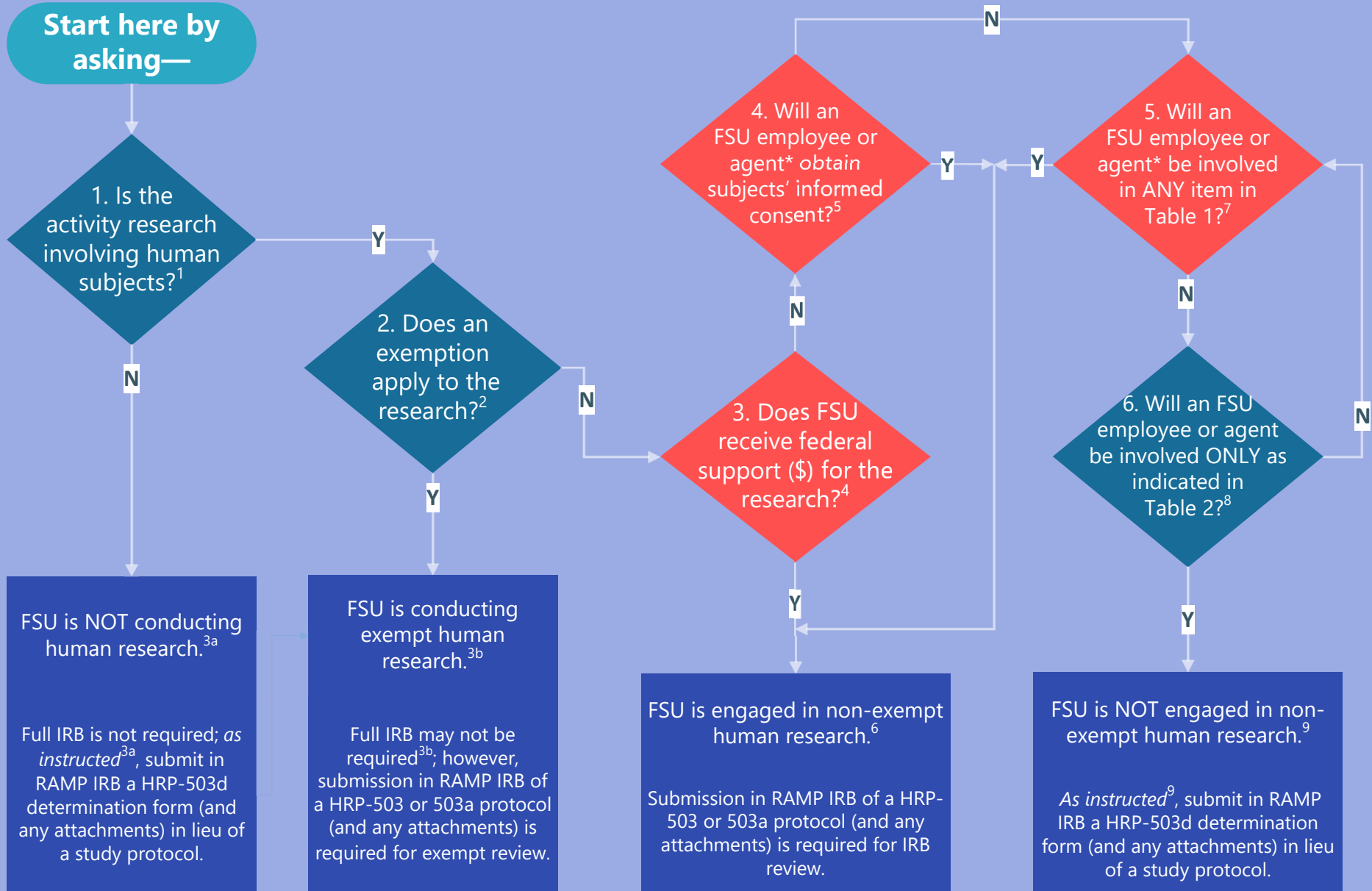


Is FSU Engaged in Human Research? (OHSP, revised July 5, 2022)



NOTES (revised July 5, 2022)

¹ Is the activity research involving human subjects?

