Marshfield Clinic

Public Health Research vs. Non-Research

1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. **Human Subject or participant** – A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information (See 45 CFR 46.102 (f)).

2.2. **Research** – a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (See 45 CFR 46.102 (d)).

2.3. **Surveillance** – The ongoing systematic collection, analysis and interpretation of health data, essential to the planning, implementation and evaluation of public health practice, closely integrated to the dissemination of these data to those who need to know and linked to prevention and control.

2.4. **Emergency response** – a public health activity undertaken in an urgent or emergency situation, usually because of an identified or suspected imminent health threat to the population, but sometimes because the public and/or government authorities perceive an imminent threat that demands immediate action. The primary purpose of the activity is to document the existence and magnitude of a public health problem in the community and to implement appropriate measures to address the problem (Langmuir, 1980)

3. RESOURCE GUIDE BODY

3.1. Purpose

a. To outline how initial determination will be made of whether a public health activity is research or not research and to outline when a non-research public health activity becomes research and therefore requires review by the Institutional Review Board (IRB).

3.2. Background

a. Individuals at Marshfield Clinic and Marshfield Clinic Research Foundation work collaboratively with the Centers for Disease Control (CDC) and the Wisconsin Division of Public Health on both research and non-research public health activities. CDC has published a guidance document entitled, "Guidelines for Defining Public Health Research and Public Health Non-Research (10/4/99). CDC has also issued the "Distinguishing Public Health Research and Public Health Nonresearch" Policy in July 2010. The 1999 guidelines is intended to provide guidance to institutions that conduct collaborative research with CDC staff or who are recipients of CDC funds. The 2010 policy is intended to strengthen CDC's longstanding guidelines on distinguishing research from nonresearch activities and support continuing

excellence in public health service, including surveillance, program evaluation and public health response activities.

b. The guidance notes that systematically obtaining and analyzing data using scientific methods and then generalizing the knowledge gained is essential to the practice of public health. Because of this, the distinction between research and non-research activities is blurred. The guidance notes that the major difference between research and non-research lies in the primary intent of the activity. The primary intent of **research** is to generate or contribute to generalizable knowledge. The primary intent of **non-research** in public health is to prevent or control disease or injury and improve health, or to improve a public health program or service. In general, the policy section of the documents state that each project must be reviewed on a case-by-case basis and states that although general guidance can be given to assist in classifying these activities as either research or non-research, no one criterion can be applied universally. It notes that attributes such as publication of findings, statutory authority, methodological design, selection of subjects, and hypothesis testing/generating do not necessarily differentiate research from non-research because these types of attributes can be shared by both research and non-research projects. These documents set forth attributes of public health research and attributes of non-research as follows:

c. General Attributes

- Public Health Research:
  - Intent of the project is to generate generalizable knowledge to improve public health practice; intended benefits of the project can include study participant, but always extend beyond the study participants, usually to society; and data collected exceed requirements for care of the study participants or extend beyond the scope of the activity Generalizable knowledge means new information that has relevance beyond the population or program from which it was collected, or information that is added to the scientific literature. Knowledge that can be generalized is collected under systematic procedures that reduce bias, allowing the knowledge to be applied to populations and settings different from the definition of research, does not refer to statistical concept of population estimation, or sampling, which is collecting information form selected individuals in order to understand health in the population from which the sample came. Holding public health activities to a standard of study every case in order to classify an activity as nonresearch is no practical or reasonable, nor is it necessary for nonresearch activities.
  - Essential characteristics of public health research

    Involves living individuals;

    Involves, in part, identifiable private health information;

    Involves research subjects who are selected and voluntarily participate (or participate with the consent of their legally authorized representative), absent a waiver of informed consent; and

Supported by principles of bioethics that focus on the interests of individuals while balancing the communal value of research.

