

Human Subjects Determination Checklist

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| **PI Name:** | WMed IRB #:  *(for IRB office use only)* |
| **Protocol Title:** | |
| **Reviewer:** | |

1. **REVIEWER CONFLICT OF INTEREST**

As a reviewer, are you an investigator, consultant, collaborator, or study personnel on the proposed study; do you have a financial interest in the study; or do you have any other conflict of interest with this study?

Yes\*\*   No

\*\*If yes, please do not perform the review and contact the HRPP/IRB Office at 269.337.4345.

# QUALITY IMPROVEMENT, PROGRAM EVALUATION ASSESSMENT

**Quality Improvement (QI)** - involves systematic activities that are designed and implemented by an organization to monitor, assess, and improve the quality of its services, processes, or programs.

**Program Evaluation** – individual systematic activities conducted to assess how well a program is working and why.

**See Appendix A at the end of this document for more information.**

* 1. Does the activity involve quality improvement?  **Yes**  **No**
  2. Does the activity involve program evaluation?  **Yes**  **No**

**Comments:**

# COMMON RULE DETERMINATION

# Research

1. Indicate whether the activity meets the following criteria:

The activity is a **systematic investigation:** an activity that involves a prospective plan which incorporates data collection, either quantitative and/or qualitative, and data analysis to answer a question

The activity is designed to develop or contribute to **generalizable knowledge:** designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

**Comments:**

1. **Are BOTH of the criteria met?**

**Yes**. The activity meets the definition of research in the Common Rule. Go on to the next section.

**No**. The activity does not meet the definition of research in the Common Rule.   
Go to Section IV – FDA Determination.

**Comments:**

# Human Subjects

1. Indicate whether the research meets the following criteria:

The research involves **living individuals**

The investigator will obtain data or information **about** those individuals

The investigator will obtain EITHER of the following:

Data through **intervention or interaction** with the individuals.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

**Identifiable private** information.

Private information includes information about behavior that occurs in a 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 (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

**Comments:**

1. **Are ALL of the criteria met?**

**Yes**. The activity involves human subjects research according to the Common Rule.

**No**. The activity does not involve human subjects research according to the Common Rule.

***If the research involves drugs, medical devices or biologics, FDA regulations may apply. If so, complete the following section. If not, go to Section V Determination.***

1. **FDA DETERMINATION**

# TEST ARTICLE

1. The activity involves a DRUG/BIOLOGIC (a chemical or biological substance – other than food – that achieves it's primary intended purposes through chemical action within or on the body or which is dependent upon being metabolized for the achievement of any of its primary intended purposes) or MEDICAL DEVICE (an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory) that is one of the following:

The article is recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them

The article is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals

The article is intended to affect the structure or any function of the body

**Comments:**

1. **Are any of the criteria met?**

**Yes**. The activity involves an FDA test article. Go on to the next section.

**No**. The activity does not involve an FDA test article. Go to Section III – Determination.

**Comments:**

# RESEARCH

1. Indicate whether the activity meets the following criteria:

The activity is an experiment that involves a test article and one or more human subjects (as defined below)

**Note:** For drugs, an experiment includes any use of a drug other than the use of a marketed (approved) drug in the course of medical practice. For medical devices, it is limited to activities being conducted to determine the safety or effectiveness of a device.

Either of the following is true:

The activity is subject to requirements for prior submission to the Food and Drug Administration; or

The activity is intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

**Comments:**

1. **Are BOTH of the criteria met?**

**Yes**. The activity meets the FDA definition of research. Go on to the next section.

**No**. The activity does not meet the FDA definition of research. Go to Section III – Determination.

# HUMAN SUBJECTS

1. Indicate whether the research meets either of the following criteria:

The research involves one or more individuals who become a subject 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.

For medical devices, an individual on whose specimen an investigational device is used

1. **Are either of the criteria met?**

**Yes**. The research involves human subjects according to FDA regulations.

**No**. The research does not involve human subjects according to FDA regulations.

**Comments:**

1. **DETERMINATION**

Based on the information in the protocol, I have made the following determination:

The activity is considered quality improvement or program evaluation.

The **activity** **does not involve** human subjects.

The activity **is not** research.

The activity **does** involve human subjects **and** is research. An application to the IRB is required.