An activity is *research* when the activity will involve a plan to examine, observe, manipulate 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 to draw conclusions that have some general applicability, inform policy or practice, including applying or extrapolating findings to persons, programs or institutions beyond those that may be involved as participants, respondents or objects of study in the activity. Thesis or dissertation studies or projects may be considered research if the above characteristics apply. Examples of research may include but are not limited to surveys, interviews, focus groups, collection or analyses of existing data or biological specimens, evaluations of social or educational programs, cognitive and perceptual experiments, clinical trials, and physiological experiments.

Research involves *human subjects* when information is obtained from individuals through intervention or interaction with the individual OR when information or biospecimens about these individuals is accessed or obtained (with or without intervention or interaction with the individual). If your activity is research and involves human subjects as described above, then answer “Yes” to Question 1 then proceed to Question 2. If your activity will not involve human subjects as described above, then answer “No” to Question 1; FSU (with you as its employee, student or agent) is not considered as conducting human research; see footnote 3a for instructions about creating and submitting in [RAMP IRB](#) a application for a formal and authoritative IRB determination about whether your activity does or does not require “full” IRB (vs. limited IRB or exempt) review.

² Does an exemption apply to the research?

While only the OHSP/IRB (not researchers, faculty advisors or college/school/department officials) can authoritatively determine that an exemption may apply to proposed research, note that the OHSP/IRB may deem that some research may qualify under one or more of eight exemption categories established by federal law, meaning that full IRB review may not be required. The law may still require limited IRB review (i.e., IRB review focused upon only one or two but not all approval criteria as with full IRB review) (for reference for how the OHSP/IRB will determine that research may qualify for exemption, see [U.S. Code of Federal Regulations](#) or a federally-provided [exemption decision tree](#) (refer to Chart 2) is available here on the OHSP web site. If the answer to Question 2 is “No” or unsure then proceed to Question 3. If the answer to Question 2 is “Yes”, see note 3b for instructions about creating and submitting in [RAMP IRB](#) an application for a regulatory exemption review for a formal and authoritative IRB determination about whether your research is exempt and does not require full IRB review (i.e., that a limited or exempt review will suffice).

^{3a} FSU is NOT conducting human research if the answer to Question 1 is “No”. This means that under applicable laws FSU is not required, after OHSP pre-review of the study, to certify to the federal government of full or limited IRB review and approval of the activity. However, a formal and authoritative OHSP/IRB regulatory determination to this effect may be required since many institutions and agencies will NOT accept a researcher’s statement that their activity does not involve conducting human research. These institutions and agencies may include federal agencies; study sponsors and funders; external institutions with which FSU employees, staff and students may collaborate or from which information about individuals may be obtained; publishers of scientific papers; and the FSU graduate school manuscript clearance office.

Therefore, before undertaking any activity that may require an official and authoritative regulatory determination about whether your activity involves conducting human research and does not require IRB review, researchers should submit in [RAMP IRB](#) an application for an official regulatory determination. Also note that the applicable laws and FSU policy do not permit retroactive reviews (after or while the activity was or is being conducted), so submit the application before commencing any activities. Finally, note that some modifications to activities may change the responses to any of the Questions 1 through 6, so researchers should revisit this algorithm and begin with Question 1 again before those modifications are implemented to ensure on-going compliance with the applicable federal laws and to receive an updated regulatory determination.

3b FSU is conducting exempt human research if the answer to Question 2 is “Yes”. Again, only the OHSP/IRB may render an official and authoritative determination about whether research is exempt from full IRB review. Therefore, before undertaking any research that may qualify for one or more of eight exemption categories, researchers must submit in [RAMP IRB](#) an application for an official OHSP/IRB regulatory determination of exemption. Note that the applicable laws and FSU policy do not permit retroactive exemption determinations (after or while the activity was or is being conducted), so submit the application before commencing any activities.

