



The University of South Alabama

The IRB Handbook  
for the  
Student Researcher



**July, 2004**

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## THE IRB - A BRIEF HISTORY

An Institutional Review Board is a committee mandated by the National Research Act, Public Law 93-348, to be established within a university or other institution that conducts biomedical or behavioral research involving human research subjects. The purpose of the IRB is to review all human subject research proposals before the research is conducted.

The principles from which IRBs emerged are found in the Nuremberg Code, the Declaration of Helsinki and the Belmont Report, documents which define the minimum codes for conducting research with human beings. Recognition of the need for guidelines dealing with human subjects in research emerged following the Nuremberg trials, where the medical experimentation abuses of World War II Nazi doctors came to public attention. This led to the creation of the Nuremberg Code in 1945, the first legal attempt to deal with ethical issues of modern research. As biomedical research efforts expanded, the need for a more specific international code of ethics was formulated in the 1964 Declaration of Helsinki. In 1974 Congress passed the National Research Act, creating the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research which sets definitive standards of the Institutional Review Board. In 1979 the National Commission published recommendations known as the Belmont Report. The report was an outgrowth of intensive discussions begun in February at the Smithsonian Institution's Belmont Conference Center and supplemented by monthly deliberations of the Commission over the next three years. **The Belmont Report** is a statement of basic ethical principles and guidelines meant to assist individuals in resolving ethical problems that surround the conduct of research with human subjects.

The Belmont Report outlines three general ethical principles that should govern human subjects research:

- **Beneficence:** To maximize benefits for science, humanity, and research participants and to avoid or minimize risk or harm.
- **Respect:** To protect the autonomy and privacy rights of participants.
- **Justice:** To ensure the fair distribution among persons and groups of the costs and benefits of research.

These regulations, which set standards for review of human research activities by IRBs now apply to all activities involving human subjects within the University. The University of South Alabama (USA) holds a Federal Wide Assurance (FWA) issued by the Office of Human Research Protections. This is a written agreement in which USA describes the jurisdiction, composition, policies and methods of procedure by which the IRB will function.

## POINTS OFTEN MISUNDERSTOOD OR DISREGARDED

1. Federal regulations for research involving human subjects is not limited to drug or medical studies. There is sometimes a misconception that if the subject is not undergoing medical procedures, the project is not covered by the regulations. **Any project where data are obtained through intervention with, manipulation of, interviewing, communicating with, or observing human subjects for the purposes of gathering data must be approved by the IRB, including the distribution of surveys for research purposes.**
2. Certain types of projects are **exempt** from full IRB review. This does **not** mean that these projects may be conducted without submitting them to the IRB for approval. An exempt protocol still requires IRB approval. Exemption from IRB review must be documented. Many journals now require proof of IRB review or exemption before accepting manuscript submissions. The explanation of projects which may qualify for exempt status can be found in the Appendix of this manual.
3. **Vulnerable populations** include: children, minors, prisoners, the mentally impaired, inmates of mental institutions, the competency-impaired aged, the economically and educationally disadvantaged, or any other person whose judgment when consenting to participation may be impaired. Research involving vulnerable subjects is **never** exempt from IRB review and approval.
4. In Alabama [Title 27, Section 26, Code of Alabama of 1940(Interim Supp.1975)], a minor is an unmarried person who has not reached the age of 19. Please note that this is a departure from most states, where the age of majority is 18. A person under the age of majority may not sign a consent to participate in research. A parent or guardian must give this consent. A child over the age of 10 who may reasonably understand the nature, risks and benefits of the research may **assent** in writing to participate, but this must still be confirmed by parental/guardian **consent**.
5. IRB approval, or a letter of exemption, must be obtained **before** a project is started.
6. The regulations regarding the content of any solicitation for subjects (advertisements, notices in newspapers, flyers, etc.) are explicit. Advertisements and methods of recruitment must be approved by the IRB.
7. Risk to a subject is not limited to physical harm. Emotional, psychological, social, or financial damage is also possible and should be considered.

