**Attendance:** Karen Vander Laan, Martina Reinhold, Kimberly Muma, Jean Nagelkerk, Steve Triezenberg, Claudia Leiras, Maureen Oostendorp, Robert Smart, Cynthia Covia

**Short-term Goal:** Streamline research projects in common with the WMIPEI educational and clinical partners. Create an online listing of scholarly interprofessional research opportunities for students. Develop a research contact list.

**Long-term Goal:** Implementation of IP scholarship across disciplines

<table>
<thead>
<tr>
<th>Agenda Item</th>
<th>Discussion</th>
<th>Action</th>
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<tbody>
<tr>
<td>1) Welcome</td>
<td>Each attendee introduced themself.</td>
<td></td>
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<tr>
<td>2) Introductions and Report of IPE Projects Currently in Progress</td>
<td>Each attendee provided an overview of any IPE projects that they are currently working on. Karen Vander Laan asked that the SH IRB News Bulletin that she provided be added to the Meeting Minutes.</td>
<td>Kim will prepare Meeting Minutes and include SH IRB News.</td>
</tr>
<tr>
<td>3) Discussion of Additional Affiliates</td>
<td>Jean Nagelkerk informed the workgroup that they are welcome to invite other attendees as deemed appropriate. Various attendees suggested inviting Research Offices at Ferris, Calvin, Hope, Mary Free Bed, and MSU Nursing. Workgroup decided to be as inclusive as possible with other health and health-related programs.</td>
<td>Who will invite suggested groups?</td>
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<td>4) Scholarship Process Mapping</td>
<td>After discussing “process mapping” of how each IRB at various institutions functions, Karen Vander Laan shared with the group that other attendees did not desire to provide detailed information on how their own internal IRBs function. It was decided that the creation of a Research Contact Person List for various organizations would be the best approach. The List will be published on the WMIPEI website.</td>
<td>Kim will create a Research Contact Person List with the names that each IPE Scholarship Workgroup attendee organization provides. Everyone, please send Research Contact Person information to <a href="mailto:mumakim@gvsu.edu">mumakim@gvsu.edu</a>.</td>
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<tr>
<td>Date</td>
<td>Meeting</td>
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<tr>
<td>10/24/2014</td>
<td>8:00 PM: Planning for Next Scholarship Workshop</td>
<td></td>
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</tbody>
</table>

**Further discussion needed:**

- WMPEL website and what information is available on it.
- Providing a "date last updated" so that people looking at the information would know how current it is.
- Liberal arts could also advertise the launch of the website from the WMPEL website. Also, discussed the possibility of Robert Smart directly from the WMPEL website.

**Research Opportunities:**

- Workshop discussed the possibility of providing links to research opportunities to members of the committee and identification of scholarly projects by making a difference on their project.
- Highlighting why working in life setting involved in life projects that would involve grad students to ask individual students' questions to develop leading interview.

**Group needs to develop leading Interview:**

- Presented at two consecutive poster discussion breakout session.
- Highlighting the role of PE in scholarly projects: 10-15 minute video discussion to be presented at the next annual WMPEL Conference (September 18th).

**Conference Planning:**

- 2014 WMPEL Annual Conference Planning.
IRB Contact Information

For IRB Questions Email or Phone:
irbassist@spectrumhealth.org
616-486-2031
IRB Website:
www.spectrumhealth.org/hrpp
For IRB Policies:
www.spectrumhealth.org/researchpolicies
For IRB Forms:
https://login.irbmanager.com

News

On May 8, 2013, the Spectrum Health Office of the IRB rolled-out a new web-based system called IRB Manager for submitting IRB forms. So far responses overall have been very favorable. Additional information on using the new system can be found on the IRB website electronic submission page:
http://www.spectrumhealth.org/electronic-submission
If you run into any problems logging in, signing-off IRB forms or attaching supporting documents please continue to contact our office directly by phone or email at irbassist@spectrumhealth.org for assistance.

Please note the office makes every effort to meet our established processing times for the various types of submissions. In general these timelines fall within 2-5 weeks dependent upon risk level, review level and the completeness of the submission. In IRB Manager if you see the submission status of “Under IRB Review” it means in general your submission is in the queue for expedited review or being placed on the next available meeting for committee review. If you would like an update on the status of your application, please email irbassist@spectrumhealth.org

Q&A with the IRB Office: Electronic Submission

Q: Can I have a Sub-Investigator sign-off on an electronic form?
A: Yes, but only in situations where the Principal Investigator (PI) is unavailable due to a family emergency, vacation, or similar situation. If waiting for the PI to sign would cause significant delays in submitting modifications or reporting of potential unexpected study problems to the IRB, then the Sub-Investigator (Sub-I) can sign for the Principal Investigator (PI) To do this, a research team member will need to contact the IRB Office at 616-486-20131 or irbassist@spectrumhealth.org explaining the situation. Depending on the situation and type of submission, additional specific instructions will be given to the research team member on how to appropriately document this surrogate approval process. This process should be reserved for situations where it is indeed necessary.

