This checklist covers the steps that are typically necessary to initiate an Investigator-Initiated Study after a funding source is identified. This checklist does not describe the process to secure funding.

There some activities referenced below that could be done simultaneously or in a different order, but all applicable steps must be completed prior to study initiation and subject enrollment.

Some of the links below may require a UW-Madison NetID to access.

Activity/Task	Instructions and Resources
Study Feasibility	
Consult with applicable ICTR Services and Resources if needed	Clinical Research Unit Office of Clinical Trials ICTR IND/IDE Consultation Services ICTR Study Monitoring Service ICTR Data Monitoring Committee ICTR OnCore Form Development team
Develop the protocol	The protocol is a study plan, or an investigational plan, that describes how the clinical research study will be implemented. It should be written in a comprehensive manner to leave no room for misinterpretation. The contents of a clinical research protocol should generally include the elements included in the Protocol Checklist, available in the "Before you Begin" tab of the Clinical Research Toolkit. Refer to the Health Sciences Institutional Review Board Protocol Guidance for more information. The ICTR Protocol Development Office can provide additional guidance when you are writing a clinical protocol based on a grant application.
Feasibility Assessment	Ensure the PI has the necessary resources and capabilities to carry out the proposed protocol (i.e. access to subject population, adequate time and resources)
Reach out to UW Health Ancillary Services that may be involved in the conduct of study procedures	Initiate communication with groups that provide ancillary services, such as CRU, PRC, Radiology, etc. Refer to the Contact Information on the Ancillary Services Page. *This step is important to complete as early in the process as possible not only to determine the feasibility of the services conducting the applicable study procedures, but also because you may need a budget for the services they offer. This step is also important for the applicable services to determine the workload and effort involved and to start putting procedures in place for orders, visits, etc. To avoid delay, you should start this portion of the process as soon as possible instead of waiting until you have IRB approval. It is also important to continue to communicate with the applicable services throughout the study.*

Administrative	
Enter the study in the OnCore system if the study meets the OnCore entry requirements	Learn more about which studies are required to use the OnCore system: ICTR OnCore UWCCC OnCore Reach out the OnCore Support Teams to request access and training to use the system. Refer to the ICTR OnCore User's Guide with instructions for Building OnCore Protocols
Create the Protocol Calendar/Specifications in the OnCore system	After the feasibility has been determined and the protocol has been developed, create the procedure schedule/calendar of events. Identify the procedures that will be performed and the cost center/location of each. This is done to facilitate Ancillary Services Review to ensure the appropriate procedures have been selected prior to budget development/negotiation. Refer to the ICTR OnCore User Guide for instructions to build a protocol calendar.
Complete the Clinical Trial Billing Checklist as applicable	Complete the Clinical Trial Billing Checklist, as applicable, and upload it to the corresponding OnCore system.
Route study through Ancillary Services Review	Use OnCore to route study to groups such as CRU, PRC, etc. (reference above section) via Ancillary Services Review.
Administrative: Budget & Funding	
Budget Development	Refer to the Budget Development Guidance. The Budget Development process differs based on the funding agency or sponsor. **Grant Submission:** The budget development process would have occurred as part of the grant submission process. **Contract/Agreement with a sponsor (industry or organization):** Developing a budget as part of a contract or agreement with a sponsor will likely require some negotiation. It is important to determine if you can fulfill the contract/agreement based on the amount that you are able to negotiate. **Departmental or Institutional funds:** When developing a budget using departmental or institutional funds, it is important to ensure that all costs of all procedures have been properly accounted for. Ensure that the applicable Ancillary Services that may be involved in the conduct study procedures have the opportunity to give input.
Route Contract/Agreement through the Office of Research	Ensure the appropriate agreement (Notice of Grant Award, Clinical Trial Agreement, Contract, etc.) related documentation is complete and