## **POLICY FOR STUDENT RESEARCH INVOLVING HUMAN SUBJECTS**

### **Student Policy:**

Students at the University of South Alabama who are conducting research that involves human subjects must go through the same process as faculty members or other USA employees to secure IRB approval for their research. All student research projects involving human subjects conducted outside the classroom requires IRB review. This includes surveys/questionnaires that may pose minimal or no risk and may not contribute to generalizable knowledge (e.g., publishing, presenting, or archiving). The IRB reviews the contents of the survey instruments for specific purposes such as confidentiality issues, sensitive information, etc.

When research projects involve more than minimal risk, the student cannot be the principal investigator, instead the faculty advisor or another faculty member must take on the role as principal investigator and the student be listed as the co-investigator. When research projects involve no more than minimal risk, the student may be listed as the principal/student investigator if the project is wholly generated and carried out by the student with minimal input or oversight by a faculty advisor.

### **Definition of Research and Human Subjects:**

Research is defined as “a systematic investigation including research development, testing and education designed to develop or contribute to generalizable knowledge”. An intent to publish and/or present the findings of research is generally understood to indicate that the investigation will contribute to generalizable knowledge. A “human subject” is a living individual about whom an investigator (whether professional or student) conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information.” (As stated in section 46.101 - definition of CFR Title 45, Part 46, Protection of Human Research Subjects Policy).

### **Classroom Projects:**

Classroom demonstrations, exercises, and/or experiments designed for the exclusive purpose of education are excluded from the University’s IRB policy. When these activities do not directly result in advancing or disseminating generalizable knowledge beyond the course or classroom, they are not considered to be research and therefore need not be reviewed by the IRB. For purposes of education, examples of projects that are excluded from IRB review, but not limited to, include practicing various research methods such as interviewing, observation and survey techniques, measurements of behavior, and data analysis. Typically these projects are quite limited in scope, do not lead to generalizable knowledge and are not undertaken with that goal in mind.

### **Dissertations or Masters Research Projects/Thesis:**

Any research conducted by students, graduate or undergraduate, which uses human beings as subjects and is intended to contribute to generalizable knowledge, must be reviewed and approved by the IRB. This includes all independent undergraduate research projects, masters’ thesis and dissertations. All student-initiated research must be submitted as an independent project, not as an amendment to an already approval protocol.

### **Responsibility of Faculty Advisors:**

Faculty advisor’s have three responsibilities: 1) supervision of the student’s research, 2) assistance in preparing the student’s application for IRB review and approval, 3) maintenance of the research records for the required three years post termination of the research project. Faculty advisors are ultimately responsible for ensuring that the research is conducted in accordance with the University of South Alabama’s Federal Wide Assurance and with applicable USA policies involving human subjects research. If a student violates a protocol, the faculty advisor should immediately report it to the IRB.

## THE STUDENT GUIDE TO PREPARING A RESEARCH PROPOSAL

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<b>Step one:</b>	<b>Determining if your research paper requires IRB approval.</b>		
1.	Does your research involve contact with a human subject?	<b>9Y</b>	<b>9N</b>
2.	Does the research involve seeking information from records or surveys about a human subject?	<b>9Y</b>	<b>9N</b>

**NOTE:** If the answer to either one of these questions is yes, then you are required to seek review of your proposal by the IRB to obtain approval to conduct the research. If the answer to both questions is no, you do not need IRB approval.

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<b>Step two:</b>	<b>Determining the appropriate type of review</b>		
1.	Does the research involve the collection of anonymous data which will be derived from information about a human subject?	<b>9Y</b>	<b>9N</b>
2.	Does the research involve no more than minimal risks?	<b>9Y</b>	<b>9N</b>
3.	Does the research involve <u>more</u> than minimal risks?	<b>9Y</b>	<b>9N</b>
4.	Does your project involve children under the age of 19?	<b>9Y</b>	<b>9N</b>

If yes to:  
Question 1, Exempt review. (See IRB policy manual page 18-20)  
Question 2, Exempt or Expedited review. (See IRB policy manual page 13-18)  
Question 3, Full Board review (See IRB policy manual page 10-12)  
Question 4, Full Board review.(See IRB policy manual page 10-12)

**NOTE:** IRB Review Category checklist located in the Appendix of this manual may be used for determining the appropriate IRB review process.

