TITLE: Institutional Review Board Informed Consent in Research  
IC 701 Informed Consent Document Content

ORIGINATOR: IRB Chairperson

APPROVAL: [Signature]

POLICY STATEMENT: Federal regulations require investigators to conduct an effective informed consent process with each and every potential human research participant or his or her legally authorized representative before the participant may be enrolled in a research study. The exceptions to this requirement are limited and must be approved by the IRB before the commencement of the study. Informed consent reflects the basic principle of respect for persons elaborated in the Belmont Report by ensuring that prospective participants understand the nature of the research in order to decide knowledgeably and voluntarily whether to participate. The elements required to be included in the informed consent process are enumerated in the consent form, which documents the informed consent process. While there are a few circumstances in which the IRB may grant a waiver or provide an alternative to the informed consent process, the principle of obtaining legally effective informed consent is the standard for all research with human participants.

GENERAL PROVISIONS:
Informed consent is not a single event or form to be signed, but an educational and ongoing process that takes place between the Principal Investigator (or their designee when appropriate) and the prospective participant. It is the process by which the research study is explained to the potential participant and the participant asks questions and then voluntarily agrees to participate in the research. The process involves the ongoing, interactive exchange of information, beginning with the recruitment of the participant and ending with the completion of the study. The basic elements of this process are: full disclosure of the nature of the research and the participant’s involvement; adequate comprehension on the participant’s part; minimization of the possibility of coercion or undue influence; and the participant’s voluntary choice to participate.

The IRB has the final authority as to the content of the consent form presented to the prospective study participants. The IRB may require that the form include, in addition to the information required by the regulations and/or the Sponsor, information adjudged by the IRB to add meaningfully to the protection of the participants’ rights and welfare. The IRB also has the authority to observe, or to request a third party to observe, the consent process.

Informed consent, no matter the form (written or oral) or language (English, Spanish, or other), must contain all federally required elements of informed consent, as set forth in 45 CFR 46.116. The IRB may also require additional elements it believes necessary to ensure the health and welfare of the research participants. The informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must also be organized and presented in a way that facilitates comprehension and understanding of the reasons why one may or may not want to participate. The Mercy Health Regional IRB
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requires the first page of the informed consent document include this specific information as required by federal regulations.

Consent must be sought under circumstances that (a) provide the participant or the legally authorized representative sufficient opportunity to consider whether or not to participate, and (b) minimize the possibility of coercion or undue influence.

Consent may not include any exculpatory language (a) through which the participant or the legally authorized representative is made to waive or appear to waive any of the participant’s legal rights, or (b) which releases, or appears to release, the investigator, the Sponsor, or Mercy Health or its agents from liability for negligence.

Building upon the federally required elements of informed consent specified in the federal regulations (45 CFR 46), the IRB has identified a set of standard elements that all researchers should include in their informed consent process.

1. A statement that the study involves research (including prominent use of the term “research”)
2. Explanation of the purposes of the research, including the name of the study and who is conducting the study. The IRB can waive or alter this element if the study involves deception, as long as there is a debriefing session after the research has been conducted.
3. A description of the procedures to be followed/what will happen to the participant.
4. Expected duration of the participant’s involvement, including the time commitment for each component of the study and the total expected time to complete the study.
5. Identification of any procedures that are experimental, if any.
6. A description of any reasonably foreseeable risks, side effects, or discomforts to the participant.
7. A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
10. A description of any benefits to the participant or others which may be reasonably expected from the research.
11. Disclosure of appropriate alternative procedures or courses of treatment/therapy, if any, that might be advantageous to the participant.
12. A description of the manner and extent to which the confidentiality of records identifying the participant will be maintained.
13. A statement as to what audio or visual recording devices will be used, if any, and what will be done with such recordings upon completion of the study. The consent form should include a separate signature line for the participant to agree to be video- or audio-taped or photographed.
14. Explanation as to whether and what compensation is provided. If participant is to receive compensation, the informed consent document must also include a statement outlining their social security number will be collected for tax reporting purposes and that participant may receive a tax reporting form 1099.
15. When appropriate, contact information and emergency contact information for the participant in the event of a research-related injury to the participant.
16. When appropriate, information regarding available medical treatments for research-related injuries, payments for these treatments, and contact information for additional information about these issues.
17. Name and contact information of the Principal Investigator (PI) for answers to pertinent questions by the participant about the research and his or her rights as a participant, at any time before or during the research.
18.
19. A statement that participation is voluntary, that refusal to participate will not involve any penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
20. IRB contact information and statement that the participant may contact the IRB at any time with any questions or complaints.
21. A statement that the participant will be provided with a signed copy of the informed consent document.
22. A line for participant initials in the footer of each page of the document.
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23. Signature line for participant (or legally authorized representative)
24. Signature line for person obtaining consent
25. Signature line for witness (when applicable)
26. Signature line for principal investigator

