Marshfield Clinic

Exempt Projects, Review of

1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. Research:

- A systematic investigation including research development, testing and evaluation, designed to contribute to generalizable knowledge.

2.2. Human subject:

- Under the Common Rule [45 CFR 46.102(f)], "human subject" is a living individual about whom an investigator conducting research obtains: 1) data through intervention or interaction with the individual or 2) identifiable, private information.
  - ◊ "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulation of the subject or the subject's environment that are performed for research purposes.
  - ◊ "Interaction" includes communication or interpersonal contact between investigator and subject.
  - ◊ "Private information" is information that is not available to the general public, and includes information about behavior that occurs in the context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be *individually identifiable* in order for obtaining the information to constitute research involving human subjects.
- Under FDA regulation [21 CFR 56.102(e)], "human subject" is an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. If the research involves a medical device, individuals are considered "subjects" when they participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control [21 CFR 812.3(p)].

2.3. Individually identifiable:

- The identity of living individuals is, or may readily be, ascertained by the investigator or associated with the information.
  - ◊ At a minimum, data containing an individual's name, street address, social security number or phone number would be considered individually identifiable.
  - ◊ Also includes circumstances where private information or specimens can be linked to specific individuals by the investigator, either directly or indirectly

through coding systems (e.g., medical history number or other code linked to a legend including a direct identifier, such as name). Information is not ordinarily considered individually identifiable if: (1) the investigator and the holder of individually identifying information sign an agreement prohibiting the release of individually identifying information to the investigator under any circumstances, or (2) there are other legal requirements prohibiting the release of the link to the investigator.

2.4. Generalizable Knowledge:

- Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside the specific study population), to inform policy, or to provide general, applicable conclusions.

3. PROCEDURE BODY

Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations each allow exemptions for certain categories of not greater than minimal risk research. Marshfield Clinic Research Foundation Office of Research Integrity & Protections (ORIP) is charged with determining whether a given research project meets the criteria for exemption from the regulations. An exempt research project is still subject to the HIPAA Privacy Rule, as well as the institutional policies and ethical standards of Marshfield Clinic's human research protection program. Ultimately, DHHS and FDA have final authority as to whether a particular research project conducted or supported by their respective agency is exempt, should they be consulted. Research involving prisoners is not exempt, nor is research regulated by the FDA.

3.1. Human Subjects Research Determinations

Prior to considering whether an activity is exempt, the Principal Investigator (PI) should first determine whether the project meets the definition of "research" and "human subjects." Projects that do not meet the definitions of research and human subjects from Section 2.1 of this document do not require IRB review or an exemption determination. A Human Subject Research Determination Form should be completed and submitted to ORIP if there is any uncertainty as to whether an activity meets the definitions of "human subject" and "research."

3.2. Federal Regulation Exemption Categories

a. 45 CFR 46.101(b)(1): Evaluation/Comparison of Instructional Strategies/Curricula

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

b. 45 CFR 46.101(b)(2): Educational Tests, Surveys, Interviews or Observations

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public

behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, or reputation (Note: Survey or interview research involving children does not qualify for exemption, nor does observation of public behavior unless the investigator(s) do not participate in the activities being observed.)

c. 45 CFR 46.101(b)(3): Public Officials or Candidates for Public Office

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not covered under the previous paragraph if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

d. 45 CFR 46.101(b)(4): Collection or Study of Existing Data

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. Note: To qualify, the data, documents, records, or specimens must be in existence before the project begins. Additionally, an investigator with proper authorization may inspect identifiable records, but may only record information in a non-identifiable manner.

e. 45 CFR 46.101(b)(5): Research and Demonstration Projects

Research and demonstration projects which are conducted by or subject to approval of federal department or agency heads (such as the Secretary of Health and Human Service), and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; (iv) possible payment for benefits or services under those programs.

f. 45 CFR 46.101(b)(6) and 21 CFR 56.104: Taste and food quality evaluations and consumer acceptance testing

Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of

the U.S. Department of Agriculture.