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### Step three: Completing the protocol application

IRB website: <http://southmed.usouthal.edu/com/research/humansubjects.html>

1. **Research purpose:** Include a brief definition of the problem being investigated and the purpose of the research (hypothesis) and the information you seek to gain.
2. **Subject population:** Identify all categories of vulnerable subjects to be recruited. These populations must be given extra protection.
3. **Experimental design and methodology:** Describe how and where the study will be conducted, what information will be collected and how it will be analyzed.
4. **Risks/benefits to participant:** Explain all possible risks or discomfort which may include physical, psychological, inconvenience, or loss of privacy.
5. **Recruitment:** Explain how subjects will be selected and/or contacted. Advertisements, notices and flyers produced for subject recruitment must be approved by the IRB.
6. **Privacy/confidentiality:** Indicate if the research records will be anonymous and how you plan to maintain the anonymity of the subject. If using informed consent (a document requesting permission from the subject to perform said research), explain how the informed consent document will be managed.
7. **Human Subjects Training:** In October 2001, the National Institutes of Health mandated education on the protection of human participants which has been adopted by the IRB as policy for all investigators, co-investigators, and key personnel involved in the research study. **NOTE: Research under exemption #4 is not required to complete the human subjects protection training.**

8. **Outcome of research:** Describe how the information collected will be used.
9. **Project dates:** These dates should include when the project is anticipated to begin and end.

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**Step four: Tips on preparing the informed consent (see page 27 of the IRB policy manual for consent guidelines)**

1. **Heading and title:** Include a reference to the University of South Alabama, investigator's name, and research project title.
2. **Explanation of the purpose and background of the study:** Introduce the study, explain who is doing the research, the aim of the study and why the potential subject is being asked to participate. Be sure to name yourself as the principal investigator and your affiliation with USA.
3. **Procedures:** Emphasize the voluntary nature of the study. Suggestive wording, "You have been asked to . . ., If you agree to participate . . . ,
4. **Risks/discomforts:** Explain the potential risks in order of severity. If there is a chance of injury, explain if there is compensation for this.
5. **Benefits:** Explain any rewards the potential subject will receive, if applicable.
6. **Alternatives:** If there are alternatives to participation, explain. Sometimes the only alternative is to decline.
7. **Costs:** If there are no costs for participation, state this in the consent.
8. **Contact:** Include the name and phone number of someone the potential subjects can call if they have questions about the research, as well as the number of the IRB Office.
9. **Consent:** Explain that the participant will be given a copy of the consent form and their signature is considered agreement to participate in the research.
10. **Signature:** Include a signature line for the potential subjects signature, a line for your signature as witness and any third party who has authority to give consent.

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**Step five: Complete the NIH training program in the Protection of Human Subjects online**  
<http://cme.cancer.gov/c01/>

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**Step six: Finalizing the process**

1. Obtain required signatures from faculty advisor.
2. Compile and copy all documents.
3. Submit to the IRB.

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**REMEMBER, YOU MAY NOT INITIATE HUMAN SUBJECT RESEARCH UNTIL YOU HAVE RECEIVED APPROVAL FROM THE IRB. DO NOT ASSUME YOU HAVE APPROVAL JUST BECAUSE YOU HAVE SUBMITTED YOUR APPLICATION.**

## PROCEDURES FOR PROJECT APPROVAL

1. Use the IRB website – <http://www.southalabama.edu/com/research/humansubjects/index.shtml> to find the current IRB Student Application and guidelines or contact the IRB Office at 460-6308.
2. Discuss your project with your faculty advisor and/or department chair to help determine the correct IRB review you need (ie, full board, expedited review, or exempt)
3. Fill out all sections of the form as completely as possible and attach letters of consent, surveys, questionnaires and other applicable information.
4. Secure all signatures.
5. Check dates for application deadlines for IRB review full board review at <http://www.southalabama.edu/com/research/pdf/calendar.pdf> **NOTE:** There is no deadline for submission of expedited or exempt protocols. Allow enough time for your thesis/dissertation committee and the IRB to review your research proposal.

