Non-Human Subject Research Letter & Checklist

If your proposed activity is not deemed "human subject research" by DHHS and FDA Regulatory definition it does not need to be evaluated by the Office of Research Compliance or the Institutional Review Board.

Please review the below definitions that are used in making this determination.

A) Research means a systematic investigation designed to develop or contribute to generalizable knowledge. Most case reports and most oral histories are not generalizable and, therefore, not research. Many classroom projects, if not intended to be published, are also not considered research. Many quality improvement or program evaluation studies are not research.

B. Human Subjects. According to federal definitions, a human subject is a living individual. If the research does not include living individuals, the project is not human subject research and should not be submitted for evaluation. Note, however, if the study involves the collection of protected health information (PHI), even if the records are from deceased individuals, a HIPAA waiver may be required for your study. The use of a HIPAA waiver must be justified, and its use must be approved by the IRB even if the study itself is not "human subject research".

C. In order to be considered human subject research, individually identifiable private information must be obtained or used in the research. If there is no individually identifiable private information involved, the project is not human subject research and does not required being submitted to the Office of Research Compliance. Private information must be individually identifiable (i.e., the identity of the subject is or may be readily ascertained by the investigator or someone else associated with the information) in order to constitute research involving human subjects.

We hope these definitions are helpful. If you need further clarification or additional information, please contact IRB

If the answer is NO to any of these, it is Non-Human Subject Research

YES NO

Does the study fulfill both definitions of research?

1) The activity is a systematic investigation, including research development, testing and evaluation; AND

2) The activity is designed to develop or contribute to the generalizable knowledge.

YES NO

The data the investigator is planning to obtain is about living individuals.

YES NO

The study involves individually identifiable private information.

1) Data is gathered by any of the following:

a. physical procedures performed on individuals

b. manipulations of individuals c. manipulation of individuals' environment d. interpersonal contact with individuals

2) The data is private because:

a. The information is about behavior that occurs in context in which an individual can reasonably expect that no observation or recording is taking place, OR

b. The individual has provided the information for specific purposes and can reasonably expect that the information will not be made public (i.e. medical record).

3) The data is individually identifiable because:

a. The identity of the participant is or may be readily ascertained by the investigator, OR

b. The identity of the participant is or may be readily associated with the information.

FDA Regulations - Drugs, Medical Devices, Test Articles This IRB has decreed that all drugs, medical devices, and test articles used on human beings are human subjects research and must be reviewed initially by the IRB.

DRUGS

The study involves an FDA regulated test article, because:

• This activity involves the use of a drug, including the use of a marketed drug during medical practice.

• This activity involves the use of a drug meaning:

an article recognized in the official US Pharmacopoeia, official Homeopathic Pharmacopoeia of the US or official National Formulary, or any supplement to any of them. o an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

an article (other than food) intended to affect the structure or any function of the body of humans or other animals. o an article intended for use as a component of any article specified in the above items.

- The drug is NOT approved by the FDA for marketing.
- The drug is NOT being used during medical practice.

MEDICAL DEVICES

The activity involves the use of a medical device, other than the use of a marketed medical device during medical practice.

Secondary Data Matrix

When is secondary data (e.g., medical records, purchased data, data from the Internet, etc.) considered human subjects research? Research involving secondary data analysis is considered human subjects research when data about individuals is both private and identifiable.

Examples	
Projects that are unlikely to be human subjects research because they involve only:	• Public use data sets such as data from the National Center for Health Statistics—data is available to the public at large and not restricted to researchers. • Data sets from an outside source that have been stripped of all identifying information and of links back to identifiers before being provided to researcher. • Facebook public profiles found from Google searches. • Twitter tweets not in private setting. • Publicly accessible forums or comments sections where users have no expectation of privacy (e.g., New York Times, YouTube, etc.). Researchers who are unsure whether their project fits under this category should contact the UB IRB(irb@ubalt.edu) for consultation.
Projects that might be human subjects research because they involve:	• Purchasing/obtaining enhanced data sets—data on individuals which may include enough information to potentially identify the individuals. • Receipt of coded data where data holder has code key—depending on whether the data holder only provides data or is a collaborator in the research, and whether an agreement between institutions prohibits receiver from ever receiving identifiers, etc. • Forums or chats where users must register as belonging to a certain group (e.g., cancer survivors) or housed in areas that are not public, e.g., where special passwords are needed to join. Researchers should generally submit an IRB protocol, however if you are unsure whether your project falls under human subjects research, contact the UB IRB for consultation.
Projects that are human subjects research because they involve:	• Private data sets obtained with identifiers (e.g., traffic violation data with driver's license numbers, survey data with email addresses, medical records with protected health information [PHI], restricted use datasets, etc.). • Stolen, hacked, accidentally released data about individuals—although data may now be publicly available (such as on the surface web or the dark web), the individuals whom the data is about had expectation of privacy, i.e., that the data would not be hacked, stolen, etc. An IRB protocol must be submitted via Kuali protocols to be reviewed. Researchers must obtain IRB approval before the research begins.