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| ETSU and ETSU/VA IRB Form 129 | | |
| Determining Whether a Proposed Activity is Human ResearchAccording to DHHS or FDA Regulatory Definitions | | |
| **Submitter Name:** | |  |
| **Department:** | |  |
| **Phone #:** | |  |
| **Email:** | |  |
| **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, SUBMIT THIS FORM TO VA R&D OFFICE**   * 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 |
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| 1. Please provide a detailed description of the proposed activity:      1. Will you be using an organized approach to study a specific topic, test a specific hypothesis(es), answer a specific question, or develop a theory?  Yes  No 2. Is your intent to develop or contribute to generalizable knowledge?  Yes  No    1. If yes, explain: 3. What do you intend to do with the results? *(check all that apply)*   use for thesis or dissertation  publish or present the findings (including the ASRF)  release the information outside of ETSU or VA  use only for a class project, with no intent to use the results for something other than the course assignment  none of the above; Explain:   1. Will you obtain, use, study, analyze, or generate information or biospecimens “about” a living individual? (*Example: asking people their opinions is “about” them; only asking people to provide the policies or operations of an organization is not “about” them*)   Yes  No   1. How will you be collecting your information or biospecimens? *(check all that apply)*   performing procedures on individuals (ex. drawing blood)  communicating with people (ex. sending an email or letter asking them to complete a survey)  contacting people personally (ex. calling/meeting with people for interviews)  changing the environment of a person (ex. putting up posters and seeing how people respond)  observing people  secondary data  other:   1. If you chose “secondary data” above, please answer these questions. Skip this question if your study does not involve secondary data. 2. What are the sources of the information or biospecimens? 3. Is all the information publically available (i.e., anyone can access it)?  Yes  No 4. Will you, or any of the people on this project, be able to match the information or biospecimen with an individual at any time during this project?  Yes  No 5. Are you doing surveys, interviews, or focus groups?  Yes  No   *If yes, please attach draft questions.*   1. Is your activity a medical case study?  Yes  No   *If yes, answer questions a-f; otherwise go to question 10.*   1. Does all the information that you want to use in the case study exist right now?   Yes  No   1. Were only clinically indicated interventions or data collection done? *(example: you are not adding any other tests for this case report, but only using information that was done solely for clinical reasons)*   Yes  No   1. Will you ensure that the information is de-identified for this case report?   Yes  No   1. Will you ensure that any photographs, etc., that may be used are not identifiable (e.g. do not show the face or other images that might be identifiable)?   Yes  No   1. Is any part of this case unusual enough that the patient might be identifiable even when you remove the normal patient identifiers? *(example: report of a rare case that was discussed in the news would make the case report identifiable)*   Yes  No   1. How many patients will you include in this case study?  1  2  3   Note: if the proposed activity involves 4 or more patients, it must be submitted as human subject research   1. Will your project involve the use of a drug, other than use of a marketed drug in the course of routine clinical practice?  Yes  No 2. Will your project involve the use of a medical device?  Yes  No 3. Will your project include providing data to the FDA, or holding data for the FDA?   Yes  No   1. Will your project involve things that the FDA regulates? Examples are: food or dietary supplement, biological product for human use, electronic product for human use, infant formula food or color additive for human consumption, or other thing subject to the FD&C Act  Yes  No   **If you answered “yes” to any question from 10-13, see questions below. Otherwise, sign this form and submit.**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Submitter Date | | |

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| **If you answered “yes” to question 10, you must answer the next three questions.**   1. Will the test article be used on one or more humans?  Yes  No 2. Will 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  C. 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    **If you answered yes to question 11, you must answer the next four questions.**    A. Will the test article be used on one or more humans?  Yes  No   1. Are all of the following true?  Yes  No   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.   1. Will 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 its  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 its primary intended  purposes   1. 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  **If you answered “yes” to question 12-13, you must answer the next question.**   1. Will the test article be used on one or more humans?  Yes  No |

**^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)

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| **FOR VA USE ONLY** |
| Reviewed by VA R&D Office or RCO: |
| Comments: |