IRB approval is granted for a period of no more than one year after the date on which the application was approved. In order to continue the research beyond this time, the investigator must request a renewal of approval.

## CONTACT INFORMATION

### **USA's Institutional Review Board:**

<http://www.southalabama.edu/com/research/humansubjects/index.shtml>

### **IRB forms online:**

<http://www.southalabama.edu/com/research/humansubjects/irb.shtml>

### **IRB Office:**

Pamela Horner

IRB Compliance Specialist

CSAB 138

Phone: (251) 460-6308; FAX: (251) 461-1595

Email: [phorner@usouthal.edu](mailto:phorner@usouthal.edu)

### **Office of Research Compliance and Assurance:**

<http://www.southalabama.edu/com/research/>

Dusty Layton

Manager

CSAB 140

Phone: (251) 460-6625; FAX: (251) 461-1595

Email: [dlayton@usouthal.edu](mailto:dlayton@usouthal.edu)

**Sample Informed Consent Statements for Student Research Project**  
*Use and modify as needed.*

There are sections in the informed consent document that are required statements which are to be used in all consent forms and also a few sections have selected statements you may choose from depending on the type of study you are going to do. When writing your consent form(s), please use one tense throughout the document (ie, "You") for consistency and use headings if needed. You must use copies of the current consent as approved by the IRB with the IRB approval stamp affixed to the consent document, unless consent has been waived.

**Required Heading for Student Research:**

[Project Title]  
[Principal/Student Investigator, Other Investigators]  
[Faculty Advisor, Phone Number]  
[Department, Course (if applicable)]  
University of South Alabama  
[Date]

**A. PASSIVE INFORMED CONSENT FOR SURVEYS OR QUESTIONNAIRES**

This [insert survey or questionnaire] concerns [insert descriptive statement]. It is being conducted to fulfill the requirements of the above named course. Your participation is voluntary and you may stop completing the [insert survey or questionnaire] at any time and you do not have to answer any question(s) you choose not to answer. Risks associated with you completing this [insert survey or questionnaire] have been explained to you and must be acceptable to you or you must not complete the survey. Your identity will not be revealed in any way through your participation in this study; do not write your name on this document; the results will not be reported in a way that will reveal individual participants. If you do not want to complete this [insert survey or questionnaire] you may return the survey uncompleted as instructed for completed documents or you may keep it. If you do choose to participate, please return this document [insert return instructions].

**B. ACTIVE INFORMED CONSENT FOR INTERVIEWS**

You have been asked to participate in a research study on [insert descriptive statement]. The purpose of this study will be to determine [insert descriptive statement]. You understand that you will be asked to [insert activity(s)]. Potential risks from participating in this survey include [insert list], they have been explained to you and you have accept them. You understand that your participation is entirely voluntary and you may end your participation in this research at any time. You understand that your identity will be protected at all times and that your name will not be used without your separate written permission. You understand that the results of this study will not be reported in a way that would identify individual participants. You may call the investigators [insert name(s)] or the other individuals listed in the heading of this document if you have any questions or concerns about this research and your participation. You may call the Institutional Review Board at 251-460-6308 for information regarding your rights as a research subject.

By signing this consent form, you are agreeing to participate in this research study.

\_\_\_\_\_  
Name of Subject

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Investigator

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of person obtaining consent

\_\_\_\_\_  
Signature of person obtaining consent

\_\_\_\_\_  
Date

## CONSENT FORM

*(Project Title - must be at the top of each page)*

*Principal Investigator  
University of South Alabama  
Address, Telephone Number*

**INVITATION TO PARTICIPATE:** You are being asked to participate in a research study because, etc.

**PURPOSE:** The purpose of the study should be expressed in lay language (ie, 8<sup>th</sup> grade level) and should clearly state the nature of the research project.

