

Student-led Research: Human Research Review Guidance

FSU Office for Human Subjects Protection (February 1, 2021)

INTRODUCTION

This guidance is intended to clarify when student-led research must be reviewed by the FSU Office for Human Subjects Protection (OHSP) and/or Institutional Review Board (IRB).

STUDENT-LED RESEARCH

All FSU students (undergraduate, graduate or post-graduate) that plan to lead and conduct activities that are defined as human subjects research¹ must obtain OHSP or IRB review and approval or exemption BEFORE the activities may begin. Review is required by federal law and applicable FSU policy. Approval cannot by law be granted retroactively. Student-led research is subject to the same policies and procedures that apply to faculty and staff research. Figure 1 below depicts the key decision points and outcomes that apply for determining what if any OHSP and/or IRB review will be required of student-led research.

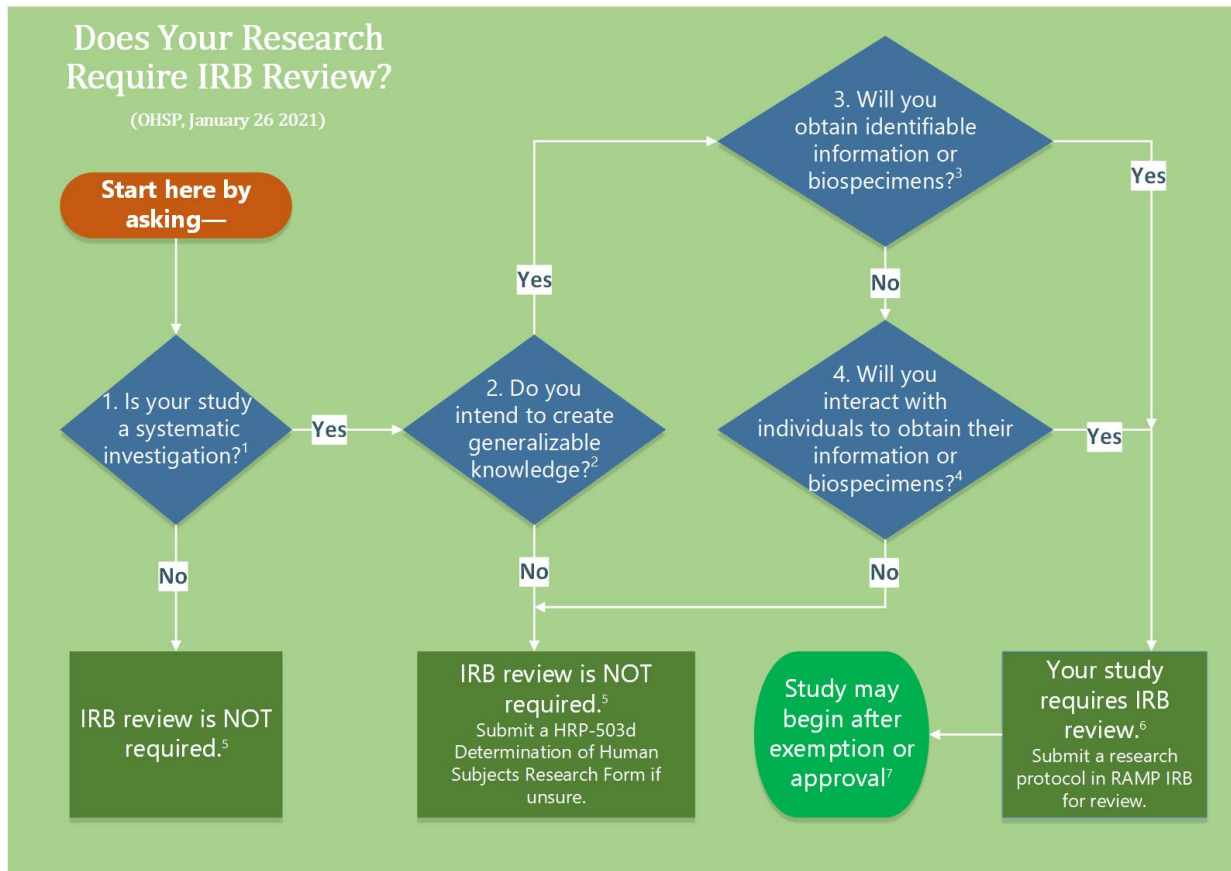


Figure 1. Does Your Research Require IRB Review?

