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. First read Section V *Notes* before completing this form since use of this form may not be permitted if your study or activity will involve certain populations as human research participants. For key terms and concepts used in this form, refer to the footnotes. Complete all fields, answer all questions and provide the requested documentation, as applicable (e.g., consent-related forms, instruments/measures, variables list/data dictionary etc.); 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 (Be specific: 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, including describing the respondents/samples, approach, methods and analyses that will be performed):      |
| **Proceed to Sections I-V** |

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| **Section I: Is my study *research*?** | Check Yes or No |
|  | Is the planned activity a systematic investigation[[1]](#footnote-1) (see footnote below about what constitutes a systematic investigation)? If you are not sure mark “Yes”. | Yes |[ ]
|  |  | No |[ ]
| 1.
 | Is the planned activity designed to develop or contribute to generalizable knowledge[[2]](#footnote-2) (see footnote below about what constitutes developing or contributing to generalizable knowledge)? If you are not sure mark “Yes”. | Yes |[ ]
|  |  | No |[ ]

| **Section II. Does the activity involve human subjects?** | Check Yes or No |
| --- | --- |
|  | Is any information[[3]](#footnote-3) or biospecimens[[4]](#footnote-4) that you plan to obtain about living individuals? If you are not sure (you have no authoritative and documented basis to ascertain that ALL individuals are deceased) then mark “Yes”. | Yes |[ ]
|  |  | No |[ ]

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|  | Do you plan to obtain information or biospecimens about individuals through interactions[[5]](#footnote-5) or interventions[[6]](#footnote-6) with the individuals?If you will have any interaction or intervention with these individuals, then you must obtain their consent to participate in your project; therefore, **separately provide all recruitment and consent-related forms using the authorized FSU templates [**[link](https://myrampirb.research.fsu.edu/IRB/sd/Rooms/DisplayPages/LayoutInitial?container=com.webridge.entity.Entity%5BOID%5BF4B150F37E318B4DB8B0D7249015488D%5D%5D&tab2=294B1E5FDD6A8142A2AF57F5F7F197BF)**]**.[[7]](#footnote-7)  | Yes |[ ]
|  |  | No |[ ]
|  | Do you plan to obtain identifiable private information or health information[[8]](#footnote-8), or identifiable biospecimens[[9]](#footnote-9) (*regardless* of whether you will have any interactions or interventions with the individuals about whom the information or biospecimen pertain)? | Yes |[ ]
|  |  | No |[ ]
|  | If “Yes” then thoroughly describe in detail below how you will protect the confidentiality of the information and biospecimens:      *To see what must be included in your description, refer to our Research Information Security page, under “Describing in Your Study How Data will be Protected” [[link](https://www.research.fsu.edu/research-offices/ohsp/investigator-resources/research-information-security/)]**Refer to our OHSP HIPAA in Research web page to learn more as well as to access, prepare and submit required materials along with this determination form. [*[*link*](https://www.research.fsu.edu/research-offices/ohsp/hipaa-in-research/)*]* |
|  | Will (a) any individuals be recruited through, (b) individuals’ information or biospecimens be obtained from, or (c) any interaction or intervention take place at, a non-FSU institution, agency, site or location?[[10]](#footnote-10)*Studies involving non-FSU sites, institutions or agencies, such as TMH, CRMC, FAMU, state agencies and other organizations, may require those sites' IRB, research review or other approvals. Go to our non-FSU IRB review page to learn more [*[*link*](https://www.research.fsu.edu/research-offices/ohsp/human-research-review/other-reviews/#SingleIRB)*]. Also, collaborations involving TMH are subject to specific requirements; visit the FSU Office for Clinical Research Advancement (OCRA) for further information [OCRA [link](https://ocra.fsu.edu/)].* | Yes |[ ]
|  |  | No |[ ]
|  | If the answer to question 12 is “Yes” then describe non-FSU site approval, permission, clearance or the non-FSU site’s statement that no such approval, permission or clearance is required, and attach documentation thereof (*note that documentation must come from the non-FSU site’s own IRB, Privacy Board or Privacy Officer, or other official authorized to do so*):       |