- Non-Research
  - Intent of the project is to identify and control a health problem or improve a public health program or service; intended benefits of the project are primarily or exclusively for the participants (or clients) or the participant's community; data collected are needed to access and/or improve the participant's community; knowledge that is generated does not extend beyond the scope of the activity; and project activities are not experimental. The guidance goes on to state that non-research project may generate generalizable knowledge after the project is undertaken even though that was not that was not the activity's primary intent. In this case, any subsequent analysis of identifiable private information undertaken to generate or contribute to generalizable knowledge would constitute human subjects research that requires IRB review prior to the analysis.
  - Essential characteristics of public health practice (nonresearch)

    Involves specific legal authorization for conducting the activity as public health practice at the federal, state or local levels;

    Includes a corresponding governmental duty to perform the activity to protect the public's health

    Involves direct performance or oversight by a governmental public health authority (or its authorized partner) and accountability to the public for its performance;

    May legitimately involve persons who did not specifically volunteer to participate (i.e. did not provide informed consent);

    Is supported by principles of public health ethics that focus on populations while respecting the dignity and rights of individuals

  The guidance also states that if a project includes multiple components and at least one of those components is designed to generate generalizable knowledge, then the entire project is classified as research unless the components are separable.

  The Wisconsin Division of Public Health does not have written guidelines on classification of research versus non-research.

d. Public Health Surveillance

- A series of systematic activities, including collection analysis , and interpretation of health-related data essential to planning, implementing, and evaluating public health practices closely integrated to the dissemination of data to those who need to know and linked to prevention and control. Surveillance is predicated on the need to address a defined public health problems or question and aimed at the use of data to guide efforts to protect and promote population health. Surveillance can be either research or non research depending on the purpose.

- Nonresearch is when they involve the regular ongoing collection and analysis of health-related data conducted to monitor the frequency of occurrence and distribution of disease or a health condition in the population. Data generated by the surveillance systems are used to manage public health programs. Nonresearch attributes of surveillance are generally found in state statue or regulations where the intent of the activity, its purpose and uses of the data are specified. Subjects are rarely selected according to a design; rather, observed cases are entered into the surveillance system as they are identified. Hypothesis testing is rarely part of the system.
- Research surveillance systems involve the collection and analysis of health-related data conducted either to generate knowledge that is applicable to populations and settings other than the ones from which the data were collected or to contribute to new knowledge about the health condition.
- Sometimes, CDC funds state and local health departments establish surveillance systems with dual intentions on the part of CDC: to build state capacity in disease reporting and for CDC to generate new knowledge thus it is important to distinguish between event reporting activities that are nonresearch ad uses of the reported data that can be considered research. Disease reporting activities conducted at the state level are generally nonresearch. However, if these are aggregated and analyzed at the national level to generate new knowledge, then those activities would constitute research at the national level, but might or might not be research at the state level. If the state' purpose for data collection is solely to identify and control a health problem, their activity would be considered nonresearch. If states are participating beyond merely providing the date, they might be considered as engaged in the research. Institutions providing information to state health departments would not be considered engaged in research (OHRP, 2008).

e. Emergency Response

- Activities that tend to be nonresearch because these projects are undertaken to identify, characterize, and solve an immediate health problem and the knowledge gained will directly benefit those participants involved in the investigation or their communities. However, emergency response might have a research component if for example, samples are stored for future use intended to generate generalizable knowledge or additional analyses are conducted beyond those needed to solve the immediate health problem. For emergency responses, whenever a systematic investigation of a non-standard intervention or systematic comparison of standard intervention occurs, the activity is research.
- When unapproved drugs or devices are used or used for unapproved purposes, their use might either fall under an Emergency Use Authorization (EUA) or under FDA regulations. Decision-making about these activities is particularly complicated, as they might or might not meet the definition of research at 45 CFR46.102(d) and it may also not meet the definition of a clinical investigation at 21 CFR 56.102(c). Consideration and consultation

with the Center ADS and the chief of Human Research Protections Office at CDC is warranted in these situations.

