Is FSU Engaged in Human Research? (OHSP, December 1, 2021)

Start here by asking—

1. Are human subjects involved?[1]

No → FSU is NOT engaged in human research.[3]

Yes → 2. Does an exemption apply to the research?[2]

Yes → Submit an application for regulatory exemption review.

No → 3. Does FSU receive federal support ($) for the research?[4]

Yes → Submit an application for regulatory exemption review.

No → 4. Will an FSU employee or agent* obtain subjects' informed consent?[5]

Yes → Submit an application for regulatory exemption review.

No → 5. Will an FSU employee or agent* be involved in ANY item in Table 1?[7]

Yes → Submit an application for regulatory exemption review.

No → 6. Will an FSU employee or agent be involved ONLY as indicated in Table 2?[8]

Yes → FSU is NOT engaged in human research.[9]

No → FSU engaged in non-exempt human research.[6] Submit an application for IRB review.

**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.*

NOTES

[1] Are human subjects involved?

Human subjects are involved in research (or "Yes") when a researcher obtains for a research purpose any information or biospecimens about a living individual through intervention or interaction with the individual OR obtains these individuals' identifiable private information or identifiable biospecimens. This may be referred to as "human research." Refer to the pertinent federal legal definitions at Title 45 of the U.S. Code of Federal regulations, Part 46 (45 CFR 46, or analogous regulations of other federal agencies that have adopted the federal policy, which are referred to as the Federal Policy for the Protection of Human Subjects). 45 CFR 46 is available here (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/revised-common-rule-regulatory-text/index.html) or at this U.S. Code of Federal Regulations location. If the answer to Question 1 is "Yes" then proceed to Question 2. If the answer to Question 1 is "No" then FSU is not engaged in human research; see footnote 3. If unsure, then before undertaking a study FSU researchers should create and submit in RAMP IRB a study for OHSP and/or IRB regulatory review for a formal and authoritative determination.

[2] Does an exemption apply to the research?

An exemption may, based upon the OHSP's pre-review, apply to proposed research (or "Yes"), and thus not require further IRB review, only if the proposed research falls into one of eight exemption categories established under federal law. Refer to the pertinent federal exemption categories at 45 CFR 46, available here (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/revised-common-rule-regulatory-text/index.html) or at this U.S. Code of Federal Regulations location. For ease of reference, 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" then proceed to Question 3. If the answer to Question 2 is "Yes" or unsure, then before undertaking a study FSU researchers should create and submit in RAMP IRB an application for a regulatory exemption review for a formal and authoritative determination; in many cases and based upon regulatory exemption review, researchers will be notified that further IRB review is not required.

[3] FSU is NOT engaged in human research if the answer to Question 1 is "No". If FSU is not engaged in human research, then in accordance with applicable federal laws FSU is not required to certify IRB approval of the research. However, if other FSU policy (e.g., graduate office or publication clearance) nonetheless require documentation of IRB review, then before undertaking a study FSU researchers should submit in RAMP IRB an application for a regulatory review for a formal and authoritative determination for the record. Also note that some research modifications 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.

[4] Does FSU receive federal support for the research?

FSU receives federal support for the proposed research (or "Yes") if FSU receives a grant, contract, or cooperative agreement directly from a federal agency (e.g., National Science Foundation; Departments of Defense, Education or Transportation; or a U.S. Public Health Service entity such as the National Institutes of Health, Centers for Disease Control and Prevention, Substance Abuse and Mental Health Services Administration, or the Health Resources and Services Administration), even where all human research activities will be carried out 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 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 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.

Keep in mind that many FSU research projects begin before receipt of federal support; receipt of federal support for FSU research after the research project has started and for which project FSU may have been deemed not engaged in human subject will mean that FSU is engaged in human research. If so, then FSU researchers involved in the research are required to create and submit in RAMP IRB a study modification for OHSP and/or IRB review.

5 Will an FSU employee obtain subjects' informed consent?

Answer "Yes" to this Question 4 if an FSU employee or agent will in any way interact with individuals to obtain their informed consent (including parental permission and/or child assent). Interaction includes any communication or interpersonal contact with prospective or current human subjects. 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." Therefore, FSU researchers involved in the research are required to create and submit in RAMP IRB a study for OHSP and IRB regulatory review, which 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? Answer "Yes" to this Question 5 if any item 2-6 in TABLE 1 applies; if so 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 5 is "No" then proceed to Question 6.

8 Will FSU employees be involved ONLY as indicated in Table 2? Answer "Yes" to this Question 6 if the involvement of FSU employees or agents in the project is limited to ONLY one or more items 1-11 in TABLE 2. If so, then FSU is not engaged in human research, and in accordance with applicable federal laws FSU is not required to certify IRB and approval of the research; see footnote 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.

9 FSU is NOT engaged in human research. FSU is NOT engaged in human research if the answer to Question 6 is "Yes." If FSU is not engaged in human research, then in accordance with applicable federal laws FSU is not required to certify IRB and approval of the research. As earlier noted, some research modifications may change the responses to Questions 5 and 6, so researchers should revisit this algorithm and begin with Question 1 again, paying particular attention to Questions 5 and 6, before those modifications are implemented to ensure on-going compliance with the applicable federal laws.

TABLE 1

<table>
<tr><td colspan="3">FSU is considered in accordance with applicable laws engaged in non-exempt human research when FSU employees or agents* for the purposes of the research obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

FSU is considered engaged in a non-exempt human research project (and is therefore required to have a federal assurance and to certify IRB review and approval) when the involvement of FSU or its employees or agents in that project includes ANY of the 6 following scenarios:</td></tr>
<tr><td>1.</td><td colspan="2">FSU receives federal support (grant, contract, or cooperative agreement) for the non-exempt human research project, even where all activities involving human subjects are carried out by employees or agents of another institution.</td></tr>
<tr><td>2.</td><td>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.</td><td rowspan="2">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.</td></tr>
<tr><td>3.</td><td>FSU employees or agents intervene for research purposes with any human subject of the research by manipulating the environment.</td></tr>
<tr><td>4.</td><td>FSU employees or agents interact for research purposes with any human subject of the research.</td><td>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.</td></tr>
<tr><td>5.</td><td>FSU employees or agents obtain the informed consent of human subjects for the research.</td><td>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.</td></tr>
<tr><td>6.</td><td>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</td><td>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.</td></tr>
</table>

	research even if the FSU employees or agents do not directly interact or intervene with human subjects.	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. "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.
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

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) when the involvement of FSU employees or agents in that project is **LIMITED TO ONE OR MORE** of the following or similar scenarios:	
1.	FSU employees or agents perform only commercial or other services for non-FSU investigators if ALL the following conditions also are met: • 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 *FSU employees or agents do not administer ANY study intervention being tested or evaluated under the protocol*.
2.	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 are 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: • *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.
3.	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: • 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; *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.
4.	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) *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.
5.	FSU permits use of FSU facilities for intervention or interaction with subjects by non-FSU investigators.

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.