Additional Elements that may be required by the IRB
1. A statement that the particular treatment or procedure may involve currently unforeseeable risks to the participant (or to the embryo or fetus if the participant is or may become pregnant).
2. A statement of anticipated circumstances under which the participant’s participation may be terminated by the PI or the Sponsor without regard to the participant’s consent.
3. A description of what will be done with the data once the study is completed.
4. A statement of any additional costs to the participant which may result from his or her participation in the research.
5. A description of the consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation.
6. A statement that the subject will be notified of significant new findings, should they develop during the course of the research, which may relate to the subject’s willingness to continue participation.
7. Indication of the number of subjects planned to be enrolled in the study.
8. If the research involves the collection of identifiable private information or identifiable biospecimens, one of the following statements must be included:
   (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
   (ii) A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Non-English Speaking Potential Participants
If it is known in advance that a potential participant or a significant percentage of the prospective participants does not speak English, a written consent form in the language of the consenting participant(s) must be submitted to the IRB as part of the protocol application.

The English consent form should be translated into the appropriate foreign language for review and approval by the IRB, preferably by the two-way process. Translated versions of research instruments must also be provided to the IRB for their review and approval before they can be used.

If convenient for investigators, the translation and back translation of the approved consent form may be submitted as a modification to the IRB and approved before a research participant is authorized to use the translated consent form or participate in the research protocol.

The IRB must approve all foreign language versions of written or oral consent documents and all survey instruments as a condition of approval under 45 CFR 46.117(b)(2). The translation process for IRB approval can be carried out in one of two ways:

1. A two-way process where, first, there is a forward translation from English to non-English by a translator fluent in both languages, followed by a back-to-English translation by a second bilingual translator who has not seen the original English consent form. The Principal Investigator and the IRB then assess the adequacy of the non-English translation by comparing the two English versions. The IRB must approve the translation as accurate before it can be used to enroll participants. This method is preferred, particularly for protocols and consent forms that are somewhat complex, difficult to understand, etc.

2. A one-way translation of the English version into the non-English version which is certified as accurate by a translator who is certified to be a translator for that language. Under this process, the IRB will accept a certified translation for review and approval without requiring a back-to-English translation.

If the protocol and the English versions of the consent form(s) have already been approved by the convened IRB, translation(s) may be reviewed and approved by the Chair of the IRB or the Chair’s designee. However, if an
additional risk for the non-English-speaking participant is identified, the translation(s) should be referred to the convened IRB for review and approval.

**Short Form**

If the majority of anticipated research participants are English speakers, but the Principal Investigator identifies for enrollment an individual who does not speak and read the language of the approved consent form, he or she may use the IRB-approved consent “short form”. The short form must be in the language that the participant knows fluently. The consent short form is a written informed consent form stating the elements of informed consent required by §46.116. The short form must be presented orally to the subject or the subject's legally authorized representative, and the key information required by §46.116(a)(5)(i) must be presented first to the subject, before other information, if any, will be provided. When this method is used, there shall be an interpreter for the individual obtaining informed consent and also a witness who is a certified translator to the oral presentation. The witness and interpreter must speak the language the participant knows fluently. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness and the translator shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form. Several translated versions of the short forms are available through the Mercy Health Office of the IRB.

