FLORIDA STATE UNIVERSITY

OFFICE *of the* VICE PRESIDENT *for* RESEARCH



**Determination of Human Subjects Research Form**

Use this form to submit and request an official determination from the Office for Human Subjects Protection (OHSP) about whether your proposed study or activity requires submission of a full protocol for regulatory or Institutional Review Board (IRB) review. If your study or activity involves specific populations, read Section V first since use of this form may not be permitted. For key terms and concepts used in this form, be sure to refer to the footnotes. Complete all fields, answer all questions and provide the requested documentation, as applicable; your submission will be returned to you if incomplete. Once complete, see **Submission Directions** at the end of this form.

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| **Background Section** | Principal Investigator of study/dissertation (Last, First AND FSU email address): |
| Faculty Advisor (Complete if PI is a student) (Last, First, Department/School/College AND FSU email address): |
| Project Title (Provide a complete title and avoid abbreviations or jargon. For students: Do not indicate “Dissertation” only): |
| If the project is extramurally funded, indicate the (1) funding organization, (2) funding organization’s award, grant or contract identification number and (3) internal FSU Grant project number: |
| Describe the primary objective of the project (what do you hope to learn AND to what purpose will you put any findings): |
| Procedures and/or activities to be conducted for this project (Be specific): |
| **Proceed to Sections I-V** | |

|  | | | Use Drop-down to check Yes or No (or Not Sure for some questions) |
| --- | --- | --- | --- |
| **Section I. Does the activity involve human subjects?** | Is the information[[1]](#endnote-1) or biospecimen[[2]](#endnote-2) that you are obtaining about living individuals? If you are not sure mark “Yes”. | |  |
| Do you plan to obtain information or biospecimen about individuals through interactions[[3]](#endnote-3) or interventions[[4]](#endnote-4) with the individuals?  If you will have any interaction or intervention with these individuals, then their consent to participate in your project is required. Separately provide all recruitment and consent-related forms using the authorized templates.[[5]](#endnote-5) | |  |
| Does the information or biospecimens include identifiable, private information[[6]](#endnote-6) or identifiable biospecimens[[7]](#endnote-7)? If you are not sure mark “Yes”. | |  |
| If any response in the section above is “Yes” proceed to next sections below.  If all responses above are “No” then stop and submit this form along with other supporting documentation to OHSP as directed below. | | | |
| **Section II: Is my study *research*?** | Is the activity a systematic investigation (including research development, testing and evaluation)? If you are not sure mark “Yes”. |  | |
| Is the activity designed to develop or contribute to generalizable knowledge? If you are not sure mark “Yes”. |  | |
| **Section III: Is my study quality assessment or quality improvement?** | Is this activity designed only to assess, analyze, critique and/or improve current processes in the institutional setting(s) within which the activity is conducted? |  | |
| Is the activity designed only to improve services, treatment, care or other programmatic activity or function in the institutional setting(s) within which the activity is conducted? |  | |
| Do you intend your findings to be applied to populations or contexts beyond your specific study population or context? |  | |
| **Section IV: Additional Questions** | Does the activity involve secondary research[[8]](#endnote-8) use of identifiable private information or identifiable biospecimens? If you are not sure mark “Yes”. |  | |
| Does the activity involve use of biospecimens or cell lines from other institutions or are they commercially available? |  | |
| Are the information or biospecimens collected with the intention of publication? If you are not sure mark “Yes”. |  | |
| Does the activity involve the use of only publicly available information or biospecimens? If you are not sure mark “Yes”. |  | |
| Does the activity involve the use of any sensitive information? Sensitive information is information that if lost, compromised, misused, or disclosed could result in participants’ harm, embarrassment, discomfort, inconvenience or unfairness.[[9]](#endnote-9) |  | |
