## 9C20844B-9BFB-4AB9-A757-14007340F01B@local

## Request to Defer IRB Oversight

## SP Code *(if previously assigned by MCRF Sponsored Programs)*:

## Title:

**Principal Investigator:**       **Routing Location:**

**Email**:       **Phone:**

**Co-Investigator (s):** *(List only those co-investigators for whom MCRF serves as the IRB of record)*

**Research Coordinator:**       **Routing Location:**

**E-mail:**

**Person Completing Application:**

**I am requesting (select one):**

[ ]  MCRF IRB to defer to an external IRB **(Section 1)**

[ ]  To have a collaborator's IRB defer to MCRF IRB **(Skip to Section 2)**

**Section 1 Deferral to an External IRB**

**Please identify the entity to which you seek to defer:**

[ ]  Wisconsin IRB Consortium (WIC) Member - identify:

 Follow the procedures outlined at [www.wicshare.com](http://www.wicshare.com) (Skip to signature.)

[ ]  HCSRN Member - identify:

[ ] **A copy of the completed "HCSRN Research Approval Cover Sheet" is attached.** (Skip to signature.)

[ ]  NCI CIRB (Skip to signature.)

[ ]  GCP Member – identify:

**[ ]  Collaborator's IRB application is attached.**

[ ]  Other - identify:

**Have you collaborated/deferred to this site prior to this request?**

[ ]  Yes

[ ]  No (an IRB Authorization Agreement (IAA) will need to be executed if MCRF

 has not previously deferred to the site)

**[ ]  Collaborator's IRB application is attached.**

**IRB Contact person’s name, email and phone number:**

**Type of Research (check all that apply):**

[ ]  Drug

[ ]  Device

[ ]  Observational

[ ]  Secondary Use of Data

[ ]  Data Repository

[ ]  Bio-specimen

[ ]  Interventional

[ ]  Other – specify:

**Study Population includes:**

[ ]  Children

[ ]  Pregnant Women, Fetuses and/or Neonates

[ ]  Prisoners

[ ]  Non-English Speakers

[ ]  Individuals with impaired decision-making ability

[ ]  Other Potentially Vulnerable Populations

[ ]  None of the above

**Check the appropriate boxes to describe involvement in this project:**

**Marshfield Clinic:**

[ ]  Recruitment or Consent

[ ]  Clinical Procedures

[ ]  Data Analysis

[ ]  Publication

[ ]  Lab-Based Research Analysis

**Proposed IRB of Record's Institution:**

[ ]  Recruitment or Consent

[ ]  Clinical Procedures

[ ]  Data Analysis

[ ]  Publication

[ ]  Lab-Based Research Analysis

**Other Collaborating Organizations:**

[ ]  Recruitment or Consent

[ ]  Clinical Procedures

[ ]  Data Analysis

[ ]  Publication

[ ]  Lab-Based Research Analysis

**Describe Marshfield Clinic participants’ involvement in this research:**

**Describe the Marshfield Clinic participant data to be used in this research, and how it will be protected:**

**OHRP Guidance states that an IRB of Record be familiar with any issues of local research context that have the potential to impact the conduct of a study. Please describe how you will ensure MCRF’s local research context is taken into consideration by the reviewing IRB, if applicable:**

**Does the proposed IRB of Record and its human research protection program have AAHRPP Accreditation?**

[ ]  Yes

[ ]  No

**Is there potential for deferral to this IRB for research in the future?**

[ ]  No

[ ]  Unsure

[ ]  Yes - describe under what circumstances:

**Section 2 Deferral to MCRF IRB**

**MCRF IRB is requested to serve as the IRB of record for the following entity(ies) (select all that apply):**

[ ]  Wisconsin IRB Consortium (WIC) Member - identify:

 Follow the procedure outlined at [www.wicshare.com](http://www.wicshare.com) (Skip to signature.)

[ ]  HCSRN Member - identify:

**[ ] A copy of the completed "HCSRN Research Approval Cover Sheet" is attached.**(Skip to signature.)

[ ]  GCP Member – identify:

[ ]  Other - identify:

**Have you collaborated/deferred to this site prior to this request?**

[ ]  Yes

[ ]  No (an IRB Authorization Agreement (IAA) will need to be executed if MCRF

 has not previously deferred to the site)

**[ ]  Collaborator's IRB application is attached.**

**IRB Contact person’s name, email and phone number:**

**Deferral to MCRF IRB- Ongoing Oversight of External Engaged Personnel**

**For each institution and individual for whom MCRF IRB is requested to serve as IRB of record, list the engaged personnel by name and their role in the research:**

**Check the appropriate boxes to describe involvement in this project:**

**Marshfield Clinic:**

[ ]  Recruitment or Consent

[ ]  Clinical Procedures

[ ]  Data Analysis

[ ]  Publication

[ ]  Lab-Based Research Analysis

**Proposed IRB of Record's Institution:**

[ ]  Recruitment or Consent

[ ]  Clinical Procedures

[ ]  Data Analysis

[ ]  Publication

[ ]  Lab-Based Research Analysis

**Other Collaborating Organizations:**

[ ]  Recruitment or Consent

[ ]  Clinical Procedures

[ ]  Data Analysis

[ ]  Publication

[ ]  Lab-Based Research Analysis

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 Signature of Principal Investigator Date

**Attach the following as applicable:**

MCRF **Institutional Certification Form for IRB Deferred Studies** form (completed & signed)

Protocol

Consent document(s)

Approval letter from deferral IRB of Record

Deferral Site Approval Cover sheets

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