Title: Core Standard Operating Procedure for Informed Consent Process

I. Procedure Statement
To explain the process for obtaining consent from potential research subjects or their legally authorized representative.

II. Definitions
1. Informed Consent (IC): A voluntary agreement to participate in a research study or trial; not merely a form, but an ongoing process in which the subject understands and is aware of the purpose of the research and its risks.
2. Legally Authorized Representative (LAR): According to federal regulations, this is “an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research.”

III. Procedure/Content/Scope
This SOP will apply to all clinical trials research within MU Health including the School of Medicine, School of Health Professions, School of Nursing, and MU Healthcare. This SOP will cover the processes and procedures that must occur during the informed consent process, which begins with recruitment and extends through the end of the study, and includes the process of obtaining a signed and dated informed consent form (ICF). Throughout this SOP, all references to the patient or subject apply also to their LAR, where applicable.

1. For FDA-regulated, and applicable sponsor-initiated research, investigators and research staff must complete and document protocol-specific training, prior to prescreening or discussing a clinical trial with a potential subject.
2. The investigator, or an appropriately trained and delegated research staff member, must ensure that the potential subject meets the study-specific entry criteria.
3. Only approved investigators and staff may take part in the informed consent process. Roles should be confirmed prior to engaging in the consent process to ensure that consenting personnel are qualified by education, training, IRB role designation, and experience, to conduct the process, and obtain consent. Personnel must be delegated the task of obtaining consent by the Principal Investigator.
4. When a potential research participant is identified, the investigator or research staff must obtain the most current IRB-approved ICF. The research staff should check the IRB date stamp to verify that only the currently IRB-approved version of the ICF is being used.
5. The investigator or delegated research staff should secure a private location to review the ICF with the potential subject. The Research Patient Advocate is available to the potential
Title: Core Standard Operating Procedure for Informed Consent Process

subject and research team to witness the consent process, if required.

6. The potential subject must be given sufficient time to review the ICF in its entirety, and to
discuss the research study with their family, friends and health care provider, if they so
desire.

7. Before the potential subject signs the ICF, the person obtaining consent should ensure
that they have had adequate time to consider whether to participate, and that all of their
questions and concerns have been answered to their satisfaction.

8. The investigator, or delegated research staff member, must make every effort to minimize
the possibility of coercion or undue influence, and must ensure that the subject
understands the voluntariness of participation.

9. The subject must sign and date the ICF prior to any study-related activities, including
screening activities and procedures.

10. A copy of the informed consent should be given to the person signing the form. Some
studies require this to be a signed copy.

11. When informed consent is obtained from an LAR due to subject incompetency, informed
consent should be obtained from participating subjects at the first possible opportunity
following the determination that the subject is competent. The subject should be given a
copy of the ICF.

12. When informed consent is obtained from an LAR for a minor subject, the subject must be
consented when they reach the age of majority, if deemed competent. They must be
given a copy of the ICF.

13. If substantive changes are made to the ICF, the sponsor requires re-consent, or there are
other circumstances that warrant re-consent, the subject should sign and be given an
updated version of the consent document. The details of the new ICF should be discussed
and an opportunity for questions should be provided. Re-consent is only required for
subjects actively participating in a study, unless the changes relate to the use or disclosure
of samples, or sharing of information obtained during the study.

14. To ensure that the informed consent process is appropriately ongoing throughout the
course of a subject’s participation on a trial, the investigator and research staff should
ensure that:
   a. Subjects remain aware of the purposes, risks, and procedures of the study, and
      the voluntary nature of participation.
   b. New information arising from the study that may have an impact on a subject’s
      willingness to continue participating in the study, is disclosed in a timely manner.

IV. REFERENCES

1. Title 21 CFR Part 312.60 General Responsibilities of Investigators
2. Title 21 CFR Part 50 Protection of Human Subjects
3. Title 45 CFR Part 46 Protection of Human Subjects
4. ICH E6 Good Clinical Practice: Consolidated Guidance
5. FDA Guidance for Industry: Investigator Responsibilities – Protecting the Rights, Safety,
   and Welfare of Study Subjects
Title: Core Standard Operating Procedure for Informed Consent Process

6. FDA Informed Consent Information Sheet Draft Guidance for IRBs, Clinical Investigators, and Sponsors
7. Title 21 CFR 312.62 Investigator Recordkeeping and Record Retention
8. Title 21 CFR 312.68 Inspection of Investigators’ Records and Reports