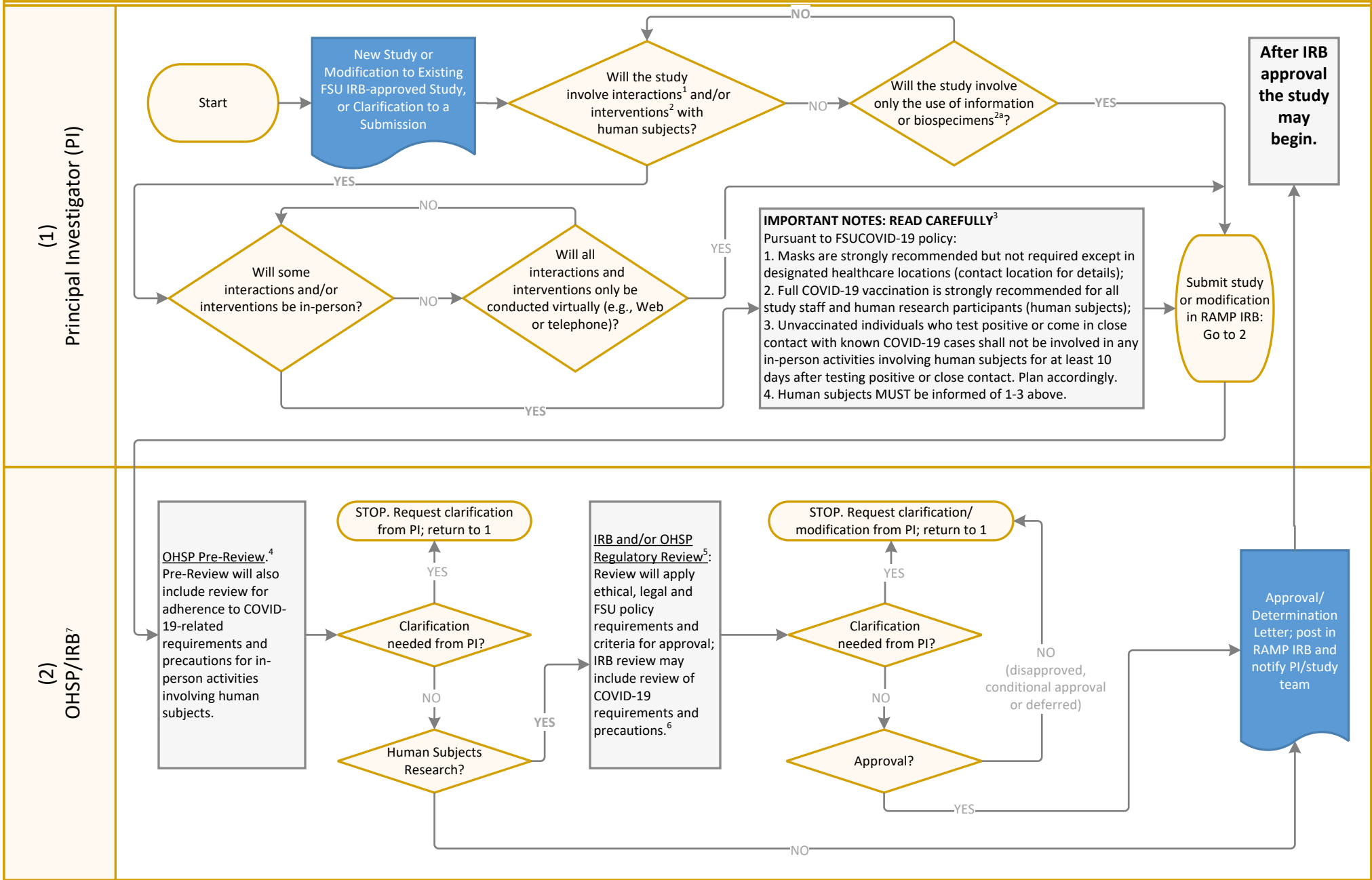


# REVIEW OF HUMAN RESEARCH DURING COVID-19 NATIONAL EMERGENCY (AUGUST 4, 2021)



ENDNOTES:

<sup>1</sup>*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).

<sup>2</sup>*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).

<sup>2a</sup>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 regulatory distinction for IRB review purposes.

<sup>3</sup>FSU research policy relating to in-person interactions and interventions with human subjects during the COVID-19 national emergency can be found on the FSU Office for Human Subjects Protection (OHSP) COVID-19-related web page; copy and paste this URL: <https://www.research.fsu.edu/research-offices/ohsp/covid-19-and-human-research-studies/>

<sup>4</sup>Pre-Review is a formal OHSP process intended to ascertain and document that an IRB submission is "review ready" (ALL required study materials have been submitted that should enable the IRB to make a decision about whether applicable regulatory criteria for approval have been satisfied; otherwise pursuant to pre-review investigators will be notified to either submit and provide clarification for any missing or incomplete materials or to explain any matter that might raise an issue during IRB review). 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).

<sup>5</sup>Regulatory review is a formal IRB and/or OHSP regulatory 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, or is otherwise exempt from IRB review or is exempt but still requires limited IRB review. 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.

<sup>6</sup>Under federal law, the FSU IRB has broad authority to require and to ensure that risks to human subjects and others are minimized (see Title 45 of the U.S. Code of Federal Regulations, Part 46 (45 CFR 46), sections 46.109 and 46.111). The IRB may require that for in-person research activities that the study team clearly document and implement COVID-19-related precautions to protect human subjects. Therefore study teams should carefully and thoroughly plan accordingly, including by evaluating possible risks (including COVID-19 risks) to human subjects, establishing any necessary exclusion criteria and screening prospective subjects based upon possible risks, taking concrete steps to minimize possible risks, and unambiguously explaining in the protocol and to prospective subjects during the consent process about possible risks and how the study team will mitigate such risks.

**Important Note: Institutional officials are prohibited by law from approving of any study that is not approved by the IRB, including a study's failure to satisfy the IRB's conditions for approval (45 CFR 46, section 46.112).**

<sup>7</sup>OHSP=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.