and Sponsored Program (RSP) using the Wisconsin Proposal Electronic Routing (WISPER) system	routed as appropriate. Refer to the instructions for using WISPER to electronically route your agreement.
Obtain study account number	Request and obtain a study account number from RSP and secure internal requisitions and/or external work orders.
Regulatory	
Submit applications (IND, IDE, BLA) to the FDA as appropriate	Consult with the ICTR IND/IDE Consultation Services if you have questions or need assistance with your submission.
Become familiar with the investigational product	Review and become familiar with the investigational product by reviewing the packet insert, investigator drug brochure (IDB), Investigator's Brochure, device manual or published literature, as applicable.
Draft the Informed Consent Document	Refer to the UW-Madison Health Sciences IRB, Informed Consent webpage.
Develop study data collection forms (visit/procedure checklists, worksheets, source documents, CRFs, etc.)	Develop the study specific data collection forms to collect the necessary data in a consistent and analyzable manner (available networks, OnCore CRFs). Refer to the Clinical Research Toolkit > Case Report Form/Source Documents for templates that can be customized for your study.
Confirm all procedures are in place for specimen/sample handling	Create an instruction or laboratory manual and corresponding documentation related to specimen/sample handling.
Develop a Manual of Procedures	Develop Standard Operating Procedures (SOPs) and/or a Manual of Procedures to describe how to conduct the study procedures described in the protocol and complete the corresponding documentation.
Develop study database	Develop a database or an electronic data capture mechanism to consistently collect, maintain, and securely store study data. ICTR supports options, including REDCap or OnCore, or refer to your department IT office/staff.
Prepare Recruitment Materials	Develop a recruitment plan that is appropriate for your subject population and prepare recruitment materials. Refer to the HRPP Recruitment of Research Participants Guidance.
Obtain applicable committee	Depending on the study, there may be other applicable committee

approvals	approvals that will be necessary prior to IRB review, such as; Scientific Review Committee or UWCCC PRMC Biosafety Committee VA R&D Committee Radioactive Drug Safety Committee There may be others depending on the study design, study procedures and/or agents that will be used in the study.
IRB Initial Application Submission	Submit the Initial IRB Application using the electronic UW-Madison IRB electronic submission software, Application Review for Research Oversight at Wisconsin (ARROW).
Initiate the ClinicalTrials.gov registration as applicable	All necessary information must be completed prior to subject enrollment (if study meets ICMJE criteria) by the Responsible Party, which may be the PI if the study is investigator initiated Refer to the Registration Requirements for ClinicalTrials.gov
Create the Regulatory Binder (including essential documents such as the Delegation of Authority/Signature log, Training log, contact list, etc.)	Develop the essential documents and create the Regulatory Files/Binder to organize the documentation currently available, designating sections for future documentation. Refer to the Regulatory Binder Guide available in the "Study Initiation" tab of the Clinical Research Toolkit.
Document IRB Approval	Include a copy of the IRB approval letter, approved protocol, consent form and HIPAA Authorization form in your regulatory files (paper), upload to the OnCore system, and enter the review in OnCore (PC Console > Reviews > IRB). Refer to the Documenting IRB Review of a Protocol instructions.
IND/IDE Activation	Retain documentation of the FDA's approval to begin the study or lapse of 30 days since previous submission/correspondence. Add this date to your calendar to ensure FDA annual reports are submitted in a timely manner.
Finalize the ClinicalTrials.gov registration as applicable	All necessary information must be completed by the Responsible Party, which may be the PI if the study is investigator initiated.
SMPH Review	Initiate the SMPH Review Process to ensure the study is ready for UW Health Study Registration.

Study Initiation	
Study/Site Initiation Visit	Conduct a team meeting to review the protocol and related procedural details prior to initiating subject enrollment. ● Background and purpose of the study ● Inclusion/Exclusion criteria ● Study procedures and schedule of events ● Study treatment procedures and investigational product administration ● Adverse event documentation and reporting criteria ● Data collection and data entry expectations
Open your study to Accrual	Complete necessary steps to open the study to Accrual. This may be done using the OnCore clinical trial management software.
Subject Recruitment/Enrollment	After the study is Open to Accrual, the study is ready to begin recruiting and enrolling subjects.
Maintain all study related documentation	It is important to maintain IRB approval and all study related documentation throughout the course of the study.

References:

International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. Document titled "E6 (R2) Good Clinical Practice: Integrated Addendum to ICH E6 (R1)" Adopted by the FDA as guidance in March 2018 and available on the FDA website: https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf

Basics of Conducting Clinical Research at UW-Madison (taken from Lesson 6 of the online training available through Learn@UW and the accompanying clinical research manual Chapter 6). Information available at: https://ictr.wisc.edu/program/basics-of-conducting-clinical-research-at-uw-health-online-training/