Organizational Announcement
November 5, 2018

Mercy Health and SJMHS Research Compliance came together under the leadership of Darlene Wahlberg, Director. Our partnership with Mercy Health did not just start in November, as we have had a strong working relationship over the years.

We would like to extend a warm welcome to our talented west market colleagues Cindy Johnston and Tiffany VanTilburg. Cindy handles the submission process and administers the monthly regional IRB meetings and Tiffany focuses on education and program reviews.

Our team will continue to have a physical presence in Grand Rapids and Ann Arbor. Together, we are a small but dedicated department that will cover all aspects of research compliance including but not limited to—conflicts of interest as well as research misconduct. There are now three IRBs, which provide an opportunity for two monthly IRB meetings for the review of non-oncology research endeavors. This expands our ability to respond to the volume of research submissions and offers some flexibility for full board review. We’ve got you covered in the mitten!

IHA

SJMHS IRBs will be the designated IRB of record for IHA in all matters related to human subject protection in the conduct of research. We have worked closely with IHA and ClinSite to overcome any perceived or known barriers in this new relationship. There have been six new study submissions in the 2018 calendar year from this collaboration.

FY 2020
Research Compliance Department Plans

- Streamline processes to create a single source for Michigan Research Compliance policies
- Harmonize program reviews and audits across Michigan
- Offer flexibility in IRB full board reviews by utilizing two monthly meeting dates
- Explore opportunities to eliminate redundancies that offer value-based enhancements to the Human Research Protection Program
# Performance Metrics and IRB Review/Oversight

## FULL BOARD

<table>
<thead>
<tr>
<th>Metric</th>
<th>IRB 1</th>
<th>IRB 2</th>
<th>GR-IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial New Study Reviews: Total number</td>
<td>25</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>• Average days for initial new study review and approval</td>
<td>20.96</td>
<td>23.50</td>
<td>27</td>
</tr>
<tr>
<td>• Range of days until approval</td>
<td>14-52</td>
<td>22-25</td>
<td>22-34</td>
</tr>
<tr>
<td>• Tabled studies for initial review</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Continuing Reviews</td>
<td>52</td>
<td>47</td>
<td>18</td>
</tr>
<tr>
<td>Addenda / Revisions</td>
<td>50</td>
<td>38</td>
<td>8</td>
</tr>
<tr>
<td>Adverse Events: Internal</td>
<td>3</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

## EXPEDITED

<table>
<thead>
<tr>
<th>Metric</th>
<th>IRB 1</th>
<th>IRB 2</th>
<th>GR-IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial New Study Reviews: Total number</td>
<td>39</td>
<td>3</td>
<td>22</td>
</tr>
<tr>
<td>• Average days for initial new study review and approval</td>
<td>3.62</td>
<td>2.33</td>
<td>8.92</td>
</tr>
<tr>
<td>• Range of days until approval</td>
<td>0-22</td>
<td>0-6</td>
<td>0-51</td>
</tr>
<tr>
<td>Continuing Reviews: Total number</td>
<td>56</td>
<td>120</td>
<td>34</td>
</tr>
<tr>
<td>• Average days for turnaround time</td>
<td>2.47</td>
<td>3.05</td>
<td>4</td>
</tr>
<tr>
<td>Amendment &amp; Revisions: Total number</td>
<td>313</td>
<td>263</td>
<td>75</td>
</tr>
<tr>
<td>• Average days for turnaround time</td>
<td>1.74</td>
<td>3.18</td>
<td>0.8</td>
</tr>
</tbody>
</table>

## EXEMPT

<table>
<thead>
<tr>
<th>Metric</th>
<th>IRB 1</th>
<th>IRB 2</th>
<th>GR-IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial New Study Reviews: Total number</td>
<td>7</td>
<td>1</td>
<td>26</td>
</tr>
<tr>
<td>• Average days for turnaround time</td>
<td>2.43</td>
<td>4</td>
<td>8.1</td>
</tr>
</tbody>
</table>

