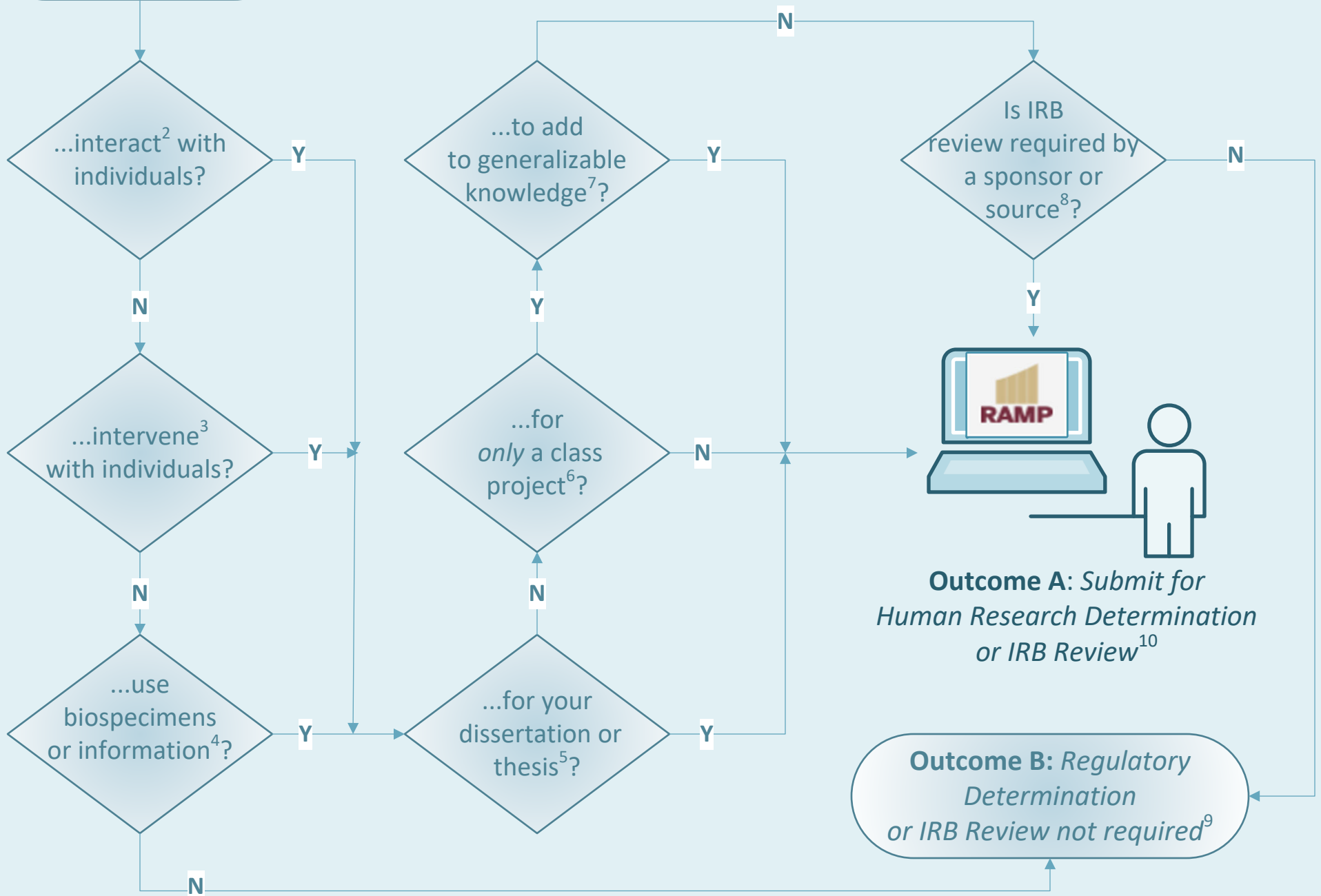


Start here and ask—
Will you...