While the institution provides versions of the short form in a number of languages, the PI is responsible for identifying and using the services of a translator.

If the PI finds that he or she is using the consent short form in the same language frequently (for 2 or more participants), the PI should have the full length consent form translated and approved by the IRB.

**Assent**

Assent for a child participant is addressed in IRB SOP SC 501. Assent for adults with impaired decision making capacity is addressed in SC 502. The assent document should address the following core elements in lay terms:

- The name, institution, phone number and name of the investigator
- The name of the study sponsor
- The individual is being asked to participate in research
- Definition of research
- Purpose of the study
- Why the individual is being asked to be part of the study
- What the individual will have to do if they agree to be part of the study
- What will happen if the individual decides not to be part of the study
- Any payment the individual will get for being part of the study
- Any risks the study may have
- Any benefits the study may have
- A name and phone number for someone the individual may contact with study related questions
- How the individuals' identity, health information and study records will be protected while they are in the study
- A line for the individual's signature
- A line for the person obtaining assent signature

**Process of IRB Review**

Each informed consent document will be reviewed by the IRB Chairperson or a designee using the Informed Consent and HIPAA Review Worksheet IC 701-A.

Where the protocol application is subject to the Expedited Review process, the Expedited Reviewer or the IRB Chair will review the consent documents for content and either approve them or recommend changes. The Expedited Reviewer is responsible for determining whether waivers of informed consent or documentation of informed consent are applicable and appropriate. In the case of Convened Committee Review, the IRB members at the convened meeting will review the consent process (or request for waiver of consent) and the content of the consent documents. The IRB will either approve the consent documents or recommend changes to their content or to some other aspect of the consent process. In the event the consent process/documents are in a language other than English, the IRB must receive appropriately translated documents and assess their accuracy before approving their use.
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When Changes are requested by the IRB
When IRB-requested changes are returned by the PI, the IRB Chairperson or designee will confirm that all changes have been made. If necessary, the updated documents may be placed on the next IRB meeting agenda for review by the convened IRB.

Once consent documents are approved by the IRB, the Office of the IRB will issue an approval letter and each informed consent document will be stamped indicating the approval date and expiration date established for the document. The stamped IRB-approved versions must be used during the consent process, as they are the only versions considered valid. The informed consent document approval period expires at midnight on the date of expiration.

Broad Consent
Per the Secretary's Advisory Committee on Human Research Protections (SACHRP) recommendations, "Broad consent permits researchers to engage in research use of identifiable biospecimens and identifiable data without the requirement to obtain additional consent for the future storage, maintenance, or research uses, so long as the future activities are within the scope of the broad consent. Broad consent may be the most suitable pathway for research involving identifiable private information or identifiable biospecimens in cases in which waiver of consent would not be available, based in part on the new criterion under the Final Rule requiring that an IRB grant a waiver only if, among other prerequisites, the research could not practically be carried out without using such information or biospecimens in an identifiable format. However, under the Final Rule, as described above, researchers who seek broad consent are bound by the regulatory limitation that if an individual "refuses to consent,“ the IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

To implement fully a broad consent program, health care institutions would be required to install a system to track biospecimens and data for which individuals provide their broad consent, as well as the terms of the broad consent to determine which future research uses remain within scope. Notably, if an individual is offered to provide broad consent but refuses, the limitation only proscribes secondary research uses of the identifiable materials – meaning that researchers could simply choose to de-identify the subject’s data and biospecimens to conduct further research with them. A subject’s refusal to give broad consent also does not prevent the unconsented uses of their identifiable data and biospecimens for purposes that are not considered “research” under the revised Common Rule. For these reasons, if a person who is offered a broad consent refuses to give that consent, health care institutions have three basic options. First, if allowed by other law, they may simply destroy that person’s identifiable information and biospecimens. Second, they may de-identify the person’s information and biospecimens and use them for future research without restraint. Third, they may decide to retain the identifiable information and biospecimens, but allow their future use only for non-research purposes, such as quality improvement. In this third option, however, the institution must track that person’s information and biospecimens to ensure they are not used for future research purposes.