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| **Section III: Is my study quality assessment or quality improvement?**(to assist with your answers below, refer to our FAQ page <https://www.research.fsu.edu/research-offices/ohsp/faqs/>, FAQ #6 under General Questions) | Check Yes or No |
|  | 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? | Yes |[ ]
|  |  | No |[ ]
|  | 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? | Yes |[ ]
|  |  | No |[ ]
|  | Do you intend your findings to be applied to populations or contexts beyond the specific study population or context involved in your study? | Yes |[ ]
|  |  | No |[ ]

| **Section IV: Additional Questions** | Check Yes or No |
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|  | Does the activity involve secondary research[[11]](#footnote-11) use of identifiable private information, health information or biospecimens? If you are not sure mark “Yes”.(s*ee footnotes 8 and 9 for definitions of identifiable private information, health information and biospecimens*) | Yes |[ ]
|  |  | No |[ ]
|  | Does the activity involve use of biospecimens or cell lines from other non-FSU institutions or that are commercially available? | Yes |[ ]
|  |  | No |[ ]
|  | Are the information or biospecimens collected with the intention of publication or other scholarly dissemination? If you are not sure mark “Yes”. | Yes |[ ]
|  |  | No |[ ]
|  | Does the activity involve the use of only publicly available information or biospecimens? If you are not sure mark “No”. | Yes |[ ]
|  |  | No |[ ]
|  | 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.[[12]](#footnote-12) | Yes |[ ]
|  |  | No |[ ]
|  | Does the activity involve the use of any measure or instrument (e.g. survey, questionnaire, focus group or interview guide, log, data collection form) through which participants’ responses, answers, data or other information are collected, provided or entered by any means, such as paper, electronic device, computing equipment or online program?**If so, separately provide or attach a legible copy or print out of each measure and instrument**.[[13]](#footnote-13) Do not provide a summary, a sample or a web link (as these do not suffice for review and IRB finalization), and only provide in Word or pdf format*.* | Yes |[ ]
|  |  | No |[ ]
|  | Does the activity or study only 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?[[14]](#footnote-14) | Yes |[ ]
|  |  | No |[ ]
|  | Does the activity or study only 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? | Yes |[ ]
|  |  | No |[ ]
|  | Does the activity or study only 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? | Yes |[ ]
|  |  | No |[ ]
|  | If your activity or study will involve the primary or secondary use of any individual-level information or biospecimens (whether or not identifiable or public), **you must 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 (the list, description and/or dictionary should be sufficient for the reviewer to understand in layperson terms the nature, characteristic or attribute of each variable):
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| **Section V. Will any study interaction or intervention intentionally or incidentally include any of the populations below?** | For each of the populations below, check Yes or No(**if any are Yes then see Notes following**) |
|  | Prisoners or inmates | Yes |[ ]
|  |  | No |[ ]
|  | Children (any persons under the age of majority in their state of residence) | Yes |[ ]
|  |  | No |[ ]
|  | Decisionally incapacitated or cognitively impaired | Yes |[ ]
|  |  | No |[ ]
|  | Economically disadvantaged (e.g., indigent or impoverished) | Yes |[ ]
|  |  | No |[ ]
|  | Educationally disadvantaged (e.g., illiterate, lack of high school graduation or GED) | Yes |[ ]
|  |  | No |[ ]
|  | Students or employees under the supervisory or evaluative authority of the Principal Investigator (PI) or the PI’s Faculty Advisor | Yes |[ ]
|  |  | No |[ ]
|  | Non-English speaking or persons with limited English proficiency | Yes |[ ]
|  |  | No |[ ]
| *NOTES:**Studies involving prisoners or children*:For any study involving prisoners or children, submission of a complete protocol[[15]](#footnote-15) (i.e., not this form) using one of the FSU-approved protocol templates is required. An exception may be made if OHSP 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, health information or biospecimen. If you are not able to categorically preclude interactions, interventions and use of identifiable private information, health information or biospecimens involving prisoners or children, then submit a complete protocol.*Studies involving non-English speaking study participants*: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. See our Consent-related templates intended for use with these study participants [[link](https://www.research.fsu.edu/research-offices/ohsp/investigator-resources/templates-and-required-forms/%22%20%5Cl%20%22panelBodyConsentrelatedTemplates)] |

**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 (at <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 therein or in this form. Once you have completed the application, don’t forget to click “Submit” and then “OK” 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 if you have any questions****.***

