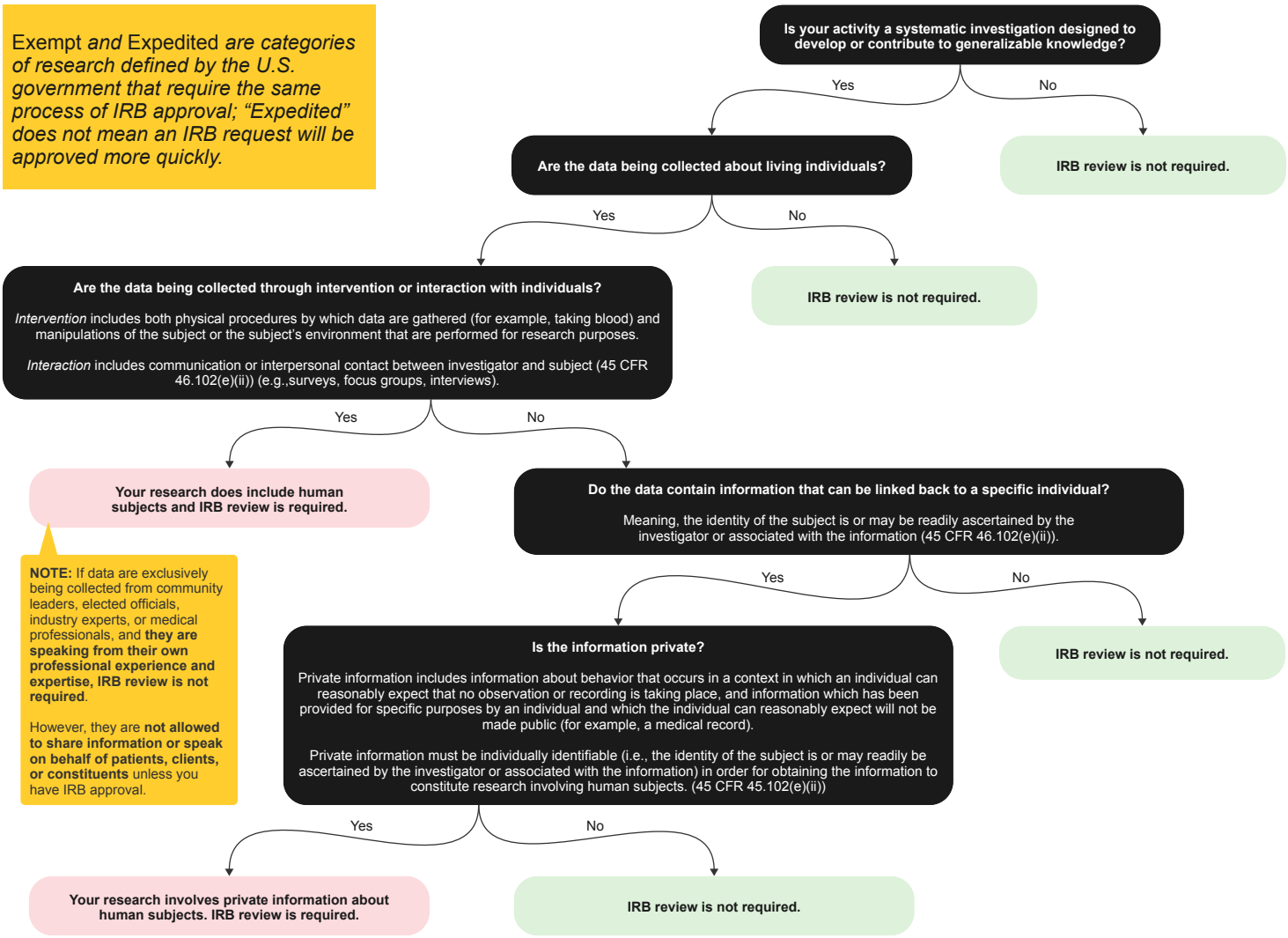
IRB Decision Tree:
Determining if Activities Involve Human Subjects Research

This decision tree is intended to assist investigators in determining if their activity requires IRB review. All projects conducted at Pratt involving human subjects that meet the definition of research must be reviewed by the IRB. This document does not need to be submitted with your IRB proposal.
Note: See page 2 for definitions of Exempt and Expedited Reviews.

Exempt *and* Expedited *are categories of research defined by the U.S. government that require the same process of IRB approval; "Expedited" does not mean an IRB request will be approved more quickly.*



Is it RESEARCH?

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102 (l)).

Generalizable Knowledge: Investigations designed to draw general conclusions (i.e., may be applied to populations outside of the specific study population), or to inform policy. For conclusions to be generalizable, they must be disseminated or be part of a program of investigation that will be disseminated. Dissemination is sharing material beyond Pratt Institute.

Examples include publication in a scholarly journal, presentation at a professional conference, sharing results with a newspaper reporter, or presentation to an outside client for a capstone course. Thesis or capstone projects conducted to meet the requirement of a graduate degree are usually considered generalizable.

Oral presentation to classmates and the course instructor(s) in a research methods course or internal presentation to Pratt administrators for utilization and review purposes are NOT considered dissemination.

Note: the following activities are NOT considered human subjects research:

Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected (45 CFR 46.102 (l)(1)).

Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority-setting during the course of an event or crisis that threatens public health (including natural or man-made disasters) (45 CFR 46.102 (l)(2)).

Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes (45 CFR 46.102 (l)(3)).

Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions (45 CFR 46.102 (l)(4)).

Classroom activities solely to fulfill course requirements or to train students in the use of particular methods or devices and, for which you have no desire to publish or share this information outside the classroom.

Internal data collection for Pratt Institute departmental, school, or other institutional administrative purposes only (i.e., teaching evaluations, customer service surveys), for which you have no desire to ever share or publish.

Information-gathering where questions focus on things, products, or policies rather than about people or their thoughts. (i.e., canvassing about inter-library loan policies or rising journal costs).

Coded data that were not collected for the currently proposed projects, so long as the investigator cannot link that data back to an individual (e.g., national datasets with no identifiers).

Pilot studies which are used to develop or test measures are not considered human subjects research, so long as you have no desire to publish or share this information. If it is possible that the data collected in your pilot study will be used solely or in combination with other data for publication purposes, IRB review and approval is required BEFORE data collection begins.

If there is any doubt as to whether or not your activities could qualify as human subject research, please contact the Office of Research and Strategic Partnerships at irb@pratt.edu.

"Exempt" vs. "Expedited"

Exempt and **Expedited** are categories of research defined by the U.S. government that require the same process of IRB approval; **"Expedited" does not mean an IRB request will be approved more quickly**.

Most research at Pratt falls under the Exempt category, which typically involves studies on human behavior. Expedited review applies to projects that involve the collection of biological samples or physical engagement. A third category, Full Board Review, is required for research that involves greater or more complex risks to participants. Pratt does not offer Full Board reviews, which is usually reserved for advanced or high-risk studies.