***Principal Investigator (PI) Oversight/Staff Roles and Responsibilities***

1. **PURPOSE**

To ensure clinical research staff are qualified by relevant, substantiated education and training to recognize the fundamental principles of clinical research in order to safely and ethically carry out their responsibilities, and those responsibilities delegated to them by the Principal Investigator.

**(MANDATORY LANGUAGE)**

1. **SCOPE**

This Standard Operating Procedure (SOP) applies to personnel involved in the conduct of clinical trials at the University of Michigan. It is common practice for Principal Investigators (PIs) to delegate certain clinical trial related tasks to employees, colleagues, and/or other third parties. This SOP may also apply to individuals or entities not under the direct supervision of the investigator. The management of the financial aspects of conducting a clinical trial is not within the scope of this SOP.

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 *[Optional: Insert any additional details necessary to further define the scope of this SOP]*

1. **POLICY**

This Standard Operating Procedure supports the Good Clinical Practices guidelines established by the International Conference on Harmonization (ICH), Section 4.2.4: *The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.*

In addition, ICH 4.1.5 states *the investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.*

FDA Guidance ☐ N/A

*[If this SOP is not intended for FDA regulated clinical trials, check the N/A box]*

Guidance for Industry - Investigator Responsibilities- protecting the rights, safety, and welfare of study subjects. Procedural 2009 states*: Investigators who conduct clinical investigations of drugs, including biological products, under 21 CFR Part 312, commit themselves to personally conduct or supervise the investigation. Investigators who conduct clinical investigations of medical devices, under 21 CFR Part 812, commit themselves to supervise all testing of the device involving human subjects. It is common practice for investigators to delegate certain study-related tasks to employees, colleagues, or other third parties (individuals or entities not under the direct supervision of the investigator). When tasks are delegated by an investigator, the investigator is responsible for providing adequate supervision of those to whom tasks are delegated. The investigator is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the clinical study.*

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**Additional Regulations or Policies ☐ N/A**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional project, department, sponsor, institution, state or federal policies that apply]*

1. **DEFINITIONS**

CLINICAL RESEARCH ORGANIZATION (CRO): A person that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigation, evaluation of reports, etc.

CONFLICT OF INTEREST: A financial interest or other opportunity for tangible personal benefit of an individual or his/her immediate family that may exert a substantial and improper influence on the individual's professional judgment in exercising any University duty or responsibility, including the review of research.

INTERNATIONAL CONFERENCE ON HARMONISATION (ICH): A joint initiative involving both regulators and research-based industry representatives of the European Union, Japan and the USA in scientific and technical discussions of the testing procedures required to assess and ensure the safety, quality and efficacy of medicines

MONITOR: Designated individual selected by a sponsor or contract research organization to oversee the progress of a clinical investigation.

PRINCIPAL INVESTIGATOR (PI): The lead scientist or engineer for a particular well-defined science (or other research) project, such as a laboratory study or clinical trial.

RESEARCH TEAM MEMBER: An individual fulfilling a role related to the planning, conduct, and/or completion of a clinical trial. Team members may be affiliated with organizations or departments outside the direct supervision of the Principal Investigator, such as participating research centers for a multi-site trial, Contract Research Organizations, laboratories, pharmacies, etc.

 **(MANDATORY LANGUAGE)**

*[Optional: Insert any additional definitions for technical or special terms used within the Standard Operating Procedure that may not be familiar to the lay reader]*

**Note:** Many of the definitions above were obtained from the IRBMed Glossary. These definitions were current as of 28-Jul-2015 and are subject to change. Please see the [IRBMed Glossary](http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/glossary) for the most current definitions and additional guidance.

**(MANDATORY LANGUAGE)**

1. **ROLES AND RESPONSIBILITIES**

**Principal Investigator/Designee**

The Principal Investigator is responsible for ensuring that individuals conducting or monitoring clinical research are appropriately educated, trained, informed of their obligations related to the clinical trial, and supervised in order to protect the rights and safety of research participants. The Principal Investigator shall be responsible for the following activities:

