Four levels of IRB review

	Non Human-Subjects Research	Human-Subjects Research		
\	**Level 1: Submission not needed**	**Level 2: Excused review**	**Level 3: Expedited review**	**Level 4: Full review**
Description	Research activities which the investigator is not obtaining data through interaction or intervention with living subjects or is not obtaining identifiable private information.	Research activities involving the use of human subjects or use of data with private information.	Research activities where the procedures and/or characteristics of the subject population require consideration of human subjects protections beyond those normally applied in the Excused category to ensure that any harm or discomfort created solely by the research procedures is not greater than minimal risk.	Research activities where, based on scientific or professional knowledge, there is a significant probability that participants will experience a magnitude of risk that is greater than minimal and that cannot be adequately reduced through risk-minimizing procedures.
Details	• Scholarship outside of the definition of human-subjects research, such as biographies, personal observation, or fact checking with sources for nonfiction writing. • Public information outside of the definition of human-subjects research from these types of sources: o Observing, coding, or recording the behavior of individuals in public settings where there is no interaction or intervention and no assumption of privacy, such as recording admissions lines to study social interaction in crowds at sporting or cultural events, coding informational content of publicly published Facebook pages; observing differences in tipping behavior in restaurants. o Demographic, sociological, or other research that uses publicly available data sources, such as birth or decedent records, home ownership, court records where the information is public and there is no assumption of privacy. o Research that uses certified public-use data files; that is, data files tested to ensure respondents cannot be identified; public-use files available from such studies as the Panel Study of Income Dynamics, Early Childhood Longitudinal Program, National Longitudinal Study of Adolescent Health, among many others.	• Use of pre-existing research and nonresearch data that includes private information, including use of extant research data under restricted use provisions or use of non-research data that is accessible but includes private information about individuals that they may not expect to be public. • Benign interactions or interventions that involve methodologies that are very familiar to people in everyday life and in which verbal, behavioral, or physiological responses would be the research data being collected (e.g., educational tests, surveys, focus groups, interviews, fieldwork or "participant observation," and similar procedures; and sociolinguistic studies; simulation studies; games, markets, negotiations, voting; individual or group decision making; studies of educational processes, teaching, and learning; studies of social perception and judgment; personality, achievement, and ability tests, and role playing involving routine activities or tasks under different scenarios and that do not in and of themselves introduce or heighten physical pain or psychological discomfort. • Would not be limited to adults.	• The participant population is known to have decisional vulnerabilities empirically established to require enhanced informed consent protections for the type of study to be conducted. • The study is designed to produce clinical changes in health, health-related behaviors or symptomology, and includes identifiable information. • Public awareness of recruitment procedures can jeopardize participants' physical safety or reveal criminal behavior. • The nature of the research data collected requires specific plans for reporting illegal behaviors, providing emergency treatment, or protecting a participant or third party from physical harm. • Use of deceptive techniques are specifically designed to induce psychological, social, or physical discomfort. • When additional protections are necessary to avoid harms produced by an existing professional or service relationship with research staff that would compromise voluntary participation.	• To avoid overestimation of risk, expedited review should be considered the default procedure for evaluating social and behavioral science research that is not excused. Decisions to require full board review should be based on established scientific or professional knowledge indicating a significant probability that participants will experience a magnitude of risk that is greater than minimal and that cannot be adequately reduced through risk-minimizing procedures.

Source: National Research Council of the National Academies (2014): *Proposed revisions to the common rule.* Washington, D. C.: National Academies Press.