## NOT HUMAN SUBJECTS RESEARCH

<table>
<thead>
<tr>
<th>Metric</th>
<th>IRB 1</th>
<th>IRB 2</th>
<th>GR-IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial New Project Determinations</td>
<td>9</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>• Average days for turnaround time</td>
<td>6.00</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

## TOTALS

<table>
<thead>
<tr>
<th>Metric</th>
<th>IRB 1</th>
<th>IRB 2</th>
<th>GR-IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL NEW STUDY SUBMISSIONS</td>
<td>71</td>
<td>8</td>
<td>56</td>
</tr>
<tr>
<td>TOTAL SUBMISSIONS TO THE IRB</td>
<td>545</td>
<td>478</td>
<td>194</td>
</tr>
</tbody>
</table>

*GR = Grand Rapids Regional IRB (Grand Rapids and Muskegon locations)*

---

**Mission:** Our mission is to protect the rights and welfare of research participants at Mercy Health + SJMHS. This is accomplished through maintaining professional relationships with investigators and interested citizens within our community who are dedicated to the promotion and execution of ethical science.

All research protocols under the auspices of Mercy Health + SJMHS that involve human subjects, including protocols conducted through the Michigan Cancer Research Consortium, must be formally reviewed and approved by the relevant IRB prior to initiation of the study.

---

**Single IRB Review and Oversight**

As of January 25, 2018, per NIH policy, NIH applicants are to include a plan for the use of a single IRB review in all grant applications and contract proposals for multi-site research. To prepare for research undertaken with NIH monies the SJMHS IRBs became a participating member of the SMART IRB, a national reliance initiative, in March of 2018. Mercy Health Regional IRB became a participating member in January 2019.

This means that Investigators and study staff from our institutions may now submit requests for reliance involving other SMART IRB participating institutions. In addition, our institutions may be named in a request where the Principal Investigator is from another participating institution. This platform allows us to streamline the IRB reliance agreement process by using a single resource that uses previously established templates (reviewed initially by Trinity Health’s legal office, with Institutional Official concurrence). This allows for a quicker turnaround time and reduction in additional legal reviews, and has fostered collaboration within disparate institutions and organizations. SMART IRB is funded by the NIH Clinical and Translational Science Awards (CTSA) Program and is available for free but does require a submission process that includes documentation of assessments of the human subjects protection program.
Research Code of Conduct established by Trinity Health

Trinity Health Integrity and Audit Services has developed the Code of Conduct – Supplement for Research, which provides guidance to individuals engaged in the performance of research, including medical research involving human subjects. It is a supplement to the Trinity Health Code of Conduct, which describes behaviors and actions expected of all who work in Trinity Health. The Code of Conduct – Supplement for Research will be formally rolled out across the Trinity Health system during the year.

Common Rule-OHRP Regulations

The federal government general compliance date for the “2018 Requirements” (formally referred to as OHRP) was January 21, 2019. With these new regulations, we have addressed changes in the review processes of new definitions and regulatory categories to provide various allowances for expedited reviews, exemptions, studies not considered to be human subject research and, under certain conditions, the lack of an annual review requirement.

Note: Research that is subject to FDA regulations remains unchanged at this time.

The new regulations do not impact studies approved prior to January 21, 2019.

Salient to note our locations will not be implementing the use of broad consent at this time, which is associated with two new exemption categories, because required elements for execution are not currently present in our organizational infrastructure.

Some of the challenges are, but are not limited to:

• a coordinated way of providing consent at the time of registration
• tracking who has accepted consent and under what terms (to assure that it is within the consented scope)
• tracking who has declined and any declinations to be assured that research is not performed on the participant’s biologic specimens or their data
• assuring that any update to the broad consent, if substantial, is provided to those who initially stated consent
• consent and refusals will need to be tracked for the lifetime of the participant to assure specimens and data are used.

Statewide Program Reviews/Auditing

Both the SJMHS and Mercy Health locations offer auditing services: in SJMHS, auditing encompasses ongoing research, IRB determinations and review, as well as Research Compliance actions, documentation, and policies and processes.

