**Emory University School of Medicine**

**Department of Psychiatry and Behavioral Sciences**

**Research & Scholarship Consultation Service**

**Quality Improvement and Program Evaluation Guidance Document**

Disclaimer: The following document was collated to provide guidance based on the best understanding of the committee in consultation with many helpful experts in the Emory community, including most notably Heather Johnson, Paula Edwards, Kathryn Black. We thank you for your consultation as we pulled this together. **Please consult with IRB if you have any questions or concerns as regulatory authority resides with them and all decisions and policy can change over time**. The two attached appendices are pulled from the Emory IRB and federal OHRP websites (06/30/2022) and represent the official stance as of that date.

Target Audience: Emory BHC clinical program managers, clinical investigators, and staff who are interested to use data obtained in clinical practice to evaluate their services, including but not limited to patient outcomes, resources use, etc.

**Key Decision point:**

If the data you are collecting or the project to collect data that you are designing is intended to answer a specific research question with the intent to contribute to generalizable knowledge (i.e., your intent is to publish the outcomes as others can learn from your findings), then it is most likely research that requires regulatory review and approval. There are some exceptions for data pulls in “preparation to research” such as pilot data for grant submissions or to support recruitment plans or study feasibility in a grant application (see the Emory IRB website for details).

If you are designing the project or pulling clinical data to examine a question that is relevant to evaluation of your practice or clinic resource use that is focused on results to feedback into your program practice and development, then it is Quality Improvement or Program Evaluation (QI-PE) and not considered research. The investigator CAN make this determination on your own OR if you prefer to consult with the IRB you can do that (See Appendix A or Contact the IRB staff at (404) 712-0720 or irb@emory.edu)

**As soon as you are aware that you will be using the data for the purpose of generalizable knowledge, pursuit of regulatory review is required. This may include evaluation of a prospective study with patient consent required OR a retrospective data pull of data previously collected for clinical purposes but now being used to examine a research question for generalizable knowledge.**

Transition to EPIC will likely provide additional avenues for data review and collection for both research and QI-PE.

**Current Data Sources**

**Amazon Web Service at Emory (AWS)**

Please see the website below for complete details of this resource.

<https://aws.emory.edu/>

Relevant Use Case:

<https://it.emory.edu/aws-overview/faculty-use-cases/machine_learning_to_predict_psychosis.html>

 **Resources Within AWS**

 ***CRADLE***

Office of Information Technology collates EHR and other Emory data. OIT can work to pull a limited data set (requires time for the effort) for review in CRADLE

Relevant Faculty Use Case

<https://it.emory.edu/aws-overview/faculty-use-cases/predicting_cardiovascular_outcomes_with_cradle.html>

Article that covers CRADLE

<https://scholarblogs.emory.edu/lits/2020/05/01/data-solutions-team/>

**Brain Health Personalized Medicine Data Set**

With funding provided through the new Brain Health Personalized Medicine Institute under the direction of Dr. Levey and Administrative Leadership of Heather Johnson and occurring over the next 7 years, a harmonized data set that combines clinical care data from CERNER and EPIC with clinical trials data from laboratory, imaging, etc. will be made available to BHC faculty and staff for use in QI-PE as well as research projects. There will be a platform created to query this data set and additional training and details will be available when this is created.

**Children’s Healthcare of Atlanta (CHOA) Data Resources**

Resources for project feasibility and data collection, mining, analysis, and statistical projects.  These resources are accessible to CHOA-affiliated researchers. For questions about availability of use to you, please email data@choa.org.

***Advanced Analytics & Outcomes***

The Advanced Analytics & Outcomes team provides services to collect, extract, mine, and analyze EPIC, HR, and other CHOA-sourced data.  Extraction also includes clinical chart review extraction by a nurse.  To get started, submit a Data request [here](https://sp.choa.org/apps/reportrequests/_layouts/15/ReportRequest/ReportRequestForm.aspx) or email data@choa.org.

**EEMR (CERNER and EPIC)**

Given transition to EPIC new data projects using CERNER sources are not recommended and may not be possible. Much of the historical data from CERNER will be pulled into the harmonized Brain Health Data set (see above).

**Emory University IT (including some healthcare)**

<https://it.emory.edu/catalog/data-and-reporting/index.html>

**12b2-** Searchable resource of Emory Healthcare patients available without charge and supported by Emory OIT and CTSA

**Grady Hospital**

Grady Office of Research Administration- <https://www.gradyhealth.org/office-of-research-administration/#team-members>

**Observational Medical Outcomes Partnership (OMOP)**

Standardized and modelized common healthcare data elements- unsure of rules for access as they vary by site (GRADY, EMORY, CHOA, VA) site specific resources may include OMOP.

 What is OMOP?

<https://ohdsi.org/omop/>

 <https://www.ohdsi.org/wp-content/uploads/2014/07/AMIA-CRI-2015-OHDSI-Panel.pdf>

Emory Use Case:

<https://etd.library.emory.edu/concern/etds/9z902z90g?locale=en>

Use case from another healthcare system of OMOP with EPIC

<https://health.ucdavis.edu/data/omop.html>

**Emory Clinical Data Warehouse**

Runs on Oracle so most clinical staff do not know how to pull or use data in this database. As true for all data, requires IRB approval for research data pulls. See below for additional information, training resources, and access requirements.

<https://it.emory.edu/clinical-research-data/sources/warehouse.html>

**EPIC (used at Grady and transitioning to use at Emory)**

TBD

**Qualtrics**

A tool for survey and data collection. Below is the link for **Emory University School of Medicine** use of Qualtrics. Must ensure HIPPA compliance if measures are used in clinical decision-making. Please confer with IRB and Emory Healthcare for latest practice. Training and requirements for use are also on the site.

<https://emory.sharepoint.com/sites/SOMITS/SitePages/Qualtrics.aspx>

**REDcap**

A tool for collection of measures in mostly research and some limited clinical projects. Below is the link for **REDcap**. Must ensure HIPPA compliance if measures are used in clinical decision-making. Please confer with IRB and Emory Healthcare for latest practice. Training and requirements for use are also on the site.

<https://it.emory.edu/catalog/data-and-reporting/redcap.html>

**TONIC**

For collection of measures in EEMR if standard of care. Likely no longer used with EPIC.

**Attachments**

**Human Subject Regulations Decision Charts: 2018 Requirements**

<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html>

**Emory IRB Chart**

<https://www.irb.emory.edu/_includes/documents/sections/pyramid-guidance.pdf>

**Emory- Does my Project need IRB Review?**

<https://www.irb.emory.edu/guidance/getting-started/review.html>