



**Institutional Review Board**  
University of South Alabama

**PROTOCOL APPLICATION FOR  
HUMAN SUBJECTS RESEARCH  
NEW PROJECTS**

**Investigator's Assurance:** By submitting this protocol, I attest that I am aware of the applicable principles, policies, regulations, and laws governing the protection of human subjects in research and that I will be guided by them in the conduct of this research.

To submit a protocol application please complete the following.

**For exempt** protocols: Submit **two** copies of this application, **two** copies of the consent form and **two** copies of the protocol (including questionnaire or survey if applicable).

**For expedited** protocols: Submit **three** copies of this application, **three** copies of the consent form, and **three** copies of the protocol (including questionnaire or survey if applicable).

**For full board** review: Submit **thirty(30)** copies of this application, **thirty(30)** copies of the consent form and **four** copies of the protocol. Sponsored drug studies also require **four** copies of the investigator's brochure, **one** copy of the FDA Form 1572, and **three** copies of the drug summary sheet.

**In the following judgment of the Principal Investigator, this research qualifies for which of the following:** *(please note: protocols involving children <19 years of age cannot be submitted as exempt)*

**Exempt** \_\_\_\_\_  
**Category** \_\_\_\_\_  
[\(See Guidelines Part V\)](#)

**Expedited** \_\_\_\_\_  
**Category** \_\_\_\_\_  
[\(See Guidelines Part IV\)](#)

**Full Board** \_\_\_\_\_  
[\(See Guidelines Part III\)](#)

\_\_\_\_\_ Date of submission

\_\_\_\_\_ Title of Research

\_\_\_\_\_ Principal Investigator Dept/School Room # Phone Email

\_\_\_\_\_ Other Investigator Dept/School Room # Phone Email

\_\_\_\_\_ Other Investigator Dept/School Room # Phone Email

\_\_\_\_\_ Site(s) of Human Subject Data Collection (If sites are separate from the University, please submit approval letter)

\_\_\_\_\_ Funding Agency (if applicable)

**For Student Research**

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Faculty Sponsor	Dept/School	Room #	Phone	Email
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Student Street Address	City	State	Zip	Phone
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Type of Research (dissertation, master's thesis, class project, other)

**Purpose of Research**

**Relevant Background and Rationale for the Research:**

**Subject Population:** *NOTE: Federal guidelines require selection of subjects be equitable within the exclusions, and subjects meeting the criteria cannot be discriminated against for gender, race, social or financial status, or any other reason.*

Approximate number of subjects \_\_\_\_\_ Male/Female Ratio \_\_\_\_\_

Subjects will be (check only if applicable):

Minors (under 19) \_\_\_\_\_ Involuntarily institutionalized \_\_\_\_\_ Mentally handicapped \_\_\_\_\_

**Procedures and Agents (if applicable) to be Used**

**The Experimental Design and Methodology:**

*Please limit this description to the portions dealing directly with the use of human subjects.*

**What incentives will be offered, if any?**

**Risk/Benefits to participants and precautions to be taken**

*Identify possible risks to subjects. These may be of a physical, psychological, social or legal nature. If subjects are vulnerable populations, or if risks are more than minimal, please describe what additional safeguards will be taken.*

In your opinion, do benefits outweigh risks?      Yes \_\_\_\_\_      No \_\_\_\_\_

**Privacy/Confidentiality**

*Please describe whether the research would involve observation or intrusion in situations where subjects have a reasonable expectation of privacy. If identifiable existing records are to be examined, has appropriate permission been sought, i.e. from institutions, subjects, and physicians? What provision has been made to protect the confidentiality of sensitive information about individuals?*

**A Disclosure of Financial Conflict of Interest Form is to be submitted with each proposal for funded research.**

**If x-rays or isotopes are to be used specifically in support of the research, approval of the Radiation Safety Committee must be obtained.**

**If a biological hazard may exist for either subjects or investigators, approval of the Biohazards Committee must be obtained. Under Federal Regulations, this includes all handling of human blood or other tissues for research (not clinical) purposes.**

**If a medical procedure is to be performed using human subjects, the investigator must have been approved for such procedures by the hospital's Credentials Committee.**

**Consent for Participation Instructions ([see Guidelines Part IX](#))**



**CLINICAL TRIALS DATABASE**  
**UNIVERSITY OF SOUTH ALABAMA**

The University of South Alabama Clinical Trials Database is accessible via the world-wide web at <http://southmed.usouthal.edu/com/trials/> and serves as a useful tool to recruit subjects for the study protocols, enhance physical referral, and address patient inquires.

IRB Protocol Number \_\_\_\_\_  
(to be filled in by IRB administrator)

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Title of Protocol

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Principal Investigator

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Sponsor

Participants:

Male/Female \_\_\_\_\_/\_\_\_\_\_ Age range \_\_\_\_\_

Eligibility:

Exclusions:

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Brief description of research in lay terms

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Primary Disease Category \_\_\_\_\_

Keyword(s): \_\_\_\_\_

Experimental Drug/Device: \_\_\_\_\_

Please indicate your preference for inclusion below. Unless you indicate “no” your protocol will be listed on the website.