4 Does FSU receive federal support for the research?

FSU is considered to receive federal support from a federal department or agency if FSU will or has received any grant, contract, or cooperative agreement from the department or agency to support some or all of proposed research, or even if all research activities will be carried out by non-FSU employees or agents. If the answer to Question 3 is “Yes” then FSU is engaged in human research, and the FSU researchers are required to create and submit in [RAMP IRB](#) a study for OHSP and/or IRB regulatory review. If the answer to Question 3 is “No” then proceed to Question 4. If unsure, then FSU researchers should create and submit in [RAMP IRB](#) a study for OHSP and/or IRB regulatory review for a formal and authoritative determination.

5 Will an FSU employee or agent* obtain subjects’ informed consent?

*An FSU employee or agent refers to an individual who: (1) acts on behalf of the FSU; (2) exercises FSU authority or responsibility; or (3) performs FSU-designated activities. Employees and agents can include staff, students, contractors, and volunteers, among others.

Answer “Yes” to this Question 4 if an FSU employee or agent will in any way be involved in soliciting or obtaining an individual’s informed consent (including parental permission and/or child assent, legally authorized representative permission, use of an consent-type information sheet, providing and “opt-out” type notice). This involvement may include any communication or interpersonal contact with an individual or through a third party who may have communication or interpersonal contact with an individual. 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, synchronous or asynchronous, and whether or not the communication or interpersonal contact is direct or indirect. If the answer to Question 4 is “Yes” then FSU is engaged in human research, and the FSU researchers involved in the research are required to create and submit in [RAMP IRB](#) a study for OHSP and/or IRB regulatory review. If the answer to Question 4 is “No” or if unsure, then proceed to Question 5.

6 FSU IS engaged in human research if the answer to Question 3, 4 or 5 is “Yes.” Full IRB review and approval is required. Therefore, FSU researchers involved in the research are required to create and submit in [RAMP IRB](#) an application for OHSP and IRB review, using a FSU-approved template protocol (i.e., HRP-503 or

503a). Review may include certification of FSU IRB review and approval, or depending upon study-specific circumstances, local FSU review and deferral to a non-FSU IRB for certification of review and approval.

7 Will an FSU employee be involved in **ANY** item in Table 1?

An FSU employee or agent refers to an individual who: (1) acts on behalf of the FSU; (2) exercises FSU authority or responsibility; or (3) performs FSU-designated activities. Employees and agents include faculty, staff, students, contractors, and volunteers, among others.

Answer “Yes” to this Question 5 if ANY item 1-6 in TABLE 1 applies. Under applicable law, such involvement by a FSU employee or agent makes FSU engaged in human research, and therefore requires that the FSU researchers create and submit in [RAMP IRB](#) a study for OHSP/IRB regulatory review. If the answer to Question 5 is “No” then proceed to Question 6.

8 Will FSU employees be involved **ONLY** as indicated in Table 2?

An FSU employee or agent refers to an individual who: (1) acts on behalf of the FSU; (2) exercises FSU authority or responsibility; or (3) performs FSU-designated activities. Employees and agents include faculty, staff, students, contractors, and volunteers, among others.

Answer “Yes” to this Question 6 if the ONLY involvement of FSU employees or agents is limited to one or more items 1-11 in TABLE 2. Under applicable law, when such involvement by FSU employees or agents is limited to only items 1-11 in TABLE 2, then FSU is not considered engaged in human research. See Note 9.

If the answer to this Question 6 is “No” then return to Question 5 since answering “No” to Question 6 may indicate that an FSU employee or agent may in fact be involved in an item in TABLE 1. However, if the answers to Question 6 and 5 are still both “No” then submit in [RAMP IRB](#) an application for an official regulatory determination.

