***Medical Equipment and Instrument Use and Maintenance***

1. **PURPOSE**

This Standard Practice Guideline (SPG) describes the procedures, processes, and responsibilities for the use and maintenance of medical equipment and instruments during a clinical trial.

(**MANDATORY LANGUAGE**)

1. **SCOPE**

This Standard Practice Guideline (SPG) applies to all research staff that utilizes and maintains medical equipment and instruments for use in clinical trials. Investigational Devices are out of scope for this SPG.

(**MANDATORY LANGUAGE**)

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

1. **POLICY**

**Good Clinical Practice (ICH GCP)**

This Standard Practice Guideline aligns with the Good Clinical Practice (ICH GCP) guidelines established by the International Council on Harmonization (ICH), Section 5.18.4 (b): *monitors must verify that the staff and facilities, including laboratories and equipment, are adequate to safely and properly conduct the trial and these remain adequate throughout the trial period*.

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

**(MANDATORY LANGUAGE)**

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

1. **DEFINITIONS**

CALIBRATION:The demonstration that a particularinstrument or device produces results within specified limits by comparison with thoseproduced by a reference or traceable standard over an appropriate range of measurements.

MEDICAL EQUIPMENT: Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

INTERNATIONAL COUNCIL 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

(**MANDATORY LANGUAGE**)

Note: Some of the definitions above were obtained from the IRBMed Glossary. These definitions were current as of 01-Oct-2022 and are subject to change. Please see the [IRBMed Glossary](https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/guidance/glossary) for the most current definitions and additional guidance.

**(MANDATORY LANGUAGE)**

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

1. **ROLES AND RESPONSIBILITIES**

**Principal Investigator/Designee**

An individual filling the role of Principal Investigator (PI) is ultimately *responsible* for the following activities:

* Identifies the medical equipment and instruments required to conduct a specific clinical trial
* Follows recommendations pertaining to service and maintenance of the equipment and instruments
* Ensures the appropriate equipment/instruments are available and functioning appropriately prior to implementation of the trial
* Delegates the responsibility for using and maintaining equipment and instruments to the appropriate members of the research team
* Ensures that equipment not maintained by the research team is maintained by other appropriate staff
* Ensures that applicable research staff are trained on any relevant equipment and/or instruments
* Ensures that equipment including manuals and other related materials are inspected, and accurately labeled by the applicable University department/unit/organization prior to use on trial subjects
* Ensures problems with equipment are appropriately managed (e.g. back-up equipment, adequate coverage for service issues, access to trouble-shooting manuals, etc.)
* Delegates responsibilities as appropriate

(**MANDATORY LANGUAGE**)

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

**Study Coordinator(s)/Designee**

An individual filling this role may be responsible for the following activities:

* Completes and documents relevant training prior to using medical equipment or instruments for clinical research purposes
* Follows documented procedures for preparation, maintenance and storage of medical equipment and instrumentation
* Maintains written records of equipment/instrument maintenance, temperature logs, calibration logs, etc.
* Contacts the appropriate individuals when equipment needs to be repaired and or replaced
* Stores equipment/instrument user manuals, manufacturer contact information, documentation of maintenance etc. in an area accessible to research team members and audit personnel
* Archives maintenance records, along with other study documents, at the end of the trial

(**MANDATORY LANGUAGE**)

*[Optional: Insert any additional details regarding the responsibilities of the Study Coordinator/Designee*]

**Additional Roles and Responsibilities** [ ]  **N/A**

**(MANDATORY LANGUAGE)**

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

1. **PROCEDURE**

**Instrument/Equipment Acquisition**

*[Describe the process for obtaining equipment/instruments and reference materials]*

**Instrument Calibration**

*[Describe the process and staff responsible for the calibration of equipment/instruments used in the trial]*

**Instrument/Equipment Maintenance**

*[Describe the process for documenting and tracking the maintenance of equipment/instruments used in the trial]*

**User Training**

*[Describe the process for documenting and tracking equipment/instrument required user training]*

**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.]*

1. **REFERENCES**

International Council on Harmonisation (ICH):

<http://www.ich.org/>
<https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>

International Council on Harmonisation - Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients Q7:

<https://database.ich.org/sites/default/files/Q7_Guideline.pdf>

University of Michigan - Equipment Management Plans:

[PolicyStat :: PolicyStat](https://michmed-clinical.policystat.com/search/?q=medical%20equipment)

**University of Michigan - Clinical Alarm Systems - Maintenance and Monitoring of Priority Clinical Alarms (UMHHC Policy 62-11-015):**

<https://michmed-clinical.policystat.com/policy/6408684/latest/>

World Health Organization (WHO):

<https://www.who.int/>

(**MANDATORY LANGUAGE**)

 *[Optional: Insert any additional SPG references]*

1. **APPENDICES**

(**MANDATORY LANGUAGE**)

**Appendix A:** Research Equipment Sign-Out/Lending Log [ ]  **N/A**

**Appendix B:** Research Equipment Maintenance Log [ ]  **N/A**

*[Optional: Insert any additional SPG appendices]*