3.3. Ethical Considerations and Protection of Subjects in Exempt Research

The investigator and the institution are obligated to consider the protection of subjects who take part in exempt research. Investigators will be asked to adequately give consideration to the following:

a. Equitable subject selection;

b. privacy of research subjects;

c. confidentiality of data; and

d. if the research involves interaction with subjects:

- subjects' understanding of the activity as research and voluntary participation;
- freedom from of coercion or undue influence;
- subjects' ability to contact information the principal investigator in case of questions or concerns.

3.4. Determining Exemption Status

Initial Assessment by Principal Investigator

- Investigators are encouraged to consult the Exemption Decision Charts (for the more common exemptions) or the descriptions above for help in determining whether a project potentially qualifies for exemption.
- If a proposed project appears to be exempt, the PI should submit an Exemption Request Form to ORIP.
- If an investigator is using or disclosing Protected Health Information as part of the project, the investigator must obtain authorization or be granted a waiver of the requirement to obtain authorization by MCRF IRB (see the policy, "Use and Disclosure of PHI in Research," and "Procedure for Use and Disclosure of PHI in Research" for more information).

Confirmation of Exemption Determination and Ethical Considerations

- ORIP staff, under the direction of the IRB Administrator in the Office of Research Integrity & Protections and the IRB Chairperson, or an Expedited Reviewer (in cases where an authorization is requested) will review the proposed research to determine whether the activity meets exemption criteria and whether the investigator has adequately addressed the ethical considerations in 3.3. above.

3.5. Exempt Research Which Utilizes Protected Health Information (PHI)

If the exemption request involves the use or disclosure of PHI and includes a request to waive the requirement to obtain authorization from subjects, the review will be conducted and a waiver request will be considered via the expedited IRB review mechanism.

3.6. Communication and Documentation of Exemption Determinations

The determinations made by ORIP or the Expedited Reviewer will be convey to the PI and all documentation related to the submission and review will be stored electronically in accordance with the Record Retention policy.

3.7. Changes to Projects Originally Determined to Be Exempt

If an investigator seeks to change a project that was originally determined to be exempt, it is the responsibility of the PI to submit a new IRB Exemption Request to ORIP. ORIP will re-evaluate the project to determine whether the proposed changes make the project non-exempt human subjects research. The re-evaluation will be conducted by ORIP staff in the same manner as original exemption review.

4. ADDITIONAL RESOURCES

4.1. References:

- OHRP FAQs – Exempt Research Determination
  http://answers.hhs.gov/ohrp/categories/1564

4.2. Supporting documents available:

- Decision Chart 3-Exempt Research (at end of document)
- Decision Chart 4 – Exempt Research (at end of document)

4.3. IRB Request Form for submission

- IRB Exemption 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 - #784.5. Updated professional titles of ORIP staff.
2.0	Add hyperlink to IRB Exemption Request form Add hyperlink to applicable policies and procedures.