9 FSU is NOT engaged in human research if the answer to Question 6 is “Yes.” Under applicable law FSU is not required to certify IRB and approval of the research; however, a formal and authoritative OHSP/IRB regulatory determination to this effect may be required. Many institutions and agencies will NOT accept a researcher’s statement that FSU is not engaged in non-exempt human research. These institutions and agencies may include federal agencies; study sponsors and funders; external institutions with which FSU employees, staff and students may collaborate or from which information about individuals may be obtained; publishers of scientific papers; and the FSU graduate school manuscript clearance office.

Therefore, before undertaking any activity that may require an official and authoritative OHSP/IRB regulatory determination, researchers should submit in [RAMP IRB](#) an application for an official regulatory determination. Applicable laws and FSU policy do not permit retroactive reviews (after or while the activity was or is being conducted), so submit the application before commencing any activities. Finally, note that some modifications to activities may change the responses to any of the Questions 1 through 6, so researchers should revisit this algorithm and begin with Question 1 again before those modifications are implemented to ensure on-going compliance with the applicable federal laws and to receive an updated regulatory determination.

TABLE 1

<p>FSU is considered in accordance with applicable laws engaged in non-exempt human research when FSU employees or agents* obtain (1) data about individuals through intervention or interaction with them, (2) identifiable private information about the individuals, or (3) the informed consent of the individuals, for ANY of the 6 following scenarios:</p>		
1.	<p>FSU receives federal support (grant, contract, or cooperative agreement) for the research, even where all activities involving the individuals (human subjects) are carried out by employees or agents of another institution.</p>	
2.	<p>FSU employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures. Some limited exceptions apply; see TABLE 2 below at items 1-3 for exception conditions.</p>	<p>Examples of interventions may include for example, (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.</p>
3.	<p>FSU employees or agents intervene for research purposes with any human subject of the research by manipulating the environment.</p>	
4.	<p>FSU employees or agents interact for research purposes with any human subject of the research.</p>	<p>An FSU employee or agent is interacting for research purposes with a human subject if the employee or agent will have any communication or interpersonal contact with a human subject to collect, use or generate any information or biospecimens about the individual (whether or not the information or biospecimen is identifiable). The terms “communication” and interpersonal contact” are very broadly construed and may be in or by any format or means, synchronous or asynchronous 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.</p>
5.	<p>FSU employees or agents obtain the informed consent of human subjects for the research.</p>	<p>An FSU employee or agent is obtaining informed consent from a human subject if the employee or agent will have any communication or interpersonal contact with an individual to solicit, explain, collect or document an individual’s consent, parental permission or assent. The terms “communication” and interpersonal contact” are very broadly construed and may be in or by any format or means, synchronous or asynchronous, 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.</p>
6.	<p>FSU employees or agents obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research. It is important to note that FSU employees or agents are considered engaged in the research even if the FSU employees or agents do not directly interact or intervene with human subjects.</p>	<p>An FSU employee or agent is obtaining identifiable information or biospecimens for research purposes when the employee or agent will collect, use or generate any information or biospecimens about an individual, AND the identity of the individual is or may be made known to you or be associated with the information or biospecimen.</p> <p>The term “information” is very broadly construed 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, file, instrument, article or artifact form.</p>

		<p>“Biospecimen” is also very broadly construed as any quantity of tissue, blood, urine, or other human-derived material; this includes subcellular structures, cells, tissue (bone, muscle, connective tissue and skin), organs, blood, gametes, embryos, fetal tissue, and waste (urine, feces, sweat, hair and nail clippings, shed epithelial cells, and placenta). “Identity” and “identifiable” refer to an individual’s name; unique identifiers or codes specific to an individual such as Social Security, employee, student, beneficiary, license, health record numbers and unique codes linked to specific persons or their identifiers; email addresses; photographs, videos and audio recordings of individuals; and biometric identifiers.</p>
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Before engaging in non-exempt human research, an institution must: (1) hold or obtain federal assurance; and (2) certify that the research has been reviewed and approved by an IRB designated in the FWA. IRBs designated under an FWA may include IRBs of other institutions or independent IRBs.

