REDCap GOVERNANCE
University at Buffalo (UB)
Definition and Key Overarching Principles

DEFINITION

REDCap Governance is the organizing framework for aligning strategy, defining objectives and establishing policies for Administrative and Research Electronic Data Collection (EDC) via REDCap. It aligns research information needs with university strategy, regulatory guidelines and oversees the day-to-day execution of REDCap policies.

PURPOSE

The Purpose of REDCap governance at UB is to support UB research, administrative uses and to monitor UB affiliates who choose to use UB’s REDCap Instance:

- Provide faculty and administrative staff with the means to perform electronic data collection;
- Ensure Administrative and Research projects meet all regulatory and compliance guidelines;
- Help support UB in its efforts to facilitate research and scholarly activity.

GUIDING PRINCIPLES FOR REDCap GOVERNANCE

1. **Project Development** - Administrative teams or Research Project Staff can build their own projects or solicit the Project Support Team for assistance. Once a project is built in REDCap but BEFORE it is made public (ready to receive data) it must be approved for use by the REDCap Governance Group. Once approved, the project will be sent to the REDCap Support Team who will then make it public.

2. **Data Downloads** - Data downloads will be managed according to IRB approved protocols which ensures there are adequate provisions to maintain the confidentiality of data. This may be the function of system admins, The Project Support Team or the Principal Investigator.

3. **Integration** - Project information can be integrated into other applications as needed by The Project Support Team.

4. **Authentication** - Two types of authentication are permitted: LDAP and Local Login. All UB Administrators, Faculty, Staff and Students who have UB credentials will be required to use LDAP authentication. Local logins are accepted and will use email addresses as user ID’s. No local login account will be created using Gmail, yahoo, Hotmail, etc.
5. **IRB Protocol Review** - No research project will be made public without IRB approval. If IRB approval is required, the protocol will be reviewed by the individuals or group deemed responsible by the REDCap Governance Group to ensure REDCap content adheres to the approved IRB protocol. If it is determined the project is Administrative no IRB Approval is necessary and the project will be created. Research Projects must adhere to proper HIPAA regulations. *(See Addendum)*

6. **System Upgrades** - REDCap upgrades will be determined by the REDCap Governance Group. REDCap Upgrades and enhancements will occur every two months by Project Support team and System Admins.

7. **Evaluation** - REDCap usage and governance will be reviewed annually by the REDCap Governance Group and UB System Administrators to improve effectiveness, usability and administration.

8. **No HIPAA regulated data** - UB REDCap cannot be used for any activity regulated by HIPAA that would involve the creation/use/maintenance/transmission/destruction of HIPAA regulated PHI. This would include use of UB REDCap for Treatment, Payment, or Health Care Operations activities, such as QA/QI, of a HIPAA regulated entity (UBMD, hospitals, UB Dental School, etc.), or that would create a HIPAA Business Associate relationship between UB and a HIPAA regulated entity by providing a service to that entity which would involve the creation/use/maintenance/transmission/destruction of PHI on behalf of that entity. UB REDCap can be used with UB Research Function data that has been provided to UB by a HIPAA regulated entity in a manner permitted by HIPAA since that data is no longer regulated by HIPAA. UB REDCap personnel may assist HIPAA regulated entities who wish to deploy their own REDCap instance, but if that assistance provides UB personnel with access to HIPAA regulated PHI, they can only provide the assistance after being made volunteers of the covered entity's workforce so that a HIPAA Business Associate relationship is not created between the covered entity and UB.

**Addendum:**

The HIPAA defined permission that a UB investigator can use to collect information in RedCap are:

* De-identification
Prohibits 18 specific identifiers from appearing in the data:
http://www.hpitp.buffalo.edu/hipaa/Resources/identifiers.htm

*Authorization
Authorization is not the same as informed consent, but can be combined with it if in written form. The IRB approved Authorization must contain: “(i) A description of the information to be used or disclosed that identifies the information
in a specific and meaningful fashion." RedCap projects can only collect information pursuant to an Authorization that is consistent with that description.

*Waiver or Alteration of Authorization
The IRB's can Alter or Waive the required elements of an Authorization. As part of documenting that it is has issued a Waiver the IRB Waiver documentation must contain "(iii) Protected health information needed. A brief description of the protected health information for which use or access has been determined to be necessary by the institutional review board or privacy board, pursuant to paragraph (i)(2)(ii)(C) of this section;" RedCap projects can only collect information pursuant to a Waiver that is consistent with that description.

*Research on Decedents
Any data collected pursuant to the IRB approved protocol is permitted

*Limited Data Set with Data Use Agreement This mechanism is not typically used. When it is used, there must be a fully executed Data Use Agreement with the data provider which will describe the data to be collected. This data cannot contain any of the 15 elements not followed by a '*' listed for De-identified data