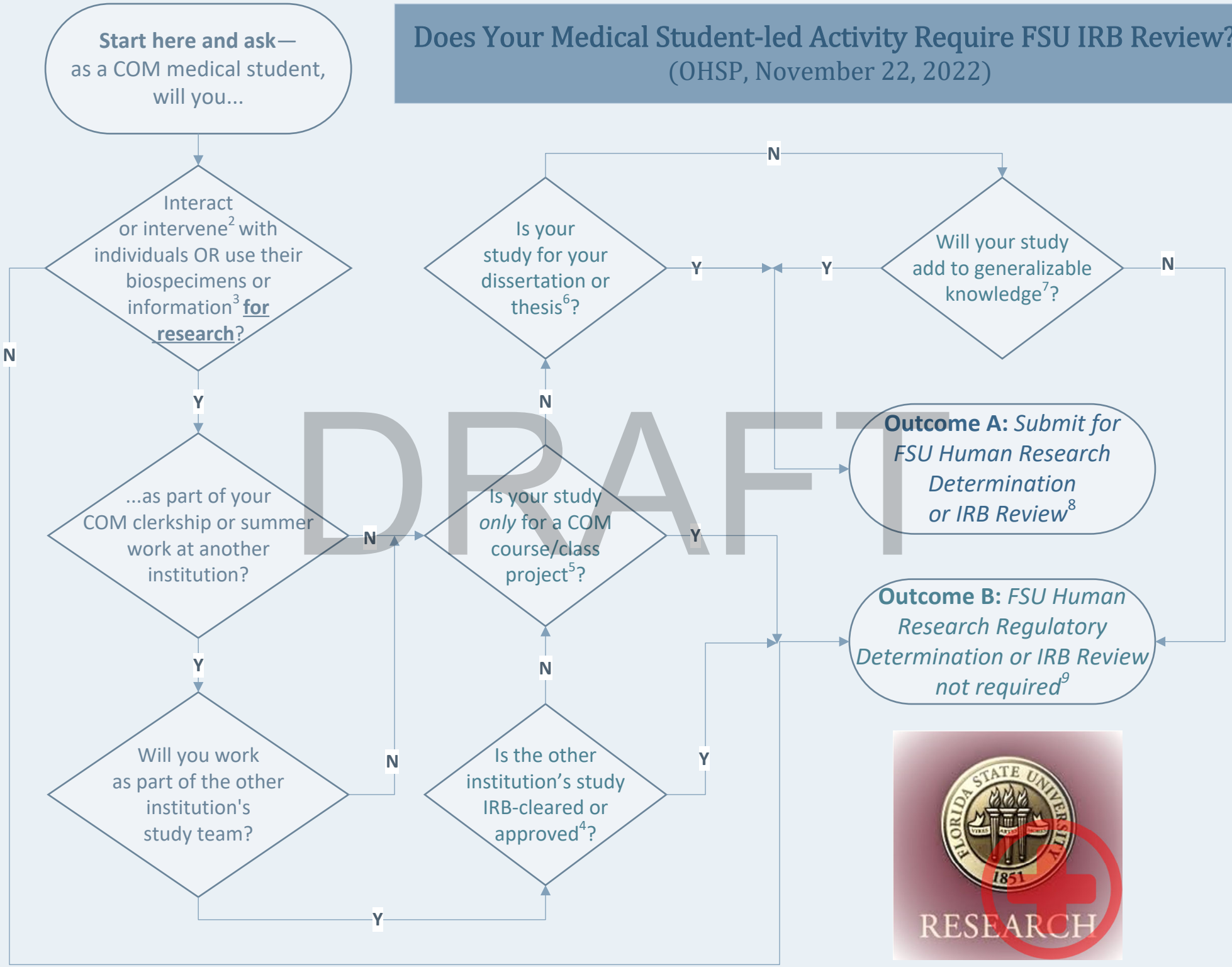
Does Your Medical Student-led Activity Require FSU IRB Review?[1]

(OHSP, November 22, 2022)



NOTES (revised November 22, 2022)

1 This algorithm illustrates when a FSU College of Medicine (COM) student, for their student-led activity, may be required to submit application to the FSU Office for Human Subjects Protection (OHSP) or FSU Institutional Review Board (IRB) for regulatory review. COM student-led activities may be subject to requirements that are in addition to those for non-student FSU studies. The algorithm depicts key decision points and outcomes; other requirements may apply in specific circumstances.

COM Students who are involved as team members in studies that are led by *other* non-student FSU or non-FSU researchers are generally not considered as conducting student-led activities. These students should be listed as study team members on those studies, and this algorithm would therefore not apply to such students. See however Note 6 for COM 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 A, 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 COM students nor their faculty advisors are authorized to render official human research regulatory determinations.

2 *Interact* means any communication or interpersonal contact with an individual (e.g., patient, caregiver, clinician etc.) to obtain *information*[2a] or *biospecimens*[2b] from the individual for a *research*[2c] purpose; "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). Common types of communication or interpersonal contact may include for example patient observations, clinical interviews, risk screening and health assessments.

