expected to perform study procedures or assessments outside of clinic or unit hours? | | ☐ | ☐ | ☐ | ☐ |
| 1. Are staff credentialed to perform required study procedures? | | ☐ | ☐ | ☐ | ☐ |
| 1. Is current staffing adequate to conduct the trial? | | ☐ | ☐ | ☐ | ☐ |
| 1. Are pharmacy personnel adequate to conduct the study? | | ☐ | ☐ | ☐ | ☐ |
| 1. Are laboratory personnel adequate to conduct the study? | | ☐ | ☐ | ☐ | ☐ |
| 1. Does the sponsor require special study training for all personnel? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will the dosing schedule be complex or create scheduling issues for personnel? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will the study utilize personnel outside the department? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will this study involve personnel with clearance to conduct data exchange or data extraction from any EHR system (e.g. HealthLink) or other sources of patient data (e.g., MyChart, tumor registry)? | | ☐ | ☐ | ☐ | ☐ |
| **Space and Facilities** | | **Yes** | **No** | **Unknown** | **N/A** |
| 1. Will the study involve invasive procedures? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will study procedures be performed within a clinical health care system facility (e.g. UW Hospital & Clinics; UW 1 S. Park; UW TAC; Meriter)? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will clinical care areas be utilized, and appropriate clinical notification provided to access said clinical care areas for study purposes? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will non-clinical space (e.g., research offices) be utilized for study procedures? | | ☐ | ☐ | ☐ | ☐ |
| * If yes, are the study procedures to be conducted within non-clinical space appropriate with the necessary safeguards for subject safety present? | | ☐ | ☐ | ☐ | ☐ |
| 1. Are standard clinic or unit supplies required to conduct the study? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will the study utilize the Clinical Research Unit (CRU)?  * If yes, see [Clinical Research Unit (CRU).](https://ictr.wisc.edu/groups/clinical-research-unit-cru/) | | ☐ | ☐ | ☐ | ☐ |
| 1. Will the study utilize WIMR imaging services?  * If yes, see [WIMR Medical Research Imaging Facility](https://ictr.wisc.edu/groups/wisconsin-institutes-for-medical-research-imaging-facility/). | | ☐ | ☐ | ☐ | ☐ |
| 1. Will the study utilize pathology services?  * If yes, see [Translational Science BioCore (TSB)](https://cancer.wisc.edu/research/resources/tsb/) and [TRIP Lab](https://www.pathology.wisc.edu/research/trip). | | ☐ | ☐ | ☐ | ☐ |
| 1. Are the arrangements for shipping samples or specimens practical given the available facilities and collection equipment? | | ☐ | ☐ | ☐ | ☐ |
| 1. Are laboratory tests required outside of laboratory hours? | | ☐ | ☐ | ☐ | ☐ |
| 1. Does the study team have adequate space to store specimens? | | ☐ | ☐ | ☐ | ☐ |
| 1. Does the study team have adequate space to store subject records and other study materials? | | ☐ | ☐ | ☐ | ☐ |
| **Equipment and Test Articles** | | **Yes** | **No** | **Unknown** | **N/A** |
| 1. Does the study require submission of an IND/IDE?   If yes, see [ICTR IND/IDE consultation service](https://ictr.wisc.edu/ind-ide-consultation-service/)*.* | |  |  |  |  |
| 1. Is specialized equipment required to conduct the study? | | ☐ | ☐ | ☐ | ☐ |
| 1. Is specialized pharmacy equipment or procedures required for the test article? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will specialized equipment procured specifically for the study be appropriately obtained, housed, inventoried, and returned/accounted for at end of study? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will equipment require plant engineering certification and can that be arranged? | | ☐ | ☐ | ☐ | ☐ |
| 1. Is access to existing clinical equipment required and can approval of such access be obtained? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will test articles (e.g., drugs, devices) be procured, inventoried, stored, secured, dispensed, labeled and disposed of in accordance with FDA regulations, UWHC, UWMF and UW SMPH policy 4.11 “[Investigational and Study Drug Control Policy](https://uconnect.wisc.edu/policies/administrative/uwhc/uwhc-wide/legal-affairs/411.policy) and HS IRBs Policy on the [Control of Test Articles Used in Research](https://kb.wisc.edu/page.php?id=58860). | | ☐ | ☐ | ☐ | ☐ |