Yes \_\_\_\_\_ No \_\_\_\_\_

**Contact/Referral Information**

Physician referrals are encouraged                      Yes \_\_\_\_\_                      No \_\_\_\_\_

Patient inquiries are encouraged                      Yes \_\_\_\_\_                      No \_\_\_\_\_

For additional information about this research please contact:

\_\_\_\_\_  
Principal Investigator

\_\_\_\_\_  
Address

\_\_\_\_\_  
Phone                                      Email                                      Fax

## **PART IV: NEW PROJECTS IRB APPLICATION EXPEDITED REVIEW**

### **A. GENERAL INFORMATION**

In November 1998, DHHS issued a list of "expedited review categories," categories of research that pose no more than minimal risk and are eligible for "expedited" IRB review. This 1998 list replaced and expanded on the original list published by the agency in 1981.

Investigators may apply to the IRB for expedited review if their research falls into one of the nine categories on the new list. The first step in applying is to review the Expedited Review Categories section below. Both the "Applicability" and the "Research Categories" sections of the regulations need to be considered, and the expedited review category must be noted on the IRB Application form. Investigators are encouraged to call the IRB office at 460-6308 with any questions about the regulations and about the specific review categories.

If expedited review seems to be appropriate, the next step is to prepare and submit an IRB Application for New Projects (see sample form, [Appendix I](#)). The expedited review regulations allow for review by a member of the Expedited Review Subcommittee of the IRB. If any of the reviewers believes that the research does not fit into an expedited category, or believes the study should be reviewed by additional members, he/she may refer the application to the Full IRB for further review.

Turnaround time for review of Expedited applications is two to four weeks depending on whether review occurs in the office or at a full board meeting.

### **B. EXPEDITED REVIEW CATEGORIES**

The 1998 expedited review regulations are quoted on the following pages. The first section of the regulations is titled "Applicability" and discusses concepts that apply to all types of expedited review research. The second section is titled "Research Categories" and lists the specific categories that are eligible. One or more of these categories must be cited in your application. Each of the nine categories is labeled with a short descriptive heading in bold and italicized text; these headings were added for explanation and are not quoted from the regulations. Parts of the regulations are followed by Comments sections; again, these comments are provided for explanation and are not quoted from the regulations.

Following the list of categories is an explanation of the specific requirements for submitting an expedited application.

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure (published in the Federal Register, 63FR60364, effective November 9, 1998):

*An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.*

#### **Applicability**

- Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply

because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involved no more than minimal risk to human subjects.

- The categories in this list apply regardless of the age of subjects, except as noted.
- The expedited review procedure 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 not greater than minimal.
- The expedited review procedure may not be used for classified research involving human subjects.
- IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review-expedited or convened-utilized by the IRB.
- Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Comments: If as part of the study subjects will be randomized to a treatment group, then the study does not qualify for expedited review.

## Research Categories

1. **A very limited number of studies of approved drugs and devices:** 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 Part 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 Part 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.

Comments: The drug or device must be approved and used exactly according to its labeling. All study procedures other than use of the drug or device must themselves be of minimal risk for the study to qualify for expedited review. Few studies fit this category.

2. **Blood sampling:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, 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; or

b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, 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.

*Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a). In Alabama, minors are less than 19 years old.*

**3. Noninvasive specimen collection:** Prospective collection of biological specimens for research purposes by non-invasive 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 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. Noninvasive clinical procedures:** 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 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. **Use of data or specimens collected for non-research purposes:** 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.)

*Comments:* (a) This category refers to materials collected for "non-research purposes," but can be used to cover research materials if the investigator's role is simply to analyze them. That is, if an investigator is receiving materials from colleagues who have separate approval to collect them, and the materials are handled with code numbers and other protections for confidentiality, he or she may apply for expedited review for the analysis; (b) This type of research is exempt from review only if the data collected has no link whatsoever to identifiers (not even a code number).

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

7. **Low risk behavioral research:** 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.

*Comments:* Only very specific types of behavioral research are exempt from review. Again, there usually must be no link whatsoever to identifiers (not even a code number).

8. **Renewal of inactive research protocols or protocols that are essentially complete:** 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. **Renewal of other minimal risk research protocols:** 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.

### C. SPECIFIC SUBMISSION REQUIREMENTS

Three copies of the protocol (including questionnaire or survey if applicable), three copies of the New Projects IRB Application Form (see sample form, Appendix I), and three copies of the consent form must be submitted for an initial, expedited review. The sets should be individually stapled and collated in the order listed below.

1. Cover letter (optional)
2. New Projects IRB Application Form (three copies)
3. Protocol (three copies)
4. Consent Form (three copies)
5. Special Requirements/Attachments

#### a. Disclosure of Financial Conflict of Interest

A Disclosure of Financial Conflict of Interest Form ([Appendix I](#)) is to be submitted with each proposal for funded research, either through the Office of Sponsored Projects (for most federally funded applications), or through the College of Medicine Business Office (for grants that are processed through the Medical Sciences Foundation). If a significant financial interest is felt to present a possible conflict of interest the application may be given to the University Conflict of Interest Committee to determine appropriate management following review by the University's Senior Vice President for Academic Affairs or the Office of the Vice-President for Medical Affairs.

