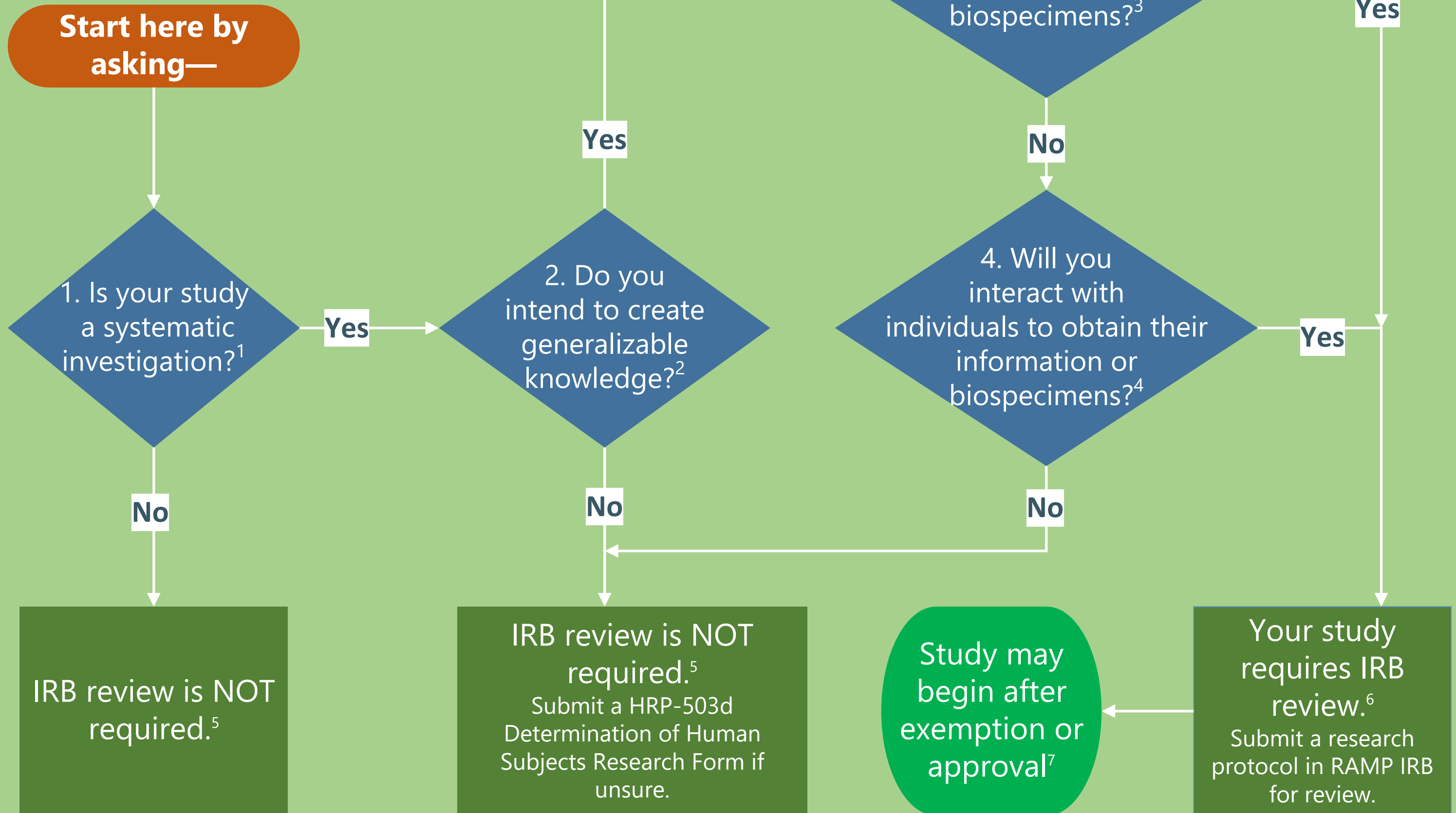


Does Your Research Require IRB Review?

(OHSP, January 26 2021)



Does Your Research Require IRB Review?

(Office for Human Subjects Protection (OHSP), January 25, 2021)

Footnotes for Decisions and Processes

◇ Question 1: Is your study a systematic investigation?¹

¹ **Your study or project is a systematic investigation** if your study or project will involve a plan 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. Thesis or dissertation studies or projects are considered systematic investigations.

Study or project plans usually include a formal protocol that includes an objective(s) and procedures designed to reach that objective. Examples of systematic investigations may include surveys, interviews, focus groups, analyses of existing data or biological specimens, evaluations of social or educational programs, cognitive and perceptual experiments, clinical trials, and physiological experiments. Haphazardly or arbitrarily collecting information or specimens is generally not a systematic investigation.

The term “systematic investigation” is a term of art that is included in the definition of *Research* in federal regulations at Title 45 of the U.S. Code of Federal Regulations (CFR), Part 46 (45 CFR 46).

