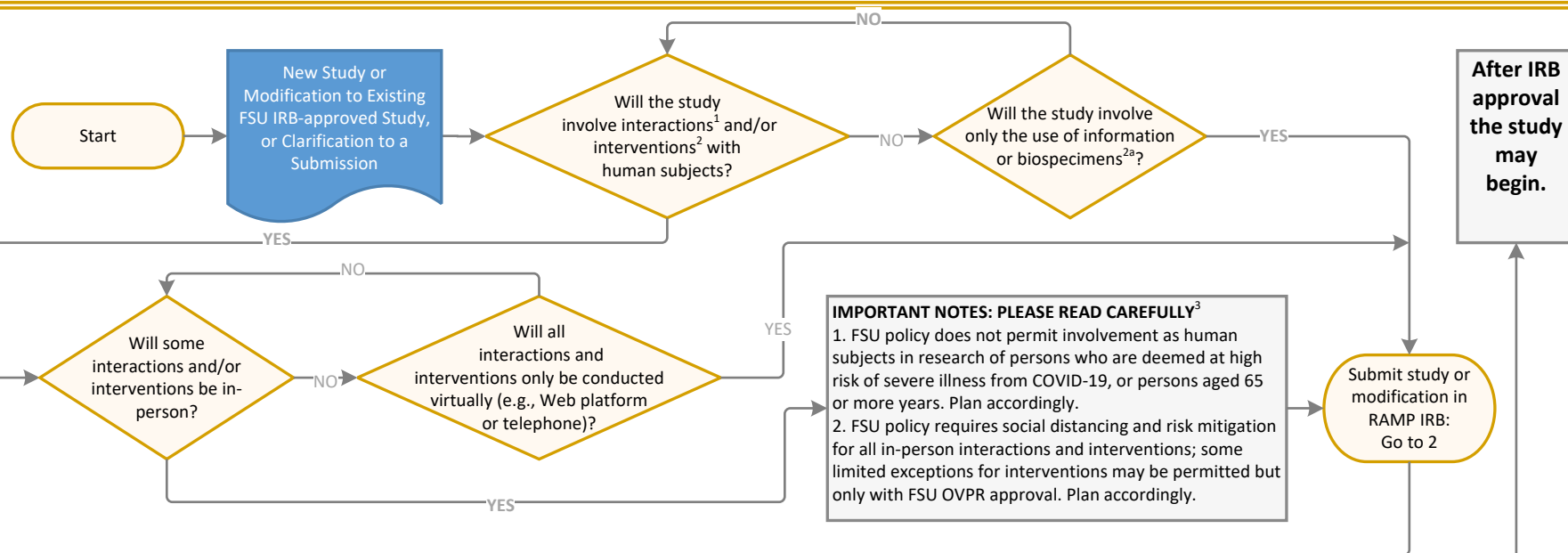
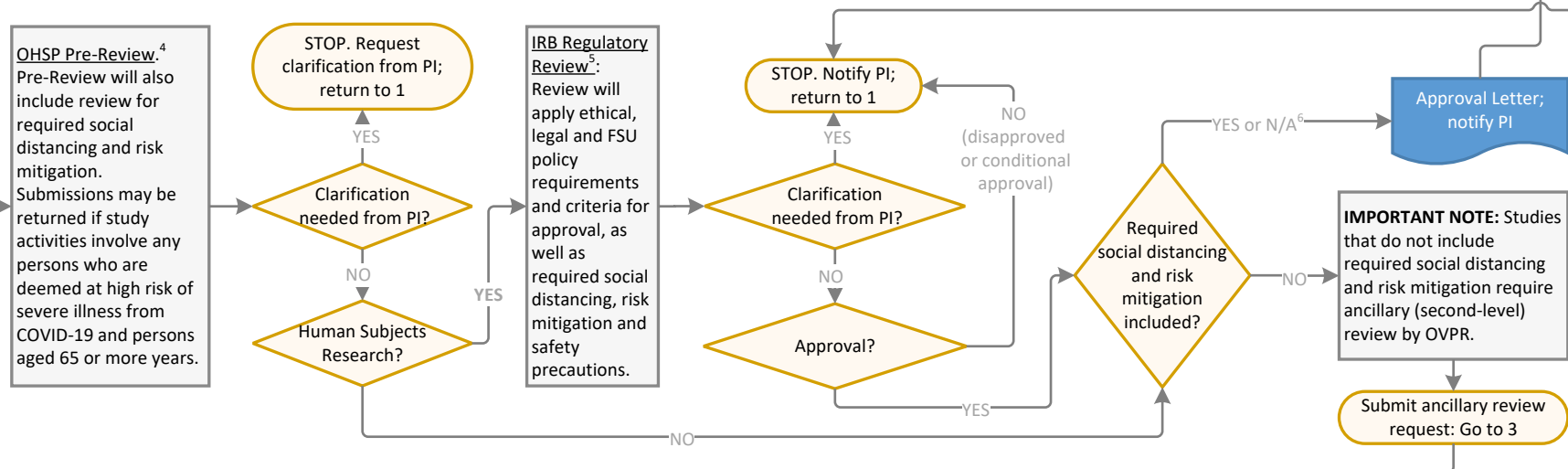


REVIEW OF HUMAN RESEARCH DURING COVID-19 NATIONAL EMERGENCY (AUGUST 18, 2020)

(1)
Principal Investigator (PI)



(2)
OHSP/IRB⁷



(3)
OVPR

OVPR Ancillary (second-level) Review⁸
Ancillary review will include OVPR review for social distancing and risk mitigation required under FSU policy. Considerations may include in part the scope and duration of interactions and interventions, anticipated risks, and expected direct benefits to human subjects.

Approval?

YES

NO

ENDNOTES:

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).

^{2a}Some 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 an 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.