Within the SJMHS, two clinical trial program reviews and a third mentoring audit with a Research Coordinator from St. Mary’s Mercy Livonia were conducted in 2018, with a focus on preparing for the Common Rule changes. The outcome of the program reviews of on-going research and IRB documents have included detailed recommendations for improvements in the system, development of forms, new training opportunities, and the creation of new educational tools and resources aimed at addressing the needs identified for our researchers, IRB members, and Research Compliance Department staff.

In the West Market, the focus is on auditing ongoing research, with the purpose of providing feedback and recommendations to the research team. In 2019, this service will be expanded to mirror the program reviews done at SJMHS in Ann Arbor. In 2018, an industry-sponsored clinical trial, an investigator-initiated study, and three retrospective chart review studies involving post-approval monitoring reviews were conducted. Minor findings were noted on each review and investigators and study staff were educated and worked collaboratively to address all findings in a timely manner.

We thank those researchers across Michigan who have participated in these important internal audits and program reviews.
Research Participant Experience Survey – Ann Arbor

Since 2017, four research departments at St. Joseph Mercy Ann Arbor have participated in surveying their research participants’ experience.

The survey broadly measures five dimensions of the participant experience:
- Coordination of the research experience
- Information and education about the study
- Informed consent process and the informed consent document
- Overall rating of care during the research
- Respect for research participant preferences

The number of research participants that have been surveyed since 2017 is 289 with a response rate of 34%. With two years’ worth of data collection, comprehensive data summary reports were prepared at the end of the year for three of the four departments, with a focus on trends in the data over the past two years. Some of the trends in participant feedback are illustrated below and were shared with IRB membership as well as researchers; these included participants desire to understand which tests/procedures and visits are for research purposes vs standard of care; desire to know about research studies open to enrollment; and the informed consent document being understandable. As our team works through the revised Common Rule, the IRBs have reviewed the consent requirements and are working diligently to address the feedback that we are receiving from our research participants.

Our thanks to the Michigan Heart, Medical Oncology, Academic Research and Huron Gastro Ann Arbor research teams for continuing to participate in this opportunity

The Human Research Protection Program (HRPP)-What Is It?

The Human Research Protection Program (HRPP) is committed to advancing the ethical treatment of research participants, protecting the rights, welfare and privacy of human subjects in all research conducted at Mercy Health + St. Joe’s, regardless of funding.

The program adheres to the principles outlined in the Belmont Report and the regulations of the U.S. Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA) and other federal agencies, and conforms to Health Insurance Portability and Accountability Act (HIPAA).
Changes in the IRB membership/staff

We sincerely thank all the IRB members who volunteer their time and expertise in performing critical reviews and upholding human subject protections. They are invaluable in making the clinical research enterprise a success at our Michigan locations.

IRB 1

We want to thank Mary Jo Smith RN, MS, St. Joseph Mercy Ann Arbor for over 20 years of dedication and service. She brought to us Melissa Villerot, RN, MSN as her replacement in June 2018. Unaffiliated member Marcia Jablonski was an important contributor as a non-scientist, but resigned in May.

New Staff
Kimberly Brown, MBA, IRB Administrator

IRB 2

We want to thank the following members for their dedication and service:

Kerry Pulver, MD & Alan Langerak, MD - Saint Alphonsus Health System - 6.5 years
Nora Lorenc - Lehigh Valley Health Network, 2017-18

New Members
Madeline Bondi and K’Lynne McKinley, DMIN

Mercy Health Regional IRB (Grand Rapids and Muskegon)

We want to thank the following members for their dedication and service:
Peter Sartorius, BA, MA, MS
Kevin Furmaga, PharmD, BCPP
Teri Holwerda, PhD, ACNS-BC, RN, NP (IRB Vice Chair)
LeAnn Smart, BS; and Dick Benedict, MBA
Brenda Hoffman, Chairperson, 9 years

New Members:
Christine Oltree, RN, MS, OCN, AOCN and Kristina Baas, MS

Annual IRB Member and Research Compliance Staff Picnic

June 2018

SJMHS IRB picnic was held at The Farm at St. Joe’s located on the Ann Arbor campus. The picnic was well attended by members of both IRBs and included a tour of the three hoop houses. The picnic continues to be an opportunity for staff and members to make connections outside of the work we do. It is also a way to thank the members for their service and dedication.

