

Institutional Certification Form for IRB Deferred Studies

SP Code *(if previously assigned)*:       Title:

Principal Investigator:       Routing Location:

Co-Investigator(s):

Research Coordinator:       Routing Location:

[ ]

This form must be completed prior to deferral of review to *any* IRB other than MCRF.

Please indicate which site you are requesting deferral to:

[ ]  NCI CIRB

[ ]  HCSRN IRB – identify ,

[ ]  GPC IRB – identify

[ ]  WIC IRB – identify

[ ]  Other – identify

**Submit this form to ORIP (1R-4) along with the IRB Deferral Request form and prior to submitting any materials to the reviewing IRB.**

**Human Subject Protection Training (CITI Training)**

 [ ]  The PI and Co-Investigators have completed the required CITI Training in compliance with the institutional policy, “Human Subject Protection Training.”

**Interest Disclosure Requirement**

Does the PI, Co-Investigator(s) or anyone else responsible for the design, conduct, or reporting of this research have a significant financial or associational interest to disclose, as described in the institutional policy, “Investigator Conflicts of Interest in Research?”

[ ] *No.* By checking this box, I as Principal Investigator, certify that the individuals listed in these capacities have made the required annual disclosure and have no additional interests or updates to previously reported interests to disclose.

[ ] *Yes.* Disclosure review must take place before a study deferral is finalized, or for CIRB studies, before the “Study-Specific Worksheet About Local Context” is submitted. Contact ORIP for assistance with the disclosure process and access to the disclosure form. Please list the individuals still needing to make a disclosure:

**Consistency Review**

Does this study involve any financial support for clinical procedures or services (e.g., office visits, phlebotomy, imaging, etc.)?

 **[ ]** *No.*

 **[ ]** *Yes.* The required Consistency Review has been completed.

**Collection of Participant Diagnoses**

Does this research collect information about participant diagnoses, potentially including HIV status?

 **[ ]** *No.*

**[ ]** *Yes.*

 **[ ]** If yes, as principal investigator, I attest that HIV status identified via Marshfield Clinic records will only be used as required for this research study. It will not be released to any person not connected with this study, and the final research product will not reveal information that may review the identity of the participant unless I obtain consent for this disclosure form the participant.

**Use and/or Disclosure of PHI - Reviews Preparatory to Research**

Will the Principal Investigator, co-investigators, or study staff access identifiable health information (see HIPAA Identifiers) for research purposes (i.e., screening or recruitment) prior to obtaining informed consent/authorization from the patients or research subjects?

 **[ ]** *No.*

 **[ ]** *Yes.* If yes, the PI makes the following representations for reviews preparatory to research, as required by the HIPAA Privacy Rule:

*1. I am requesting the minimum necessary protected health information;*

*2. The use or disclosure of protected health information is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;*

*3. No protected health information will be removed from the Marshfield Clinic in the course of the review;*

*4. The protected health information requested is necessary for research purposes.*

**Waiver of HIPAA Authorization to Access Ministry Health Care Databases**

Will the Principal Investigator, co-investigators, or study staff access identifiable health information (see HIPAA identifiers) from any records or database specific to Ministry Medical Group/St. Joseph’s Hospital for research purposes without obtaining authorization from the patients or research subjects?

 **[ ]** *No.*

 **[ ]** *Yes.* If yes, please complete section 2 of the institutional form, “IRB Waiver - Consent and Authorization,” located in the Forms Library and submit it along with this representation.

##### **Use and/or Disclosure of PHI For Research**

Will anyone other than the investigator and study personnel at Marshfield Clinic have access to, or be given, identifiable health information (see the policy “Use and Disclosure of PHI in Research”)?

 [ ]  *No.*

 [ ]  *Yes.*

How will the use and/or disclosure of PHI satisfy the HIPAA Privacy Rule?

 [ ]  Written Authorization from Subjects

 [ ]  Waiver of Authorization (to be approved by the reviewing IRB)

 [ ] Limited Data Set and Data Use Agreement (a “Request to Transfer Data or Materials” form will be submitted to ORIP)

**Assurance**

I certify that statements herein and attached are true and complete to the best of my knowledge.

Signature of Principal Investigator Date

Printed Name of Principal Investigator Routing Location

**Attached Documentation**

 [ ]  IRB Waiver - Consent and Authorization

 [ ]  N/A

**\*\* Submit completed paperwork to: Office of Research Integrity & Protections – 1R4**

**\*\* ORIP Approval** (signature and date)**:**