MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

PRIM&R – Ethics of Data Access

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Informed Consent Guidance

Objectives of our Multi-stakeholder Work:

- Discuss the risk of re-identification and determine protective mechanisms

    1. Achieve clear definitions of identifiable data, anonymized data, anonymous data, de-identified data, and re-identified data.

- Provide guidance in two areas:

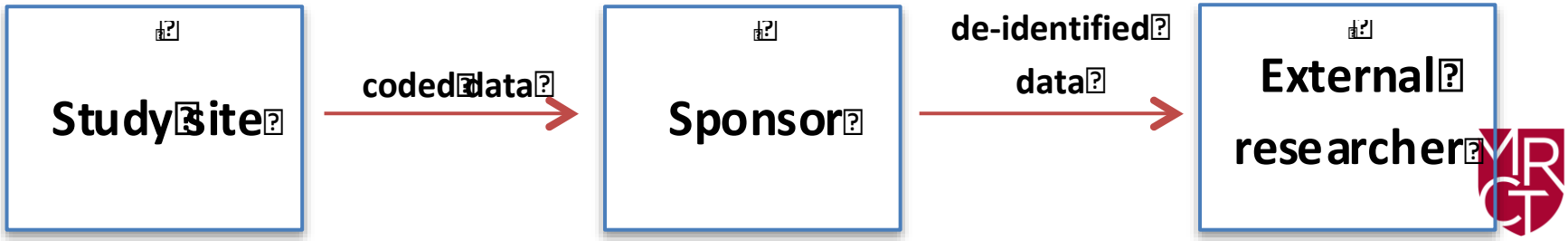
    2. Retrospective consent: Interpret the limitations imposed by language in existing informed consent forms (ICF's) upon data-sharing.

        - *Silent, narrow sharing, broad sharing or conflicting language found in existing forms*

    3. Prospective consent: Develop ICF language for patient-level data-sharing acceptable to IRBs and patients groups.

Suggested Definitions for ICFs - Definitions

Term	Definitions
personally identifiable data	information that directly or indirectly identifies you (e.g. name, SSN, address, telephone number, email address)
coded data	study participant data and samples for which a code is given to replace a person's name or other specific information.
de-identified data	data modified to remove the presence of personally identifying information
your data	your personal and medical data collected during the study, which may be coded or de-identified



Proposed ICF Language for Data Sharing

Key Sections

- What information about me will be used in the study?
- Who may see, use and share your personal and health information?
- How will my information be used?
- How may my data be used for additional research?
- What other information is shared?
- Do I have to participate?
- Can I change my mind?

NOTE: sharing is linked to participation in the study and the form takes an “inform” approach

http://mrctcenter.org/resources/2015-03-23-template-informed-consent-template-external-sponsor/