| 1. Will imaging equipment be required as part of the study? | | ☐ | ☐ | ☐ | ☐ |
| * If yes, which of the following imaging equipment is required:   ☐ MRI  CT  PET  Ultrasound  BART  XRAY  Other: | | | | | |
| 1. Will the study require image de-identification, analysis and data transfer? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will the study require institutional biosafety committee approval?   If yes, see [Institutional Biosafety Committee (IBC)](https://ehs.wisc.edu/institutional-biosafety-committee-ibc/) | | ☐ | ☐ | ☐ | ☐ |
| 1. Does the study team have access to adequate equipment to store samples and/or specimens? | | ☐ | ☐ | ☐ | ☐ |
| **Constituent Endorsement** | | **Yes** | **No** | **Unknown** | **N/A** |
| 1. Have other departments, clinics, or operational units that may be impacted by, or provide services for, the research (e.g., Clinical Research Unit, Office of Clinical Trials, informatics, pharmacy, nursing, laboratory, and imaging) been informed and agreed to support the conduct of the study? | | ☐ | ☐ | ☐ | ☐ |
| 1. Are other sites in the local area participating in the study? | | ☐ | ☐ | ☐ | ☐ |
| 1. Does the study support institutional objectives, such as patient care, education, physician relations, and marketing? | | ☐ | ☐ | ☐ | ☐ |
| **Acceptable Clinical Practice** | | **Yes** | **No** | **Unknown** | **N/A** |
| 1. Does the proposed research utilize acceptable practice for the discipline? | | ☐ | ☐ | ☐ | ☐ |
| 1. Can the study be successfully implemented into routine standard of care practice? | | ☐ | ☐ | ☐ | ☐ |
| 1. Are there any alternatives available for this patient population? | | ☐ | ☐ | ☐ | ☐ |
| 1. Is there a clinical impact on patient treatment or need for therapy? | | ☐ | ☐ | ☐ | ☐ |
| 1. Are there any procedures that are not standard of care? | | ☐ | ☐ | ☐ | ☐ |
| 1. Is the use of a placebo acceptable? | | ☐ | ☐ | ☐ | ☐ |
| 1. Is the safety profile of the investigational product acceptable? | | ☐ | ☐ | ☐ | ☐ |
| 1. Are frequent and severe adverse events expected? | |  |  |  |  |
| 1. Will subjects incur any costs due to participation? | | ☐ | ☐ | ☐ | ☐ |
| **Recruitment** | | **Yes** | **No** | **Unknown** | **N/A** |
| 1. Are similar studies open to enrollment or under consideration that will draw from the same population? | | ☐ | ☐ | ☐ | ☐ |
| * If yes, is there a plan to address competing recruitment goals? | | ☐ | ☐ | ☐ | ☐ |
| 1. Is there a sufficient study population from which to recruit participants? | | ☐ | ☐ | ☐ | ☐ |
| 1. Does the proposed recruitment plan support meeting target recruitment goals? | | ☐ | ☐ | ☐ | ☐ |
| 1. Are the inclusion/exclusion criteria reasonable to meet enrollment goals? | | ☐ | ☐ | ☐ | ☐ |
| 1. Is enrollment competitive? | | ☐ | ☐ | ☐ | ☐ |
| 1. Is the enrollment goal realistic? | | ☐ | ☐ | ☐ | ☐ |
| 1. Are the proposed enrollment milestones achievable? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will participants include populations with extra recruiting and informed consent requirements (e.g. LAR consent, translated recruitment materials)? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will the intervention (e.g., drug, device) be available to subjects for continued treatment at the end of the study? | | ☐ | ☐ | ☐ | ☐ |
| 1. Is subject retention and compliance of concern? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will any of these factors impede enrollment: | | ☐ | ☐ | ☐ | ☐ |
| * Washout period? | | ☐ | ☐ | ☐ | ☐ |
| * Age? | | ☐ | ☐ | ☐ | ☐ |
| * Duration of participation? | | ☐ | ☐ | ☐ | ☐ |
| * Frequency of visits? | | ☐ | ☐ | ☐ | ☐ |
| * Frequency of dosing? | | ☐ | ☐ | ☐ | ☐ |
| * Procedural discomfort? | | ☐ | ☐ | ☐ | ☐ |
| * Other medical conditions? | | ☐ | ☐ | ☐ | ☐ |
| * Medication restrictions? | | ☐ | ☐ | ☐ | ☐ |
| 1. Are there any procedures that are difficult for the patient population to tolerate? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will this study require participant education on procedures? | | ☐ | ☐ | ☐ | ☐ |