| Does the activity involve the use of any measure or instrument such as a survey, questionnaire, focus group or interview guide, log or other document through which participants’ information is collected?  If so, separately provide or attach a legible copy of each measure and instrument[[10]](#endnote-10); do not provide a web link to any measure or instrument*.* |  | |
| Does the activity or study involve scholarly and journalistic activities such as oral history, journalism, biography, literary criticism, legal research, and historical scholarship that includes the collection and use of information that focus directly on the specific individuals about whom the information is collected? |  | |
| Does the activity or study involve public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority? |  | |
| Does the activity or study involve the collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes? |  | |
| If your activity or study will involve the secondary use of any individual-level information or biospecimens (whether or not identifiable or public), describe below or attach documentation as applicable regarding the following:   1. Specific name or identity of the source of the information or biospecimens and description of the purpose for which the source initially collected the information or biospecimens (e.g., admission, registration, education, employment, hospitalization, judicial administration, human services, treatment, counseling, law enforcement, clinical or research registry): 2. The type and scope of the information or biospecimens to be used (e.g., student, service, employment or health records; test, registration, assessment, hospitalization, or demographic information; periods of time over which information or biospecimens had been collected; whether information or biospecimens will be retrospectively and/or prospectively obtained): 3. Whether the information or biospecimens will be randomly and uniquely coded; if not, explain rationale for not coding. If so, how the information or biospecimens will be coded, who will code, who will have access to the code, when the code will be destroyed, and if any researcher will be able to identify individuals: 4. For multiple data sets, how data across data sets will be linked (e.g., names, Social Security numbers, student or employee IDs, email or postal addresses; GPS), by what linking key, who will have access to the linking key and when the linking key will be destroyed (if multiple data sets are not used, enter N/A): 5. Separately attach or provide below a complete list and description of all data variables that will be extracted or obtained; alternatively provide a copy of the data dictionary with extracted variables highlighted: | | | |
| **Section V. Does the research focus on a specific population?** | For each of the specific populations below, use the Drop-down to check Yes, No or Not Sure | | |
| Pregnant women, human fetuses or neonates |  | |
| Prisoners or inmates |  | |
| Children (any persons under the age of majority in their state of residence) |  | |
| Decisionally impaired |  | |
| Economically disadvantaged |  | |
| Educationally disadvantaged |  | |
| Students or employees under the supervisory or evaluative authority of the researcher |  | |
| Institutionalized individuals |  | |
| Non-English speaking |  | |
| *Notes about studies involving prisoners or children*:  For any study involving prisoners or children, submission of a complete protocol[[11]](#endnote-11) (i.e., not this form) using one of the OHSP protocol templates is generally required. An exception may be made if OSHP determines based upon review of this submitted form that (a) the study does not include any interaction or intervention with these individuals, and (b) the study does not include use of these individuals’ identifiable private information or identifiable biospecimen. If you are not able to categorically preclude interactions, interventions and use of identifiable private information or identifiable biospecimens involving prisoners or children, then submit a complete protocol.  *Note about studies involving non-English speaking subjects*:  Any study involving interactions or interventions with *non-English speaking* human research participants will require submission of (a) both non-English and English language consent-related materials as well as (b) any measure or instrument in both non-English and English language that will be used to query and collect responses from participants. | | |

