Non-Human Subject Research Letter & Checklist

Your proposed activity is being returned because it was determined that it is not “human subject research” by DHHS and FDA Regulatory definition and, therefore, does not need to be evaluated by the Office of Research Compliance or the Institutional Review Board.

You may wish to review the definitions below that were used in making this determination. Your proposed activity does not meet one of the criterion below:

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 me at (304) 293-7555 or by email at lilo.ast@mail.wvu.edu.
If the answer is NO to any of these, it is NHSR:

**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 in the course of medical practice.
- This activity involves the use of a drug meaning:
  o 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.
• 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 in the course of medical practice.

MEDICAL DEVICES
The activity involves the use of a medical device, other than the use of a marketed medical device in the course of medical practice.
• The activity will involve the use of a medical device, meaning one of the following:
  o Recognized in the official National Formulary, or the US Pharmacopoeia, or any supplement to them.
  o Intended for use in the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, in humans or other animals.
  o Intended to affect the structure or any function of the body, of humans or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon metabolized for the achievement of any of its primary intended purposes.
• The medical device is NOT approved by the FDA for marketing.
• The medical device is NOT being used for the course of medical practice.

The activity is otherwise subject to FDA regulation.
• Data from the activity will be submitted to, or held for inspection by the FDA.
• The activity involves an FDA-regulated article. One or more of the following:
  o Food or dietary supplement that bears a nutrient content or a health claim
  o Food or color additive for human consumption
  o Infant formula
  o Biological product for human use
  o Other article subject to the FD & C Act
• The activity involves human participants because:
  o The test article will be used on one or more humans; AND/OR
  o All of the following are true:
    ♠ The test article is a medical device
    ♠ The medical device will be used on human specimens
    ♠ The activity is being done to determine the safety or effectiveness of the device
    ♠ Data from the activity will be submitted to, or held for inspection by the FDA