| 1. Are any of the procedures inconvenient causing subjects to miss work/school or require lengthy scheduling? | | ☐ | ☐ | ☐ | ☐ |
| 1. Are the screening procedures practical, limits and yields reasonable, and payments acceptable? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will participants be compensated for participation? | | ☐ | ☐ | ☐ | ☐ |
| 1. Are there unusual reporting or other administrative requirements? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will participants receive any benefits from participation? | | ☐ | ☐ | ☐ | ☐ |
| 1. Will participants complete diaries? | | ☐ | ☐ | ☐ | ☐ |
| * If yes, will the diaries require staff time for transcription or interpretation? | | ☐ | ☐ | ☐ | ☐ |
| **Data Security and EHR Considerations** | | **Yes** | **No** | **Unknown** | **N/A** |
| 1. Are the following data and/or sample processes identified: | | ☐ | ☐ | ☐ | ☐ |
| * Designation of who maintains the data and/or samples? | | ☐ | ☐ | ☐ | ☐ |
| * Process for data and/or sample storage? | | ☐ | ☐ | ☐ | ☐ |
| * The sources from which data and/or samples are collected? | | ☐ | ☐ | ☐ | ☐ |
| * How the data and/or samples are collected? | | ☐ | ☐ | ☐ | ☐ |
| * Designation of who will collect the data and/or samples? | | ☐ | ☐ | ☐ | ☐ |
| * How the data and/or samples are labeled? | | ☐ | ☐ | ☐ | ☐ |
| * Location where the data and/or samples will be stored? | | ☐ | ☐ | ☐ | ☐ |
| * How the data and/or samples are secured? | | ☐ | ☐ | ☐ | ☐ |
| * How the data and/or samples will be accessed and/or shared? | | ☐ | ☐ | ☐ | ☐ |
| * Is the expected data volume larger than 500 patients (e.g., expected number of patient records and specification of data elements, including test and control groups) | | ☐ | ☐ | ☐ | ☐ |
| 1. ICTR’s [Clinical and Health Informatics Institute (CHI2)](https://ictr.wisc.edu/biomedical-informatics/) has been consulted and agreed to support research that requires: | | ☐ | ☐ | ☐ | ☐ |
| * Data extraction services from the electronic health record (e.g., HealthLink, tumor registry). | | ☐ | ☐ | ☐ | ☐ |
| * Modification(s) or addition(s) of electronic health record functionality (e.g., best practice alerts to support recruitment, flowsheet, data entry forms). | | ☐ | ☐ | ☐ | ☐ |
| * Complex data transformations such as Natural Language Processing (NLP), geocoding, data linkage, de-identification or de-identification/re-identification | | ☐ | ☐ | ☐ | ☐ |
| * Secured data environment for data storage and data analysis (e.g. [Research Computing Platform](http://it.med.wisc.edu/rcp-v1/)). | | ☐ | ☐ | ☐ | ☐ |
| * Research patient registries. | | ☐ | ☐ | ☐ | ☐ |
| * Data export to national or multi-site registries. | | ☐ | ☐ | ☐ | ☐ |
| 1. Is a DSMB or DMC required? If yes, has a DSMB or DMC been identified? See [ICTR Data Monitoring Committee](https://ictr.wisc.edu/groups/data-monitoring-committee/) | | ☐ | ☐ | ☐ | ☐ |
| 1. Will the study utilize OnCore for data management? See [ICTR OnCore](https://ictr.wisc.edu/oncore/). | | ☐ | ☐ | ☐ | ☐ |
| 1. Will the study utilize REDCap for study data management? See [REDCap](https://ictr.wisc.edu/redcap/). | | ☐ | ☐ | ☐ | ☐ |
| **Multi-Site Investigator-Initiated Research** | | **Yes** | **No** | **Unknown** | **N/A** |
| 1. Is this a multi-site, investigator-initiated study in which UW is the lead institution? If yes… | | ☐ | ☐ | ☐ | ☐ |
| * Are a sufficient number of investigators and other performance sites interested in conducting the study? | | ☐ | ☐ | ☐ | ☐ |
| * Will UW provide other performance sites with source documents and consent form templates? | | ☐ | ☐ | ☐ | ☐ |
| * Is a budget template available to share with performance sites? | | ☐ | ☐ | ☐ | ☐ |
| * Is current regulatory staffing capable of managing a multi‑site IRB application? If no, see [Office of Clinical Trials](https://ictr.wisc.edu/groups/office-of-clinical-trials-oct/). | | ☐ | ☐ | ☐ | ☐ |
| 1. Is this a multi-site, investigator-initiated study in which UW is **NOT** the lead institution? If yes… | | ☐ | ☐ | ☐ | ☐ |
| * Will the lead site provide source documents and consent form templates to UW? | | ☐ | ☐ | ☐ | ☐ |
| * Will the lead site provide funding to support study conduct at UW? | | ☐ | ☐ | ☐ | ☐ |
| * Will the study involve participation in a multi-site research registry? | | ☐ | ☐ | ☐ | ☐ |