ETSU and ETSU/VA IRB Form 129

Determining Whether a Proposed Activity is Human Research According to DHHS or FDA Regulatory Definitions

Submitter Name	
Contact Address	
Contact Phone #	
Title of Proposed Study	
Institutions Responsible for Review:	Is this proposed activity to be conducted at VA facilities, or using VA patients, time or equipment? ☐ Yes ☐ No - If yes to above, is this a VHA Operation Activity*? ☐ Yes ☐ No - If yes to above, is the activity you are involved in directed by a VHA Program Office? ☐ Yes ☐ No Is this proposed activity subject to MSHA rules? ☐ Yes ☐ No

1. Provide a DETAILED description of the proposed activity:

2. Is this project intended for:
(check all that apply)
- ☐ **thesis**
- ☐ **dissertation**
- ☐ **potential publication or presentation**
- ☐ **dissemination of information outside of ETSU**

3. Does this project involve interview, survey, or focus groups? ☐ Yes ☐ No
If yes, attach a copy of the proposed questions.

4. Describe the subject population or data/specimens to be studied.

5. Answer the following questions.

A. Is the activity a systematic investigation, including research development, testing and evaluation? ☐ Yes ☐ No

B. Is the activity designed to develop or contribute to generalizable knowledge? ☐ Yes ☐ No*
If answering "no", you must provide explanation for your answer:

C. Are you planning to obtain data about living individuals? ☐ Yes ☐ No

D. Are you planning to obtain the data through one or more of the following? ☐ Yes ☐ No
- ☐ Physical procedures performed on those individuals
- ☐ Manipulation of those individuals
- ☐ Manipulation of those individuals' environments
- ☐ Communication with those individuals
- ☐ Interpersonal contact with those individuals

E. Does the study involve access to private, identifiable 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. Private information also includes 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 means the identity of the participant is or may readily be ascertained by the investigator. Individually identifiable information also means the identity of the participant is or may readily be associated with the information.
☐ Yes ☐ No*

If answering “no”, you must provide explanation for your answer:

F. Does the activity involve the use of a drug, other than the use of an marketed drug in the course of medical practice? ☐ Yes* ☐ No (* If yes, complete page 3)
G. Does the activity involves the use of a medical device, other than the use of an marketed medical device in the course of medical practice? ☐ Yes* ☐ No (*If yes, complete page 3)
H. Will data from the activity will be submitted to, or held for inspection by, the FDA? ☐ Yes ☐ No
I. Does the activity involve one or more of the following FDA-regulated articles? ☐ Yes ☐No
   - ☐ Food or dietary supplement that bears a nutrient content or a health claim
   - ☐ Biological product for human use
   - ☐ Electronic product for human use
   - ☐ Infant Formula
   - ☐ Food or color additive for human consumption
   - ☐ Other article subject to the FD&C Act

M. Will the test article be used on one or more humans? ☐ Yes ☐ No ☐ N/A, no test article
N. Are all of the following true? ☐ Yes ☐ No ☐ N/A, study does not use device
   - ☐ 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.

6. Is this proposed activity a medical case study? ☐ Yes* ☐ No

*If yes, answer the following questions. If no, skip this section.

A. Is the activity solely retrospective (all data exist at the time this Form 129 is submitted to the IRB)? ☐ Yes ☐ No
B. Were only clinically indicated interventions or data collection done? ☐ Yes ☐ No
C. Will the data be de-identified for the case report? ☐ Yes ☐ No
D. Is any aspect of the case unusual enough that the patient might be identifiable even though normal patient identifiers are removed? ☐ Yes ☐ No
E. How many patients are included in this proposed case study? ☐ 1 ☐ 2 ☐ 3 (note: if the proposed activity involves 4 or more patients, it must be submitted as human subject research)

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Signature of Submitter Date

***If the answer is Yes to question F or question G, you must complete page 3.**

❑ **Determining Whether a Proposed Activity is Human Research According to DHHS or FDA Regulatory Definitions Page 2 Form 129**

1. If the activity involves the use of a drug, other than the use of an marketed drug in the course of medical practice (question I on page 1), answer all of the following questions.

A. The activity will involve the use of a drug, meaning one of the following? ☐ Yes* ☐ No
(If yes, check the appropriate box below)

- ☐ An article 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
- ☐ 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

B. Is either of the following true? ☐ Yes* ☐ No (If yes, check the appropriate box)

- ☐ The drug is **NOT** approved by the FDA for marketing
- ☐ The drug is **NOT** being used in the course of medical practice

2. If the activity involves the use of a medical device, other than the use of an marketed medical device in the course of medical practice (question J on page 1), answer all of the following questions.

A. The activity will involve the use of a medical device, meaning one of the following:
☐ Yes* ☐ No (If yes, check the appropriate box below)

- ☐ Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them
- ☐ Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals
- ☐ Intended to affect the structure or any function of the body of humans or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes

B. Is either of the following true? ☐ Yes* ☐ No (If yes, check the appropriate box)

- ☐ The medical device is **NOT** approved by the FDA for marketing
- ☐ The medical device is **NOT** being used in the course of medical practice

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Submitter signature Date

***VHA Operations Activities.** Operations activities are certain administrative, financial, legal, quality assurance, quality improvement, and public health endeavors that are necessary to support VHA's missions of delivering health care to the Nation's Veterans, conducting research and development, performing medical education, and contributing to national emergency response. Operations activities may or may not constitute research.

Per VHA Handbook 1058.05:

Examples of Non-Research Activities:

1. All Employee Surveys, Voice of VA Surveys, and similar Surveys
2. Educational Activities designed and implemented for internal VA purposes (i.e., patient satisfaction surveys, performance evaluation activities) that are not designed to expand the knowledge base of a scientific discipline or other scholarly field (i.e., peer reviewed journal publication external to VA)

Operational Activities Always Considered Research:

1. Activities funded or otherwise supported as research by ORD or any other entity
2. Clinical investigations as defined under Food and Drug Administration (FDA)