Marshfield Clinic

Ending IRB Oversight

1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

For purposes of this document only:

2.1. Anonymized Data

- Data that have been stripped of all identifiers and, either or alone or when combined with other data available at the same institution, would not allow a person to establish the identity of an individual, including any code that will identify an individual only through the use of a key or link.

2.2. Direct Identifier

- Any data that, either alone or when combined with other data available at the same institution, would allow a person to establish the identity of an individual.

2.3. External Party

- Any organization or individual outside of Marshfield Clinic.

2.4. Indirect Identifier

- Any data that, either alone or when combined with other data available at the same institution, would not allow a person to establish the identity of an individual. Also includes a code that will identify an individual only through the use of a key or link.

3. PROCEDURE BODY

This document outlines the procedures for voluntarily terminating research that has been previously approved by the IRB, thereby ending IRB oversight of the research. Federal regulations 45 CFR 46.109(e) and 21 CFR 56.109(e) require the Marshfield Clinic Research Foundation IRB ("IRB)" to conduct continuing reviews of ongoing research activities that involve human subjects at intervals appropriate to the degree of risk, but not less than once a year. Representatives from the Department of Health and Human Services Office of Human Research Protections (OHRP) have stated that IRB oversight must continue through the data analysis phase of research when the analysis involves identifiable data (which differs from the HIPAA definitions. See the definitions above). Recognizing that data analysis can take years to complete and is often accomplished by external parties, this document aims to ensure that adequate protections are in place for research subjects and that the regulatory requirements are met, while minimizing burdens on the IRB and investigators.

3.1. When IRB Oversight May End

a. IRB oversight of a particular research study may end if one of the following applies:

□All study activity is complete, including data analysis;

- ☐ Study activity is limited to analysis of anonymized data; or
- ☐ All local subjects are deceased.

b. IRB oversight must continue if any of the following circumstances apply:

- ☐ Research subjects are being screened, recruited, and/or enrolled in the study;
- ☐ Research subjects are receiving treatment or study intervention;
- ☐ Research subjects are being followed, and/or data are being collected/reviewed;
- ☐ There is ongoing analysis of data with direct identifiers, either locally or externally; or
- ☐ There is ongoing, local analysis of data that have indirect identifiers.

c. Investigators should refer to the guide "Can IRB Oversight of My Study End" located at the end of this document.

3.2. Submission of Termination Report

a. Principal Investigators (PI) are responsible for submitting requests to terminate continuing IRB oversight to the MCRF Office of Research Integrity and Protections (ORIP). Each such request is made by submitting an "IRB End IRB Oversight Request Form." The PI must sign the termination report, attesting to the accuracy and comprehensiveness of the information provided.

b. A termination report should provide a summary of the results for local subjects.

c. If data will be retained locally and/or externally with direct identifiers or indirect identifiers, the PI must provide the following explanations as part of the request to terminate IRB oversight of the study:

