Akron General Medical Center (AGMC)
Standard Operating Procedure for Obtaining Written Informed Consent/Authorization for Human Subject Participation in Research

Purpose: To obtain informed consent and authorization of human subjects within Akron General Medical Center according to federal (21CFR50 Subpart B, 45CFR46 Subparts A-D), state and institutional regulations.

Definitions:

1. Informed consent: The process by which a principal Investigator or designee discusses the elements of informed consent as defined by 21CFR50.25 with a potential research subject.
2. Legally Authorized Representative: The person capable of signing informed consent on behalf of a patient unable to do so. In the event that a patient does not have a legally authorized representative, based on guidelines for consent for treatment, consent will be obtained in the following order:
    a. Legal guardian or Durable Power of Attorney for Healthcare
    b. Spouse
    c. An adult child of the patient or, if there is more than one adult child, a majority of the adult children who are available
    d. Parents
    e. An adult sibling of the patient or, if there is more than one adult sibling, a majority of the adult siblings who are available
    f. The nearest adult who is not one of the individuals described above, who is related by blood or adoption, and who is available
    g. If a conflict arises, discuss with supervisor or request a consultation with the IRRB chairman
3. Authorization: Written permission to use or disclose protected health information from a patient's medical record as defined by HIPAA 45 CFR 164.508c. Authorization is necessary only when information will be obtained from the medical record.

Procedure:

I. IRRB Approval: Prior to enrolling subjects:

The Principal Investigator will submit the protocol specific informed consent form, (including authorization) the protocol and any other written information that will be given to the subject to the AGMC IRRB for approval prior to any subject enrollment. (See AGMC Intranet site for consent form and authorization template and forms)
Once the protocol, informed consent and authorization form have received IRRB approval and the IRRB approved stamped informed consent and authorization forms have been received by the investigator, subject enrollment may begin.

The Principal Investigator is responsible for ensuring that only a current, stamped AGMC IRRB approved consent form designed specifically for the study is utilized for each potential subject.

II. Obtaining Informed Consent/Authorization

A. Informed consent and authorization must be obtained prior to initiating any protocol-related procedures or activities.
B. Informed consent and authorization may be obtained by the Principal Investigator/Sub-Investigator or a designated and qualified member of the research team who can discuss and answer protocol specific questions competently.
C. Neither the Principal/Sub-Investigator, nor study staff should coerce or unduly influence a subject to participate or continue to participate in a trial
D. As part of the consent process, the subject or his/her authorized representative must be given ample time and opportunity to have all questions answered, discuss any concerns and decide whether or not to participate in the trial.
E. If a patient is incapable of giving informed consent, consent may not be obtained by telephone from a legally authorized representative.
F. If authorization is not signed, subject may not participate in the study (when applicable).
G. Prior to a subject's participation in a trial, the written informed consent form and authorization must be signed and personally dated with time of consent by the subject or by the subject's legally authorized representative, and the person who conducted the informed consent discussion.
H. In the event that the patient is capable of providing informed consent but is unable to sign their name, their mark (typically an "X") will be obtained on the signature line of the informed consent form and be considered their signature.
I. An individual sponsor may require a witness signature or the principal investigator signature but this is not an institutional requirement.

III After Informed Consent/Authorization Is Obtained

A. The subject or the subject's legally authorized representative will receive a copy of the signed consent form and authorization.
B. In-patient studies:

1. A copy of the signed consent form and authorization including the subject's name, a current account number recorded on the front page, and bar code label placed in the lower left corner, must be placed on hospital medical record.
2. A copy of the signed consent form and authorization will be placed on the subject's medical record(s) of all departments/services involved in the care of the subject.
3. The informed consent process must be documented in the medical record progress notes. Progress notes should contain the following information:

- The protocol title, Protocol ID number or short title
- That the informed consent discussion took place and questions were answered
- That the patient agreed to participate in the study
- The name of the principal investigator and contact person if applicable

C. Out-patient studies:

1. A copy of the signed consent form and authorization should go on both the patient's office medical record and hospital medical record if the study involves treatment or if the medical record is involved in the study (IE information will be obtained from the medical record).

2. Document study participation on the office medical record if the study involves a treatment or if access to the medical record is an approved part of the study (IE for data collection). Document as stated for in-patient studies.

3. If the consent form is required for the hospital medical record (as described above) the informed consent should be forwarded to medical records for scanning. If sending the consent form by interoffice mail, make sure subject identifiers are not visible. Either place the consent form and authorization in a plain envelope and enclose in the interoffice envelope or cover the front page with a plain piece of paper. Mark confidential on the interoffice mail envelope.

D. In the event that a subject on active protocol treatment is re-admitted to the hospital, the PI or designee will place a copy of the informed consent in the consent section of the patient's chart and document in the progress notes the following information:

- That the patient is on a research study and receiving active treatment
- That the informed consent is located in the consent section of the patient chart
- Contact information for who to call with questions

E. E. If the consent form subsequently undergoes amendments or revisions that require the subject to sign a revised, IRRB-approved consent form, the subject will be informed of the change(s), given the opportunity for discussion and the option of continuing or withdrawing from the study based on the new information.

F. As part of the ongoing consent process, the subject or his/her representative's questions must be answered not only during the initial consent discussion but also throughout the study and follow-up process.

IV. Special At-Risk Populations

Special considerations are necessary if research participants include the following populations:

Children	Medical students
Subjects with cognitive impairment	Resident physicians
Psychiatric patients	Employees
Illiterate subjects	Pregnant subjects
Non-English speaking subjects	Prisoners

Contact the IRRB office at 330-344-6947 if guidance is needed.

Accountability: The Principal Investigator/Sub-Investigator is responsible for determining whether a subject is capable of giving informed consent and authorization. If the subject is unable to give informed consent and authorization due to cognitive impairment, sedation, impaired judgment or other causes determined by the Principal Investigator to preclude the subject from providing informed consent, the Principal

Investigator/Sub-Investigator or designee may obtain consent and authorization from a legally authorized representative.

Consequences: Non-compliance with federal regulations may result in the immediate termination of any or all research activities for the non-compliant parties and potentially AGMC as a whole, and may also result in legal action against the Investigator or hospital. Failure to comply with institutional policy may result in the suspension or termination of any or all of the non-compliant party's research activity, mandatory exclusion of the data obtained during the period of non-compliance in any data analysis, publication or other dissemination related to the project, and other institutional actions as deemed appropriate. For sponsored projects, failure to comply with this policy may result in the termination or suspension of the study at AGMC, major protocol deviations, non-payment for study procedures by the sponsor, and other actions by the sponsor as deemed necessary. All Institutional and Sponsor Policies are written in accordance with Federal Regulations.