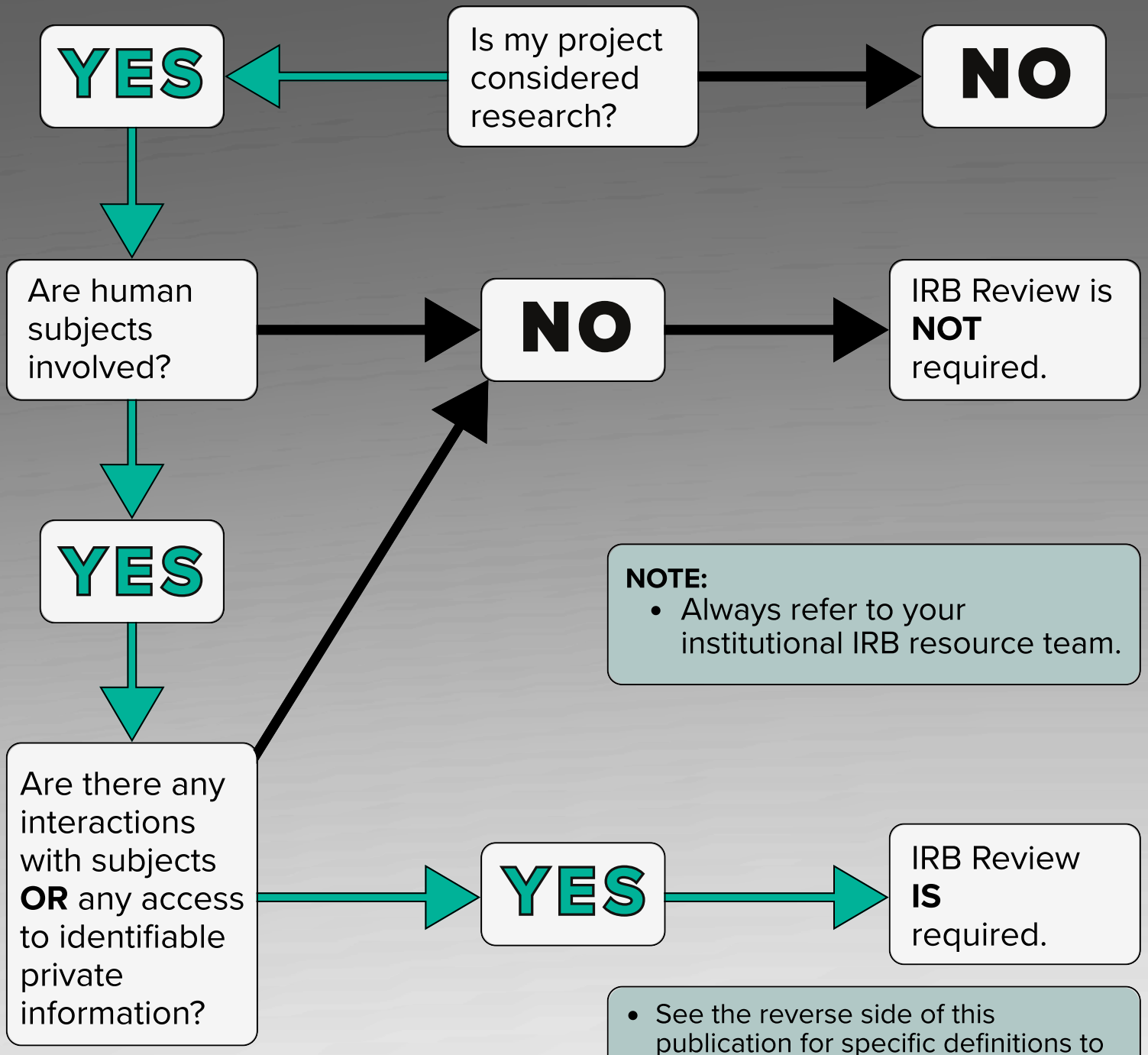
The Path to Institutional Review Board (IRB) Review (Human Subjects):

The Regulations:

- Federal regulations require that an IRB review research projects involving human subjects.
- The IRB must approve or determine the project to be exempt before starting any research activities.



NOTE:

- Always refer to your institutional IRB resource team.

- See the reverse side of this publication for specific definitions to effectively answer the above questions.

References:

- https://web.uri.edu/research-admin/integrity-security/human-subjects
- https://irbo.nih.gov/irb-review/do-you-need-to-submit-to-the-irb/

Define Your Research for IRB Review

- If your activity **does not fit** one of the definitions of research (below), you **do not** need to obtain IRB approval or a determination of exempt status.
- The specific definition (if any) that applies to your activity determines which regulations and requirements govern your research.

What is Research?

- A **systemic investigation**, including research development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge**. Research is defined as using human data only; metanalysis, animal study, etc. require different approval.

Systemic Investigation:

- Follows a predetermined plan for looking at a particular issue, testing a hypothesis or research questions, or developing a new theory.

For Example:

- Collection of quantitative data
- Collection of data using surveys, testing or evaluation procedures, interviews, or focus groups
- Collection of data using experimental designs such as clinical trials
- Observation of individual or group behavior

Generalizable Knowledge:

- The purpose or intent of the project is to test or to develop scientific theories or hypotheses, or to draw conclusions that are intended to be applicable and/or shared beyond the populations or situations being studied.

For Example:

- Presentation of the data at meetings, conferences, seminar, poster presentations. etc.
- The knowledge contributes to an already established body of knowledge.
- Other investigators, scholars, and practicitioners may benefit from this knowledge.
- Publications including journals, papers, dissertations, and master's theses.

What is a Human Subject?

- A Human Subject is a living individual about whom an investigator conducting research obtains (1) data through **intervention** or **interaction** with the individual or (2) **identifiable private information**.
- Under Food and Drug Administration (FDA) regulations, human subjects research includes using drugs or devices on humans or specimens, identifiable or not.

Intervention:

- Physical procedures or manipulations of the subject or his/her environment (e.g. taking blood samples, exercise studies, use of devices, cognitive tasks, etc.)

Interaction:

- Any communication or interpersonal contact between the investigator(s) and the subjects. This includes in-person, mail, telephone, etc. Online surveys (even if anonymous) involve interaction.

Identifiable Information:

- The identity of the individual(s) may be readily ascertained by the investigator or others, directly or indirectly, through codes and other data points. There can be no indirect links to the subject identifier. One cannot obtain databases from the original investigators and then de-identify them.

Private Information:

- Information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place (e.g. person's home, exam room, public restroom, etc.) OR has been provided for specific purposes with a reasonable expectation that it will not be made public (e.g. medical records, student records, employee file, etc.)

References:

- https://web.uri.edu/research-admin/integrity-security/human-subjects
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