Extensive and seamless IT system capacity will be necessary for any institution or health system to implement fully a broad consent tracking system, as both broad consents as well as refusals to consent (unless the materials are destroyed) must be tracked over the lifetimes of persons who give broad consent and persons who refuse to give such consent. Due to these systems requirements for electronic tracking processes, SACHRP expects that, practically speaking, institutions or systems without interconnected, interfacing and fully interoperable medical records systems will not be able to implement and benefit from the broad consent regimen established in the Final Rule. A “confederated,” non-IT-unified health system will simply not be able, without significant error, to track these consents and refusals to consent. These logistical barriers will greatly limit the utility of the broad consent option.

The practical utility of the broad consent will probably include (1) an identified biorepository or databank study, whose defined purpose is to collect biospecimens and associated data from a well-defined set of individuals and for which the broad consent elements can be included in the study consent, thus giving researchers downstream access to the related exemptions, and (2) primary research studies in which the researchers seek to use an “add-on” or integrated broad consent to facilitate future research uses of the identified data and biospecimens collected as part of that primary study. In each of these cases, however, the use of broad consent would be specifically targeted to well-defined subject groups, rather than to a broad swath of all newly-admitted patients or all newly-enrolled clients.
SACHRP recommends that HHS interpret “refusal to consent” to include only a person’s express declination to give broad consent, as demonstrated by an individual’s unambiguous written or oral communication to that effect. SACHRP does not believe that silence or failure to respond in the face of a request for broad consent, or failure to communicate an unambiguous declination to give broad consent, should constitute “refusal to consent” for these purposes.

Due to the extensive tracking processes that must be in place, Mercy Health will not allow broad consent use at this time.

Posting of Clinical Trial Consent Forms
For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (e.g., confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol. At this time, two publicly available federal websites that will satisfy the consent form posting requirement have been identified: ClinicalTrials.gov and a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).

REFERENCES:
45 CFR 46.109(b), (c), & (e):
45 CFR 46.117
45 CFR 46.111(a)(4), (a)(5), & (b)
45 CFR 46.116

21 CFR 50.25

ATTACHMENTS:
IC 701-A Informed Consent and HIPAA Review Worksheet
IC 701-B Mercy Health Informed Consent Document Template
IC 701-C Glossary of Medical to Lay Terms
IC 701-D Short Form Informed Consent Template-English
IC 701-E Short Form Informed Consent Template-Bosnian
IC 701-F Short Form Informed Consent Template-Burmese
IC 701-G Short Form Informed Consent Template-Somali
IC 701-H Short Form Informed Consent Template-Spanish
IC 701-I Short Form Informed Consent Template-Vietnamese
IC 701-J SACHRP Broad Consent Template

PROCEDURE:

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#### IRB Specialist/IRB Coordinator

1. Review incoming submissions and identify those with an informed consent document that requires review.
2. Prepare the informed consent document for review and notify the IRB Chairperson of the need for completion of an informed consent document review.
3. Document clearly in the minutes the outcome of any IRB discussion relating to the consent document.
4. Issue IRB correspondence as advised by the IRB Chairperson.

#### IRB Chairperson (or designee)

1. Review the informed consent document and complete the checklist ensuring the document contains the information required by federal regulations and Mercy Health IRB Standard Operating Procedures.
2. Request necessary changes to the informed consent document based on reviewer's comments and findings.
3. Request the IRB Specialist issue appropriate approval correspondence.

#### IRB Committee Members

1. Review informed consent document to ensure the investigator provides required and appropriate information to potential participants.
2. Vote for: approval as submitted; minor revisions required; not approved, as substantial revisions are required; abstain or recuse.

#### Investigator

1. Submit informed consent documents to the Office of the IRB for review and approval prior to use.
2. Ensure the informed consent documents contain all information required by federal regulations and Mercy Health IRB Standard Operating Procedures.