

SUPPLEMENTAL IRB INFORMATION

(These pages are for the information of the researcher and do not need to be submitted with your application. The following information may help you determine if your study might qualify for either exempted or expedited status. The IRB will make the final determination of status.)

DOES YOUR PROJECT QUALIFY FOR EXEMPTED STATUS?

Federal regulations specify that certain types of research pose no or very low risks to participants, and therefore require minimal review from the IRB. For exempt status studies, implied consent may be acceptable. One member of the IRB, appointed by the IRB Chair, will vote by mail or e-mail. To determine if your project is NOT exempt, check all the following that apply:

YOUR PROJECT IS NOT EXEMPT IF IT FITS INTO ANY OF THE FOLLOWING CATEGORIES:

- SURVEY / INTERVIEW. Research involving survey or interview procedures where any of the following conditions exist: (a) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (b) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, or (c) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol
- OBSERVATION. Research involving the observation (including observation by participants) of public behavior where all of the following conditions exist: (a) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (b) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (c) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol. These studies require full review.
- CORRECTIONAL / DETENTION FACILITY. At least one participant is confined in a correctional or detention facility.
- LEGAL COMPETENCE.. At least one participant may not be legally competent.
- PERSONAL RECORDS . Personal records (medical, academic, etc.) will be used with identifiers and without written consent.
- ALCOHOL / DRUGS . Alcohol or drugs will be administered.
- BLOOD / BODY FLUIDS. Blood/body fluids will be drawn.
- AUTOPSY SPECIIMENS. Specimens obtained from an autopsy will be used.
- PREGNANT WOMEN. Research will use pregnant women by design.
- FETUSES. Live fetuses participants will be used in this research.

If you CHECKED ANY of the questions above, then your project is NOT exempt, but may still qualify for expedited review .

If you CHECKED NONE of the above items, your research might be EXEMPT if it fits into one of the following categories. (Check below all that apply)

YOUR PROJECT MIGHT BE EXEMPT IF IT MEETS ANY OF THE FOLLOWING CRITERIA:

- EDUCATIONAL RESEARCH: Research conducted in established or commonly accepted educational settings, involving normal educational practices. This is research that is concerned with improving educational practice and does not include variables traditionally investigated in clinical and counseling research (self-esteem, anxiety, aggression, withdrawal, shyness, social skills, etc.)
- EDUCATIONAL TESTS: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- SURVEYS, QUESTIONNAIRES, INTERVIEWS, OR OBSERVATION OF PUBLIC BEHAVIOR-1. To meet this exemption, the subject matter must not involve "sensitive" topics, such as criminal or sexual behavior, alcohol or drug use on the part of the participants, unless they are conducted in a manner that guarantees anonymity for the participants and informed consent cannot be reasonably obtained (such as in anonymous observations).
- SURVEYS, QUESTIONNAIRES, INTERVIEWS OR OBSERVATION OF PUBLIC BEHAVIOR-2. Surveys that involve sensitive information and participants identities are known to the researcher may still be exempt if (1) the participants are elected to appointed public officials or candidates for public office; or (2) federal statute(s) specify without exception that confidentiality will be maintained throughout the research and thereafter. Otherwise, such research requires expedited status.
- ARCHIVAL RESEARCH. Research involving the collection or study of existing data, documents, records, pathological or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants. These data/samples must be preexisting, which means they were collected prior to the current project.
- RESEARCH EXAMINING PUBLIC BENEFIT OR PUBLIC SERVICE PROGRAMS. To qualify for this exemption, the research must also be conducted by or subject to review by an authorized representative of the program in question. Studies in this category are still exempt if they use pregnant women by design and their purpose is to examine benefit programs specifically for pregnant women.
- TASTE EVALUATION RESEARCH. Studies of taste and food quality evaluation. Studies of taste evaluation qualify for this exemption only if (1) wholesome foods without additives are consumed; or (2) if a food is consumed that contains a food ingredient at or below the level of and for a use found to be safe.

FINAL QUESTION: Are any participants under 18 years of age? YES NO

If your study uses participants under 18 years of age, and you plan to use surveys, questionnaires or do interviews, then your project must go to full review. All other exemptions apply even if participants are under the age of 18. All externally funded studies must receive full review.

DOES YOUR PROJECT REQUIRE EXPEDITED STATUS?

Expedited reviews are for studies involving no more than minimal risk or for minor changes in previously approved protocols. Written consent is required and, consent forms are to be kept on record by the investigator. A special two-member subcommittee of the IRB, appointed by the IRB Chair, votes by mail or e-mail. To meet expedited review criteria your protocol must expose participants to no more than minimal risk. Check any of the following expedited criteria that apply to your project:

EXPEDITED (GENERAL)

- RECORDINGS. Collection of data from voice, video, digital, or image recordings made for research purposes.
- CONTINUING REVIEW. Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects, (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where not subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
- EXERTION. Research involving moderate exercise (or activity requiring a level of exertion similar to moderate exertion) by healthy volunteers.
- BEHAVIOR / CHARACTERISTICS. Experimental research on individual or group behavior or on the characteristics of individuals, such as studies of perception, cognition, game theory or test development. This does NOT include studies that involve significant stress to the participants. that are intended to produce a relatively lasting change in behavior. These require full review.
- SURVEY / INTERVIEW. Research involving survey or interview procedures where any of the following conditions exist: (a) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; or (b) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and the research deals with sensitive or potentially embarrassing aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
- ARCHIVAL DATA. Studies of archived data, records or diagnostic specimens that are not exempt.