#### b. Approval of the Radiation Safety Committee

If x-rays or isotopes are to be used specifically in support of the research, approval of the Radiation Safety Committee must be obtained.

#### c. Approval of the Biohazards Committee

If a biological hazard may exist for either subjects or investigators, approval of the Biohazards Committee must be obtained. Under Federal Regulations, this includes all handling of human blood or tissues for research (not clinical) purposes.

#### d. (IND) (Investigational New Drug) Number and Investigator's Brochure

When a study involves use of an unapproved drug, or an approved drug for a new use, the investigator must submit an IND number obtained from the FDA, and one copy of the Investigator's Brochure for the drug, which provides background information such as information from animal research and toxicity data.

#### e. IDE (Investigational Device Exemption) Number and Investigator's Brochure

When a study includes an unapproved device, or an approved device for

a new use, and a "significant risk" device is involved, the investigator must submit an IDE number obtained from the FDA, and one copy of the Investigator's Brochure for the device. If the investigator believes that the device poses a non-significant risk, FDA regulations allow the option of requesting a "non-significant risk" IDE determination from the local IRB. The Investigator must submit this request to the IRB with an explanation of why the study should be considered of non-significant risk, and other supporting information. This request and justification should be presented separately or distinctly from the application for approval of the protocol. The IRB will make a determination based on the criteria described in the FDA "Guidance on Significant and Non-Significant Risk Device Studies" Depending on the circumstances of the study, additional safety or liability assurances may be required on an individual, case-by-case basis.

f. Approvals from other IRBs

When a study is being carried out on a non-USA site, and approval from other institutional review boards must be sought, the IRB recommends that a copy of each IRB approval be submitted.

g. Questionnaires/Other Instruments

Any questionnaires, tests, survey instruments or data collection sheets which are not standard and well-known must be submitted as part of the application.

h. Advertisements/Notices/Recruitment Flyers

The text of any advertisement, video display, notice, sign, brochure or flyer used to recruit subjects either should be included as an attachment.

D. THE NEW PROJECTS IRB APPLICATION FORM-EXPEDITED REVIEW

The following are explanations given for each of the sections of the application form.

1. Purpose of Research

This section should discuss the purpose of the investigation, defining the problem to be investigated. Whenever possible, it should state the specific hypothesis to be tested. If specific hypotheses are not being tested, the questions to be answered, data to be tested, description to be made or the information hoped to be gained should be explained. For pilot or exploratory studies, this section should discuss the way in which the information obtained will be used in future studies, so that the potential long-range benefits of the pilot work can be assessed.

2. Relevant Background and Rationale for the Research

This section should present the context of the work by explaining the relation of the proposed research to previous investigations in the field. Relevant laboratory

and animal studies should be summarized. If the study involves an investigational new drug or device, the summary in the protocol must be supplemented with detailed information in the Investigator's Brochure for the drug or device. This section should present clear justification for participation of human subjects at this stage of the investigation.

### 3. Procedures and Agents (if applicable) to be Used

This should give an explanation of what will be done to each subject for research purposes, and how this compares with what would be done were the individual not in the study. Agents used in the study should be included in this section.

### 4. The Experimental Design and Methodology

The purpose of this section is to acquaint the IRB with the specific nature of the procedures to be carried out on human subjects so that the risks of the study may be evaluated. This section should also present an explanation of how the methods employed will, in fact, allow the investigator to evaluate the hypotheses posed or gather the data sought.

### 5. What incentives will be offered, if any?

This section should indicate whether or not subjects are to be paid for their participation in the study and how and when they will be paid. If they will be paid, it should clearly state how much subjects will receive, and the rationale for that amount. This section should note whether payment is pro-rated if a subject does not complete the entire study, and whether a bonus payment is offered for completion. A reimbursement schedule should be provided if appropriate.

The proposed payment should be commensurate with the time required for participation, travel expenses, and/or inconvenience assumed by the subject, but should not be so great as to constitute undue influence on an individual to assume risks of study participation that would not otherwise be undertaken.

### 6. Risks/Benefits to Participants and Precautions to Be Taken

This section should discuss all possible risks and discomforts from participation in the study, indicating both severity and likelihood of occurrence for each. Risks may range from the physical to the psychological. Inconvenience, travel or boredom may also be considered risks of participation in the study. The methods that will be used to minimize these risks should also be discussed. Many studies hold the potential for loss of privacy and confidentiality. These concerns should be noted in this section.

### 7. Privacy/Confidentiality

This section should indicate whether or not research records will be anonymous. If not, there should be discussion of how records will be coded, and where and how they will be stored. It should also note where and how signed consent forms will be maintained. If video or audio tapes will be made as part of the study, disposition of these tapes should be addressed. In general, the IRB recommends that research tapes be destroyed as soon as the needed data are transcribed,

and that only restricted study personnel be allowed access to the tapes. If other procedures are proposed (for example, retaining tapes for future use, allowing individuals other than study investigators access to the tapes) justification should be presented, and separate consent may be required.