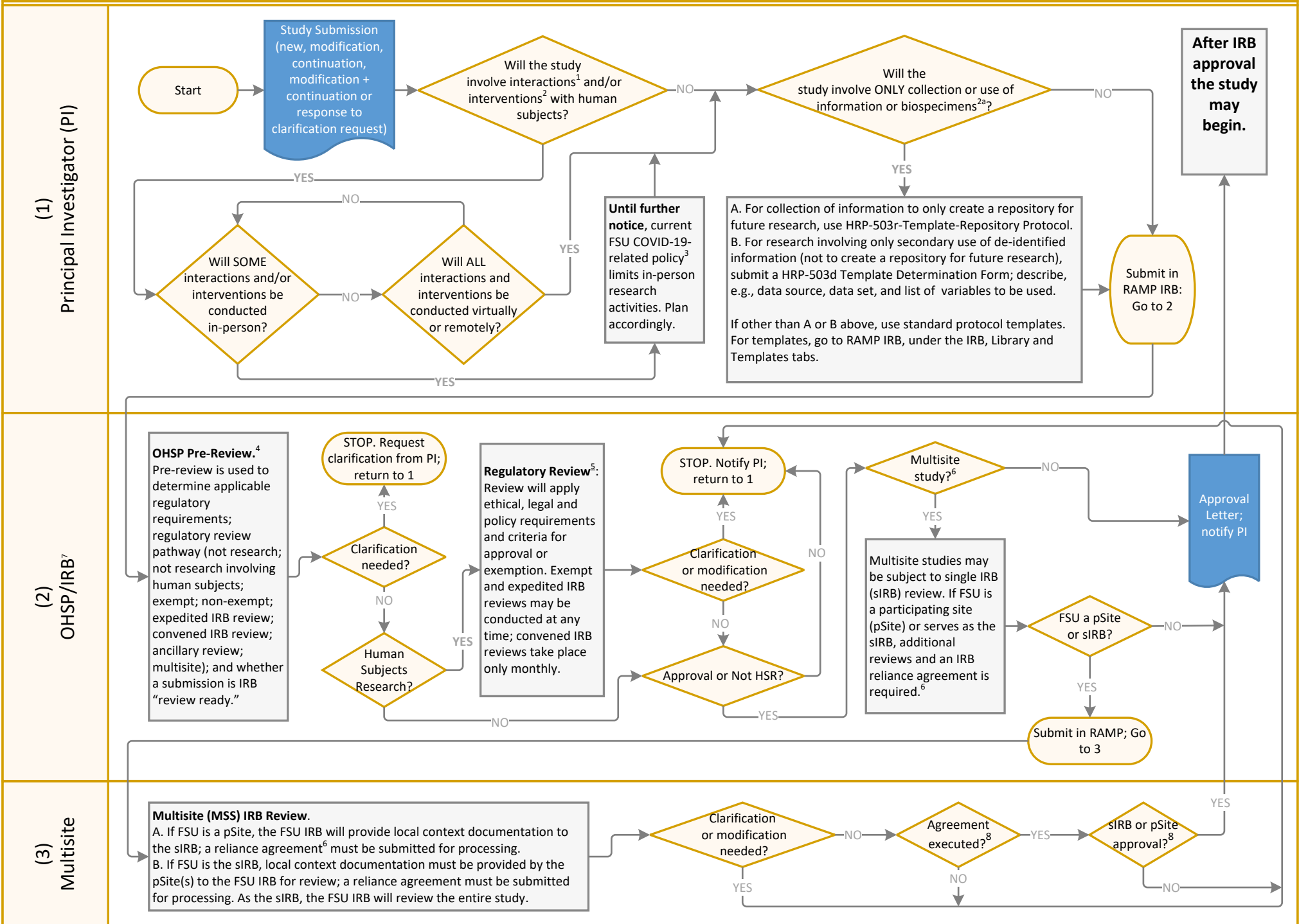


DECISION ALGORITHM: REVIEW PATHWAY FOR HUMAN RESEARCH (VERSION: NOVEMBER 6, 2020)



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

³FSU COVID-19-related 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 by the Florida Board of Governors of the State University System of Florida. Any continuation submission that involves COVID-19-related changes requires instead a submission of a continuation/modification or MOD/CR.

⁴Pre-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; investigators submitted or provided clarification for any missing or incomplete materials; investigators clarified 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 satisfactory 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 should 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). One outcome of Pre-Review may be that a submission does not involve research or human subjects research (HSR), and that therefore no further IRB review is required.

⁵Regulatory review is a formal process intended to determine and document that research involving human subjects meets, or continues to meet, the regulatory criteria for exemption or IRB approval, including compliance with applicable ethical, legal and FSU policy requirements. Review is applied to initial research submissions, modifications to previously exempted or IRB-approved research, continuing review of previously IRB-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 and other applicable laws and policies.

⁶ Multisite studies are studies that involve more than one institution. Single IRB (sIRB) review is generally required for multisite studies that are considered cooperative research (research that involves more than one institution located in the U.S. and for which research is conducted in the U.S.) in accordance with federal regulation at 45 CFR 46, section 46.114. An sIRB is the only IRB authorized under law to conduct review for the applicable institutions involved in a cooperative research study. When the FSU IRB does not serve as an sIRB and FSU is designated as a participating site (or pSite), then the FSU IRB must conduct local context review and provide documentation of this review to the sIRB. When the FSU IRB serves as the sIRB, then all other pSite IRBs must provide the FSU IRB with documentation of the pSites' local context review. Regardless of whether FSU is a pSite or the FSU IRB serves as the sIRB, an IRB Authorization Agreement (termed generically as a reliance agreement) must be executed that covers the pSite(s) and sIRB. The submission of these agreements must be entered into the FSU RAMP Agreements module before review of any RAMP IRB submission may be completed; the agreement must be fully executed before any research at FSU may be conducted. Note that for studies involving TMH, coordination by FSU's OCRA is required before IRB review; visit OCRA at <https://ocra.fsu.edu>.

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.

⁸For disapproval of execution of an Agreement and/or sIRB and/or pSite disapproval, the PI will be notified and the submission returned.

For definitions for any term used above, refer to HRP-001- SOP-Definitions in RAMP IRB, under the IRB, Library and Standard Operating Procedures tabs.