Does Your Student-led Activity Require FSU IRB Review?¹

(OHSP, June 17, 2022)



NOTES

¹ The objective of this algorithm is only to illustrate when a student must, for their student-led activity, submit an application to the FSU Office for Human Subjects Protection (OHSP) or FSU Institutional Review Board (IRB) for regulatory review as required by applicable federal law and FSU policy. Student-led activities may be subject to requirements that are in addition to those for non-student FSU studies. Not all decision points and outcomes that pertain to student-led research are included in this algorithm.

Students who are involved as team members in studies that are led by *other* non-student FSU researchers are generally not considered as conducting student-led activities. These students are typically listed as study team members on those studies, and this algorithm would therefore not apply to such students. See however Note 9 for students conducting activities for dissertation, theses or other graduation purposes.

Important Note: Federal laws and FSU policies do not permit retroactive (after activities have started) regulatory review. This applies to either Outcome A or B in this algorithm. Therefore, consider the questions very carefully. For Outcome B, failure to submit for a formal regulatory review due to misinterpretation, error or mistake when an application should have been submitted may result in non-compliance with applicable federal law and FSU policies. Neither students nor their faculty advisors are authorized to render regulatory determinations about whether an activity constitutes human research or requires OHSP or IRB review.

² You will *interact* with an individual if, as part of your activity, you will have any communication or interpersonal contact with the individual (e.g., an acquaintance, stranger, colleague, co-worker, friend, relation or any other person, whether or not another student) to obtain *information*^{2a} or *biospecimens*^{2b} from the individual; the terms “communication” and interpersonal contact” are broadly construed and may be in any format or by any means (e.g., written, verbal, electronic, in person or face-to-face, telephone, online or virtual, and whether or not the communication or interpersonal contact is direct or indirect). Types of communication or interpersonal contact may include observations, interviews, focus groups, surveys, discussions, presentations, meetings or other exchanges or interactions with individuals.

^{2a}The term *information* is also broadly construed, and may include for example any record, file, response, image, text, data or video/audio recording in any form or format, whether electronic, verbal, non-verbal or written.

^{2b}*Biospecimens* refer to any quantity of tissue, blood, urine, or other human-derived material; 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.

³ You will *intervene* with an individual if, as part of your activity, you will or will cause any other person to perform, conduct or take any action to initiate, alter, effect, modify or stop a process or outcome involving the individual, including to obtain *information* or *biospecimens* from the individual. Examples may include (a) actions and activities such as exercises, body movements, stress tests and human factor measures; (b) medical, psychological and behavioral examinations or procedures, use of and/or tests involving medicinal or nutritional supplements, and implantation or application of medical devices or other sensors; (c) collection

of biospecimens^{2b}; and (d) manipulations of individuals or their environments such as watching a video, altering or testing a lived, learning or occupational environment, completing computer tasks, and undergoing training. See Note 2 second paragraph for meanings for the terms *information* or *biospecimens*.

⁴ You will use *biospecimens* or *information* if you will acquire, obtain, collect, generate, study, analyze or share information or biospecimens about an individual as part of your activity, whether or not you will interact or intervene with the individual about whom the information or biospecimen pertains. Examples may include obtaining information or biospecimens that was previously collected for a wide range of purposes, including information or biospecimens previously collected by the following:

- Federal or state government agencies, programs or services (e.g., Medicaid, Medicare, Veterans Administration, licensing, vital records);
- Health care or services providers such as hospitals and clinics (e.g., inpatient hospitalization, outpatient or ambulatory care visits, surgical or dental procedures, laboratory testing);
- Educational institutions (e.g., admissions, testing or grades, graduation, coursework);
- Employers (e.g., hiring, discharge, promotions);
- Law enforcement (e.g., arrests, charges, tickets, imprisonment); and,
- Many other public, private, non-profit and commercial organizations that collect or use individuals' information to provide individuals with services or conduct business.

See Note 2 second paragraph for meanings for the terms *information* or *biospecimens*.

⁵ If your activity will be undertaken for purposes of your FSU dissertation, theses and/or graduation, respond "Y" (for "yes"). FSU graduate school requirements include the condition that students obtain and submit to the graduate office official documentation of advance FSU OHSP/IRB approval or clearance for any activities that involve interactions or interventions with individuals or the use of individuals' information or biospecimens undertaken for dissertation, theses and related graduation purposes. Remember that that OHSP/IRB approval or clearance is not granted retroactively (i.e., after or while you are conducting your study), so plan accordingly and well in advance.

