Navigating the Research Data Request Process: An Overview of How to Request Clinical Data from Epic and the Clinical Data Warehouse (CDW) for Research Purposes

8.26.15 LUNCH ‘N LEARN

Leslie Bell, MA, CCRP
Research Navigator-SCTR SUCCESS Center
What is the CDW?

“The MUSC CDW is a single, secure, integrated database extracted from the MUSC Clinical Data Repository, which includes patient demographics, visit information, ICD-coded diagnoses, ICD-coded procedures, medications, laboratory test results since 1993, and EPIC results since July 1, 2014. Please note this CDW is NOT the Health Sciences South Carolina (HSSC) CDW.”

http://academicdepartments.musc.edu/bmic/cdw.html
Main purposes for obtaining clinical data through Epic/CDW

- Feasibility
- Chart Review
- Recruitment
Is a Research Data Request necessary?

- Feasibility
  - Self-Service CDW query
  - SlicerDicer Epic tool
- Chart Review
  - Is it research or QI?
  - Do you require identifiable information?
- Recruitment
  - Are you recruiting from outside of your own clinic?
Self-Service CDW tool

- Only MUSC faculty and faculty-sponsored staff may access the CDW. Faculty who wish to sponsor full-time MUSC staff members to access the CDW should complete the Sponsorship Form and return it to cdw-research@musc.edu.

- De-identified aggregate data through a restricted query interface and a signed data use assurance (DUA) in accordance with HIPAA guidelines.

- Some aggregate, de-identified queries that are more complex and require multiple variables may need to be performed by the honest broker and requested through the Research Data Request process.
View a basic tutorial of the CDW self-query tool at http://academicdepartments.musc.edu/bmic/CDW/cdwbasictutorial.html
Epic SlicerDicer

- Training for SlicerDicer for research teams begins 9/8/15
  - Non clinical staff will need to complete SlicerDicer for research training
- Any PI who is a physician with clinical responsibilities can currently self-enroll in 4 CATTS trainings to gain access
Research or QI/Program Evaluation?

- Only projects that classify as research projects utilize the Research Data Request process.
  - Amy Wilson (CDW) and Patricia Wagstaff (Epic) are contacts for clinical/QI data reports
- Research is defined as a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.
  - NOTE: Intent to publish does not necessarily make a project subject to IRB review.
- Quality Improvement: Activities that are done to improve quality of programs, improve services, or improve the provision of medical care, customer service, etc.
- Program Evaluation: Systematic collection and analysis of information about the effectiveness of an existing program to make judgements about the program, improve program effectiveness, and/or inform decisions about future program development.

Definitions above from SCTR’s MUSC Approval Plan for Research (MAP-R) tool
Requesting “Research Data Requests” in SPARC

- Visit https://sparc.musc.edu to request service
- Associate it to study or create new study
- Submit to start services
- Complete and submit REDCap form with details of the data request, referencing the submitted SPARC request
STEP 1: Add Users

To begin to search and add authorized users to this study/project, type in the first or last name of the user. Select as appropriate.

User Search:
Search for user:

Name: Leslie Bell
Email: bell@msu.edu
Phone: 643-702-0078
Role: Primary PI

EBA Commons Name: Leslie

User Details:
- Institution: Medical University of South Carolina
- College: Other
- Department: Other
- Credentials: MA
- Subspecialty: ALLIED HEALTH (E100)

Add Authorized User

Research Study/Project Authorized Users:

<table>
<thead>
<tr>
<th>Name</th>
<th>Access</th>
<th>Role</th>
<th>Member Only</th>
<th>View Rights</th>
<th>Request/Approve Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leslie Bell</td>
<td></td>
<td>Primary PI</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Go Back  Continue
STEP 2A: Enter Protocol Dates

Next, please enter the following information specific to your research study/project. This information will help us generate applicable SOPs/CIRS for your review.

Estimated Study Start Date: [Calendar]

Estimated Study End Date: [Calendar]

Go Back  Save as Draft  Save & Continue

STEP 2B: Visit Calendar

<table>
<thead>
<tr>
<th>Template Tab</th>
<th>Quantity Billing Tab</th>
<th>Quantity Display Tab</th>
<th>Consolidated Request Tab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Services</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unit Costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Service Rate</td>
<td>Time Cost</td>
<td></td>
</tr>
<tr>
<td></td>
<td>#</td>
<td>Units Type</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Services</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- E = Research
- T = Third Party (FT Insurance)
- % = % Effort

Go Back  Save as Draft  Save & Continue
No documents found

Add a New Document

Please add any additional information that may be helpful to service providers.
REDCap Research Data Request Form
REDCap Research Data Request Form

- [https://redcap.musc.edu/surveys/?s=4R73KJP8JK](https://redcap.musc.edu/surveys/?s=4R73KJP8JK)
Tips for completing Research Data Request Form

- Be as specific as possible with selection criteria
  - Include ICD9/ICD10 codes, CPT codes, etc.
- Make sure the data points you are requesting, have been listed and approved in your IRB application/amendment
  - If you need to submit an amendment to receive the data you need, feel free to request a regulatory consult
  - Including “Chart review” vs “Data Request” in your application
- Exempt protocols can receive only clinical data OR identifiers but not both
- Once honest broker begins fulfillment on your data request, he/she can provide additional information on the extent of the data fields available in the warehouse/Epic
Additional phases of the request process

- SUCCESS center administrator receives notification of SPARC request
  - Administrative review to gather IRB documents and REDCap Research Data Request Form
  - Occurs within one business day
- Request goes to Data Request Committee (DRC) for review and approval
  - 5 members-needs 3 approvals
  - You will be contacted for changes/clarifications if the DRC cannot approve the original request as is
- Once approved, request is placed in honest broker’s fulfillment queue to be answered in the order in which it was received
  - Epic vs. CDW is based upon purpose and date range of request-each has it’s own fulfillment queue
- Honest broker will communicate directly with requester when fulfilling the request, and send report to specified requester for review
Final thoughts

- Plan ahead and have patience
  - Complementary service + many requests = delayed turn around times
- Call the SUCCESS center for assistance in any step of the process
  - 843-792-8300