**SUBMISSION DIRECTIONS:**

When completed as instructed, submit this form along with any documentation by logging in to the FSU electronic protocol management system, [RAMP IRB](https://myramp.research.fsu.edu/). Under the IRB tab, click “Create a New Study” (or “Edit Study” if you are making any changes to an existing study) to complete the RAMP IRB application. Then upload your completed form under question #8 where it asks you to attach your protocol. Submit other forms or documents as instructed. Once you have completed the application, don’t forget to click “Submit” on your study workspace for your study to enter our queue for review. As earlier stated, your submission will be returned to you if incomplete

*Contact the OHSP at* [*humansubjects@fsu.edu*](mailto:humansubjects@fsu.edu) *if you have any questions****.***

1. The term *information* is construed very broadly, and may refer for example to any record, data, fact, figure, knowledge, document, statement or response. [↑](#endnote-ref-1)
2. *Biospecimen* refers to a quantity of tissue, blood, urine, or other human-derived material. A single biopsy may generate several biospecimens, including multiple paraffin blocks or frozen biospecimens. A biospecimen can comprise subcellular structures, cells, tissue (e.g., bone, muscle, connective tissue, and skin), organs (e.g., liver, bladder, heart, and kidney), blood, gametes (sperm and ova), embryos, fetal tissue, and waste (urine, feces, sweat, hair and nail clippings, shed epithelial cells, and placenta). Portions or aliquots of a biospecimen are referred to as samples (retrieved from <http://biospecimens.cancer.gov/bestpractices/got/#B>). [↑](#endnote-ref-2)
3. Examples of *interactions* may include interviews, focus groups, surveys, discussions or similar interpersonal contacts with participants. [↑](#endnote-ref-3)
4. Examples of *interventions* may include (a) actions and activities such as exercises, body movements, stress tests and human factor measures; (b) medical, psychological and behavioral examinations, use of and tests involving medicinal or nutritional supplements, and implantation or application of medical devices or other sensors; (c) collection of biological specimens such as blood, sputum and any other body tissue or fluids; and (d) manipulations of participants or their environments such as watching a video, altering or testing a lived, learning or occupational environment, completing computer tasks, and undergoing training. [↑](#endnote-ref-4)
5. Consent forms must be based upon the authorized Consent/Information Sheet templates; locate the templates by clicking on the IRB tab (top row) in [RAMP IRB](https://myramp.research.fsu.edu/), clicking on the Library tab (second row), then clicking on the Templates tab (third row), and selecting one of the following: HRP-502 Template Consent Document, HRP-502a Template SBER Consent Document, HRP-507 Template Consent Document-Short Form, or HRP-502i Information Sheet Template (Exempt Studies Only; if your study is not by OHSP deemed exempt, then you will be required to use one of the other templates). Complete your Consent Form/Information Sheet as instructed. When you have finished developing your Consent form/Information Sheet, return to your workspace for this study. Under Next Steps, Edit your study and under Local Site Documents, Add your Consent form/Information Sheet by uploading your Consent form/Information Sheet under the Consent forms section, then click OK and Save and Exit. When the Consent form and all other study documents and materials have been completed and uploaded (do not submit in piecemeal fashion), then under Next Steps click Submit or Submit Response and then OK. [↑](#endnote-ref-5)
6. *Identifiable private information* is private information for which the identity of the participant is or may readily be ascertained by the investigator or for which the identity of the participant is or may readily be associated with the information. [↑](#endnote-ref-6)
7. An *identifiable biospecimen* is a biospecimen for which the identity of the participant is or may readily be ascertained by the investigator or for which the identity of the participant is or may readily be associated with the biospecimen. [↑](#endnote-ref-7)
8. Secondary research is research use of information or biospecimens that were or are originally obtained for (a) a non-research purpose (e.g., information collected for education, human services, employment, clinical registry, law enforcement or the U.S. census; leftover biospecimens from routine health tests) OR (b) research studies other than the one now proposed (e.g., an experiment to compare outcomes or effects of one or more interventions). [↑](#endnote-ref-8)
9. Sensitive information, whether or not linked to an individual’s direct identifier such as their name, may include for example, non-public information about the following: Social Security or other federal or state benefit program programs; employment records; bank and financial accounts, including credit cards or loans; health care, including hospitalizations; educational records; driver’s and other licensing information; crime victim; and any other information specific to an individual. [↑](#endnote-ref-9)
10. When you are prepared to upload the measures or instruments, return to your workspace for this study. Under Local Site Documents, in the Other Attachments section, upload by adding as a separate file(s) your measure and instrument. Add a Name for the measure or instrument, select a Category (in this case Survey/Questionnaire), indicate version if appropriate, and click OK. When the measures and instruments as well as all other study documents and materials have been completed and uploaded (do not submit in piecemeal fashion), then under Next Steps click Submit or Submit Response and then OK. [↑](#endnote-ref-10)
11. Protocols must be based upon the authorized protocol templates; locate the templates by clicking on the IRB tab (top row) in RAMP IRB, clicking on the Library tab (second row), then clicking on the Templates tab (third row), and selecting one of the listed protocol templates (HRP-503 Template Protocol, HRP-503 Template Protocol Without Instruction, and HRP-503a Template SBS (Social and/or Behavioral studies) Protocol. Complete your protocol as instructed. When you have finished developing your protocol, return to your work space for this study. Under Next Steps, Edit your study and under Basic Study Information, Add your protocol by uploading your protocol, then click OK and Save and Exit. When the protocol and all other study documents and materials have been completed and uploaded (do not submit in piecemeal fashion), then under Next Steps click Submit or Submit Response and then OK. [↑](#endnote-ref-11)