⁶ Activities that will be undertaken for only a class project are activities that are intended solely to teach students research-related skills and provide opportunities for students to practice research methods such as design, sampling, literature searches, observation, interview, survey techniques, and data analyses; in these cases, respond "Y" (for "yes"). However, in cases where student-led activities are also intended to develop or contribute to generalizable knowledge⁷ about an issue, matter, field or practice, then respond "N" (for "no") to this question.

⁷ Your activity will develop or contribute to generalizable knowledge if the design or purpose of your activity will be to draw conclusions that have some general applicability, inform policy or practice, or apply or extrapolate your activity's findings to persons, programs or institutions beyond those involved your activity. An activity whose findings or outcomes will be disseminated, such as through publication or presentation, may be considered to develop or contribute to generalizable knowledge, but dissemination alone is not dispositive. Note that many journals and conference organizers may require that official documentation of FSU OHSP/IRB approval or clearance be provided with any submitted manuscripts or abstracts; if so, respond "Y" (for "yes").

8 Organizations, institutions or agencies that fund research (e.g., independent foundations, government grant agencies such as the National Institutes of Health or the National Science Foundation), that provide access to study participants (schools or local or other health care providers such as TMH), or that make available information for secondary research purposes (e.g., Florida state agencies) may require official documentation of FSU OHSP/IRB approval or clearance as a condition of funding, access to study participants or for providing information about individuals. Additionally, studies involving non-FSU sites, institutions or agencies, such as TMH, CRMC, FAMU, state agencies and other organizations, may require those sites' own IRB, research review or other approvals. Go to our non-FSU IRB review page to learn more [\[link\]](#). Also, collaborations involving TMH or other external partners may be subject to specific or other requirements; visit the FSU Office for Clinical Research Advancement (OCRA) for further information [OCRA [link](#)]. Respond “Y” (for “yes”) if these organizations, institutions or agencies require FSU IRB review.

9 As you may see from using this algorithm, many student-led activities may not require a OHSP regulatory determination or IRB review in the following circumstances: (a) there is no interaction² or intervention³ involving individuals; (b) there is no use of human biospecimens or information⁴; (c) there is interaction or intervention involving individuals or use of human biospecimens or information BUT the activity is intended solely to teach students research-related skills and provide opportunities to practice research methods⁶; (d) the activity will not develop or contribute to generalizable knowledge⁷; and (e) an OHSP regulatory determination or IRB review is not otherwise required. If in doubt or instructed otherwise however, submit in [RAMP IRB](#) a HRP-503d Determination of Human Subjects Research Form; the OHSP will advise you by formal letter whether IRB review is or is not required. *Only the OHSP/IRB—and not students, their faculty advisors, other FSU officials or department chairs or Deans, or external agencies and institutions—are authorized to render official FSU human research regulatory determinations in accordance with applicable federal law and FSU policy.*

10 Based upon this algorithm, your activity WILL require that you prepare and apply for human research regulatory review and approval/clearance in FSU’s Research Administration and Management System (RAMP) Institutional Review Board (IRB) electronic protocol management system (RAMP IRB) (see **Exception** below). You may access RAMP IRB at <https://myramp.research.fsu.edu/>. Under the IRB tab, click “Create a New Study” to complete the RAMP IRB application, answering all questions and uploading required study-related materials (e.g., study protocol or plan, instruments or measures, recruitment and consent materials) as well as completing related [CAMS/COI](#) disclosures and [CITI human subjects training](#) requirements). To access related guidance, FAQs and other information, visit our [Student-led Research](#) page.

Limited exception: Some FSU students or affiliated College of Medicine (COM) students that work at a non-FSU institution, and who—for the specific activity to which this algorithm is being applied—will only work under the direct supervision of a non-FSU Principal Investigator in a non-FSU human research activity for which submission for a student-led human research determination or IRB review might otherwise be required, need not submit for a FSU human research determination or IRB review (unless required as described in Note 5—dissertation, theses and graduation purposes). These students should be listed as study team members on those non-FSU studies.

(Revised June 17, 2022)