[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, regardless of whether health-related or otherwise.

[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.

[2c]*Research* is construed as a systematic investigation that is designed to develop or contribute to generalizable knowledge. A systematic investigation generally involves a plan (e.g., formal study protocol) 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. Generalizable knowledge is commonly interpreted as drawing conclusions that have some general applicability, informing policy or practice, or applying or extrapolating your activity's findings to persons, programs or institutions beyond those involved your activity.

You will i*ntervene* 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 Notes 2a and 2b for meanings for the terms *information* or *biospecimens*.

3 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 to acquire their information or biospecimens. Examples may include obtaining information or biospecimens that was previously collected for a wide range of purposes, including information or biospecimens previously collected by other institutions or organizations such as for example hospitals or other health care or service providers; government agencies; educational institutions or programs; and employers.

4 A non-FSU (e.g., Orlando Regional Medical Center, Sarasota Memorial Health Care System, Tallahassee Memorial HealthCare) study with which you may—for purposes of your COM clerkship or summer work—be involved as a study team member and which study is under the direction of a non-FSU Principal Investigator (PI) or clinician, is generally subject to the non-FSU institution IRB's requirement for clearance or approval. In some cases (e.g., the PI serves as FSU clerkship faculty), these non-FSU studies may have been approved by the FSU IRB. In either case, you must be listed as a study team member for the study and the IRB must have approved of your involvement in the study. If you have authoritative documentation or official communication indicating that the IRB has granted clearance or approval of the study or will other exercise review jurisdiction over the study—*including your involvement as a member of the study team*—then answer "Y" (for "Yes") to this question. If no such IRB clearance, approval or jurisdiction is in place, answer "No" to this question.

Note that many organizations, institutions or agencies that fund research or that provide access to study participants for recruitment or their data may require official documentation of FSU OHSP/IRB approval or clearance. Also, studies involving non-FSU institutions or agencies, such as TMH, CRMC, FAMU, state agencies and other organizations, may require their own IRB approval or clearance. 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].

5 Activities that will be undertaken for only a COM course or class project include activities that are intended solely to teach students clinical or medical research-related skills or provide opportunities for students to practice research methods such as design, sampling, case reports, literature searches, clinical observation, patient interview, health-related procedures or techniques, and health record or 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 knowledge[7] about an issue, matter, field or practice, then respond "N" (for "No") to this question.

6 If your activity will be undertaken for purposes of your FSU dissertation, theses and/or other formal graduation requirement, respond "Y" (for "Yes"). The FSU Graduate School or other Colleges or departments may require that students obtain and submit to official documentation of advance FSU OHSP/IRB approval or

clearance for any activities that involve research. 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.

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, although dissemination alone is not dispositive.

8 Based upon this algorithm, your activity WILL require that you prepare a submission and apply for human research regulatory or IRB review and approval/clearance in FSU's Research Administration and Management System (RAMP) IRB system [RAMP link]. RAMP IRB is a web-based system that includes use of SmartForms, with instructions, directions and Help? Buttons for you to follow for submitting study-related information and materials. To begin preparing your submission, log into RAMP IRB; under the IRB tab, start by clicking "Create a New Study". For step-by-step instructions, refer to the Researcher's Guide to RAMP IRB, or to the OHSP Researchers Training slides available in RAMP IRB Help Center.

Common materials that must be provided with a RAMP IRB submission include, for example, the study protocol; actual measures and instruments and anything that human subjects will be asked to read, complete, watch or use; recruitment fliers and messages; consent forms; and outside approvals. Many templates are available in RAMP IRB under the IRB, Library and Templates tabs, including for protocols and consent-related forms. Save time and effort: submissions that do not use or follow the templates will be returned for correction. Other materials may also be required depending upon study parameters and activities. Note that all FSU researchers must complete related CAMS/COI (conflicts of interest) disclosures and complete the CITI human subjects training. To access related guidance, FAQs and other information, visit our Student-led Research page.

If you (a) only plan to perform chart reviews or secondary research using previously collected information or biospecimens, conduct quality improvement or program evaluation activities, or conduct surveys or (b) need to know whether a complete study protocol or full IRB review is required, **then before your research is undertaken**, create a submission in RAMP IRB and complete and submit our HRP-503d determination form (in lieu of a study protocol) and any attachments (variables list from prior studies data) to request review; the HRP-503d Template Determination form is accessible by logging into **RAMP IRB**, and navigating to the IRB, Library and Templates tabs.

9 As you may see from using this algorithm, many COM medical student-led activities may not require a OHSP regulatory determination or IRB review in the following circumstances: (a) there is no interaction or intervention involving individuals and there is no use of human biospecimens or information; (b) there is interaction or intervention involving individuals or use of human biospecimens or information BUT the activity is intended solely to teach students clinical or medical research-related skills and provide opportunities to practice research methods; or (c) the activity will not develop or contribute to generalizable knowledge. 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.*