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| Please list any comments. | |
|  | |
| **Signed** | **Dated** |

**APPENDIX A**

**Determining When Quality Improvement, Demonstration Projects, and**

**Other Similar Activities are Human Subjects Research**

IRBs are frequently presented with questions regarding when Quality Improvement (QI), Demonstration Projects, and other similar activities also meet the definition of human subjects research and require IRB review and approval. While many QI and demonstration activities do not meet the definition of human subjects research under the Common Rule or FDA, it is essential to understand that some projects may. This is the case when the QI or demonstration activity is designed to accomplish a research purpose as well as the purpose of improving the quality of care or demonstrating the success/value of a program. The following materials are included to assist the investigator and the IRB in assessing whether or not individual projects require IRB review and approval.

The intent to publish is an insufficient criterion for determining whether a QI or demonstration activity involves research. Planning to publish does not necessarily mean that the project fits the definition of research; people seek to publish descriptions of non-research activities for a variety of reasons, if they believe others may be interested in learning about those activities. Conversely, an activity may involve research even if there is no intent to publish the results.

To determine whether or not IRB review and oversight applies, the following questions should be addressed in order:

1. Does the activity involve research?
2. Does the research activity involve human subjects?
3. Does the human subjects research qualify for an exemption? (*Note: At most institutions, the authority to determine a project exempt is assigned to individuals within the Human Research Protection Program and/or IRB*)

**National Bioethics Commission Statement**

**Program Evaluation and Quality Improvement** have been described as follows by the National Bioethics Advisory Commission in its August 2001 document titled “Ethical and Policy Issues in Research Involving Human Participants” (page 37):

*“These activities, generally referred to as program evaluation or quality improvement, are not intended to have any application beyond the specific organization in which they are conducted.  As is true in the area of public health, because populations are the subject of study and because the methods used in program evaluation or quality improvement are the same as those used in research, it is often difficult to determine whether an activity is research that falls under the oversight system.*

*Definitional issues regarding program evaluation or quality improvement are not limited to health care delivery. They also occur in industrial or educational settings and in social science and operations research. However, if the purpose is to assess the success of an established program, and the information gained from the evaluation will be used to improve that program, the activity should not be considered research involving human participants. Evaluation is a program monitoring tool, and the information gained will immediately benefit the program and/or the individuals involved.*

*However, when quality improvement involving human participants is undertaken to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective and can be used elsewhere, the activity is human participant research and subject to the oversight system.”*

### Comparison

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|  | **Research** | **Quality Improvement** |
| **Goal** | Advance general knowledge in academic, scientific or professional community: generate, evaluate or confirm explanatory theory or conclusion and invite critical appraisal by peers through presentation/debate in public forums | Improve patient care, a clinical program or service: identify specific services, protocols, clinical practices, or clinical processes/outcomes within a department, clinical program or facility for improvement |
| **Literature review** | Organized review of relevant literature | Available literature and comparative data, or clinical programs, practices or protocol at other institutions to design improvement plan; do not plan full scientific literature reviews |
| **Research design** | Leads to scientifically valid findings (control groups, random subject selection, statistical tests) | Established quality improvement methods (e.g. PDSA cycle) aimed at producing change. Does not include sufficient research design elements to support scientifically valid findings |
| **Benefit** | Subjects ***may not*** derive personal benefit from the knowledge gained | Most patients who participate *are expected to benefit* from the knowledge gained |
| **Risk** | May impose risk or burden on patients | Does not impose any risk or burden on patients |

*Table provided by the Baystate Health Center for Quality of Care Research (Modified from Cambridge Health Alliance)*

**Relevant Definitions**

**Demonstration Project:** A project, supported through a grant or a cooperative agreement, generally to establish or demonstrate the feasibility of new methods or new types of services. (National Cancer Institute)

Human Subject: A human subject as defined by the Common Rule is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or through identifiable private information (45 CFR 46.102(f)).

* Intervention means both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
* Interaction means communication or interpersonal contact between investigator and subject.
* Private information means information about behavior that occurs in a 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 (for example, a medical record).
* Individually identifiable information is information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

For research covered by FDA regulations (21 CFR 50 and 56), human subject means an individual who is or becomes a participant in a clinical investigation, either as a recipient of the test article or as a control. A subject may be in normal health or may have a medical condition or disease. In the case of a medical device, a human subject also includes any individual on whose tissue specimen an investigational device is used or tested.

**Quality improvement:** a systematic pattern of actions that is constantly optimizing productivity, communication and value within an organization in order to achieve the aim of measuring the attributes, properties, and characteristics of a product/service in the context of the expectations and needs of customers and user of that product. (Institute of Medicine)

**Research:** See WMed Human Research Protection Program and Institutional Review Board Handbook for full definitions.

* Common Rule: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.
* FDA: An experiment involving a FDA-regulated test article and one or more human subjects. For medical devices, activities that evaluate the safety or effectiveness of a device.