Binghamton University

Institutional Review Board Human Subjects Research Determination Checklist

This worksheet is a guide to help investigators and reviewers determine if activity is human research as defined by the Health and Human Services (HHS) or Food and Drug Administration (FDA). Please consider the following when deciding whether the criteria for human subjects research have been met.

Section A

1. Is the activity limited to the collection of data from the medical records of 3 or fewer patients?
   - ☐No, continue to section B.
   - ☐Yes: this is a case report and not considered to be research that requires IRB review 

2. Is the activity limited to journalistic activities such as oral history, journalism, biography, literary criticism, legal research, or historical scholarship?
   - ☐No, continue to section B.
   - ☐Yes: this is not considered to be research that requires IRB review. 

3. Is the activity limited to public health surveillance activities [i.e., activities mandated by a public health authority (e.g., CDC) to identify, monitor, assess, or investigate potential public health signals, disease outbreaks, etc.]
   - ☐No, continue to section B.
   - ☐Yes: this is not considered to be research that requires IRB review.

Section B: Research

Y	N	
☐	☐	Is the activity an investigation? (Investigation: a searching inquiry for determining facts; detailed or careful examination).
☐	☐	Is the investigation systematic? (Systematic: having or involving a system, method, or plan)
☐	☐	Is the systematic investigation designed to develop or contribute to knowledge? (Designed: done with a purpose and intent. Develop: to elaborate or expand in detail. Contribute: to be an important factor in; help to cause. Knowledge: truths, facts, information.)
☐	☐	Is the knowledge generalizable? (Generalizable: universally applicable)

If all checked YES, the activity meets the DHHS definition. Complete Section C.
If any checked NO, the activity does not meet the DHHS definition. If the activity involved an FDA regulated product, complete Section D.

Section C: Human Subjects

1. The investigation involves gathering **data or biospecimens** about living individuals **through intervention or interaction** for the purpose of use, study, or analysis.

   <u>Intervention:</u> physical procedures or manipulations of those individuals or their environment.
   <u>Interaction:</u> communication or interpersonal contact with the individuals (e.g. interviews, surveys, focus groups)

☐Yes: the research involves human subjects and should be submitted to the IRB.
☐No: Answer question 2.

2. The investigation involves obtaining, using, studying, analyzing or generating data or biospecimens from living individuals that is **private and identifiable** (e.g., medical record reviews, lab studies on tissue/specimens, school record reviews, etc.)

   Private: the data includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information/biospecimens which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g. a medical record).
   Identifiable: the participant's identity is or may be readily ascertained by the investigator, or will be associated with the information.

   ☐Yes: the research involves human subjects and should be submitted to the IRB.
   ☐No: Answer question 3.

3. The investigation involves obtaining, using, studying, or analyzing **coded data or specimens** that were not collected for the currently proposed research (e.g. using information/samples from data or tissue repositories)

   Coded: an individual's identifiable information such as name or MRN has been replaces by a code, such as a number, letter, or combination thereof, and there is a key to link the code to the identifiable information of that individual.

   ☐No skip to Section D.
   ☐Yes, complete 3a.

   a. The investigator cannot link the coded data/specimens back to individual subjects because at least one of the following applies:
      ☐The investigator will destroy the code before the research begins,
      OR
      ☐The holder of the key and investigator enter into an agreement prohibiting the release of the key to the investigator under any circumstance
      OR
      ☐The investigator has documentation of written policies and operating procedures from a repository or data management center that prohibits the release of the key to the investigators under any circumstances, until the individuals are deceased
      OR
      ☐There are other legal requirements prohibiting the release of the key to the investigator.

      If none of the above apply: the research involves human subjects & should be submitted to the IRB.

If at least one applies, the research does not constitute human subjects research & IRB submission is not required.

Section D: FDA Determination: Human Research (Clinical Investigation)

1. Does the research involve the administration of an approved or experimental FDA regulated product, as directed by a research protocol, and not by standard medical practice?
   ☐Yes: the research involves human subjects and should be submitted to the IRB.
   ☐No
2. Specimens (blood, tissue, etc.) are being used to test the effectiveness of a medical device (including in vitro diagnostics, assays, genetic test, etc.) and the information is being submitted to the FDA for marketing approval or clearance (510K clearance, PMA, etc.).
   ☐Yes: the research involves human subjects and should be submitted to the IRB.
   ☐No

Reviewer Comments: