FDA Regulated
Research Oversight Program
UNIVERSITY OF WISCONSIN–MADISON

Investigator Agreement Guide

1. Purpose

The purpose of this guidance is to describe the procedures to obtain and document the investigators' agreement and commitment to conduct the clinical trial according to the protocol, applicable regulations, guidance and policies prior to allowing an investigator to participate in a clinical trial, as required by 21 CFR 312 Investigational New Drug Application, 21 CFR 812 Investigational Device Exemption, and ICH Good Clinical Practice (GCP) Guidelines.

2. Scope

This guidance document applies to clinical trials conducted under an Investigational New Drug (IND) or Investigational Device Exemption (IDE) held and managed by UW-Madison faculty members or staff.

3. Investigator Agreement

3.1. Investigational New Drug (IND) Studies

The Principal Investigator (PI)/sponsor-investigator of an IND study is expected to complete and sign a **FDA Form 1572** (https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf) listing the names of all study staff that will make a direct and significant contribution to the data[1] .

3.2. Investigational Device Exemption (IDE) Studies

The PI/sponsor-investigator of an IDE study is expected to complete and sign a **Principal Investigator Agreement**. Templates are available in the Clinical Research Toolkit.

4. Sub/Co-Investigator/Team Member Agreement

4.1. Sub/Co-Investigator/Team Member Agreement Documentation Requirements

1. For both drug and device studies, the PI is expected to ensure that each study team member that performs critical trial-related procedures, makes important trial-related decisions, and/or makes a direct and significant contribution to the data[1] is informed of their trial-related duties and documents their commitment to conduct the trial according to the protocol, applicable regulations, guidance and policies.

2. The elements to be included in the commitment documentation are listed below.
   - A statement that applicable team members have been informed of their responsibilities in this study
   - A statement that applicable team members will perform delegated study activities in accordance with the relevant, current protocol(s), applicable regulations, guidance and institutional policies, and will not implement changes to the protocol until after receiving IRB approval, except when necessary to protect the safety, rights, or welfare of subjects
   - A statement that the applicable team members have reviewed the information in the investigator's brochure, device manual, investigational drug brochure and/or package insert (as applicable), including the potential risks and side effects of the investigational product

[1] *Examples of roles that make a direct and significant contribution to the data include, but are not limited to, treatment or evaluation of research subjects, performing critical trial related procedures such as a full physical to qualify subjects for the study, and/or collecting and evaluating study data.*

These roles may be performed by co-investigator(s), sub-investigator(s) and/or other study team members. (See Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions: Statement of Investigator for further information.)

- A statement that applicable team members have the appropriate, relevant qualifications and training to perform delegated study activities
- A statement that applicable team members have disclosed complete and accurate financial information and have no perceived financial conflicts of interest that could impact their involvement in the study. In addition, they will continue to provide updated information if it changes during the study and following the completion[2] of the study, per applicable regulations

4.2. Sub/Co-Investigator/Team Member Agreement Documentation Guidance and Templates

For both drug and device studies, each member of the team that performs critical trial-related procedures, makes important trial-related decisions, and/or makes a direct and significant contribution to the data[1] is expected to document their commitment to conduct the trial according to the protocol, applicable regulations, guidance and policies.

Examples of ways to document study team members' commitment are provided below. Templates are available in the Guidance Section of the FDA Regulated Research Oversight Program webpage. This is not an exhaustive list; study teams have a variety of options, including:

1. Using one of the following templates developed by the FDA Regulated Research Oversight Program:
    a. Investigator/Team Member Agreement Form – The Investigator/Team Member Agreement form is used to document each applicable study team member's commitment individually.
    b. Investigator/Team Member Agreement Log – The Investigator/Team Member Agreement log is used to document all applicable study team members' commitment collectively.
2. Adding the required elements listed above to an existing study form.
3. Adding the recommended commitment language included in the linked templates above to an existing form (i.e. training log, delegation of authority log, etc.) to document sub/co-investigator/study team member agreement. Alternatively, the recommended commitment language could be included in email correspondence with confirmation from the sub/co-investigator/team member that they commit to the described obligations.
4. Contacting the UW FDA Regulated Research Oversight Program [compliance@lists.wisc.edu] for consultation on other documentation methods.

5. Document Maintenance

The completed and signed documents described in this guidance should be maintained in the study regulatory file(s) or a centralized location accessible to all members of the study team.

6. References

- Investigational New Drug (IND) Application, 21 CFR 312.53, Selecting investigators and monitors
- Investigational Device Exemptions (IDE), 21 CFR 812.43, Selecting investigators and monitors
- Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions: Statement of Investigator: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/frequently-asked-questions-statement-investigator-form-fda-1572
- ICH Guideline for Good Clinical Practice, E6(R2): Integrated Addendum to ICH E6(R1), Section 4.1 Investigator's Qualifications and Agreements: https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf

[2] *According to the FDA Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators, completion of the study means that all study subjects have been enrolled and follow-up of primary endpoint data on all subjects has been completed in accordance with the protocol.*