Will the study involve interactions¹ and/or interventions² with human subjects? NO → NO → STOP. Request clarification from PI; return to 1

Will any interactions and/or interventions be in-person? YES → NO → NO → NO → STOP. Request clarification from PI; return to 1

Will all interactions and interventions only be conducted virtually (e.g., Web platform or telephone)? YES → NO → NO → NO → STOP. Request clarification from PI; return to 1

Will the study involve only the use of information or biospecimens²? NO → NO → STOP. Notify PI; return to 1

IMPORTANT NOTES: PLEASE READ CAREFULLY³
1. FSU policy does not permit involvement as human subjects in research of persons who are deemed at high risk of severe illness from COVID-19, or persons aged 65 or more years. Plan accordingly.
2. FSU policy requires social distancing and risk mitigation for all in-person interactions and interventions; some limited exceptions for interventions may be permitted but only with FSU OVPR approval. Plan accordingly.

Stop. Request clarification from PI; return to 1

Required social distancing and risk mitigation included? NO → NO → STOP. Notify PI; return to 1

Approval? NO → YES → Approval Letter; notify PI

YES or N/A → YES or N/A → NO → NO → Submit ancillary review request: Go to 3

IMPORTANT NOTE: Studies that do not include required social distancing and risk mitigation require ancillary (second-level) review by OVPR.

Submit study or modification in RAMP IRB: Go to 2

After IRB approval the study may begin.

Start

New Study or Modification to Existing FSU IRB-approved Study, or Clarification to a Submission

OHSP Pre-Review:⁴ Pre-Review will also include review for required social distancing and risk mitigation. Submissions may be returned if study activities involve any persons who are deemed at high risk of severe illness from COVID-19 and persons aged 65 or more years.

OHSP/IRB:⁵ OHSP/IRB Pre-Review will also include review for required social distancing and risk mitigation. Submissions may be returned if study activities involve any persons who are deemed at high risk of severe illness from COVID-19 and persons aged 65 or more years.

Stop. Request clarification from PI; return to 1

Clarification needed from PI? NO → NO → Required social distancing and risk mitigation included? NO → NO → Submit ancillary review request: Go to 3

Yes → YES → Approval Letter; notify PI

STOP. Notify PI; return to 1

Clarification needed from PI? NO → NO → Required social distancing and risk mitigation included? NO → NO → Submit ancillary review request: Go to 3

Yes → YES → Approval Letter; notify PI

Required social distancing and risk mitigation included? NO → NO → Submit ancillary review request: Go to 3

Yes → YES → Approval Letter; notify PI

YES or N/A → YES or N/A → NO → NO → Submit ancillary review request: Go to 3

IMPORTANT NOTE: Studies that do not include required social distancing and risk mitigation require ancillary (second-level) review by OVPR.

Submit ancillary review request: Go to 3

Approval Letter; notify PI

YES or N/A → YES or N/A → NO → NO → Submit ancillary review request: Go to 3

IMPORTANT NOTE: Studies that do not include required social distancing and risk mitigation require ancillary (second-level) review by OVPR.

Submit ancillary review request: Go to 3

Approval Letter; notify PI

KEY:
- FSU policy does not permit involvement as human subjects in research of persons who are deemed at high risk of severe illness from COVID-19, or persons aged 65 or more years. Plan accordingly.
- FSU policy requires social distancing and risk mitigation for all in-person interactions and interventions; some limited exceptions for interventions may be permitted but only with FSU OVPR approval. Plan accordingly.
- Studies that do not include required social distancing and risk mitigation require ancillary (second-level) review by OVPR.

NOTE: This diagram is a visual representation of the review process during the COVID-19 national emergency. It is not a replaceable IRB form. Refer to the IRB forms and policies for detailed compliance instructions.
1*Interactions* include communications or interpersonal contacts between an investigator (researcher) and a human subject. Examples of interactions include, for example, interviews, focus groups, surveys or similar interpersonal contacts and communications with human subjects. Interactions may involve the collection and use of information for research purposes. Studies may include both interactions and *interventions* (see interventions description below).

