Scope:

All users wishing to use REDCap to collect data in the following categories: Clinical, Quality Improvement, Research, and Registry.

Purpose:

To assist users in conducting data collection while protecting patient privacy and confidentiality.

Preamble:

REDCap (Research Electronic Data Capture) is a powerful software program created by Vanderbilt University and supported by the REDCap Consortium to facilitate Institutional Review Board (IRB)-approved clinical research, basic research and other data collection.

REDCap has a flexible and fine-grained authorization matrix, allowing different members of the project team to have different levels of access to data entry forms (none, read-only or edit), and access to database management and data export tools. There are provisions to restrict access to de-identified data only.

REDCap includes a full audit trail for recording all operations on the data, including viewing and exporting. The audit log records all data changes, timestamps those changes, and includes the user performing the operation.

REDCap enforces data integrity protection by design. Additionally, REDCap can help to ensure data quality through use of Double Data Entry mode, forms and records locking and electronic signatures.

Definition of Terms:

Project Sponsor

The Project sponsor is an employee of Children's Healthcare of Atlanta who has the administrative authority to authorize a project. The Project Sponsor is responsible for the appropriate use of the data and ensures that all projects are conducted in an ethical manner and in accordance with all federal, state, and local laws and regulations, and Children's Healthcare of Atlanta policies**.**

The Project Sponsor **approves,** for each team member, the levels of access to data entry forms, database management and data export tools. The Project Sponsor **approves** who gets access to the data and whether or not access to PHI is appropriate.

Clinical Lead

This person is the "Principal Investigator" of the project, the individual who initiates the request and drives the effort (research, project, QI study, or registry) forward. The Clinical Lead is responsible for supervising the conduct of the project team members, approves the final data collection tool and oversees the appropriate data collection and reporting applications. The Clinical Lead does not necessarily need to be an employee of Children's Healthcare of Atlanta. The Clinical Lead could also serve as the Project Sponsor.

The Clinical Lead **determines,** for each team member, the levels of access to data entry forms, database management and data export tools. The Clinical Lead **determines** who gets access to the data and whether or not access to PHI is appropriate.

Project Lead

The Project Lead is the person responsible for managing of the design and structure of the project, including assignment of the roles and authorizations to use specific forms and functions of the REDCap database to the members of the project team. The Project Lead is responsible for day to day oversight of the collection and reporting process. For smaller projects the Project Lead could also serve as the Clinical Lead.

The Project Lead **assigns,** for each team member, the levels of access to data entry forms, database management and data export tools. The Project Sponsor **assigns** who gets access to the data and whether or not access to PHI is included.

Database

A set of data entry forms, schedules and other REDCap instruments pertaining to a specific study or project.

Development mode

A state of database that allows authorized team members to add, modify or delete data entry forms and other elements of the study design. In the development mode, the database is temporary and is not backed up. No data is guaranteed to be preserved in the database in this mode.

All changes to your data collection tool must be done in Development mode.

External User

A user of REDCap that is not an employee of Children's.

Production mode

A state of database that allows authorized team members to add, modify or delete data. Any data entered in this mode will be protected by periodic backups.

Any modification to the data collection design must be done in Development Mode. Your REDCap Administrator will be needed to move the database out of Production mode and into Development Mode for any changes to be made. You can save earlier versions used in Production Mode and update moving forward. Be careful that you prepare a proper crosswalk if you want to combine the before and after data. REDCap Administrators will review proposed changes before approval to ensure data integrity.

REDCap Administrator

A group responsible for implementation and maintenance of REDCap, for user education, and for management of databases (moving to production, approving changes when in production, restoring from backup etc.).

Data Collection Types.

To determine whether the data you wish to collect requires IRB approval or waiver:

Clinical

Clinical data are those databases designed to **sustain** the quality of our patient care. These typically do not require IRB approval as they are used as part of the standard of patient care.

