Categories of IRB Review--Quick Reference

EXEMPT RESEARCH - Constitutes no more than minimal risk AND only involves human subjects in one or more of the following categories:

1. Research conducted in established educational settings, involving normal educational practices, such as: (i) research on education instructional strategies or (ii) research on the effectiveness of or comparison among instruction techniques, curricula, or classroom management methods.
2. Research involving the use of (a) educational tests (cognitive, diagnostic, aptitude, achievement); (b) surveys, interviews, or observation of public behavior* UNLESS (i) information is recorded with identifiers linked to subjects and (ii) subjects' responses could place subjects at risk (e.g., criminal or civil liability, financial standing, employability or reputation).
   *No exemptions are allowed under (b) when children are involved in survey/interview procedures, or observations when investigator participates in activities being observed.
3. Research involving educational tests, surveys, interviews, or observation of public behavior is exempt if: (I) the subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute requires confidentiality of identifiable information to be maintained permanently.
4. Research involving the collection or study of existing data, document, or records. Sources must either be publicly available or information must be recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to subjects.
5. Research conducted by or subject to the approval of federal department or agency heads and designated to evaluate possible changes in or alternatives to those programs or changes in methods of payment for benefits under those programs.
6. Taste or food quality evaluation involving wholesome/safe foods.

Note: Federal regulations indicate that certain research is exempt from review. However, under Teachers College's Policy for the Protection of Human Subjects, a research protocol proposing the use of human subjects must be submitted to the IRB to determine if it qualifies for exempt status. Exemptions do not apply to research conducted on pregnant women, prisoners, or vulnerable populations.

EXPEDITED RESEARCH-- Constitutes no more than minimal risk AND only involves human subjects in one or more of the following categories:

4. 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 subjects 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. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for
the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. 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 no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

9. 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.

Note: Expedited review categories 1-3 apply to biomedical research not typically conducted at Teachers College, and consequently do not appear on this list.

STANDARD REVIEW OF RESEARCH:

If your project does not precisely fit under any of the categories under either the EXEMPT or EXPEDITED review sections listed above, then it must be submitted under STANDARD review procedures. Standard Review is used for all projects involving vulnerable populations, except some minimal risk research involving children. Research involving deception and any research that entails more than minimal risk to the subject, even if it otherwise appears to fall into one of the exempt or expedited categories, must be submitted under standard review procedures.