3.3. IRB Process

a. To make a determination of Public Health Research versus Non-Research, MCRF's IRB will request from the individual collaborating with the CDC and /or Wisconsin's Division of Public Health the following be completed and submitted:

- Written documentation of the proposed public health activity and their assessment of whether the activity is Public Health Research vs Non-Research from CDC and/or the Wisconsin Division of Public Health
- Completion of the "Checklist for Making Distinction Between Public Health Practice and Research" (Appendix A)
- Completion of the IRB Review of Determination Request form

b. The IRB Chair or designee will review the submitted documents and complete the IRB section of the IRB Review of Determination Form. Upon completion of the IRB Review Form, the form will be returned to the individual collaborating in the public health activity. That individual or designee is then responsible for maintaining documentation of CDC, Wisconsin Division of Public Health or IRB determinations regarding non-research status.

c. If the public health activity is assessed by the MCRF IRB to be treated as research the IRB Review Determination Form will indicate such and then be returned to the individual collaborating in the public health activity to submit the appropriate IRB form for research review. It will then be reviewed by the IRB following standard IRB policies and procedures. Note, however, that some "research" may not involve human subjects if no one is interacting with living individuals or obtaining identifiable information about individuals. In addition, some human subject research may be exempt research or be part of research feasibility. These options should be investigated before submitting an application for IRB review.

d. If the public health activity is defined by one of these agencies as non-research and the individual from Marshfield Clinic is proposing to do nothing beyond what is defined in the contract with these agencies or otherwise requested by these agencies, then no IRB review will be required.

e. If subsequent analysis of identifiable private information is undertaken either alone or in conjunction with a representative of these agencies for the purpose of generating or contributing to generalizable knowledge, the analysis constitutes human subject research that requires review by Marshfield's IRB. The review must be conducted prior to subsequent analysis.

4. ADDITIONAL RESOURCES

4.1. References:

- www.cdc.gov/od/science/integrity/hrpo

- CDC's Policy on Distinguishing Public Health Research & Public Health Non-research (July 2010)
- Guidelines for Defining Public Health Research & Public Health Non-Research (10/4/99)
- Langmuir, AD. The Epidemic Intelligence Service of the Center for Disease Control. Public Health Reports 1980; 95:470-7
- http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html

4.2. Supporting documents available:

- Checklist for Making Distinctions Between Public Health Practice and Research
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5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control System transferred from the Policy & Handbook Library - #840.0. Added definitions. Revised purpose statement 3.1. Updated background section 3.2 to include updated CDC guidance policy (2010). Added Essential Characteristics of Public Health Research & Public Health Practice (nonresearch) 3.2.c. Added Surveillance and Emergency Response sections from CDC guidance 3.2.d & e. Revised section 3.3 IRB Process Added References (4.1) and Appendix A Checklist. Format changes.
2.0	
3.0	

6. DOCUMENT PROPERTIES

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Appendix A: Checklist for Making Distinction Between Public Health Practice and Research

Steps and Related Assumptions and Questions	YES	NO	If Yes, then	If No, then
Step 1: Check Key Assumptions				
Assumption 1.A: Are you a governmental public health official, agent, agency, or entity at the federal, tribal, state or local level (or an authorized partner conducting public health activities via contract or other agreement?			Go to A1.B	Stop. this checklist doesn't apply
Assumption 1.B: Does activity involve the acquisition, use or disclosure of identifiable health data (i.e individually-identifiable data that relate to a person's past, present, or future physical or mental health or condition or provision or payment of health care, or identifiable bodily tissues or biological samples)?			Go to Step 2	Stop. This checklist doesn't apply
Step 2: Assess the Foundation of Public Health Practice				
Assumption 2.A: In general, does activity involve the collection and analysis of identifiable health data for the purposes of protecting the health of a particular community, where the benefits and risks are primarily designed to accrue to the participating community?			Go to Q 2.A	Go to Step 3
Question 2.A: Is there a specific legal authorization (via statue, administrative regulation, or other law) and corresponding governmental duty to use identifiable health data for a public health purpose that underlie the activity?			Stop. This activity is practice.	Go to Q 2.B
Question 2.B: Does activity involve direct performance or oversight by a governmental public health authority (or its authorized partner) and accountability to the public for its performance?			Go to Q 2.C	Go to Step 3
Question 2.C: Does activity legitimately involve persons who must participate in the activity or did not specifically volunteer to participate (i.e. they did not provide informed consent absent a waiver under the Common Rule?)			Stop. This activity is Practice	Go to Step 3
Step 3: Assess the Foundations of Human Subjects Research				
Assumption 3.A: In general, does activity involve the collection and analysis of identifiable health data for the purpose of generating knowledge that will benefit those beyond the community of persons who bear the risk of participation?			Go to Q 3.A	This activity is likely practice. Go to Step 4
Question 3.A: Does activity involve living individuals?			Go to Q 3.B	Stop. This is not human subjects research
Question 3.B: Does activity involve, in part, private information as defined in the Common Rule?			Go to Q 3.C	Stop. This is not