¹ For definitions and explanations of the terms *Research* and *Human Subjects*, refer to this [OHSP web page](#). These definitions explanations are based upon the [applicable law](#) on the protection of human subjects.

Click on Figure 1 or [here](#) to access the algorithm together with the explanatory footnotes.

CLASS PROJECTS

Some student projects in research methodology classes are designed to teach students skills and provide opportunities to practice methods such as observation, interview, or survey techniques, data analysis; these may have a research component. These and other projects intended exclusively for instructional purposes and not intended to develop or contribute to general knowledge may not require further OHSP or IRB review and approval. If unsure, follow the below instructions (Submitting Research for Review) for submitting, within [RAMP IRB](#), a Determination of Human Subjects Research form.

When such projects **are** intended to develop or contribute to generalizable knowledge, they are subject to federal law and require OHSP and/or IRB review and approval, *prior to the initiation of any research activities*, including recruiting or contacting individuals as prospective study subjects or trying to obtain individuals' information (e.g., secondary use of previously collected data).

SUBMITTING RESEARCH FOR REVIEW

To initiate an OHSP or IRB review and regulatory determination, students must submit their proposed research using the FSU online Research Administration Management Portal IRB ([RAMP IRB](#)). A student's faculty advisor review (see below instructions, Faculty Advisor Requirements) as well as OHSP/IRB review and final approval should take place during the proposal stage of the activity, thesis or dissertation, *before initiating any research activities, including recruiting or contacting individuals as prospective study subjects or trying to obtain individuals' information (e.g., secondary use of previously collected data)*.

Students who are unsure about whether their activity is human subjects research, if any further OHSP or IRB review or approval is required, or whether to prepare and upload a full research protocol within RAMP IRB, may as a preliminary step submit to OHSP (also using [RAMP IRB](#)) a Determination of Human Subjects Research form (HRP-503d - Template Determination Form), available [here](#) or in [RAMP IRB](#), under the IRB, Library and Templates tabs. Follow all instructions therein, including providing any required attachments.² Students will be informed what if any additional forms or information are required, or informed that no further OHSP or IRB review is required such that their activity may commence.

RESEARCHER'S RESPONSIBILITIES

All student researchers conducting human research are responsible for adhering to the FSU policy for human research protection, 7-IRB-0 (Human Research Protection Program), the requirements described in the FSU Investigator Manual, applicable law, the decisions of the IRB, OHSP determinations, and the Institutional Official. Refer to the [References](#) below for additional information about these requirements.

FACULTY ADVISOR REQUIREMENTS

² To contact the OHSP with your questions, refer to the Contact Us section on our main [OHSP web page](#) or at <https://www.research.fsu.edu/research-offices/ohsp/>. OHSP support and workload is distributed based upon a researcher's last name, so click on the [View Staff Listing link](#) and refer to the IRB Administrator Assignments table at the bottom of that page to see which IRB Administrator you should directly contact. Keep in mind that e-mail communication is always best so that we have a record of your contact or question. If you already have a study submitted in RAMP IRB, use the Add Comment feature to directly contact the OHSP IRB Coordinator for your study.

A faculty advisor is required for all student-led research. The faculty must use [RAMP IRB](#) to perform and document their review and approval of student-led research for which the faculty is designated as the student's faculty advisor. Approval is required before the research may be submitted to the OHSP/IRB for further review.

