Instructions: This form is used to establish whether your research can be determined not to be “Human Research” or your project can be determined “Not Research” and will not require IRB Review according to the federal regulations.

To request a determination of NHSR, please complete the protocol application in the IRB system and attach this form in the Protocol section. *The IRB Office will then make the final determination on whether the activity meets the definition of Human Subjects Research under Health and Human Services regulations (HHS)45 CFR 46.102 or (FDA) 21 CFR 56.103.*

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| --- | --- | --- | --- |
| **Investigator:** | |  | |
| **Study Title:** | |  | |
| **Co-Investigators(s) (if Applicable):** | |  | |
| **Faculty Advisor (if Applicable):** | |  | |
| **Section 1 – Justification of Not Human Subjects Research/Not Research  Please Complete Applicable Section A and Section B** | | | |
| 1. **Does the research does involve Human Subjects as defined by DHHS or FDA? See HRP-310 Worksheet-Human Research Determination.** | | | |
|  | The investigator conducting research is gathering data about living individuals | | |
|  | Will the investigator gather those data through either of the following mechanisms?  Physical procedures or manipulations (this can include surveys, interviews, focus groups, prospective collection of biospecimens) of those individuals or their environment for research purposes (“intervention”).  Communication or interpersonal contact with the individuals (this can include contact via phone, email, social media etc.) ("interaction”). | | |
|  | **Will this study involve the use of existing data (examples include data sets, previously collected biospecimens. For the purpose of this form, “existing” means the data has already been collected at the time of this studies proposal).**  UCF researcher(s) or external study team members receive de-identified data or specimens.  Publically Available Data (specify the data source):  **OR**  De-identified data or biospecimens (specify the data source and who de-identifies the data):  No one on the research team has access to identifiable information.  Provide a separate list\* of the data points, variables, and/or information that will be collected and/or analyzed (i.e. data abstraction form).  UCF researcher(s) or external study team members receive identifiable data or specimens.  \* Data access is limited to the items included in the list. The IRB must be notified of any additions to the list. The list will be reviewed to confirm that no private identifiable information (i.e. 18 PHI Identifiers) will be obtained. If the list includes any private identifiable information, the activity involves human subjects. | | |
|  | Does the activity involve any of the following? **(Check all that apply)**  In the United States: The use of a drug[[1]](#endnote-1) in one or more persons other than use of an approved drug in the course of medical practice[[2]](#endnote-2).  In the United States: The use of a device[[3]](#endnote-3) in one or more persons that evaluates the safety or effectiveness of that device.  Data regarding subjects or control subjects submitted to or held for inspection by FDA[[4]](#endnote-4).  Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA[[5]](#endnote-5). | | |
| 1. **B.. Please indicate which of the following categories you think most clearly represents the study, discuss the intent of the study, and how you plan to disseminate the study results.** | | | |
|  | **Case Study**  Describe: | | |
|  | **Quality Improvement**  Describe: | | |
|  | **Program Evaluation**  Describe: | | |
|  | **Retrospective Data Analysis**  Describe: | | |
|  | **Other**  Describe: | | |
| **Section 2 – Certification and Investigator Sign-Off** | | | |
| **Decisions regarding eligibility for a Not Human Subjects Research determination will be made on a case-by-case basis by the IRB Office*.* The IRB Office may request additional documentation, including the full protocol (HRP-503 – Protocol Template), in order to make the appropriate determination.**  **By entering your initials below you certify that the information you have provided is complete and accurate. In addition, you acknowledge that any intended/proposed modifications to this project must first be submitted to the IRB as certain modifications change the review category.** | | | |
| **Investigator Initials** | | | **Date** |
|  | | |  |

1. The term ‘‘drug’’ means:

   articles 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; and

   articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

   articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and

   articles intended for use as a component of any article specified in clause (A), (B), or (C). [↑](#endnote-ref-1)
2. “Other than the use of an approved drug in the course of medical practice” refers to a practitioner providing an approved drug to a patient because the practitioner believes the drug to be in the best interests of the patient. If the protocol specifies the use of the drug, it is not in the course of medical practice unless use of the drug is completely up to the discretion of the practitioner. [↑](#endnote-ref-2)
3. The term ‘‘device’’ means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

   recognized in the official National Formulary, or the United States Pharmacopeia, 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 man or other animals, or

   intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. [↑](#endnote-ref-3)
4. This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement. [↑](#endnote-ref-4)
5. This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement. [↑](#endnote-ref-5)