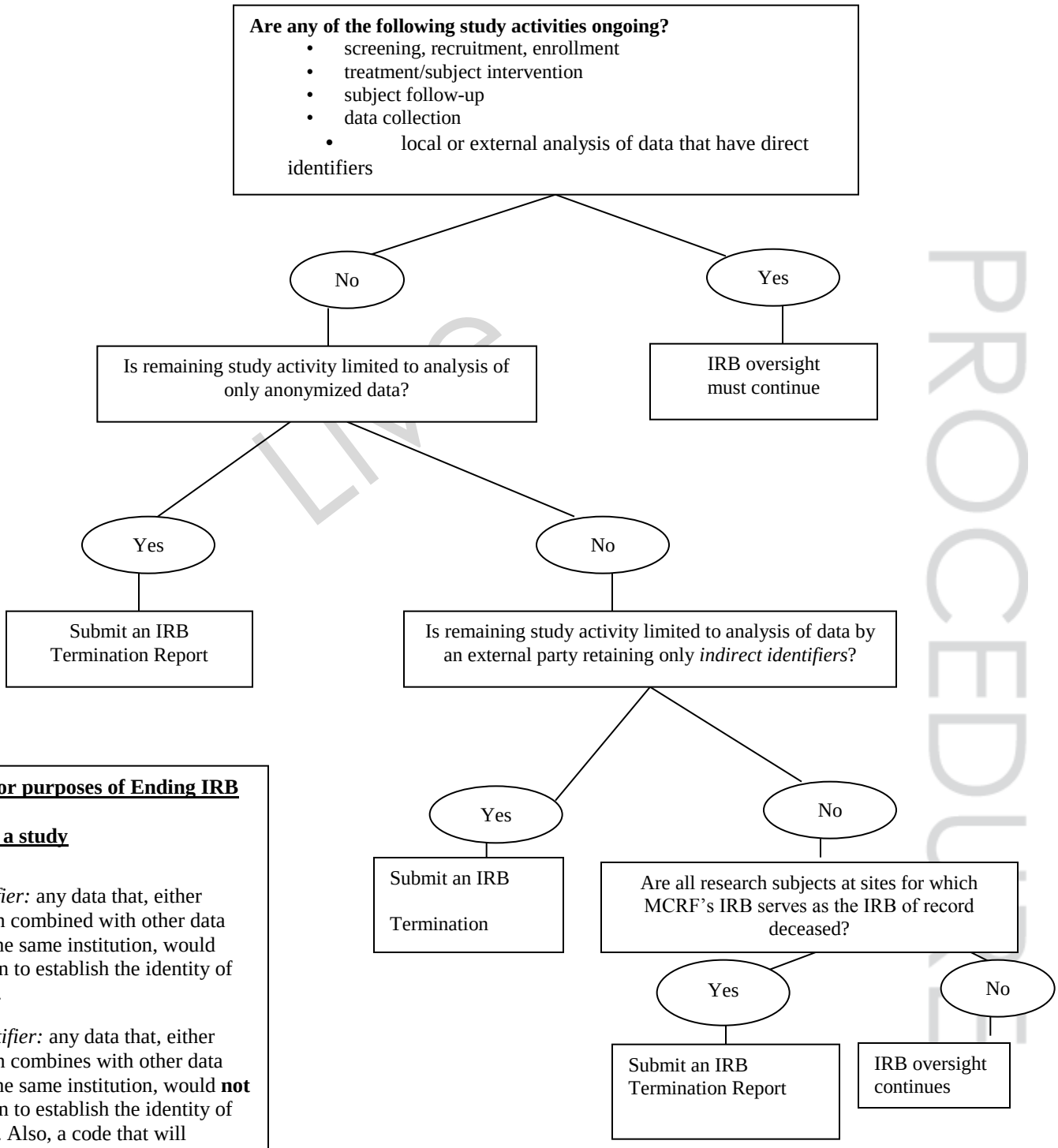
- Why the data with direct and/or indirect identifiers must be retained;
- The length of time that data with direct and/or indirect identifiers will be retained;
- Who will have access to the data with direct and/or indirect identifiers;
- Where the data with direct or indirect identifiers will be stored (if there will be more than one location, each location should be noted); and
- The methods at each location by which the data will be secured, and subject privacy will be protected.

4. ADDITIONAL RESOURCES

4.1. References:

- *Can IRB Oversight of My Study End? (see chart below)*

Can IRB Oversight of My Study End?



Definitions for purposes of Ending IRB

Oversight of a study

Direct Identifier: any data that, either alone or when combined with other data available at the same institution, would allow a person to establish the identity of an individual.

Indirect Identifier: any data that, either alone or when combines with other data available at the same institution, would **not** allow a person to establish the identity of an individual. Also, a code that will identify an individual only through the use of a key or link.

- IRB End IRB Oversight Request form (located in Policy & Handbook Library Forms)

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control System transferred from Policy & Handbook Library - #1032.5. (no changes made)
2.0	Add hyperlink to End IRB Oversight request form and hyperlink for Can IRB Oversight of my study end guide
3.0	Add decision chart for "Can IRB Oversight of My Study End?"

6. DOCUMENT PROPERTIES

Primary Author: Scheller, Lori A
Co-Author(s):
Approver(s): This document has been electronically signed and approved by: Ziemba, Steven J PHD on: 5/13/2016 4:29:26 PM