Beaumont HEALTH

Title: **Research Electronic Data Capture (REDCap) Use at Beaumont**	*Applicable to: **Beaumont Health**	Effective Date: **01/12/2018**
		Last Periodic Review Date: **01/12/2018**
Policy Owner: **Administrative Director**	Document Type: **Policy**	Functional Area: **Research Administration, Research Institute**

*For This Document, Beaumont Health Includes:
Beaumont Corporate Shared Services
Beaumont Hospital, Dearborn
Beaumont Hospital, Farmington Hills
Beaumont Hospital, Grosse Pointe
Beaumont Hospital, Royal Oak
Beaumont Hospital, Taylor
Beaumont Hospital, Trenton
Beaumont Hospital, Troy
Beaumont Hospital, Wayne
Beaumont Medical Group
Beaumont Pharmacy Solutions
Post Acute Care

I. PURPOSE:

The purpose of this policy is to provide information on the use of REDCap (Research Electronic Data Capture) system at Beaumont Health (Beaumont).

II. SCOPE:

This policy applies to investigators, key research personnel, Beaumont physicians and staff members, external collaborators and anyone else who may use Beaumont's REDCap system.

III. OVERVIEW:

REDCap is a web-based software program created by Vanderbilt University and supported by the REDCap Consortium to facilitate research and data collection. Beaumont has been granted a license to use REDCap for the collection and storage of Beaumont research data. REDCap enables rapid project development and provides researchers with access to advanced data management functionality while maintaining autonomy and direct control of projects. REDCap data can be exported to most common statistical packages.

REDCap is installed locally on Beaumont servers, which are supported and maintained by Beaumont Information Technology. REDCap data is backed up every 24 hours. The Beaumont Research Coordinating Center (BRCC) is responsible for administering the use of the software, including establishing policies for appropriate use of REDCap, providing access to users/

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databases, assuring regular audits of system use and providing general user support. Each project must have a designated Project Manager who will be responsible for administration of the specific project, including building and maintaining the database/project, facilitating role-based access for users (both Beaumont users and external users), confirming appropriate oversight committee approvals (i.e., Institutional Review Board [IRB], Animal Care Committee [ACC], Institutional Biosafety Committee [IBC]) are in place prior to any data entry and assuring the ongoing integrity of the project data in REDCap.

IV.   DEFINITIONS:

A. **REDCap Administrators –** Individuals designated by Research Administration to oversee the use of the REDCap system at Beaumont. Responsibility for oversight of REDCap and identifying individuals as REDCap Administrators has been delegated to the BRCC.

B. **Development System –** A pre-production instance of REDCap made available to build and test projects, forms and databases. Only test data may be entered into a project in the Development System.

C. **Production System –** The live instance of REDCAP where actual study data is entered and managed. Appropriate oversight committee approval (i.e., IRB, ACC, IBC) must be obtained prior to entering project data in the Production System).

D. **Project -** A database, set of surveys, data entry forms, schedules and/or other REDCap instruments pertaining to a specific study, research project or database.

E. **Project Champion -** The individual leading a project in REDCap when the project is not research (the equivalent of a PI for a research study).

F. **Project Manager** - A person with overall responsibility for a specific project within REDCap, including building and maintaining the database/project, granting users role-based access to the project, facilitating access for users from outside of Beaumont, confirming appropriate oversight committee approvals (i.e., IRB, ACC, IBC) are in place prior to any data entry and assuring the ongoing integrity of the project data in REDCap.

V.   POLICY:

REDCap is made available to Beaumont researchers for use in collecting and managing approved research data. REDCap may be made available for non-research project use as resources allow. All projects using REDCap must have a Beaumont Principal Investigator (PI)

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or Champion (for non-research related databases). It is the responsibility of the PI/Champion and the Project Manager to assure the appropriate use of REDCap for their project.

A. **Getting Started –** Each new project to be created in REDCap must have an assigned Project Manager, who accepts responsibility for creating and managing the project. Prior to being granted access to a new project, the following steps must be completed:
   1. Submit a *RedCap Database Request Form* and project protocol (if research) to the BRCC. The form will identify the Project Manager. A Project Manager must be a Beaumont employee, Beaumont physician/provider, or OUWB medical student.
   2. The Project Manager must view the following training videos found on the Training Resources page in REDCap:
      a. Brief Overview
      b. Detailed Overview
      c. Data Entry Overview
      d. Introduction to Project Development
      e. Online Designer
      f. Data Dictionary
      g. Project Field Types
      h. Applications Overview
      i. Types of Projects
      j. Traditional Project
   3. Additional training videos may be required based on type of project and if any special features are required.
   4. Complete and return the Project Manager Verification of Training Form.

B. **Project Manager Responsibilities in Building a Project -** REDCap is designed to be a self-service tool with minimal external instruction required to develop and deploy a project. Tutorial videos, a built-in Frequently Asked Questions knowledge bank, and embedded documentation are available and are used collectively to guide the user in software utilization.
   1. **Building case report forms/data entry screens -** All projects will be built in the Development system and tested prior to being moved into Production. It is suggested that prior to beginning to build a project in REDCap, the Project Manager meet with the PI to go through the protocol and highlight the data collection points to be built in REDCap. This will provide an opportunity to jointly define the questions on the data entry screens and identify potentially ambiguous sections in the protocol,

2. **Testing -** It is strongly recommended you test your project prior to moving to Production, by entering test data. *Real study data may not be entered into a project in the Development system*. Entering and saving data is the only way to test and ensure branching logic and calculated fields are working properly. Other personnel should assist the Project Manager with testing to provide a fresh look at the database, etc.

