AWRI Study Start-up Grid Reference Guide

This guide outlines the steps of the study start-up process with a brief explanation, identification of key roles, AWRI contacts, and other information for Principle Investigators to use in understanding the process.

This guidance includes information on the following new project requests:

- **Industry Sponsored**
- **Investigator Initiated**
- **Request for Funding/Grant**

Industry Sponsored Research

Step	Contacts	PI Action	What's Happening
Initial Idea	Clinical Research Team AWRI.Inquiry@Ascension.org *If you already work with a coordinator, you can provide them the information*	• Get information about the study, usually a CDA or other protocol information from the Sponsor • Email all materials and information to Clinical Research	A staff member will be assigned to assist the PI in working with the Sponsor. They will facilitate with the AWRI Contract team to complete the CDA, review the protocol materials, and complete the site selection survey.
Institutional Approval & Feasibility Review	Staff member assigned. *General contact:* *AWRI.Inquiry@Ascension.org*	• Work with AWRI staff to gather information for feasibility, required resources and budget preparation • Attend a feasibility meeting	The Clinical Research team will ensure completion of the department and institutional approvals and conduct the study feasibility assessment. They will interface with staff from the Sponsored Programs team to prepare a budget and assess legal and financial feasibility.
Contracts/ Agreements	Staff member assigned.	• Work with AWRI staff to provide information and review the final budget and contract/agreement	Clinical Research and Sponsored Programs staff will work with the Sponsor/agency and Ascension Legal to negotiate the contract/agreement.
Required Training and Disclosures	If you work with a Clinical Research Coordinator, contact them. *General contact:* *IRB@Ascension.org*	• Complete the required disclosures and training; ensure all study staff complete them • Maintain a copy of the completion certificates for the research file (of if working with a Clinical Research Coordinator, provide them copies)	All study team members must complete human subject protection training through CITI. Depending on the kind of research and funding, training for ICH-GCP, Conflict of interest and financial COI disclosures may be required to meet federal and institutional requirements. (more information and instructions here)
IRB Review	If you work with a Clinical Research Coordinator, contact them. *General contact:* *IRB@Ascension.org*	• Gather and prepare all documents for IRB review • Work with Clinical Research staff, if assigned, and IRB staff	IRB review is required for all research happening at Ascension WI or with Ascension WI patient records. This is true whether or not the institution is engaged in conducting the research or if the AWRI IRB serves as the IRB of record. IRB Office staff work with the PI and study team to ensure the submission is complete and facilitate review by the IRB.
Safety and Ancillary Reviews	If you work with a Clinical Research Coordinator, contact them. *General contact:* *IRB@Ascension.org*	• Work with IRB and Clinical Research staff, and other reviewing parties, to ensure appropriate reviews are completed	Ancillary reviews, such and scientific review or safety reviews, including Radiation Safety and Bio-safety are facilitated through the IRB Office and Clinical Research coordinators assigned to the study. Depending on the study, review may be required before or after IRB approval and may involve other Ascension WI departments, external boards or the State of WI.
Study Initiation	If you work with a Clinical Research Coordinator, contact them.	• Work with Clinical Research staff and Sponsor/agency for site initiation and training	After all reviews and approvals are complete, there may be additional steps to open the site if there is an external Sponsor.

Investigator Initiated Research

Step	Contacts	PI Action	What's Happening
Initial Idea	Sponsored Programs Brian.Scarfenberger@Ascension.org	• Develop a fairly complete idea and be able to communicate key information such as rational, scientific merit, general procedures, needed resources, etc. • Complete the Intent to do Research form and submit to the Sponsored Programs Office	AWRI does not have dedicated staff to assist with protocol design and development but may be able to facilitate support through staff mentors or other departments, like Data Analytics. If you are working with an outside collaborator/ University, they may be able to provide support as well.
Institutional Approval & Feasibility Review	Staff member assigned. *General contact:* *Brian.Scarfenberger@Ascension.org*	• Work with AWRI staff to gather information for feasibility, required resources and budget preparation • Attend a feasibility meeting	The Sponsored Programs team will ensure completion of institutional approvals and conduct the study feasibility assessment, including preparing a budget and assess legal and financial feasibility.
Contracts/ Agreements	Staff member assigned. *General contact:* *Brian.Scarfenberger@Ascension.org*	• Work with AWRI staff to provide information and review the final budget and contract/agreement	Sponsored Programs staff will work with the Sponsor/agency and Ascension Legal to negotiate the contract/agreement.
Required Training and Disclosures	IRB Staff or General contact: IRB@Ascension.org	• Complete the required disclosures and training; ensure all study staff complete them • Maintain a copy of the completion certificates for the research file (of if working with a Clinical Research Coordinator, provide them copies)	All study team members must complete human subject protection training through CITI. Depending on the kind of research and funding, training for ICH-GCP, Conflict of interest and financial COI disclosures may be required to meet federal and institutional requirements. (more information and instructions here)
IRB Review	IRB Staff or General contact: IRB@Ascension.org	• Gather and prepare all documents for IRB review • Work with IRB and Clinical Research staff, if assigned	IRB review is required for all research happening at Ascension WI or with Ascension WI patient records. This is true whether or not the institution is engaged in conducting the research or if the AWRI IRB serves as the IRB of record. IRB Office staff work with the PI and study team to ensure the submission is complete and facilitate review by the IRB.
Safety and Ancillary Reviews	IRB Staff or General contact: IRB@Ascension.org	• Work with IRB, Clinical Research staff, and other reviewing parties to ensure appropriate reviews are completed	Ancillary reviews, such and scientific review or safety reviews, including Radiation Safety and Bio-safety are facilitated through the IRB Office and Clinical Research coordinators assigned to the study. Depending on the study, review may be required before or after IRB approval and may involve other Ascension WI departments, external boards or the State of WI.
Study Initiation	Staff member assigned, if applicable.	• Work with the Sponsor/agency for site initiation and training	After all reviews and approvals are complete, there may be additional steps to open the site if there is an external Sponsor.

Request for Funding/Grant

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