As part of faculty review, a faculty advisor may be expected to:

- Meet with the student as may be needed to monitor the study progress.
- Agree to be available to assist the student in solving problems should these arise during the study.
- Advise or refer the student to obtain advice on the student's human subjects protection-related responsibilities.
- Arrange for an alternate faculty advisor to assume responsibility during periods of the faculty's absence (e.g., sabbatical, vacation, or separation from FSU), and advise the student to promptly notify OHSP of such changing arrangements.

REVIEW PROCESS

For purposes of review applied to human research, federal law provides 3 distinct review pathways according to the level of risks. Proposed student-led research is gaged to decide the scope or type of review that will be applied; thus, students' study submissions must be complete and accurate to minimize delay in and unnecessary reviews. Figure 2 below depicts the select key decision points in the FSU human research review process at FSU.

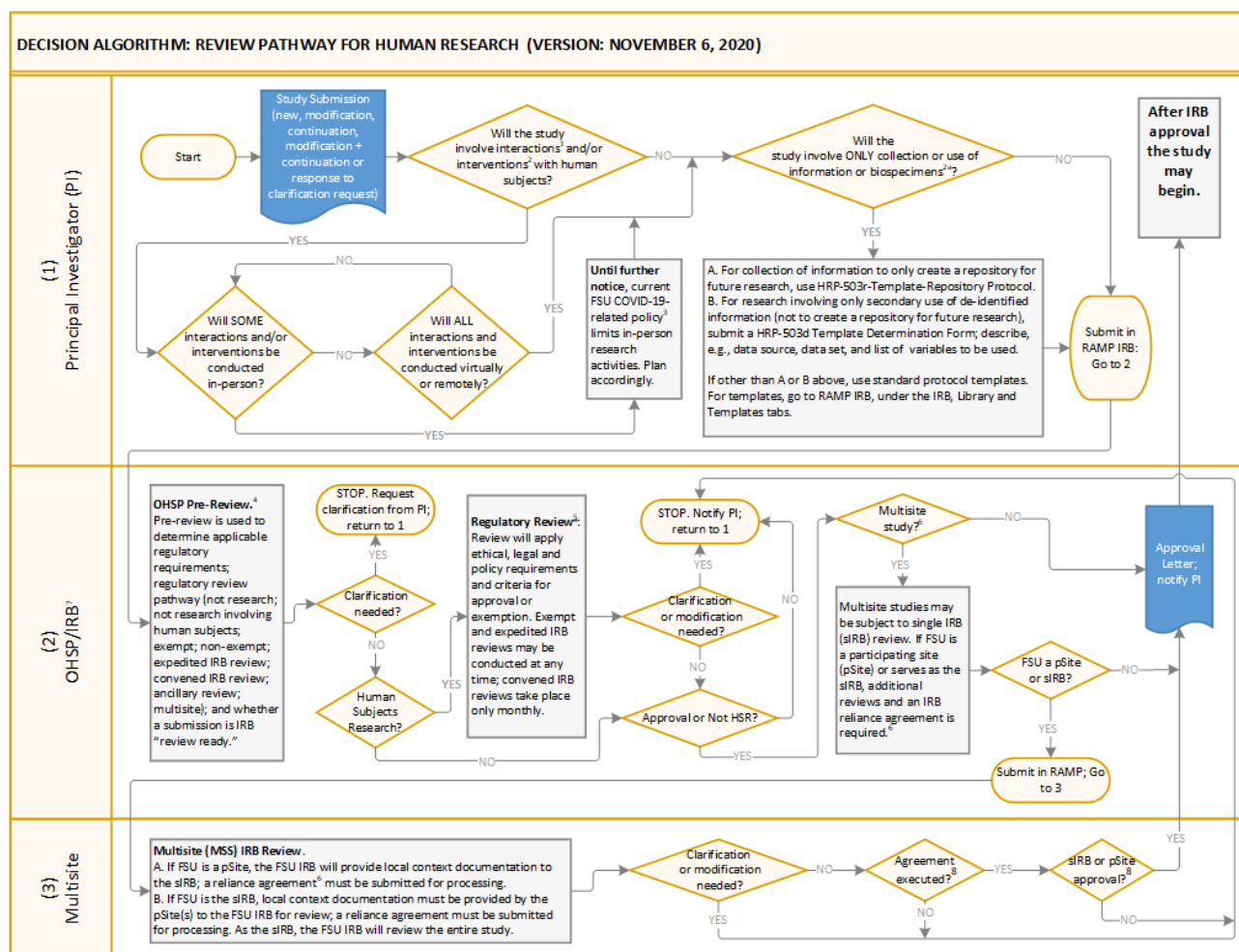


Figure 2. Review Pathway for Human Research

Click on Figure 2 or [here](#) to access a larger version of the algorithm together with the explanatory footnotes (clicking on the figure or link connects to a secure FSU location).

CITI TRAINING REQUIREMENTS

Students are required to complete an online human subjects protection training/education course (CITI's "FSU Faculty, Staff, and Student" Social/Behavioral or Biomedical/Clinical courses) as a prerequisite for OHSP or IRB approval of any research involving human subjects, including for research that may be exempt from further IRB review. This requirement applies to all members of the study team. This CITI human subjects protection training course must be completed before the OHSP/IRB will review or approve of the study.

Be sure to take the correct training course; FSU offers many different research-related courses, such as Responsible Conduct of Research (RCR) or conflicts of interest training. However, these other courses do not suffice to meet the requirement for human subjects protection training and education.

Additional information, step-by-step instructions and links for the CITI human subjects protection training requirement are available on the [CITI Training Requirements page](#) of the OHSP website.

REFERENCES

Below are listed select key references and additional resources specific to human subjects protection requirements. In the interest of brevity, not all are listed here. Carefully read through these references, then [contact us](#) if you have any questions.