1. Your planned study or project is a *systematic investigation*if your study or project will involve a plan to examine or document phenomena or to test a hypothesis, gather or use information or specimens using commonly accepted quantitative or qualitative scientific or analytical methods, and interpret results or draw conclusions relative to the phenomena or hypothesis. Thesis or dissertation studies or projects are considered systematic investigations. Study or project plans usually include a formal protocol that includes an objective(s) and procedures designed to reach that objective. Examples of systematic investigations may include surveys, interviews, focus groups, analyses of existing data or biological specimens, evaluations of social or educational programs, cognitive and perceptual experiments, clinical trials, and physiological experiments. Haphazardly or arbitrarily collecting information or specimens is generally not a systematic investigation. The term “systematic investigation” is a term of art that is included in the definition of *Research* in federal regulations at Title 45 of the U.S. Code of Federal Regulations (CFR), Part 46 (45 CFR 46). [↑](#footnote-ref-1)
2. Your planned study is intended to create *generalizable knowledge* if the design or purpose of your study or project (including class projects) will be to draw conclusions that have some general applicability, inform policy or practice, or apply or extrapolate findings to persons, programs or institutions beyond those involved as respondents in your study or project. For example, certain activities are not presumptively considered to create generalizable knowledge, such as for example oral histories, journalism, biographies, literary criticism, legal research and historical scholarship. Other activities, such as quality improvement or program evaluation, may also not be considered to create generalizable knowledge if very carefully circumscribed. However, if any such activity will be used to as noted above (e.g., have some general applicability beyond the persons, programs or institutions involved as respondents), then your study is deemed to create generalizable knowledge. The term “generalizable knowledge” is a term of art that is included in the definition of *Research* in federal regulations at Title 45 of the U.S. Code of Federal Regulations (CFR), Part 46 (45 CFR 46). A study that is not published or presented may still be considered to develop or contribute to generalizable knowledge. [↑](#footnote-ref-2)
3. The term *information* is construed very broadly and may be in any format, document or form, including for example any written, verbal, electronic, physical, or virtual format and document, and any record, data, fact, figure, knowledge, statement, response, file, instrument, article or artifact. [↑](#footnote-ref-3)
4. *Biospecimens* refer 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. [↑](#footnote-ref-4)
5. Examples of *interactions* may include interviews, focus groups, surveys, discussions or similar interpersonal contacts with participants. You are interacting with individuals to obtain their information for research purposes when you will have any communication or interpersonal contact with an individual to collect, use or generate any information or biospecimens about the individual (whether or not the information is identifiable). The terms “communication” and interpersonal contact” are very broadly construed and may be in or by any format or means, including for example written, verbal, electronic, in person or face-to-face, online or virtual, and whether or not the communication or interpersonal contact is direct or indirect. [↑](#footnote-ref-5)
6. 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. [↑](#footnote-ref-6)
7. 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 (use the link in item #10 or go to 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, 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.

 If your activity involves collaborating non-FSU researchers whose IRB has previously approved of a consent form, you may provide a copy of that consent form; if it does not suffice for FSU review we will let you know. [↑](#footnote-ref-7)
8. *Identifiable private information* may include information for which the identity of an individual about whom the information pertains may readily be ascertained by the investigator or associated with the information, and which information the individual can reasonably expect will not be made public. *Identifiable health information* may include information (including demographic information) that is created or received by a health care provider, among others, which information relates to the past, present, or future physical or mental health or condition of an individual, and which identifies the individual. Note that the list of variables that may identify an individual includes not only names and other unique identifiers, but dates related to the individual as well as their addresses; use or disclosure of identifiable health information may be subject to the federal law referred to as the HIPAA Privacy Rule. [↑](#footnote-ref-8)
9. 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. [↑](#footnote-ref-9)
10. Before submitting your studies for FSU IRB review, you must contact such sites to ascertain their review requirements (including as may be applicable payment of their IRB review fees, such as for TMH) and comply accordingly. The FSU IRB may require that documentation of such site contact be provided together with this form. [↑](#footnote-ref-10)
11. Secondary research is research use of information or biospecimens that were or will be 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. Secondary research use of identifiable private information, health information or biospecimens is distinguished from primary research use, which involves prospectively obtaining such information or biospecimens for the study now proposed. [↑](#footnote-ref-11)
12. Sensitive information, whether or not linked to an individual’s direct identifier such as their name or other unique identifier, may include for example, non-public information about the following: Social Security or other federal or state benefits; employment records; bank and financial accounts, including credit cards or loans; health care, including hospitalizations and medical records; educational records; driver’s and other licensing information; crime victim; and any other information specific to an individual. [↑](#footnote-ref-12)
13. 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. [↑](#footnote-ref-13)
14. For an activity that only involves the collection of information from specific individuals through interaction with the individuals about their experiences or documents a specific historical event, AND from which activity or analyses of the collected information there is no intent to draw conclusions or generalize findings beyond the specific individuals involved in the activity, then answer “Yes.” However, if the activity or analyses of collected information will be used to document and draw conclusions about the individuals’ collective experiences, inform policy or otherwise generalize findings beyond the specific individuals involved, then answer “No.” [↑](#footnote-ref-14)
15. 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 or HRP-503a Template SBS Protocol (Social, behavioral or educational studies). Complete your protocol as instructed. When you have finished developing your protocol, return to your workspace 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. [↑](#footnote-ref-15)