EXPEDITED (MEDICAL)

- DRUGS / DEVICES. Clinical studies of drugs and medical devices only when conditions (a) or (b) is met. (a) Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- BLOOD. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weight at least 110 pounds. Amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently that 2 times per week; or (b) from other adults and children, consider the age, weight, and health of the subjects, the collection procedure, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- BIOLOGICAL SPECIMENS. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a non-disfiguring 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 deliver; (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 prphylactive techniques; (i) mucusal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
- NONINVASIVE MEDICAL. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) 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 acuity; (c) magnetic resonance imaging; (d) electrocardiology, 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.

- NONRESEARCH MEDICAL. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
- CONTINUING REVIEW. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

If you checked none of the criteria in this section, then your project is likely EXEMPT.

Expedited review procedures may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, **unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal risk. All externally funded studies must receive full review.**

DEFINITION OF TERMS (From the Code of Federal Regulations)

ADVERSE EVENT. Any unanticipated problem involving risks to human research participants.

ANONYMOUS: Participant names are unknown to the investigator, not requested and not given. If the only time the investigator asks for a name is for a signature on a consent form, the investigator should get verbal or implied consent of participants, to preserve their anonymity.

ASSENT: Agreement by participants not competent (e.g., children or cognitively impaired people) to give legally valid informed consent to participate in a study. A special consent form, called an "assent form," is required which is signed by the parent, guardian or caretaker, and if the subject can understand, the subject.

ASSURANCE: Renewable permit granted by a Federal Department to an institution to conduct research in compliance with government standards.

BELMONT REPORT: Ethical Principles and Guidelines for the Protection of Human Participants of Research. Cornerstone document of ethical principles and Federal regulation of protection for research participants based on respect for persons, beneficence and justice. Applications of these three ethical principles to the conduct of research leads to consideration of required informed consent and privacy and confidentiality; risk/benefit assessment and scientific merit; and the selection of research participants.

BENEFIT: A valued or desired outcome to the study that will be an advantage to the participants participating. AA health-related, psychological, or other value to an individual research participant, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.

CONFIDENTIAL: Participant names are known to the investigator and are usually coded to a master list and/or kept separately from the data and results. This is usually used, for example, when the investigator must match test results with surveys or if there will be a follow-up survey. The investigator has a real need to know participant names.

DECEPTION: The protocol is designed to withhold complete information when consent is obtained.

DIRECTLY or INDIRECTLY IDENTIFIABLE: Identities of individual participants are kept by the investigator. If participant identities are inseparable from data, then data are directly identifiable. If participant identities are kept separate from data, with information connecting them maintained by codes and a master list, then data are indirectly identifiable. In either case, investigator must assure that confidentiality will be maintained, and must explain how participant identities will be protected.

HUMAN PARTICIPANTS: Individuals whose physiologic or behavioral characteristics and responses are the object of study in a project. Under the federal regulations, participants are defined as living individual(s) about whom an investigator conducting a study obtains: data through intervention or interaction with the individual; or identifiable private information.

HUMAN SUBJECTS RESEARCH: Any systematic investigation that is designed to develop or contribute to knowledge and which uses living humans or identifiable information about living humans. Examples: ethnographic interviews, drug/device comparison trials, disease prevention studies, curricular evaluation studies, psychology experiments, medical chart review studies.

INFORMED CONSENT: Participant voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in a study or to undergo a diagnostic, therapeutic or preventive procedure. The process of information exchange between researcher and participant prior to written consent to participate in research. Information includes recruitment information, written materials, as well as verbal instructions, questions and answers about research and its procedures. Participants are given the opportunity to choose research involvement based on information, comprehension, and willingness to volunteer.

INTENTIONALLY IDENTIFIED: Participant names are to be used in connection with their data when project results are presented to the public. This procedure is common for journalistic-type interview studies, where participants are public figures or in oral histories. In these cases, the investigator should seek explicit consent from the participants for the use of their names in connection with their data.

LEGALLY AUTHORIZED REPRESENTATIVE: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the Research. Legally authorized hierarchy of individuals to give prospective proxy consent:

1. A guardian for the subject, if one has been appointed
2. The subject's spouse
3. An adult child of the subject
4. A parent of the subject
5. An adult sibling of the subject
6. Possibly distant blood relatives

MINIMAL RISK: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed study is 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. The definition of minimal risk for research involving prisoners differs somewhat from that given for noninstitutionalized adults.

POPULATION: A group of people in society meeting certain criteria to be eligible as participants in a project=s protocol.

PRINCIPAL INVESTIGATOR: The individual(s) with primary responsibility for the design and conduct of a project=s protocol.

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 which the individual 'can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) for obtaining the information to constitute research involving human subjects.

PROTOCOL: The formal design or plan of a study=s activity; specifically, the plan submitted to an IRB for review and to an agency for support. The protocol includes a description of the design or methodology to be employed, the eligibility requirements for prospective participants and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

RISK: The probability of harm or injury (physical, psychological, social or economic) occurring as a result of participation in a study. Both the probability and magnitude of possible harm may vary from minimal to significant.

SIGNIFICANT RISK: A study=s design that presents a potential for serious risk to the health, safety or welfare of the subject.

AUDITS

The IRB reserves the right to audit any research activity conducted under the review authority of Roosevelt University. In addition, the IRB, the Food and Drug Administration and the sponsor may conduct periodic random audits of investigator's protocol records. Investigators are urged to keep their copies of signed Consent Forms readily accessible for review. Sufficient grounds for implementing an IRB audit include: questions of impropriety in the conduct of the study such as informed consent not being obtained; subject complaint to the IRB regarding the conduct of the study; and serious adverse events reported to the IRB by the Principal Investigator or study sponsor;

In addition, the IRB reserves the right to perform random audits of any active protocol, at any time, in order to ensure compliance with applicable federal regulations and to protect the rights and welfare of human subjects.