- ◇ Question 2: Do you intend to create generalizable knowledge?²
- ◇ Question 3: Will you obtain identifiable information or biospecimens?³

² **Your study is intended to create generalizable knowledge** if the design or purpose of your study or project (including class projects) will be to draw conclusions that have some general applicability, inform policy or practice, or apply or extrapolate findings to persons, programs or institutions beyond those involved as respondents in your study or project. *If you are not sure, proceed to Question 3.*

The term “generalizable knowledge” is a term of art that is included in the definition of *Research* in federal regulations at Title 45 of the U.S. Code of Federal Regulations (CFR), Part 46 (45 CFR 46). A study that is not published or presented may still be considered to develop or contribute to generalizable knowledge.

³ **You are obtaining identifiable information or biospecimens** for research purposes when you will collect, use or generate any information or biospecimens about an individual, AND the identity of the individual is or may be made known to you or be associated with the information or biospecimen. The term “information” is very broadly construed and may be in any format, document or form, including for example any written, verbal, electronic, physical, or virtual format and document, and any record, file, instrument, article or artifact form. “Biospecimen” is also very broadly construed as any quantity of tissue, blood, urine, or other human-derived material; this includes subcellular structures, cells, tissue (bone, muscle, connective tissue and skin), organs, blood, gametes, embryos, fetal tissue, and waste (urine, feces, sweat, hair and nail clippings, shed epithelial cells, and placenta). *If you are not sure, proceed to Question 4.*

- ◇ Question 4: Will you interact with individuals to obtain their information or biospecimens?⁴
- Outcome or Process: IRB review is not required⁵

“Identity” and “identifiable” refer to an individual’s name; unique identifiers or codes specific to an individual such as Social Security, employee, student, beneficiary, license, health record numbers and unique codes linked to specific persons or their identifiers; email addresses; photographs, videos and audio recordings of individuals; and biometric identifiers.

⁴ **You are interacting with individuals to obtain their information or biospecimens** for research purposes when you will have any communication or interpersonal contact with an individual to collect, use or generate any information or biospecimens about the individual (whether or not the information or biospecimen is identifiable). The terms “communication” and interpersonal contact” are very broadly construed and may be in or by any format or means, including for example written, verbal, electronic, in person or face-to-face, online or virtual, and whether or not the communication or interpersonal contact is direct or indirect.

⁵ **There is no need for IRB (Institutional Review Board) review** for a study or project that is NOT a systematic investigation, or if so, that is NOT intended to create generalizable knowledge. If you are unsure about whether your study or project is a systematic investigation and/or intended to create generalizable knowledge, or if you are instructed otherwise, then complete and submit within [RAMP IRB](#) the HRP-503d Determination of Human Subjects Research form, available in [RAMP IRB](#) under the IRB, Library and [Templates](#) tabs, or by visiting this [OHSP web page](#) under Protocol Templates. On the form, answer “Yes” to the questions about whether your study or project is a systemic investigation or designed to develop or contribute to generalizable

□ Outcome or Process: Your study requires IRB review⁶

knowledge; this way, you will be directed to answer additional questions and provide related information so that the OHSP is able to make a decision about whether there is a need for further IRB review of your study or project.

Important note: If your graduation, journal or other publisher will require (check ahead to be sure) formal documentation of IRB exemption or approval or other human subjects regulatory determination, *whether or not you are certain that your study or project is a systematic investigation and/or intended to create generalizable knowledge*, then complete and submit the HRP-503d Determination of Human Subjects Research form as instructed above.

⁶ **Your study or project requires IRB review** if you will be obtaining identifiable information or biospecimens, or if you will be interacting with individuals to obtain their information or biospecimens. These individuals or individuals with whom you will be interacting, or from whom you will be obtaining identifiable information or biospecimens, are considered “human subjects.” *Review and approval or exemption from IRB review is required before your study or project may be begin* (including recruiting any human subjects or obtaining any information or biospecimens).

All studies or projects submitted for review will require a protocol, in which you will describe for example your study’s background, rationale, objectives, design, methodology, statistical considerations and organization. The OHSP and IRB provides several protocol templates for use. You may, before logging into [RAMP IRB](#) to begin preparing your study or project for IRB review, check out our protocol templates by visiting this [OHSP web page](#) and look for Protocol Templates; when you are ready to begin preparing your study or project, use the templates available in [RAMP IRB](#) under the IRB, Library and [Templates](#) tabs. [RAMP IRB](#) uses business logic and SmartForms to guide you on what information and materials that you are required to provide for review.

- End: Study may begin after exemption or approval⁷

⁷ **Do not start a study or project until you have received a formal letter from the IRB that your study or project has been approved by the IRB or determined exempt from IRB review.** *Failure to secure necessary IRB approval or exemption is a violation of federal law.* Sometimes the OHSP and IRB will require clarification or modifications to a study or project before approval or exemption. If you plan to modify a study after IRB approval or exemption, such modifications must also be reviewed by the OHSP or IRB before the modification may be implemented. When your study or project is approved or exempted, you should by email receive notice about the IRB's action; the notice will include a link to your [RAMP IRB](#) study workspace, within which workspace the formal letter of approval or exemption, as well as other letters, are available.

To learn more about the IRB review process, visit the OHSP [Human Research Review web page](#).