Lapses in IRB Approval

We have seen an increase in study lapses/expiration recently. Every research study involving human subjects must be re-reviewed and approved by the IRB prior to the expiration of IRB approval. Per federal regulation and institutional policy, no human subject activity may continue once IRB approval has expired. If a study does expire this results in the PI being placed on the IRB’s internal “Restricted List”. What does this mean? If a researcher is placed on the restricted list, it means that he/she is not currently compliant with Spectrum Health’s requirements to participate in research and cannot be an approved investigator or research member of a research project until the situation is resolved. In most cases, this resolution involves either completing and submitting the Continuing Review Progress Report within 30 days of the date of expiration or completing and submitting the Study Completion Notification if the project is completed.
Notices and Reminders

**Notice:** Spectrum Health has implemented a new process for disclosing Conflicts of Interest. The process was redesigned this year to comply with updated regulations issued by the U.S. Department of Health & Human Services (HHS). Employees, physicians and affiliates involved in research and other sponsored programs who are managed by Spectrum Health, overseen by the Spectrum Health Institutional Review Board or who make use of Spectrum Health resources, are required to disclose certain financial and other interests. This is required for all researchers using the Spectrum Health IRB and must be completed before being approved to participate in a research project. The process involves 2 steps: a training module and a disclosure questionnaire.

**Reminder:** Investigators that want to enroll a subject on a clinical trial who do not meet enrollment inclusion and exclusion criteria must seek prior Sponsor approval AND if the deviation will affect the rights, safety, or welfare of the subject prior IRB approval are required. An example of a deviation that would affect a subject’s safety would include enrolling a subject with decreased renal function on an investigational drug trial where the drug is known to be nephrotoxic. This example would require prior Sponsor and IRB approval. In addition, enrolling a subject who does not meet enrollment criteria prior Sponsor and IRB approval requires notification of the protocol deviation via the IRB “Reportable New Information” form as non-compliance with the IRB approved protocol. For further information, review the FDA Guidance “Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects” (October 2009).

**Notice ICF Template Changes:** The Spectrum Health IRB Informed Consent Template has been revised with minor editorial changes and based on recommendations regarding the HIPAA HITECH final rule allowing unspecified future research use in combined consent and authorizations. Be sure to download the most current Informed Consent Template from the IRB website [http://www.spectrumhealth.org/irbforms](http://www.spectrumhealth.org/irbforms) when drafting new informed consent forms. The changes include:

- Footer: Added an IRB template version date to the blue box in the footer.
- Page 2: Removed the hyphen in the IRB email address.
- Page 2: Included bullet on future unspecified research.
- Page 3: Removed bullet about genetic research, and expanded this into its own section on pages 3-4 using the NIH template ICF language on DNA sequencing.
- Page 4: Added GINA language under the risks section, prefaced with these instructions: *(if the research involves genetic testing, profiling, or sequencing, add)*
- Page 6: Specified “DRUG (not device)” for the Medicare language.
- Page 9: Corrected run-on sentence under “When will it be destroyed?” section
- Page 10: Added a section for future/optional research use, begins with *(DELETE this section if not applicable—)*
- Page 13: Added line for “relationship to participant” to comply with HIPAA regs.
- Page 14: Removed signature line for participant to be consistent with the use of the short form.

Research Tip

**Is there guidance available to assist researchers in determining whether a study involving off-label use of a drug will require an IND?** Yes. The FDA recently issued a new guidance for investigators, sponsors, and IRB entitled “Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted without an IND (September 2013)”. The guidance includes a section covering the often grey exemption criteria regarding evaluating the level of risk involved in the proposed off-label use. Also, it includes a Frequently Asked Questions section and provides the contact details at the FDA if a researcher has further questions.
Fall Education Sessions:

How to submit to the IRB using IRB Manager Software

A general education session entitled "How to submit to the IRB using IRB Manager Software" will be offered by the Office of the IRB and held on the following dates and time. This is the same training session offered in May of this year when the IRB Office initially rolled-out the new software. This session is for those who missed the initial sessions, are new to the IRB, or desire re-training. Topics covered will include: logging into the system, completing the correct forms, common mistakes to avoid, the review process, turnaround time, and what you need to remember after you receive IRB approval. If you are interested in attending, please contact the IRB Office to register at irbassist@spectrumhealth.org and provide your preferred date to attend, name and a contact email/number. There is no charge for attending these sessions.

Thursday, Oct 17th, 1:30-2:30 pm, 25 Michigan St. Bldg, 3rd floor, Conf. Rm 3000
Thursday, Nov 7th, 9-10 am, 25 Michigan St. Bldg, 3rd floor, Conf. Rm 3001

IRB Activities Behind Closed Doors: What happens to your submission after you hit the submit button?

This educational session will give you insight into the internal workings of the IRB Office and the IRB Full-Board meetings. It will cover the steps of determining if a project is human subject research, exempt, expedited or full-board review. It will describe the pre-review process by the IRB analyst to ensure all the information is available and presentable for IRB members to review. It will also include describing the regulations the IRB members must ensure are met before approving any research proposal. No preregistration is required to attend this free educational session. Since this is over the lunch hour, please feel free to bring your own lunch to enjoy during the educational session.

Tuesday, Nov 26th, noon-1pm, 25 Michigan St. Bldg, 3rd floor, Conf. Rm 3001 & 3000