OHRP
45 CFR 46.102

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through *intervention* or *interaction* with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable *private information or identifiable biospecimens*.
Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
Interaction includes communication or interpersonal contact between investigator and subject.
Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

FDA
21 CFR 50.3 (c), (j)

Clinical Investigation means any research experiment that involves a drug, device, or biologic and one or more human subjects and is subject to requirements for prior submission to the FDA (e.g., a change in labeling) or the results of the research (e.g., safety and efficacy) are intended to be submitted to the FDA as part of an application for a research or marketing permit. Such research requires both IRB and FDA reviews. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for this definition.
Human Subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

VHA
Handbook 1200.05

Pilot Studies are full-fledged research studies that must be approved by the IRB when human subjects are involved. They are not considered to be activities preparatory to research. See below.
Preparatory to Research refers to activities that are necessary for the development of a specific protocol. PHI from data repositories or medical records may be reviewed during this process without IRB approval, subject authorization, or a waiver of authorization, but only aggregate data may be recorded and used in the protocol application (e.g., potential number of subjects meeting study criteria at each site). Within VHA, an activity preparatory to research does not include the identification of potential subjects and recording of data for the purpose of recruiting these subjects or to link with other data. The preparatory to research activity ends once the protocol has been submitted to the IRB for review.

Belmont Report:
Boundaries Between Practice and Research

Practice refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals.
Research designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

Stanford Research Policy Handbook
RPH 5.4

Student Projects: Directed or independent research projects (e.g., honors or graduate theses) do require prospective IRB review and approval. Research Practica (research training) do not require Panel review.
Pilot Study: A preliminary investigation of the feasibility of a study, usually on a small scale (e.g., fewer than 10 subjects) and exploratory in nature. It is designed to help the investigator refine data collection procedures and instruments or prepare a better, more precise research design. (However, see FDA definitions of Clinical Investigation and Investigation, as well as VHA Handbook definition of Pilot Study)
Journalism/Oral History: May not require IRB review because these projects are not generally thought to be a systematic investigation designed to contribute to generalizable knowledge. However, when using oral history as a technique in human subject research IRB review may be required. (See OHRP definition of Research).
QA/QI and Other Study Types: Projects conducted in conjunction with *program evaluations* or *quality assurance* measures may or may not fall under the jurisdiction of the IRB.

Not Human Subjects Research- OHRP

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.

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).

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. ***Authorized operational activities (***as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions***Newborn Screening Blood Spots:*** secondary research involving non-identifiable newborn screening blood spots is not considered research involving human participants (OHRP FAQ Newborn Blood Spot)

* All requests for NIH-funded research - whether conducted or supported - including competing applications submitted for due dates on or after January 25, 2022, contract solicitations issued on or after January 25, 2022, applications for awards issued under Other Transactions Authorities (OTAs) on or after January 25, 2022, and NIH Intramural Research Program (IRP) studies in which the first participant is intended to be enrolled on or after that date - must receive approval by NIH to be considered as a public health surveillance activity deemed not to be research under 45 CFR Part 46.102(k), 46.102(l)(2). NIH expects that NIH-supported or -conducted research will only be determined to be a public health surveillance activity in extremely rare cases. See NIH notice for more information.