Jefferson - Office of Human Research (OHR)

OHR Policy and Form Revisions

Subject: Revised IRB Policies and Forms - November 11, 2021

In an effort to keep the research community informed of new and revised Office of Human Research (OHR) policies and forms, we are providing a summary of recent changes.

Note: Please remember to always access the most current forms and policies on the Office of Human Research website. When opening documents, if prompted for user name and password, click cancel and the document should open.

If you have already filled out the previous version of a form for a submission, you do not have to start over with the new form indicated below. But if you just started filling out the previous version, please start over with the new form indicated below.

If you have any questions or comments about these changes, if you requested changes you do not see, or if you have any new suggestions, please contact Patrick.Herbison@Jefferson.edu. If you have any questions about filling out OHR forms or your submission, please contact Kyle.Conner@Jefferson.edu.

Thank you,

The Office of Human Research (OHR)

MAJOR CHANGE: A change to state law and the Jefferson Hospital Policy has resulted in the need to change the consent requirements for research. These requirements have been part of the research consent process for several years, and even though it is changing, it is now simpler and less restrictive. These requirements apply to all Jefferson studies regardless of location.

If a study involves MCARE procedures (see list in OHR Policy IC 701), a physician investigator or "qualified practitioner" must review the purpose, procedures, risks, benefits, and alternatives to participation with the study participant. The other elements of consent may be provided by properly trained and qualified key personnel.

For this purpose, the term "qualified practitioner" means a co-investigator or key personnel who is one of the following: Physician Assistant, Certified Registered Nurse Practitioner, Midwife, Certified Registered Nurse Anesthetist, another physician or a physician participating in a medical residency or fellowship training program who has knowledge of the patient's condition and the procedure to be conducted on the patient and shall be acting under the supervision of, at the direction of, or in collaboration or cooperation with, the physician.

There are now 2 investigator signature line options in the consent form. For each option, the investigator is certifying that the appropriate individual(s) reviewed the consent information

with the study participant. For studies involving MCARE procedures, the investigator must be a physician. Please note that in both cases the investigator signs the consent form. The difference is in what the investigator is certifying.

OPTION 1: Include for studies involving MCARE procedures.

By signing below, you the **physician investigator**, certify that you and/or a qualified practitioner who is also a co-investigator or key personnel, reviewed the purpose, procedures, risks, benefits, and alternatives to participation with the study participant. The other elements of consent may be provided by properly trained and qualified key personnel.

OPTION 2: Include for all other studies.

By signing below, you the **investigator**, certify that you, a co-investigator, or other properly trained and qualified key personnel, reviewed the elements of consent with the study participant.

For ongoing studies, you may keep the investigator signature line in the consent form as is. The options above will be used for new studies.

Please also see the list of changes below.

POLICIES

Policy Number	Title	Version Date
GA 119	**Submission and Review of Human Gene Transfer and Vaccine Trials**	**11/11/2021**
Changes: This policy has been retired. It is no longer relevant.		

Policy Number	Title	Version Date
GA 132	**Human Research Protection Program**	**11/11/2021**
Changes: OHR no longer audits community outreach activities.		

Policy Number	Title	Version Date
QA 301	**Quality Assurance/Quality Improvement Program**	**11/11/2021**
Changes: OHR no longer audits community outreach activities.		

Policy Number	Title	Version Date
G 618	**HIPAA and Activities Preparatory to Research**	**11/11/2021**

Changes: Update to Privacy Office contact information.

Policy Number	Title	Version Date
G 619	Radioactive Materials	11/11/2021
Changes: This policy been fully updated.		

Policy Number	Title	Version Date
IC 701	Informed Consent and HIPAA Authorization: General Requirements	11/11/2021
Changes: The MCARE requirements and the general requirements for obtaining informed consent have been updated and clarified.		

Policy Number	Title	Version Date
IC 704	Child Assent and Parental Permission for Participation in Research	11/11/2021
Changes: Administrative change.		

Policy Number	Title	Version Date
IC 706	Waiver and Alteration of Informed Consent and HIPAA Authorization	11/11/2021
Changes: Clarification that, when the IRB approves a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without informed consent, that when communicating directly with a potential participant either through written or verbal means and with intent to collect personal information, the investigator should make a good faith effort to communicate the goal of this information-gathering to the individual.		

Policy Number	Title	Version Date
IC 707	Surrogate Consent	11/11/2021
Changes: Clarification that for surrogate consent, the consent form and the surrogate consent form (OHR-8B) are submitted to the IRB. The surrogate consent form (OHR-8B) is used as the signature page.		

FORMS

Form Number	Title	Version Date
OHR-1	Proposal Transmittal and Approval Form	11/11/2021
Changes: There is a new, more detailed conflict of interest section. Administrative changes.		

Form Number	Title	Version Date
OHR-2	Summary of Interventional Human Subjects Research	11/11/2021
Changes: The MCARE requirements have been updated. You must now indicate how you will document that a copy of the signed and dated consent form has been given to the subject.		

Form Number	Title	Version Date
OHR-2B	Summary of Non-Interventional Human Subjects Research	11/11/2021
Changes: The MCARE requirements have been updated. You must now indicate how you will document that a copy of the signed and dated consent form has been given to the subject.		

Form Number	Title	Version Date
OHR-8	Informed Consent	11/11/2021
Changes: The MCARE investigator signature line options have changed. If you will be consistently using a different method of documenting that a copy of the signed and dated consent form was provided, the checkbox for this purpose may be replaced by a statement that this will be done.		

Form Number	Title	Version Date
OHR-8B	Surrogate Consent	11/11/2021
Changes:		

The MCARE investigator signature line options have changed.

If you will be consistently using a different method of documenting that a copy of the signed and dated consent form was provided, the checkbox for this purpose may be replaced by a statement that this will be done.

Form Number	Title	Version Date
OHR-8D	Addendum to Consent Form	11/11/2021

Changes:

The MCARE investigator signature line options have changed.

If you will be consistently using a different method of documenting that a copy of the signed and dated consent form was provided, the checkbox for this purpose may be replaced by a statement that this will be done.

Form Number	Title	Version Date
OHR-9	Continuing or Final Review of Research Protocols Involving Human Subjects	11/11/2021

Changes:

The MCARE requirements have been updated.

There is a new, more detailed conflict of interest section.

Form Number	Title	Version Date
OHR-17	Certification for Use of Protected Health Information of Decedents For Research	11/11/2021

Changes: Update to Privacy Office contact information.

Form Number	Title	Version Date
OHR-29	Review Preparatory to Research Request Form	11/11/2021

Changes: Update to Privacy Office contact information.

Form Number	Title	Version Date
OHR-32	Radiation Research Review Form	11/11/2021

Changes: This form been revised to better collect the required information.

Form Number	Title	Version Date
OHR-34	**Research Not Requiring IRB Review: A Checklist**	**11/11/2021**
Changes: Update to Privacy Office contact information.		

Other minor formatting/administrative changes have been made to these and other policies.