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 a UW-Madison faculty member.

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 data1.

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 on the Study Initiation tab of 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 data1 is informed of his/her trial-related duties and documents his/her 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 member 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 member has 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 perform critical trial-related procedures, making a direct and significant contribution to the data include, but are not limited to, treatment or evaluation of research subjects, performing 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.)
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- A statement that applicable team member has the appropriate, relevant qualifications and training to perform delegated study activities
- A statement that applicable team member has disclosed complete and accurate financial information and has no perceived financial conflicts of interest that could impact their involvement in the study. In addition, he/she 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 his/her commitment to conduct the trial according to the protocol, applicable regulations, guidance and policies.

Templates/examples of ways to document study team members’ commitment are provided below. These templates are available on the Study Initiation tab of the [Clinical Research Toolkit](#). This is not an exhaustive list; study teams have a variety of options, including but not limited to: 1.) use of one of the provided templates, 2.) addition of the required verbiage listed below to an existing study form, or 3.) contacting the UW FDA Regulated Research Oversight Program [compliance@lists.wisc.edu](mailto:compliance@lists.wisc.edu) for consultation on other documentation methods.

1. **Investigator/Team Member Agreement Form** – The Investigator/Team Member Agreement form is used do document each applicable study team member’s commitment individually.

2. **Investigator/Team Member Agreement Log** – The Investigator/Team Member Agreement log is used to document all applicable study team members’ commitment collectively.

3. The recommended commitment language included in the above templates could be extracted and added 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/applicable team member that they commit to the described obligations.

5. **Document Maintenance**

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

6. **References**

- Investigational Device Exemptions (IDE), [21 CFR 812.43](https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf), Selecting investigators and monitors
- 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](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](https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf), 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.