## **UWM IRB Guidance for Multi-Institutional Research**

When conducting research with or at other institutions multiple approvals may be required, so it is important to understand what type of approvals are required and the expected time it may take to obtain the appropriate approval(s) before submitting to the UWM IRB. Each institution has its own requirements and it is the researcher's responsibility to determine what the requirements are.

Before beginning the UWM IRB submission process, it is worthwhile to explore the possibility of an IRB deferral agreement with your partner institution. Below are some suggestions on how to approach multi-institutional research. Please be aware that not all institutions will agree to enter into a deferral agreement. If an institution will not agree to a formal agreement, please contact the UWM IRB for suggestions on how to make the dual IRB process less burdensome. Always feel free to contact the UWM IRB office for study specific guidance.

# CTSI Institutions - Medical College of Wisconsin, Froedtert Hospital, Children's Hospital of Wisconsin, Blood Center of Wisconsin, Marquette University, Milwaukee School of Engineering

- 1. Complete the <u>Coordinated IRB Request Form for CTSI Partners</u> with the requested information and submit only to one of the IRB Administrators listed on the form.
- 2. Once received by an IRB Administrator, the Request Form will be reviewed, shared, and discussed among the IRB Administrators from all involved institutions.
- 5. After deliberation among the IRBs, you will be notified by the IRB Administrator who received your Request Form if a single IRB review is acceptable and which IRB will provide review and oversight.
- 4. Do not submit an IRB application until you are notified which IRB(s) will provide review.
- 5. Once you are notified that a single IRB review is possible, an IRB application must be submitted to the reviewing IRB. The submission procedures and policies for the reviewing IRB must be followed.
- 5. Note that a coordinated or single IRB review is not guaranteed.
- 6. If you have questions about this process or the Request Form, contact one of the IRB Administrators listed on the form.

### **Aurora Healthcare**

- 1. Prior to submitting any research proposal to the Aurora IRB or requesting a deferral with UWM, you are required to obtain administrative approval from Aurora. Please visit the Aurora IRB website for specific details and forms: <a href="http://www.aurorahealthcare.org/misc/irb/index.asp">http://www.aurorahealthcare.org/misc/irb/index.asp</a>
  - a. If enrolling or accessing records of Aurora patients, approval from the Patient-Centered Research Office is required. Please contact Vicki Soerens, Executive Assistant to the Senior Vice President of Research & Academic Relations with questions or for assistance obtaining this approval. Vicki can be reached via e-mail or by phone at (414) 219-7328.
  - b. If enrolling Aurora nurses, approval from the Center for Nursing Research & Practice is needed. Please call 414.219.3606 or via e-mail at <a href="mailto:nursing.research@aurora.org">nursing.research@aurora.org</a> or visit <a href="http://www.aurorahealthcare.org/misc/irb/nursing-research.asp">http://www.aurorahealthcare.org/misc/irb/nursing-research.asp</a>
  - c. If recruiting other subject groups, please contact the Aurora IRB to determine what type of administrative approval may be required.
  - d. This administrative approval, allowing the research activities to take place at Aurora, should not be misinterpreted as IRB approval. You may only begin research activities upon receipt of a letter of Aurora IRB approval, or an appropriate written IRB deferral agreement from the Aurora IRB Manager.

2. Complete and submit the <a href="UWM and Aurora Deferral Request Form"><u>UWM and Aurora Deferral Request Form</u></a> (with a copy of the appropriate administrative approval letter) to <a href="IRB.office@aurora.org">IRB.office@aurora.org</a> (and copy <a href="irbinfo@uwm.edu">irbinfo@uwm.edu</a>). The IRB offices will discuss who will be the IRB of record and you will be notified about which IRB to submit to.

## Columbia St. Mary's

- 1. Contact Columbia St. Mary's IRB <a href="https://www.columbia-stmarys.org/clinical Research Contact Us">https://www.columbia-stmarys.org/clinical Research Contact Us</a> to determine a plan. Be prepared to explain:
  - a. Basic overview of study activities
  - b. Where activities take place
  - c. Where subjects recruited from
  - d. Who from each institution is involved in recruiting, consenting, collecting research data, analyzing research data
- 2. Determine what type of approval is required from Columbia St. Mary's.
  - e. If IRB approval is required, will the IRB be willing to defer IRB review to UW-Milwaukee IRB or willing to accept IRB oversight for UW-Milwaukee IRB?
  - f. If each IRB is required to review separately, please determine which IRB should review the study first (based on where the majority of study activities take place). Feel free to contact the UWM IRB for guidance.
- 3. If both institutions are interested in an IRB deferral/agreement, please submit the <u>IRB Deferral</u> Request Form Non-CTSI Institutions to the UWM IRB.

#### Wheaton Franciscan

- 1. Contact Wheaton Franciscan IRB <a href="http://www.mywheaton.org/services/clinical-trials/irb/about-irb/">http://www.mywheaton.org/services/clinical-trials/irb/about-irb/</a> to determine a plan. Be prepared to explain:
  - a. Basic overview of study activities
  - b. Where activities take place
  - c. Where subjects recruited from
  - d. Who from each institution is involved in recruiting, consenting, collecting research data, analyzing research data
- 2. Determine what type of approval is required from each institution.
  - e. If IRB approval is required, will the IRB be willing to defer IRB review to UW-Milwaukee IRB or willing to accept IRB oversight for UW-Milwaukee IRB?
  - f. If each IRB is required to review separately, please determine which IRB should review the study first (based on where the majority of study activities take place). Feel free to contact the UWM IRB for guidance.
- 3. If both institutions are interested in an IRB deferral/agreement, please submit the <u>IRB Deferral</u> Request Form Non-CTSI Institutions to the UWM IRB.

#### Milwaukee Public Schools

- 1. MPS requires a separate review/approval process.
  - a. It must be requested after UWM IRB approval is obtained, but before you can begin your research in MPS schools.
  - b. Please review their website for submission deadlines, forms and other details: <a href="http://mpsportal.milwaukee.k12.wi.us/portal/server.pt/comm/research\_and\_evaluation/3-40/research\_application/38464">http://mpsportal.milwaukee.k12.wi.us/portal/server.pt/comm/research\_and\_evaluation/3-40/research\_application/38464</a>

#### **Other Institutions**

- 1. Contact all institutions involved to determine plan. Be prepared to explain:
  - a. Basic overview of study activities.
  - b. Where activities take place
  - c. Where subjects recruited from
  - d. Who from each institution is involved in recruiting, consenting, collecting research data, analyzing research data
- 2. Then determine what type of approval is required from each institution.
  - e. If IRB approval is required, will the IRB be willing to defer IRB review to UW-Milwaukee IRB or willing to accept IRB oversight for UW-Milwaukee IRB?
  - f. If non IRB approvals are required, be prepared to explain in the UWM submission and attach any institutional approval letters to the submission.
- 3. If multiple IRBs are involved and interested in an IRB deferral/agreement, please submit the <u>IRB</u> Deferral Request Form Non-CTSI Institutions to the UWM IRB.
- 4. Please be aware that not all institutions will agree to enter into a deferral agreement. If an institution will not agree to a formal agreement, please contact the UWM IRB for suggestions on how to make the dual IRB process less burdensome.