Obtaining Institutional Review Board (IRB) and other approvals

March 2017

All research projects that involve human subjects, including medical chart reviews, require review and approval at the institutional level. RULES FOR *CASE REPORTS/SERIES* VARY. See notes below.

Please see the specific instructions for studies involving patients at each institution listed below. If there are no notes for your institution, please check with the administration/research office of the institution for instructions on their IRB process. If you intend to review records at more than one institution, you should process the request to all institutions at the same time. Then, if changes are needed, they can all be accommodated and re-submitted to every site simultaneously.

PLEASE NOTE that most <u>WRIGHT STATE</u> IRB APPLICATIONS MUST NOW BE SUBMITTED **ON LINE**, and that eventually all submission will be on-line. (See below.) A well-crafted research proposal makes completion of the review process more efficient, so put the effort into creating one.

As you submit your IRB application, remember that a well-crafted research proposal makes completion of the review process more efficient, so is worth the time and effort to create.

Children's Medical Center (CMC)

CMC requires that the investigator secure assent of the children along with permission from the parents or guardians.

Case Reports: <u>Submit a Petition for IRB Determination of Case Report/Non-Research Project form</u> and obtain consent from the patient along with the parents or guardians on the <u>Informed Consent for Case Report form</u>. The resident investigator will be required to name a Dayton Children's investigator on the case report form and have it signed by the related Dayton Children's department head and/or Dr. Ann Burke.

Contact: Bev Comer, comerb@childrensdayton.org; 937-641-4218

Five Rivers Health Centers

Obtain Wright State IRB approval, then Five Rivers approval. In order to obtain WSU IRB approval, you will need to have preliminary approval from Fiver Rivers. Request preliminary approval by emailing a copy of your protocol, plus a completed "FRHC report/data/survey requisition form" (2016 version attached) to: Dr. Mamle Anim mamle.anim@wright.edu.

Please see "FIVE RIVERS Policy and Procedure for Conducting Research at all FR locations" at the following link:

Once IRB approval is granted, forward the IRB approval to Dr. Anim, inform her of the anticipated start date, and request final approval for your project from Five Rivers.

CASE REPORTS do not require IRB approval or forms.

Kettering Health Network:

Kettering Medical Center, Grandview, Southview, and Sycamore Hospitals

Contact: Gail Young, gail.young@khnetwork.org, 395-8409

Premier Health System Hospitals:

Miami Valley (MVH), Good Samaritan (GSH), Upper Valley (UVH), and Atrium (AH)

Complete on-line forms for Wright State IRB. On the part of the form that asks where the research will be conducted, please click on the applicable Premier facility/Facilities. If you do this, the application will be routed to the Human Investigation and Research Committee (HIRC) for the appropriate hospital at the time that you submit the WSU IRB.

IN ADDITION TO SUBMITTING THE WSU IRB APPLICATION, you must simultaneously submit the Premier Health HIRC Application. To do this, go to:

https://premierhealth.sharepoint.com/sites/div/clinres/Pages/home.aspx*

On the left-hand menu, click on "MVH Clinical Research" (this will soon be updated to have tabs for each facility, but for now please use this for research at *all* Premier Hospitals). In the middle of the page is a link to the PH HIRC Application form. Download this form, complete it, and submit as per instructions on the form.

The respective HIRC's will coordinate with the WSU IRB, so that if/when your project is approved, it will be approved by all entities.

CASE REPORTS/SERIES (up to 3 patients): IRB approval not needed. HOWEVER, a "Case Report Form" is required. Go to the above link, click on "MVH Clinical Research" in the left-hand menu, click on "Forms" in the left hand menu, download and complete the "Case Report Form", and submit as per instructions on the form.

*Note: these links are only available if you are on the Premier intranet or VPN.

CONTACT: Clinical Research Center: rswirth@mvh.org

Veteran's Affairs Medical Center

Uses Wright State University IRB CASE REPORTS do not require IRB approval. CONTACT: www.dayton.va.gov/research/

Wright Patterson Air Force Base Medical Center

Please read the instructions here: <u>WPMC S&PR Policy</u> Contact: Frederick Funke, CIP, WPMC IRB - 937-257-4242

Wright State University

Please read instructions on: http://www.wright.edu/research/compliance/human-subjects. This will answer many questions. MOST IRB applications must now be submitted ON LINE, and eventually all will need to be submitted on line (see the website for specifics). The above webpage contains instructions on how to gain access to the InfoEd website where on-line applications are developed and submitted. Please be aware that it may take a week or so to be granted access. IRB applications are reviewed monthly or more often, depending on type. It is not uncommon to be asked to revise/improve the application before it is approved, so plan accordingly (ie: allow time)

Contact: Human Subjects Program Facilitator, Jodi Blacklidge, jodi.blacklidge@wright.edu