

## Checklist for Research Qualifying for Expedited Review with Guidelines for Protocol Preparation



Researcher(s): \_\_\_\_\_

Course #/ Grant: \_\_\_\_\_

Name of Project: \_\_\_\_\_

Directions: If you believe that your project qualifies for exemption, please submit the following materials to the IRB: (a) a completed copy of this form; (b) a copy of your training quiz for the IRB training program; (c) a research proposal or thorough document of your procedures and materials. Please check all applicable items in Parts A and B and provide all relevant information in Part C. Either complete or attach a complete research proposal that addresses the items outlined in Part D. Research activities will only be considered for exemption from further review when all items in Part A and at least one item in Part B apply. If one item cannot be checked in Part A, the research will require a full IRB Committee review.

### Part A:

1. \_\_\_\_\_ The research does not involve prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects.
2. \_\_\_\_\_ The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability, be stigmatizing, or be damaging to the subject's financial standing, employability, insurability, or reputation.
3. \_\_\_\_\_ The research does not involve the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
4. \_\_\_\_\_ The procedures of this research present **no more than minimal risk** to the subject (where minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research are no greater than those ordinarily encountered in daily life or during the performance of routine physical/psychological examinations or tests).

**Part B (at least one item should apply):**

1. \_\_\_\_\_ Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens), where these materials, in their entirety, have been collected or will be collected solely for non-research purposes. **[NOTE: These sources are not publicly available and, although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio or video recordings or names will be recorded, even if they are not directly associated with the data.)]**
2. \_\_\_\_\_ Collection of data through use of the following procedures: a) non-invasive procedures routinely employed in clinical practice excluding procedures involving x-rays or microwaves; b) 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; c) weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, Doppler blood flow, and echocardiography; d) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
3. \_\_\_\_\_ Collection of data from voice, video, digital or image recordings made for research purposes where identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability, be stigmatizing, or be damaging to the subjects' financial standing, employability, insurability, or reputation.
4. \_\_\_\_\_ Research on individual or group characteristics or behavior (including but not limited to: research involving perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior, or research employing surveys, interviews, oral history, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies).
5. \_\_\_\_\_ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. [Although confidentiality will be strictly maintained, information will not be recorded anonymously, e.g., use will be made of audio or video recordings, names will be recorded, even if they are not directly associated with the data.]

6. \_\_\_\_ Research that involves deception [**NOTE: Deception must be scientifically justified and debriefing procedures must be outlined in detail.** Based on the judgment of the reviewers, some protocols involving deception may qualify for expedited review. In other cases, the deception will be of sufficient consequence to require full IRB review.]
  
7. \_\_\_\_ Prospective collection for research purposes of biological specimens and collection of blood samples by finger stick or venipuncture.
  
8. \_\_\_\_ Research previously approved by the convened IRB as follows:
  1. 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
  2. where the research remains active only for the purposes of data analysis; or
  3. where the IRB has determined at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified; or
  4. where no subjects have been enrolled and no additional risks have been identified.

### **Part C**

1. Describe approximately how much time each subject is expected to devote to the research.
2. How data will be collected and recorded (with or without identifiers? what instruments, materials, or equipment will be used? will audio or video recordings be employed in data collection?). Append copies of all written instruments and/or describe any apparatus with which subjects will be in direct contact.
3. Describe the methods for obtaining informed consent, or assent in the case of minors.
4. Describe the methods for preserving confidentiality (including plans for storing/disposing of digital files and other data records).
5. If deception is to be employed, provide a scientific justification for its use and describe debriefing procedures. [**NOTE: If the research is such that debriefing cannot be carried out, the project must be submitted for full committee review.**]

6. Indicate any benefits/compensation that are expected to accrue to subjects as a result of their participation in the research. In the event that subjects will be paid, describe all payment arrangements, including how much subjects will be paid should they choose to withdraw from the study prior to completion of the research.
7. Describe any relationship between researcher and subjects, such as: teacher/student; superintendent/principal/teacher, employer/employee. If such a relationship exists, how will it affect the subject's ability to participate voluntarily and how will the Researcher(s) handle it?

## **Part D**

Please provide the information that is requested below. A research proposal may be attached.

1. What is the purpose of the proposed study (the research question) and what is the research hypothesis?
2. Describe the proposed subject sample and indicate the size of the sample. If subjects under the age of 18 will participate in your research, indicate the expected age range of the samples.
3. How will subjects be recruited and selected?
4. Describe all research methods and procedures that will be employed in this study.