				human subjects research
Question 3.C: Does activity involve persons who voluntarily participate via informed consent or the consent of their legally authorized representative, absent a waiver of informed consent under the Common Rule?			Go to Step 4	Stop. This activity is practice
Step 4: Consider Enhanced Guidance				
Question 4.A: General Legal Authority- Is there general legal authorization (via statue, administrative regulation, or other law) and a corresponding governmental duty supporting the use of identifiable health data for a legitimate public health purpose.			The activity is likely practice. Go to Q 4.B 1-2	Go to Q 4.B 1-2
Question 4.B.1: Specific Intent: Is there any intent underlying the activity to test a hypothesis and seek to generalize the findings or acquired knowledge beyond the activity's participants.			The activity is likely research. Go to Q 4.C	Go to Q 4.B.2
Question 4.B.2: Specific Intent: Is the primary intent underlying the activity to assure the conditions in which people can be healthy through public health efforts that are primarily aimed at preventing known or suspected injuries, disease, or other conditions, or promoting the health of a particular community?			The activity is likely practice. Go to Q 4.C	Go to Q 4.C
Question 4.C: Responsibility: Is responsibility for the health, safety, or welfare of the participants vested or assigned to an identified person, like a principal investigator?			The activity is likely research. Go to Q 4.D 1-2	Go to Q 4.D.1
Question 4.D:1: Participant Benefits: Is the activity designed to provide some benefit to the participant or their population?			The activity is likely research. Go to Q 4.E	Go to Q 4.D.2
Question 4.D.2: Participant Benefit: Does the activity impose risks on participants to make the results generalizable beyond the participation themselves?			The activity is likely research. Go to Q 4.E	Go to Q 4.E
Question 4.E: Experimentation: Is the activity designed to introduce non-standard or experimental elements or methods to the research subjects or the analysis of their identifiable health data?			The activity is likely research. Go to Q 4.F	Go to Q 4.F
Question 4.F: Subject Selection: Are the participants in the activity selected randomly so that the results of the activity can be generalized to a larger population?			Stop. The activity is likely research	Stop. The Activity is likely practice.
Step 5: Conclusions				
Conclusion 5.A: Public Health Practice. If responses affirm that activity (or some part thereof) is or is likely public health practice, the activity is not subject to the Common Rule. However, it must still be conducted consistent with principles of law and ethics designed to protect individuals and their				

privacy while furthering the public's health. In addition, while the HIPAA Privacy Rule allows sharing. Authorization for disclosures from covered entities under the Rule on public health practice, please see HIPAA Privacy Rule and Public Health: Guidance form CDC and DHHS ,available at http://www.cdc.gov/privacyrule/Guidance/content.htm.				
Conclusion 5.B: Human Subject Research. If responses affirm that activity (or some part thereof) is or is likely human subject research, follow the disclosure provisions related to human subjects research in the Privacy Rule. The Common Rule may also apply, subject to an exemption. Note, however, that the activity may be entitled to expedited review under the Common Rule. For additional guidance and a helpful flowchart, please see the Guidelines for the Conduct of Research published by the Office for Human Subjects Research at NIH, available at http://www.nihtraining.com/ohsrsite/guidelines/graybook.html.				
Conclusion 5.C. Fill out MCRF's IRB Review of Determination Request Form and submit along with this checklist and letter from CDC to Office of Research Integrity and Protections (ORIP).				