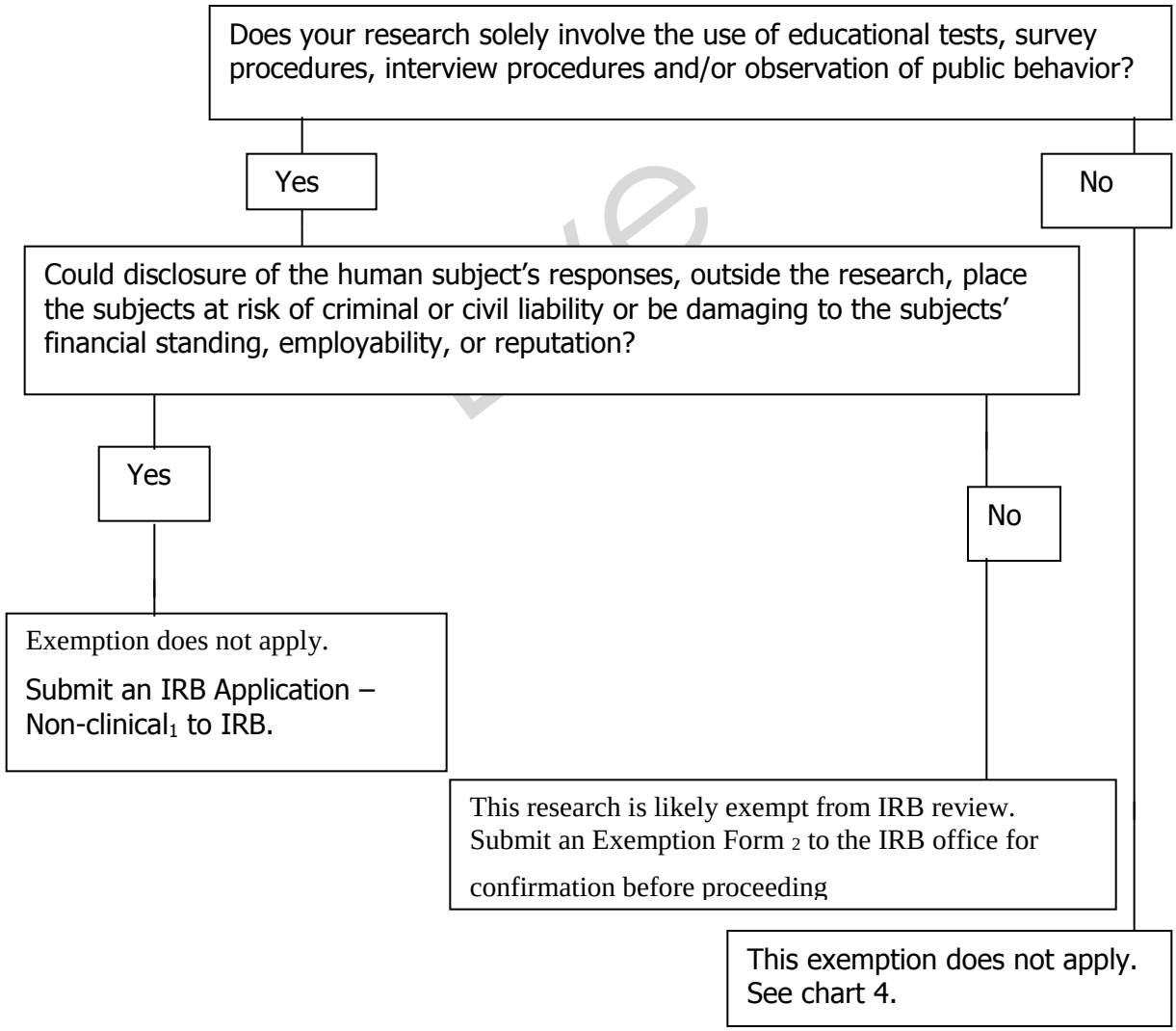
6. DOCUMENT PROPERTIES

Primary Author: Scheller, Lori A
Co-Author(s):
Approver(s): This document has been electronically signed and approved by: Ziemba, Steven J PHD on: 12/1/2015 4:12:38 PM

EXEMPT RESEARCH DECISION CHART

Some "human subject" research is exempt from <u>further</u> IRB review (after an initial determination is on file in the IRB office). The purpose of charts 3 & 4 is to determine whether you should submit an IRB Application or an Exemption Form to the IRB office.

