

## HUMAN SUBJECTS RESEARCH PROTOCOLS Guidelines and Application Instructions South College Institutional Review Board (IRB)

### Determine the Type of IRB Review that is Required for Your Project

There are four categories of human subjects research reviewed by the South College IRB: Exempt Status Review, Limited Review, Expedited Review, and Full Committee Review. Projects that receive IRB approval following an Expedited Review or a Full Committee Review must also apply for a Continuing Review at least annually from the date of initial approval. Refer to the *South College IRB Policies and Procedures Manual for Human Subjects Research* for a description of each of these research categories. If the investigator has any doubt about the appropriate level of review for a project (Exempt, Expedited, or Full Committee Review), the IRB staff is available to aid applicants in making this determination. The final determination of whether the proposed research meets federal criteria for the requested review category will be made by the IRB.

### Exempt Status Review

Although this category is called “Exempt,” this type of research requires IRB review and approval. Only the IRB can assign Exempt status to a project. The determination of Exempt status by the IRB must be made prior to initiation of the research; it cannot be made retroactively. After initial approval, an exempt research project does not require continuing review by the IRB, unless it is amended in such a way that it no longer meets exemption status. Although a project may be granted Exempt status, no interaction with human participants is exempt from the ethical principles described in the *Belmont Report*. The principal investigator is responsible for ensuring that informed consent is obtained from human subjects participating in research determined to be exempt.

### Categories of Exempt Research

Exempt research is research with human subjects that falls under one or more of the following eight exempt categories listed in the federal regulations (45 CFR 46.104d):

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
  - a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or

- b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
3. Research involving benign behavioral interventions (only for behavioral research, not biomedical research) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
- a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or
  - b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
- a) The identifiable private information or identifiable biospecimens are publicly available;
  - b) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
  - c) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
  - d) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and,

if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
6. Taste and food quality evaluation and consumer acceptance studies:
  - a) If wholesome foods without additives are consumed, or
  - b) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If your research falls in one or more of the above six categories, fill out the *Human Subjects Research Protocol: Exempt or Limited Review* form.

### **Categories of Research that CANNOT be Exempt**

1. Research that includes educational tests, survey procedures, interview procedures, observation of public behavior, or benign behavioral interventions if the information is recorded in such a way that it can be linked back to the subject either directly or indirectly through the use of a code and any disclosure of the human subjects' responses would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
2. Research involving prisoners.
3. Surveys, interviews, or benign behavioral interventions given to children (individuals younger than 18 in TN).
4. Observations of public behavior when the investigator participates in the activities being observed.

## Limited Review

Limited Review research is research with human subjects that falls under one or both of the following two limited review categories listed in the federal regulations (45 CFR 46.104d):

1. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects; any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; and the IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
2. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects; any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; and the IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

If your research falls in one or both of the above categories, fill out the *Human Subjects Research Protocol: Exempt or Limited Review* form.

If your research is not in one of the Exempt or Limited Review categories, fill out the *Human Subjects Research Protocol: Expedited or Full Review* form instead of the *Exempt or Limited Review* form.

## Expedited Review

If the research presents no more than minimal risk to human participants and it falls under one of nine

expedited categories listed in the federal regulations, the IRB may determine that it qualifies for an expedited review.

*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 ([45 CFR 46.102(j)] and [21 CFR 56.102(i)]).

## Categories of Expedited Research

Expedited research is research with human subjects that falls under one or more of the following nine expedited categories in the federal regulations [45 CFR 46.110]:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
  - a. Research on drugs for which an investigational new drug application (21 CFR 312) 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 (21 CFR 812) 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.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.
  - b. From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.
3. Prospective collection of biological specimens for research purposes by non-invasive means.

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 (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 participant or an invasion of the participant'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. 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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 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 made 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. 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.
  - b. Or where no subjects have been enrolled and no additional risks have been identified.
  - c. Or 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 the following conditions apply:
  - a. Categories two (2) through eight (8) do not apply, and
9. 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.

## Full Committee Review

Research projects that involve more than minimal risk require full board review at a convened meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the

approval of a majority of those members present. Categories of research that require a Full Committee review include:

1. Studies with procedures that present more than minimal risk to human subjects.
2. Studies involving subjects likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
3. Studies taking place internationally (particularly those with little or no provisions for protection of human subjects).
4. Studies where information may be disclosed that could require mandatory legal reporting (e.g., child/elder abuse, drugs, etc.), or damage the participant's social standing, financial standing, or employability.
5. Studies involving deception, which raises the risk level of the subjects.
6. Studies that fall under the jurisdiction of the Food and Drug Administration.

## **Continuing Review**

Continuing Review of all projects initially approved by Full Committee Review is required at least annually. The IRB may require more frequent review of a project depending on the risks to human subjects.

Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances:

- Research that received Exempt status from the IRB,
- Research approved by the IRB in accordance with Limited Review,
- Research approved by the IRB in accordance with Expedited Review,
- Research approved by the IRB in accordance with Full Review if the approved research has progressed to the point that it involves only one or both of the following:
  - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
  - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

As a courtesy, the IRB will send Continuing Review reminders to investigators approximately 90, 60, and 30 days before a project expires. However, it is ultimately the investigator's responsibility to initiate a Continuing Review application and to allow sufficient time for the review and re-approval process to be completed before the current approval expires.

**If an IRB approved project expires, all research activities involving human subjects must stop.** These activities involve subject contact, data collection, and data analysis.

## Instructions for Completing the Human Subjects Research Protocols (Initial Submissions)

1. Select the type of IRB review that is appropriate for your project: Exempt Status Review, Limited Review, Expedited Review, or Full Committee Review.
2. Complete Human Subjects Research Training. Human Subjects Research Training must be completed by all investigators associated with the project before IRB approval of an application will be granted. All investigators should submit a certificate of completion of Human Subjects Research Training with the IRB application form. Directions for completing the training and obtaining a certificate are provided on the South College IRB website in the document entitled, *Human Subjects Research Training*.
3. Download the *Human Subjects Research Protocol: Exempt or Limited Review* form or the *Human Subjects Research Protocol: Expedited or Full Review* form from the South College IRB website. These forms are MicroSoft Word documents.
4. Fill out the appropriate MicroSoft Word document on your computer.
5. Sign the form.
6. Obtain signatures from Co-PI and Co-Investigators, if applicable.
7. Obtain departmental approval of the completed form. The Department Chair (or his/her designee) must review and sign off on the IRB application before it is submitted to the IRB for review.
8. Submit the original signed form and any additional required documents to Ms. Brittany Galyon, IRB Coordinator, [bgalyon@south.edu](mailto:bgalyon@south.edu)
9. Retain copies of all documents for your records.