* Assesses the time and resources needed to supervise and conduct the research
* Identifies the roles and responsibilities that must be filled for safe and effective management of a clinical trial
* Defines the education and training required to fulfill research team member roles
* Reviews and manages conflicts of interest on an ongoing basis
* Provides documented training on the protocol and related procedures
* Provides additional training, as appropriate, to accommodate amendments to the protocol, staffing changes, changes in technology, etc.
* Delegates authority to research team members, vendors, Clinical Research Organizations (CROs), pharmacies, or other third parties based on education, experience, accreditation, etc.
* Recognizes which responsibilities may not be delegated
* Develops staff oversight procedures to assure appropriate completion of designated tasks
* Provides feedback to research team members on performance of designated tasks
* Ensures research team members possess, document, and maintain required education, training, certifications, licensures, etc.
* Ensures participating research sites, vendors, and other individuals not directly supervised by the investigator possess, document, and maintain required education, training, certifications, licensures, etc.
* Addresses medical and/or ethical issues that may arise during the conduct of a clinical trial

 **(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the Principal Investigator/Designee]*

**Research Team Member (study coordinator, data manager, statistician, etc.)**

An individual filling the role of Research Team Member is responsible for understanding the roles and responsibilities that have been delegated to them by the Principal Investigator, and for maintaining the qualifications and level of training required to perform the work assigned. The Research Team Member or Designee shall be responsible for the following activities:

* Understands the roles and responsibilities that have been assigned to all research team members to the degree necessary to coordinate the work
* Reads, understands, and periodically reviews the research protocol, training manuals and other documents and assures performance of assigned, research-related activities is consistent with the documents
* Seeks additional information or training as needed, to fulfill research team role
* Initiates and/or maintains documentation to demonstrate compliance with clinical trial oversight procedures
* Meets regularly to exchange information on progress of the clinical trial
* Brings concerns regarding training, assigned roles and responsibilities, or resourcing issues to the attention of the Principal Investigator or designee
* Documents their current level of education, experience and training
* Maintains required certifications, licensures and other training requirements associated with the roles and responsibilities assigned
* Monitors the conduct of a clinical trial to ensure both medical and ethical standards are maintained
* Understands the reporting obligation, and process for reporting potential medical or ethical issues which may arise during the course of a clinical trial

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the Research Team Member/Designee]*

**Additional Roles and Responsibilities**  **☐ N/A**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional role(s) and responsibilities that apply to this SOP]*

1. **PROCEDURE**

**Defining Roles and Responsibilities**

*[Describe the process that is used to define the roles and responsibilities associated with the conduct of a clinical trial, and how the qualifications (training, licensure, etc.) required to fill each role are determined.]*

*[Describe the process for assigning roles and responsibilities to individual research team members to ensure their availability and qualifications align with the requirements of the clinical trial]*

*[Describe the process that is used to ensure all research team members understand the roles and responsibilities delegated to each member of the research team for a given project e.g. Kick-off meeting, Statement of Work, Delegation of Authority Log, etc.]*

*[When oversight includes third parties such as vendors, Research Contract Organizations, clinical sites including multi-site trials, pharmacies, laboratories, etc., include any additional procedures that are necessary to ensure these parties understand the roles and responsibilities that have been delegated to them by the Principal Investigator/Designee]*

**Providing and Maintaining Training**

*[Describe the process that is used to provide training to the research team on the research protocol and related clinical trial procedures]*

*[Describe the process that is used to track, store, maintain, and retrieve records of training, certification, licensure, etc. and how their status is communicated]*

*[Describe the process that is used to provide training on the use of an investigational product or medical device]*

**Providing and Documenting Staff Oversight**

*[Describe the process for creating and maintaining staff oversight procedures, including expectations for completing and maintaining related documentation]*

*[Describe the process for evaluating and/or reporting on medical or ethical concerns that may arise during the course of a clinical trial]*

*[Describe any additional procedures that pertain specifically to the oversight of third parties such as vendors, Contract Research Organizations, clinical sites including multi-site trials, labs, etc.]*

**Additional Procedures** **☐ N/A**

*[Optional: Insert any additional relevant procedures. Provide enough detail to ensure the procedure is consistently carried out, without providing so much detail that violations occur due to normal or expected variations in the work.]*

**(MANDATORY LANGUAGE)**

1. **REFERENCES**

FDA.gov - Guidance for Industry Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf>

International Conference on Harmonisation:

<http://www.ich.org/>

International Conference On Harmonisation Good Clinical Practice Guidance Document:

<http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf>

U.S. Department of Health & Human Services - Investigator Responsibilities FAQs:

<http://www.hhs.gov/ohrp/policy/faq/investigator-responsibilities/index.html>

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*[Optional: Insert any additional SOP references]*

1. **APPENDICES**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional SOP appendices]*