

IRB EXPEDITED REVIEW

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 Institutional Review Board through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. 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 involve no more than minimal risk to human subjects.

**Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [45 CFR 46.102(i)]*

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 subject's 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.

The expedited review procedure may not be used for classified research involving human subjects.

The standard requirements for informed consent (or its waiver, alteration, or exception) apply.

Categories one (a) through seven (b) pertain to both initial and continuing IRB review.

RESEARCH CATEGORIES REVIEWED THROUGH AN EXPEDITED PROCEDURE

(Use categories 1 – 7 to complete question number one (1) on the second page of the application form)

- (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 Part 312) is not required.
 - (b) Research on medical devices for which (1) an investigational device exemption application (21CFR Part 812) is not required; or (2) 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, non-pregnant adults who weigh at least 110 pounds (not to exceed 550 ml in an 8 week period and collected not more frequently than 2 times per week; or
 - (b) from other adults, 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, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collected not more frequently than 2 times per week.
- (3) Prospective collection of biological specimens (hair and nail clippings, excreta and external secretions, deciduous teeth, uncannulated saliva) for research purposes by noninvasive means.
- (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.)

(Do NOT send this page with application)

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) 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. [45CFR46.101 (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 [45CFR46.101(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;
 - (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.

(Do NOT send this page with application)

Date Received in Office: _____

IRB #: _____

APPLICATION FOR EXPEDITED

Send two (2) copies (the original and a copy); three (3) copies if using minors to: *Tina Pilgreen, Research Compliance Coordinator
Sponsored Programs, Library 324*

Date:

Investigator (s)

Name:

Email:

Phone:

If Student(s), Research Advisor's Name:

Email:

Phone:

UCA Address (of Research Advisor if a student): Building:

Room #:

Department:

College:

Project Title:

Anticipated dates of project: Beginning:

Ending:

FUNDING: Anticipated source of funds, if any, including UCA Research Funds. (If this project will be funded under a grant to another investigator, please give the title of the grant, name of agency or institution, and the investigator's name.)

Proposal has been (will be) submitted for funding (date):

Will proposed research be conducted with investigator(s) from other agency/institution(s)?

Yes No

If YES, list agency/institution(s) and investigators: _____

Is proposed research being conducted to meet course or degree requirements at another university?

Yes No

If YES, has the research been reviewed by that university's IRB?

Yes No

If YES, what were the results?

(attach approval letter)

**Required Training/Education in protections for human research subjects: (Eqo r rgyg'hqt CNN investigatoru'twaf gpvu'lr'eww{.'"
wclh't'pf 't'gugctej 'cf xluqt.)"**

Name:

NIH/CITI Tutorial Certificate is: attached on file

SUBJECT INFORMATION:

1. State the Category (1-7) of Expedited Research from **pages 1 and 2:** #
2. Total number of Subjects and Controls: # of Males: # of Females:
3. Categories of Subjects and Controls Institutional Affiliation of Subjects
Adults (18 years and over) None
Adolescents (13-17 years of age) Schools/College/University
Mid-Childhood (6-12 years of age) Prisons
Preschool (3-5 years of age) Hospitals/Clinics
Infants (0-2 years of age) Other (specify)
Pregnant Women
Other (specify):
Using existing data, no subjects recruited
4. Mentally Competent **Adult** (able to give consent) Mentally Incompetent **Adult** (unable to give consent)
5. Demographic Information (check all variables included)
Names of Subjects Income
Addresses Social Security Number
Phone numbers Job Title
Age Names of Employers
Sex Types of Employers
Ethnicity Other Unique Information
Marital status (specify):
6. Briefly explain how the demographic information will be used.
7. How will the subjects be chosen? (If using existing records, attach a copy of the permission.)
8. How will the subjects be recruited and contacted?
9. Will the subjects receive any inducement or remuneration (e.g., \$\$, gift certificates, class credit) or token gifts (e.g., candy, stickers) to participate in the research? Yes No
(if **YES**, describe)
10. What is the **time** requirement for the subject?
11. Will subjects be charged for any research related procedures? Yes No
""(if **YES**, explain)
12. Describe any potential short and long term benefits from this research to the subjects and/or society. (If there are none, state none.)
Subjects:

Society (Science):
13. Study site: Where will the research be conducted? If not at UCA, has permission been granted? (Attach a copy.)

