INSTITUTIONAL POLICY & PROCEDURE
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TITLE: Institutional Review Board Informed Consent
IC 704 Waiver or Alteration of Informed Consent

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: This policy addresses the requesting of waivers, alterations and exceptions to informed consent, as permitted by regulation. Investigators are required to obtain the legally effective informed consent of each participant or their legally-authorized representative, unless the IRB approves a consent procedure which does not include, or which alters, some or all of the elements of informed consent.

GENERAL PROVISIONS

Waiver of Informed Consent

In certain circumstances, the IRB may waive the requirement to obtain informed consent if the research meets specific criteria that is in accord with provision at 45 CFR 46.116(c) and (d), 21 CFR 50.23 and 24.

The IRB may waive the requirement to obtain informed consent provided it finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
   - Public benefit or service programs;
   - Procedures for obtaining benefits or services under those programs;
   - Possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs;
   - The research could not practicably be carried out without the waiver or alteration.

   OR

2. The research involves no more than minimal risk to the participants;
   - Waiver will not adversely affect the rights and welfare of the participants;
   - The research could not practicably be carried out without the waiver; and
   - Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Prospective Review of Research in Emergency Settings

Obtaining informed consent shall be deemed feasible except in certain emergency situations where the Investigator has adequately documented the necessary exceptions described in SOP SC 510.

Retrospective Review of Emergency Use of an Investigational Article

Obtaining informed consent shall be deemed feasible except in certain emergency situations where the Investigator has adequately documented the necessary exception under guidelines described in SOP SC 508.
Allegation of Elements of Informed Consent
The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent (such as written documentation).

The IRB shall require that informed consent be obtained and documented prior to initiation of study procedures except in the following emergency situations.

Allegation or waiver of one or more elements of informed consent
The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent (described in SOP IC 701) as follows:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
   - Public benefit or service programs;
   - Procedures for obtaining benefits or services under those programs;
   - Possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs; and
   - The research could not practically be carried out without the waiver or alteration.

OR

2. The research involves no more than minimal risk to the participants;
   - Waiver will not adversely affect the rights and welfare of the participants;
   - The research could not practically be carried out without the waiver; and
   - Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Examples of when a Waiver or Alteration of Informed Consent is appropriate:

Observation.
Research involving study of individuals’ natural behavior may require that participants be unaware that research is taking place. Because participants may behave differently if they knew they were being observed researchers may request that the IRB waive the requirement for consent. Participants would not be notified of the research prior to being observed or having their behavior recorded, and therefore would not have any opportunity to provide their consent. Several examples may include studies of the behavior of passersby to staged emergencies, or the interaction between patients and staff in mental hospitals. Such research poses ethical considerations that would require careful deliberation regarding the rights and welfare of participants. The IRB may, for example, require notice to participants after the research, and/or an alternate notice.

Incomplete disclosure or deception.
For other projects, investigators may plan to withhold certain information about the research (e.g., the true purpose, or other aspects about the project), or provide false information so that participants’ responses are not biased. This would mean that a participant would receive most of the required information, but would not be fully informed prior to agreeing to participate in research. Such a procedure would require the investigator to request the IRB waive some of the elements of informed consent. Typically, participants would be provided with the full information only after participation, i.e., during a debriefing session. Such research poses ethical considerations, and the IRB would consider, among other things, whether or not the information withheld would materially affect a decision to participate.

Existing records.
Research involving the use of pre-existing records may also be impracticable to conduct if informed consent were required from each of the individuals whose records are being utilized. Obtaining informed consent may be impracticable either because a database may contain thousands of records, and/or may not contain any identifying information in order to contact the individuals. Use of such records for research would require the investigator to request that the IRB waive the entire consent process. When such records are subject to HIPAA regulations (due to use of protected health information), additional considerations for a waiver of authorization are required.