Quality Improvement

Quality improvement databases are those designed to **improve** the standard of care within our hospital system. If you have changed how care is implemented and want to collect data to evaluate the impact of this change then you are collecting QI data. Since the change in care is applied to all patients the IRB will typically grant a waiver but should always be consulted.

Research/ Clinical Trials

Research databases are those designed to **potentially change** the standard of care within and beyond our hospital system and to contribute to generalizable knowledge. All research databases will require IRB approval. Typically a treatment change is applied to a subset of patients and we compare the data on those receiving the old treatment to those receiving the new treatment. These databases are usually data or analysis requests tied to the implementation of new interventions, new treatments or novel ways of addressing a clinical question. The data are collected to answer specific hypotheses.

Registry

Registry database are those designed for **long term monitoring** of a patients care. These typically include pre, peri and post hospitalization data and depending on their purpose, may or may not require IRB approval. The IRB should be consulted prior to launching a registry. If registries are built to answer specific hypotheses, IRB approval will typically be required.

Policy

Any authenticated user has a right to access REDCap, review public databases (e.g., demo databases) and modify a database to which a corresponding authorization is granted (e.g., his/her own). Currently, CHOA network will serve as the authentication source for internal users. Project Sponsors can request an account for an external user by email (redcap@choa.org) to get access to the REDCap.

Any new user is strongly encouraged to make an appointment with a REDCap trainer for an introduction to REDCap (about 1 hour) before requesting a new database in REDCap. Please send a proposed project summary to the REDCap trainer at least 1 working day before the appointment.

Any new database will be created in development mode. When in development mode the user should not enter any identified patient information. For testing purposes use made-up identifiers. REDCap administrators will periodically review contents of all databases in development mode to ensure compliance and report any violations to the Project Lead. In the case of data regarding patients or subjects of Children's Healthcare of Atlanta, all users must comply with CHOA "Uses and Disclosures for Research Purposes & Waivers (HIPAA Research Policy)" Policy # 8.15

It is the responsibility of the Project Lead to:

- Build the REDCap database (entry forms) in such a way that it corresponds to the study design and Data Collection Type.
- Collect all the data necessary to satisfy the goals of the Data Collection Type

- Collect only minimally-necessary set of PHI, in addition to those required by study design or operational requirements, to positively identify study subject during data entry

Alternatively, the Project Lead may request that REDCap Administrators assist with development of the REDCap database for the study.

To move a database into production, the Project Lead or authorized project representative needs to request a review by REDCap Administrators, depending on the Data Collection Type, the following information must be provided:

- IRB approval letter (for research only)
- IRB waiver (QI and Registry)
- A signed copy of this policy.

After review and approval, a REDCap administrator will move the database into production.

REDCap is being supported by the Outcomes Center and IS&T. RedCap support team bears responsibility for maintenance of the software, database deployment (moving to production).

The Project Lead is responsible for managing access to the Project database(s) to ensure compliance with HIPAA and other state and federal regulations protecting patient privacy and confidentiality.

REDCap is also supported by Emory University. It is recommended that you use the Emory REDCap tool (https://redcap.emory.edu) when your Data Collection Type is Research / Clinical Trial as their administrative team are specifically trained in developing databases to support research.

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RedCap Appropriate Use Agreement Signature Page

I have read and understand the appropriate use of REDCap and the requirements of the program.

This Appropriate Use Agreement is made effective and entered into on [_______________] by Children's Healthcare of Atlanta, Inc. employee(s),
[____]
for the following REDCap Project[____]

I accept and agree to abide by the appropriate use agreement of REDCap.

My REDCap role is:

☐ Project Sponsor

☐ Clinical Lead

☐ Project Lead

Date: ____________________

____
Signature:

____
Print name:

____
Title:

____
Role (if more than one person signs agreement)

Upon final acknowledgement and understanding, please sign and date agreement.
Scan to:
Redcap@choa.org

Date: _____ _____

Signature:

_____

Print name:

_____

Title:

_____

Role (if more than one person signs)

Date: _____ _____

Signature:

_____

Print name:

_____

Title:

_____

Role (if more than one person signs)