Does my project need to be reviewed by the Institutional Review Board (IRB)?

1. Is your project or activity a systematic investigation designed to develop or contributed to generalizable knowledge?
    a. Note that assessment of courses, departments or programs is information obtain to contribute to the knowledge of our specific course, department or program; therefore it is not generalizable.
2. Does your research involve obtaining information about living humans?

If you answered yes to both questions, then your project needs to be reviewed.

Which form should I use?

There are 3 different types of review for new projects:

1. Full Review by the whole IRB
2. Expedited Review by the IRB chair
3. Review of a Request for Exemption by the IRB chair

There is also a **Continuing Review** for projects that have already received approval from the IRB and the researchers want to continue past the 1 year approval period. In this case, please use the Continuing Review Form.

Please use the checklists below to determine what type of review your project will need:

Step 1. If you answer Yes to **any** of the following questions, then you should use the **Full Review Form**:

Does the proposed project involve:

1. Prisoners or persons awaiting trial?
2. Pregnant women (research related to pregnancy, or puts the women or fetus at risk)?
3. Potentially painful or purposely stressful procedures or activities?
4. Procedures that are not anonymous and which may be considered an invasion of privacy (e.g. survey or interview questions about sexual orientation, sexual behavior, drug or alcohol use, abuse, medical history or mental health history)?
5. Procedures that are not anonymous and where identification of subjects and/or their responses would place them at risk of criminal or civil liability, could be stigmatizing, or could be damaging to the subject's financial standing, employability, insurability, or reputation?
6. Any risks that are more than a minimal risk to the subjects?
    a. *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

If you answered No to all of the questions in Step 1, go to Step 2.

Step 2. If you answer Yes to any of the following questions, then you should use the **Expedited Review Form**:

Does the proposed project involve:

1. Clinical studies of a drug or medical device when the product is: 1. being used in accordance to its approved labeling, 2. the research is not investigating a new use of the product **and** 3. the proposed use does not increase the risks associated with use of the product?

2. The collection of blood by finger, heel or ear stick, or venipuncture in:
    a. Healthy, non-pregnant adults who weigh at least 110 pounds (draws may not exceed 550 ml in and 8 week period and collection may not be more frequent than twice a week),
    b. Or other adults and children when considering the age, weight and health of the subject (draws may not exceed the lesser of 50 ml or 3ml per kilogram in an 8 week period, and collection may not be more frequent than twice a week)?
3. Prospective collection of biological specimens by noninvasive means?
    a. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures routinely employed in clinical practice (this excludes procedures that use general anesthesia, sedation, x-rays or microwaves)?
    a. Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Collection of data from voice, video, digital or image recordings made for research purposes?
6. Using data, documents, records, pathological specimens or diagnostic specimens that **will be collected** solely for non-research purposes (such as medical treatment or diagnosis)?
7. Using **existing** data, documents, records, pathological specimens or diagnostic specimens (i.e. materials that exists before the research is proposed to the IRB), and the investigators will be recording the information in such a manner that the subjects **can be identified,** either directly or through identifiers link to the subject?
8. Investigating individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies, and the investigators will be recording the information in such a manner that the subjects **can be identified,** either directly or through identifiers link to the subject?
9. Research that will include **minors** (under 18 years of age) as participants, and is employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies, and the investigators will be recording the information in such a manner that the subjects **cannot be identified,** either directly or through identifiers link to the subject?
    a. This does not include research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Request for Exemption

The following are types of research that can apply for exemption from IRB review by completing the **Request for Exemption Form**, as long as **you answered No to all of the questions in Step 1 and Step 2:**

Does your project include only:

1. Using **existing** data, documents, records, pathological specimens or diagnostic specimens (i.e. materials that exists before the research is proposed to the IRB) and the investigators will be recording the information in such a manner that the subjects **cannot be identified,** either directly or through identifiers link to the subject?
2. Observing individual or group characteristics or behavior in a public setting without participation in the activity by the investigator(s)?
3. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods?
4. Research excluding **minors** (under 18 years of age) as participants, and employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies, and the investigators will be recording the information in such a manner that the subjects **cannot be identified,** either directly or through identifiers link to the subject?
5. Research involving survey or interview procedures, where the human subjects are elected or appointed public officials or candidates for public office?
6. Research involving public benefit or service programs that is approved by the department or agency head?
7. Research involving taste and food quality evaluation and consumer acceptance studies?
    a. In these studies, the following condition must be met:
        i. Wholesome foods without additives are consumed, or
        ii. A food is consumed that contains a food ingredient at or below the level and for use found to be safe by the FDA or approved by the EPA or the USDA, or
        iii. Agricultural chemical or environmental contaminant is consumed at or below the level found to be safe by the FDA or approved by the EPA or the USDA

Created from the *Code of Federal Regulations, Title 45, Part 46: Protection of Human Subjects*; available at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html