RESEARCH PROJECT DESCRIPTION:

Use *LAY TERMS* and/or *PROVIDE DEFINITIONS* of technical terminology. [Use extra pages as necessary.]

1. Briefly describe the background or justification for your research.

2. Describe your research focus (the purpose or questions to be answered).

3. Describe the research design including the use of a control group and any intervention or treatment to be administered to the subjects, whether performed by the researchers or others.

4. Describe your data collection procedures in detail.
What will the subjects (and controls) be doing to create the data (e.g., filling out a survey, performing a task, etc.)?
If the subject will need training, explain in detail. (Attach copies of any instruments, tests, surveys, interview guides, etc., and descriptions of any research data collection equipment.)

RISKS AND CONFIDENTIALITY:

1. RISKS TO SUBJECTS

Will the subjects be placed **at risk of harm* as a consequence of participating in this research? Yes No

**Definition of at risk of harm – to be placed in a position with greater potential for physical, mental, social, legal or financial harm than would be expected for that individual in his or her normal occupation or daily activities.*

If you are not sure of the answer to the above question, talk to your faculty advisor (if student research), the Research Compliance Coordinator, or an IRB member from your college. If the answer is YES to the above question, then this research needs to be reviewed by the full IRB, so if you are unsure, please ask for guidance.

2. CONFIDENTIALITY OF DATA

Will any data be part of a permanent record that can be identified with the subject(s)? Yes No
(if yes, explain)

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What steps will be taken to ensure the confidentiality of the data? (How will the subject’s privacy be protected?)

Where will the data be stored for the three (3) year minimum? Specify the precise location, preferably in a locked file cabinet with limited access by others, and on the UCA campus. If student research, the advisor should store the data.

INFORMED CONSENT PROCEDURES: (See the consent/cover letter/permission/assent templates.)

1. What type of informed consent will be used? (Check one, or more, as appropriate to your project.)

Informed consent agreement, parent permission, assent (signatures obtained).

Informed consent cover letter (no signature obtained). **One of the criteria below must be met and checked off.**
the research presents no more than minimal risk of harm and involves no procedures for which a signature is normally required outside of the research
the only record linking the subject and the research would be the consent and the principal risk would be potential harm from a breach of confidentiality

Waiver from informed consent process. **All four criteria must be met. Describe this need in your project description.**

the research involves no more than minimal risk to subjects,
the waiver will not adversely affect the rights and welfare of subjects,
the research could not practicably be carried out without the waiver, and
whenever appropriate, subjects will be given additional pertinent information after participation

Oral consent. (Attach a copy of the script for informed consent and the short written form that will be signed by the subject and a witness.)

2. Describe clearly (step-by-step) how informed consent/permission/assent will be obtained from or presented to subjects, parents and/or legal guardians.

3. Are you purposely withholding some information from subjects or using deception in the research? Yes No
(if YES, provide the following information)

Describe the withheld information or the deception:

Justify the reason:

Describe the post-research debriefing of the subject, including when and where subjects will be debriefed.
(Attach a copy of the debriefing statement that will be given to subjects.)

INVESTIGATOR AGREEMENT:

I agree to follow the procedures outlined in this summary description and any attachments to ensure that the rights and welfare of human subjects in my research are properly protected. **I understand that no contact may be initiated with subjects until I have received written approval of these procedures from the Institutional Review Board and complied with any required modifications in connection with that approval.**

I further understand that additions or changes in the procedures involving human subjects or any adverse events or problems with the rights or welfare of the human subjects must be promptly reported to the Research Compliance Coordinator.

I further understand that **subject data and research records must be maintained in a secure and safe location for a period of at least three (3) years** after research is completed. The original data will be provided to the IRB if so requested.

_____ Signature of Investigator	_____ Date
_____ Signature of Investigator	_____ Date
_____ Signature of Investigator	_____ Date
_____ Signature of Investigator	_____ Date
_____ Signature of Investigator	_____ Date
_____ Signature of Investigator	_____ Date
_____ *Signature of Research Advisor (if the above are students)	_____ Date

***As Research Advisor**, I agree to be responsible for the ethical conduct of the research and for the maintenance of the data and any signed consent forms for a minimum of three years.

_____ Signature of Human Subjects Committee Chair (Department of Psychology and Counseling Only)	_____ Date
_____ Signature of Department Chair (I am aware that IRB approval is being sought for human subject research.)	_____ Date