2*Interventions* include both physical procedures by which information or biospecimens are gathered from human subjects, and manipulations of human subjects’ environment. Examples of interventions 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) taking biological specimens such as blood, sputum and any other body tissue or fluids; and (d) manipulating human subjects or their environments such as having human subjects watch a video, look at images, read materials or take notes, alter or test a human subject’s lived, learning or occupational environment, complete computer tasks, and undergo training. Interventions will generally involve interactions with human subjects (see interactions description above).

2aSome studies involve only the collection of information or biospecimens OR only the use of information or biospecimens that may have been collected by others (e.g., secondary use by researchers of information or biospecimens that was collected by others). This is an important distinction for IRB review purposes.

3FSU policy limiting or restricting interactions and interventions with human subjects can be found on the FSU Office for Human Subjects Protection (OHSP) COVID-19-related web page. This policy was formally approved in the FSU Fall 2020 Plan (refer to page 20) by the Florida Board of Governors of the State University System of Florida. The OHSP COVID-19-related web page and the FSU Fall 2020 are accessible at https://www.research.fsu.edu/research-offices/ohsp/covid-19-and-human-research-studies/.

4Pre-Review is a formal OHSP process intended to ascertain and document that an IRB submission is “review ready” (determine that all required study materials have been submitted; notify investigators to submit or provide clarification for any missing or incomplete materials; seek clarification from investigators regarding any issues with the submission that might pose a challenge for the review itself). A study will not proceed to further IRB review unless a researcher submits a response to a request for clarification. Any substantive issues found during Pre-Review and not subsequently and satisfactorily clarified or corrected by an investigator may be returned to an investigator to correct as instructed, or may be noted and left for the IRB to address in the review process; in the latter case IRB review is understandably and likely to be significantly delayed so plan accordingly. OHSP staff may provide or upload any HRPP Toolkit Worksheets and Checklists that should be used for IRB review of a submission. Pre-review is conducted in accordance with federal regulation at Title 45 of the U.S. Code of Federal Regulations, Part 46 (45 CFR 46), sections 46.101-102, 46.104, and 46.108(a)(3), (4).

5Regulatory review is a formal IRB process intended to determine and document that research involving human subjects meets, or continues to meet, the regulatory criteria for approval, including compliance with applicable ethical, legal and FSU policy requirements. Review is applied to initial research submissions, modifications to previously approved research, continuing review of previously approved research, and review of reports of new information (e.g., events that represent potential problems for participants or others). Regulatory review is conducted in accordance with federal regulations, including 45 CFR 46, sections 46.101-102, 46.104, 46.108(a)(3), (4), and 46.109-111, and other applicable laws.

6In certain human research studies, social distancing and risk mitigation may not be applicable, such as studies that (1) will not involve any interactions or interventions with human subjects, such as studies that only involve secondary use of human subjects’ identifiable private information; (2) studies for which all interactions and interventions with human subjects will be conducted remotely, such as through use of web-based platforms or telephone; and (3) studies for which any interactions or interventions, if approved by the IRB, will not be implemented until the applicable FSU policy is revised or rescinded.

7OHSP=FSU Office for Human Subjects Protection; the OHSP is a directorate of the FSU Office of Research. IRB=FSU Institutional Review Board; IRB review of human research is required by federal laws, and is a condition of receipt of federal support for FSU research.

8Ancillary review is a FSU Office of the Vice President for Research (OVPR) review to determine and document that any exception to the FSU policy requirement for COVID-19-related social distancing and risk mitigation meets criteria for approval. When applicable, OVPR ancillary review outcomes will be documented in the IRB approval letter that is sent to a PI. In accordance with federal regulation at 45 CFR 46, section 46.112, research that has been approved by the IRB may be subject to further review and approval by FSU officials, including the OVPR.