‘Passive’ consent.
Researchers may utilize a consent process whereby participants are provided with all required information about research, and automatically enrolled unless they ‘opt-out’ by notifying the investigator. This process is sometimes
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termed ‘passive’ consent, because subjects are not required to take any positive action (e.g., sign a consent form, return a survey, answer questions, etc.) to indicate their agreement to participate in research. However, this process does not constitute legally authorized informed consent and its use requires that the IRB approve a waiver or alteration of informed consent requirements. When the ‘passive’ process is used in lieu of obtaining parental permission for a child/guardian to take part in research, IRB approval of a waiver or alteration of parent/guardian permission would also be required.

Waiver of Documentation of Informed Consent
Request for a waiver of documentation of informed consent should be completed if the investigator proposes to obtain informed consent for the research activity without also obtaining the subjects' signature on the consent form. If the IRB grants this waiver, the investigator will still be required to provide information about the research to each potential subject but the subjects signature on the form will not be required. A written script of the information that will be read or given to potential subjects must be provided for IRB review with the submission. In addition to describing the study, the script must contain the basic elements of information consent, as referenced in 45 CFR 46.116 and 21 CFR 50.25. If the study will collect protected health information, the script must also present the core elements of authorization as referenced in 45 CFR 164.508(c). A request for waiver of alteration of HIPAA Authorization must also be submitted.

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:
1. The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. That the research presents no more than minimal risk of harm to subjects, and involves no procedures for which written consent is normally required outside of the research context.
3. The requirements for written informed consent cannot be waived or altered for research involving drugs or devices except for previously approved emergency research.

In cases, in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. If the IRB waives the documentation requirement, the waiver determination will be documented in the study file as well as on correspondence provided to the investigator. The minutes of the IRB meeting must document protocol specific findings that justify the IRB's waiving or altering the elements of subject informed consent.

This type of waiver is useful for some telephone and internet surveys, questionnaires, or when signing the consent document could have a negative consequence for the participant.

Approval of research that uses deception or passive consent requires approval of a waiver or alteration of the consent process.

DEFINITIONS:
Informed consent: the voluntary agreement of a participant, or their legally authorized representative, to take part in research after being provided with sufficient information about the study, in a language and terminology understandable to them, and sufficient opportunity to consider their decision.

Legally authorized representative: an individual authorized by a judicial body or other appropriate body to give consent on behalf of a prospective subject to the subject's participation in research. May include: a health care agent (named as a durable power for health care decision maker while the subject had competency), or a court-appointed guardian.

Minimal risk: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

REFERENCE:
45 CFR 46.116
45 CFR 46.117
OHRP Guidance Documents on Informed Consent
21 CFR 50.20
21 CFR 56.109(c)
21 CFR 50.23
ATTACHMENTS: IC 704-A Request for Waiver or Alteration of Informed Consent (Part of Initial Application)  
IC 704-B Reviewer Worksheet for Review of Requests of Waiver or Alteration of Informed Consent  
IC 704-C Reviewer Worksheet for Review of Requests of Waiver of Documentation of Informed Consent

PROCEDURE: All Mercy Health Campuses

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| IRB Clinical Research Associate/IRB Coordinator | 1. Review incoming submissions and identify those that have a request for waiver or alteration of informed consent.  
2. Prepare request for waiver or alteration of informed consent for review by completing the IC 704-A form where applicable and provide to the assigned reviewer.  
3. Ensure the approval of the waiver or alteration of informed consent is addressed in the IRB approval letter. |
| IRB Chairperson (or designee)                | 1. Review the request for waiver or alteration of informed consent using the checklist for review of waiver or alteration of informed consent. |
| IRB Committee                                | 1. When assigned review of waiver or alteration of informed consent must ensure the waiver or alteration of informed consent is appropriate for the proposed study.  
2. Vote when required as outlined in IRB SOP RR 408. |
| Investigator (or delegated individual)       | 1. Assess the proposed research to determine if it meets regulatory requirements for a waiver or alteration of informed consent.  
2. Provide the IRB with required information for requesting a waiver or alteration of informed consent.  
3. Create study enrollment note indicating the proper informed consent process has been conducted (see IC 702) as required by the IRB. |

CONCURRENT CONSENTS:

Institutional Official [Signature]

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