The Farm embraces innovative ways to improve health and wellness along with serving the community. Through nutrition education, The Farm aids in improving access to vegetables for all age groups, as well as offering an accessible environment for physical therapy individuals in the Eisenhower hoop house.

Witchy Fun!

Halloween 2018

SJMHS group donned broomsticks and hats and rode out across the hospital campus delivering candy and treats to our research customers, in our traditional reverse trick-or-treating festivities. Our jovial group visited our research customers and then took an impromptu swirl through the infusion bays in Oncology. We flew through the central hospital labs, delivering our final treats before turning our broomsticks back to our lair for caldron bubble.
Education, Training and Conference Opportunities

Education, Training and Pre-Review

The research ethics regulations span several federal agencies and can be a challenge to investigators, IRB members and staff to understand, especially given the recent changes to the Common Rule. In the past year, training audiences have included research teams, IRB members, Research Compliance Department staff, chaplain residents, physician residents, Trinity Health and the ministry IRBs, research committees and councils, and research regulatory staff. Training topics included the Common Rule changes, forms, guides on determination of clinical research vs. non-human research, introduction to research ethics and the IRB, misconduct in research, Principal Investigator responsibilities, continuing reviews, waivers, exempt vs. expedited research, engagement, and much more. To request training or a pre-review, contact anyone from our team — we are here to help!

Trinity Health issued a policy entitled “Education and Training Requirements for Individuals.” Involved in Human Subjects Research in 2017 that establishes the minimum standards for training and education:
intranet.trinity-health.org/web/integrity-audit-services/research-policies-and-procedures.

New changes include:

- **Ethical and Religious Directives (ERD) for Catholic Health Care**
  A training module on the ERDs has been developed specifically for the research community and will be added to CITI menu soon.

  In addition, a reference tool has been created that can be used for researchers, IRB members and our team to determine if the study activity will have conflict with the ERDs. The ERDs are an additional layer of adherence within the realm of human subject protection. The tool is available upon request and will soon be posted to our web pages for quick access.

- **Good Clinical Practice (GCP) education and training**
  GCP training is required for biomedical and social-behavioral researchers and their teams involved in a clinical trial (OHRP definition changed effective January 21, 2019 to be inclusive of behavioral research), regardless of the source of research funding. Training is offered in two formats: one for social-behavioral researchers and the other for biomedical researchers. This training will need to be completed every three years.

  **These courses can be downloaded by enrolling in CITI subscription service with your user ID and password: about.citiprogram.org/en/homepage/**

Other resources

The SJMHS IRB SharePoint site houses the tools, resources, flowcharts and helpful links and can be accessed at: sjmhsmi.che.org/sjmca/dept/IRB/default.aspx. This site has cheat sheets that aid in understanding the complex regulatory landscape and how regulatory requirements may apply to a given type of research project. Please check the SJMHS IRB website for policies and forms, as many policies were revised to comply with the new Common Rule. Specific forms are available at stjoesannarbor.org/IRBFoms.

Save the Date

May 2, 2019

Trinity Health: Annual Research Virtual Summit

Colleagues and residents are invited to attend any or all sessions.

Registration is encouraged, but not required: ereg.me/virtualresearch2019

PRIM&R Advancing Ethical Research Conference

November 2018

Public Responsibility in Medicine and Research (PRIM&R), hosted a conference in San Diego, CA. Four staff members from East and West Michigan attended along with Jim Mitchiner, MD, IRB 1, Chair, SJMHS and Dan Keyes, MD, researcher at St. Mary’s Mercy Livonia. The conference focused on interpreting and understanding the nuances of the revised Common Rule.

Front to back: Kim Brown, Cindy Johnston, Brenda Hoffman, Rozelle Copeland and Kelly Smid

stjoeshealth.org