3. **Moving project to production -** Once all testing is completed, the Project Manager is confident in the data entry screens and fields, and appropriate oversight committee approval has been obtained (i.e., IRB, ACC, IBC), the project may be moved into the Production system. Moving a project to Production ensures data accuracy and integrity are maintained. The post-production change control process provides an additional check to ensure data which has already been collected is not deleted, re-coded or overwritten unintentionally. When you click the "Move project to Production" button on the Project Setup page, a pop-up will prompt you to "Delete ALL data, calendar events, documents uploaded for records/responses, and (if applicable) survey responses?" Check the option to delete data to assure test data is deleted prior to adding real data into your project in Production.

4. **Identifying users and assigning appropriate access -** All REDCap users must have their own account. Accounts are not to be shared. Users working on research involving human participants must be approved by the IRB as key personnel prior to being granted access to a project. REDCap has an authorization matrix, allowing different members of the study team to have different levels of access (none, read-only or edit) to data entry forms, and access to project management and data export tools. There are provisions to restrict access to data export to allow export of de-identified data only. REDCap enforces authorization granted to each user by providing and/or enabling certain functions, tabs, links and buttons according to granted privileges. REDCap maintains a full audit trail, recording all operations on the data, including viewing and exporting. The audit log records operation, date and time, and the user performing the operation, permitting review of the audit trail as necessary. Any individual with an active Beaumont ID will be able to login to REDCap using their standard Beaumont ID and password. However, they will not have access to any projects until they are granted access by a REDCap Administrator.

5. **External users -** External collaborators or sites may be granted access to a project provided the appropriate clinical trial or data sharing agreements are in place. To request access for an external collaborator, complete the *REDCap External User Request Form* and forward to the BRCC.

6. **Accessing Project Data -** The project PI or Champion is responsible for all accesses and uses of project data. Access is facilitated by the Project Manager and rights may vary by

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individual. Only those who will be scrubbing or analyzing the data should be granted Full Data Export rights for projects, especially those which include Protected Health Information (PHI). Data exports may only be done by a Beaumont employee, Beaumont credentialed physician/provider or OUWB medical student and should be saved to a Beaumont network, SharePoint folder or other Beaumont approved, secure place or into a secure statistical software program. PIs and REDCap Project Managers must manage access to the project to ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) and other state and federal regulations protecting patient privacy and confidentiality, ensuring each user is granted the minimum amount of access needed to perform his/her project related duties. **Databases must be assessed for PHI. According to HIPAA, de-identified data will <u>not</u> include any of the following variables:**

a. Names
b. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:
    (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
    (2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000
c. All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
d. Telephone numbers
e. Vehicle identifiers and serial numbers, including license plate numbers
f. Fax numbers
g. Device identifiers and serial numbers
h. Email addresses
i. Web Universal Resource Locators (URLs)
j. Social security numbers
k. Internet Protocol (IP) addresses
l. Medical record numbers
m. Biometric identifiers, including finger and voice prints
n. Health plan beneficiary numbers
o. Full-face photographs and any comparable images
p. Account numbers

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q. Certificate/license numbers
r. Any other unique identifying number, characteristic, or code
s. The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

These data variables may be flagged in REDCap as "identifiers". In the Data Export Tool, the identifier variables appear in red and the user will have options to de-identify data prior to exporting it.

C. **Project Completion -** At project completion, the Project Manager may lock all forms in REDCap to ensure users do not accidently make further modifications without authorization.

Note: Projects that have been added to REDCap, but have had no database development activity after 90 days will be inactivated.

VI. CHARGES FOR USING REDCap:

In the event the BRCC is requested to provide ongoing support or act as Project Manager (e.g., build, create, maintain the database, etc.), the PI or Project Champion will be required to provide a department ID where the BRCC staff member's time will be charged. Estimates will be provided upon request (see *REDCap Request Form*).

VII. SYSTEM AUDITS:

Audits of REDCap projects and users will be performed regularly.

VIII. REFERENCES:

Research Repositories, Databases, and the HIPAA Privacy Rule, NIH publication number 04-5489, January 2004
45 CFR 46 Protection of Human Participants
21 CFR 50 Protection of Human Participants
21 CRF 56 Institutional Review Board
45 CFR 160 and 164 Privacy and Security Rule

IX. ASSOCIATED POLICIES:

Research Administration Policy *131 Processing Data and Material Sharing Agreements*
IRB Policy *IRB Initial Review of Research Protocols*
IRB Policy *HIPAA and Research*
IRB Policy *Quality Assurance / Quality Improvement Projects*
IRB Policy *Research Exempt from Full IRB Review*
IRB Policy *Using Databases, Repositories and Registries in Research*
IRB Policy *Limited Data Use Agreements-SOP*

X.   ATTACHMENTS: (see upper right corner)

REDCap Request Form
External Request for REDCap User ID and Password

CORPORATE AUTHORITY:

Beaumont Health ("BH") as the corporate parent to William Beaumont Hospital, Botsford General Hospital, and Oakwood Healthcare Inc., ("Subsidiary Hospitals") establishes the standards for all policies related to the clinical, administrative and financial operations of the Subsidiary Hospitals. The Subsidiary Hospitals, which hold all health facility and agency licenses according to Michigan law, are the covered entities and the providers of health care services under the corporate direction of BH. The Subsidiary Hospitals' workforces are collectively designated as BH workforce throughout BH policies.

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