**In accordance with applicable federal laws, an institution’s employees or agents refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. “Employees and agents” can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.*

TABLE 2

<p>FSU would generally not be considered engaged in a non-exempt human research project (and would therefore not be required to certify IRB review and approval, but see note 9) when the involvement of FSU employees or agents in that project is LIMITED TO ONE OR MORE of the following or similar scenarios:</p>	
1.	<p>FSU employees or agents perform only commercial or other services for non-FSU investigators if ALL the following conditions also are met:</p> <ul style="list-style-type: none"> the FSU employees or agents' services performed do not merit professional recognition or publication privileges; the services performed are typically performed for non-research purposes; and <i>FSU employees or agents do not administer ANY study intervention being tested or evaluated under the protocol.</i>
2.	<p>FSU is not a research site, and FSU employees or agents only provide clinical trial-related medical services that are dictated by the protocol and which services would be performed as part of routine clinical monitoring and/or follow-up (e.g., medical history, physical examination, assessment of adverse events, blood test, chest X-ray, or CT scan) of subjects enrolled at a non-FSU study site, if ALL the following conditions also are met:</p> <ul style="list-style-type: none"> <i>FSU employees or agents do not administer the study interventions being tested or evaluated under the protocol; the clinical trial-related medical services are typically provided by FSU for clinical purposes; FSU employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research; and non-FSU investigators retain responsibility for overseeing protocol-related activities and ensuring appropriate arrangements are made for reporting protocol-related data, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.</i>
3.	<p>FSU is not a research site, and FSU employees or agents only administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis exception, if ALL the following conditions also are met:</p> <ul style="list-style-type: none"> a non-FSU investigator from an institution engaged in the research determines that it would be in the subject's best interest to receive the study interventions being tested or evaluated under the protocol; <i>FSU employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research; non-FSU investigators retain responsibility for: overseeing protocol-related activities; ensuring the study interventions are administered in accordance with the IRB-approved protocol; and ensuring appropriate arrangements are made for reporting protocol-related data, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol; and, an IRB designated on the engaged institution's FWA is informed that study interventions being tested or evaluated under the protocol will be administered at FSU, which the IRB is also informed is not selected as a research site.</i>
4.	<p>FSU employees or agents only inform prospective subjects about the availability of the research; provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) <i>but do not obtain subjects' consent for the research or act as representatives of the investigators; provide prospective subjects with information about contacting non-FSU investigators for information or enrollment; and/or seek or obtain the prospective subjects' permission for non-FSU investigators to contact them.</i></p>
5.	<p>FSU permits use of FSU facilities for intervention or interaction with subjects by non-FSU investigators.</p>

6.	FSU employees or agents release to non-FSU investigators identifiable private information or identifiable biological specimens pertaining to the subjects of the research. However, if FSU employees or agents obtain identifiable private information or identifiable biological specimens from a non-FSU institution, the FSU employees or agents would be engaged in human subjects research (see item 6 in TABLE 1 above).
7.	FSU employees or agents obtain coded private information or human biological specimens from a non-FSU institution involved in the research, which non-FSU institution retains a link to individually identifying information; and FSU employees or agents are unable to readily ascertain the identity of the subjects to whom the coded information or specimens pertain.
8.	FSU employees or agents access or utilize individually identifiable private information only while visiting a non-FSU institution that is engaged in the research, provided FSU employees or agents' research activities are overseen by the IRB of the institution that is engaged in the research.
9.	FSU employees or agents access or review identifiable private information for purposes of study auditing (e.g., a government agency or private company will have access to individually identifiable study data for auditing purposes).
10.	FSU employees or agents receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.
11.	FSU employees or agents author a paper, journal article, or presentation describing a human subjects research study.