1. Federal Policy for the Protection of Human Subjects (also known as the "Common Rule" as a multitude of federal agencies have adopted this policy). The Common Rule requires that FSU comply with human research protection requirements, such as OHSP and IRB review of human research. FSU has an executed agreement, known as a Federalwide Assurance, under which FSU agrees to adhere to the Common Rule and other applicable laws, including international, federal, state, and local laws and policies. Much more about the Common Rule is accessible [here](#) or at: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>.
2. FSU Human Research Protection Program Plan (FSU Policy 7-IRB-0). 7-IRB-0 is FSU's official policy for compliance with ethical and legal requirements applicable to human research. 7-IRB-0 is accessible [here](#), at: <https://regulations.fsu.edu/policies/vice-president-research> or may be found at the OHSP [Policies and Procedures](#) web page.
3. FSU Investigator Manual (HRP-103). The Investigator Manual is intended to provide researchers with comprehensive guidance about FSU's policies and procedures related to human research. FSU policy 7-IRB-0 requires that researchers adhere to the requirements described in this manual. The Investigator Manual is accessible in RAMP IRB, under the Library and General tabs (look for HRP-103 – Investigator Manual), or may be found at the OHSP [Policies and Procedures](#) web page (scroll down under Investigator Procedures).

CONTACT US

To contact the OHSP with your general or specific questions, refer to the Contact Us section on our main [OHSP web page](#) or at <https://www.research.fsu.edu/research-offices/ohsp/>. The main

email is humansubjects@fsu.edu. Keep in mind that e-mail communication is always best so that we have a record of your contact or question, and so that your inquiry is readily forwarded to the person best suited to respond. The main telephone number is 850-644-7900; leave a detailed message. Messages may also be forwarded as needed.

For specific questions: OHSP support and workload is distributed based upon a researcher's last name, so click on the [View Staff Listing link](#) and refer to the IRB Administrator Assignments table at the bottom of that page to see which IRB Administrator you should directly contact. If you already have a study submitted in RAMP IRB, use the Add Comment feature in your study's workspace to directly contact the OHSP IRB Coordinator for your study; using the Add Comment features helps to ensure that any of your inquiries are linked to an existing submission, which will facilitate a response.