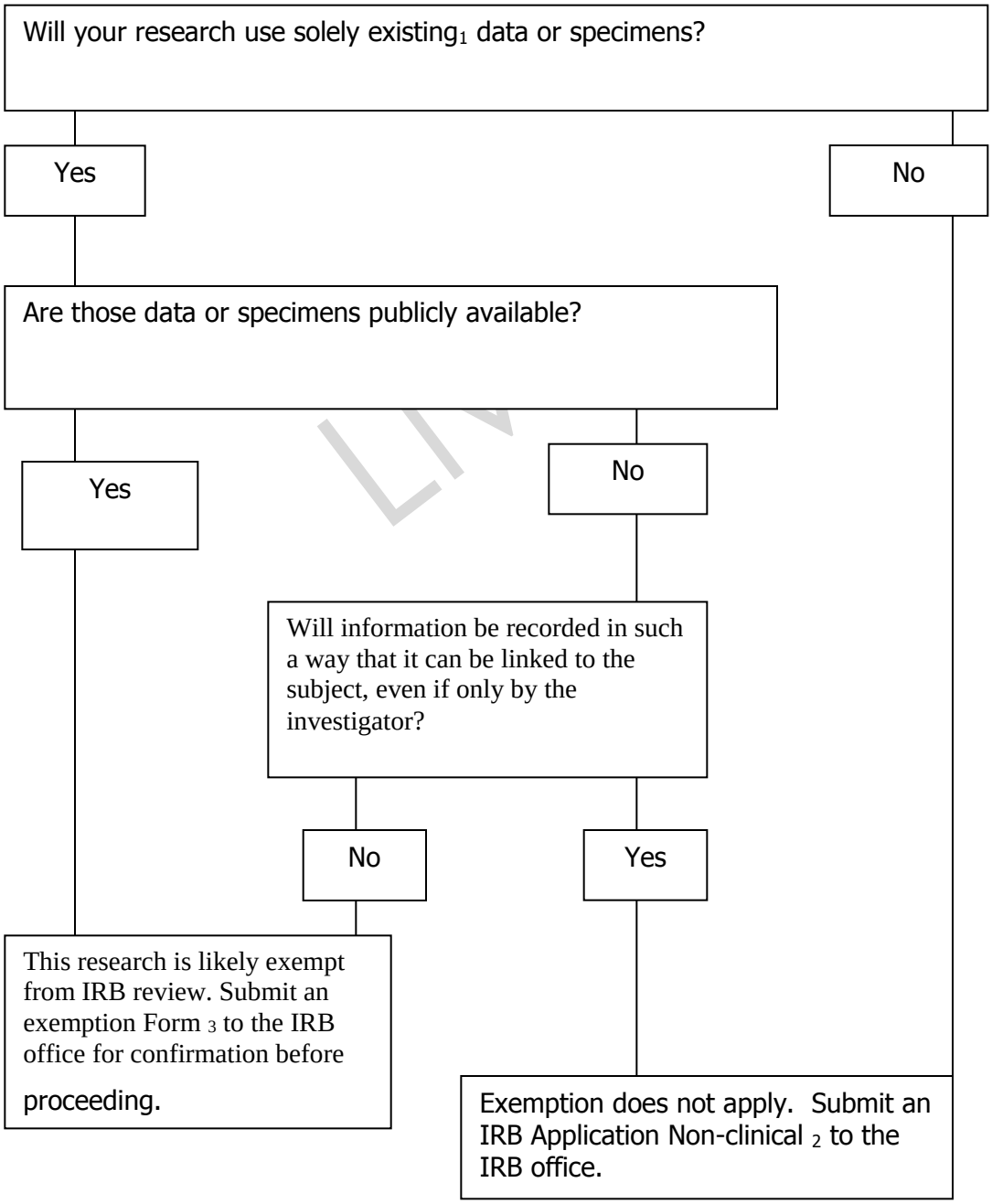
- **Chart 3: Exemption at section 46.101 (b) (2)** regarding research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior.



1. Available electronically from the Marshfield Clinic Intranet in the Clinic's Handbook and Policy Library, Forms Library.
2. Available electronically from the Marshfield Clinic Intranet in the Clinic's Handbook and Policy Library, Forms Library.

EXEMPT RESEARCH DECISION CHART (continued)

- **Chart 4: Exemption at Section 46.101 (b) (4)** regarding research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.



1. "Existing" means collected (i.e., on the shelf) prior to the start of the research for a purpose other than the proposed research. It includes data or specimens collected in research and non-research activities.
2. Available electronically from the Marshfield Clinic Intranet in the Clinic's Handbook and Policy Library, Forms Library.
3. Available electronically from the Marshfield Clinic Intranet in the Clinic's Handbook and Policy Library, Forms Library.