**PROCEDURES:** The subject must be informed exactly what his/her participation will involve. This may include the length and frequency of hospitalization; types of medication; placebo administration; types and number of tests; amount of blood to be drawn (in terms a lay person can understand such as ounces, tablespoons, teaspoons); randomization; questionnaires, including the type of information to be asked; video-taping; diets; withholding of standard treatment; follow-up studies; duration of participation; etc. If a test article is involved, the consent form should explain that: 1) It is routinely used for the proposed purposes of the study; and 2) It is experimental and not approved for general use in the United States but has been approved for use in this study.

**RISKS:** Describe potential physical and psychological risks in lay language.

**BENEFITS:** Direct or to society. If there is not direct benefit to the subject, a statement reflecting this fact must be recorded.

**ALTERNATIVES:** Describe in lay language how the subject would be treated if not otherwise in a research study and any potential adverse effects from the alternatives. (NOTE: Not needed for most non-medical research)

**COMPENSATION:** Describe any fees (dollar amount) to be paid to the subject for participation, describe partial payment or no payment for early termination or bonus for completion, or a statement that there will not be financial compensation for participation. Other forms of compensation such as gift certificates, coupons, etc. should also be listed.

**CONFIDENTIALITY:** There are two standard statements of confidentiality, one of which needs to be included in this section.

**For clinical trials:** You understand that all information collected in this study will be kept strictly confidential, except as may be required by law. You further understand that representatives of the Sponsor, as well as the Food and Drug Administration, may review the data collected from this study and your medical records. If any publication results from this research, you will not be identified by name.

**For non-clinical trial studies:** You understand that all information collected in this study will be kept strictly confidential, except as may be required by law. If any publication results from this research, you will not be identified by name.

**ADDITIONAL INFORMATION:** Include a statement that any significant new findings developed during the course of the study that may relate to the subject's willingness to continue participation will be provided to the subject. The investigator must provide the subject and the IRB with a written statement concerning any significant finding(s) that may potentially influence a subject's decision to continue participating in the study. In this circumstance the investigator must renegotiate informed consent.

**For Clinical Trials involving investigational medications:** You understand that there is no guarantee that you may continue receiving the medication at the end of this study.

**PREGNANCY:** The following statement (as is or amended as appropriate) must be included in the informed consent only if the study drug/device could effect women of child-bearing age, the unborn fetus or a women breast-feeding a child.

Due to the effect of this drug/device, there could be serious harm to unborn children (or children who are breast-feeding) and it could also jeopardize the health of the mother. In addition, it is possible that harmful side effects that are not yet known could occur to both the mother and unborn or breast-feeding child. For this reason, if your pregnant, you will inform the principal investigator or research staff and understand you will not be included in the study. If you are still capable of becoming pregnant, you will be given a pregnancy test prior to entry into the study. You also understand that

you will practice a medically approved method of birth control during my participation in the study. Further, you understand that while your taking this drug/device you should not become pregnant, and if you do become pregnant, you must discontinue the drug/device.

**DISCLAIMER/WITHDRAWAL:** There are two standard statements of disclaimer/withdrawal, one of which needs to be included in this section.

**For medical studies:** You agree that your participation in this study is completely voluntary and that you may withdraw at any time without prejudicing my present or future care. You also understand that should your physician find it necessary, and/or in your best interest, he/she may withdraw you from the study.

**For non-medical studies:** You agree that my participation in this study is completely voluntary and that you may withdraw at any time without prejudicing your standing within the University of South Alabama or your class.

**INJURY/COMPLICATIONS:** The following statement is used in 95% of all consent forms:  
You understand that in the event of an injury resulting from the research procedures, medical treatment in excess of that covered by third party payors will be provided without cost to you, but financial compensation is not available.

For studies where an adverse effect is not separately identifiable from a patient's disease process:

You understand that complications may arise during the course of therapy either due to your disease or due to the treatment. You have been advised that therapy for any such complications will be carried out by your doctors and costs associated with such care may be provided by third party payers. You have been advised that no compensation will be provided to you as a result of your participation in this study.

**SUBJECT RIGHTS:** You understand that if you wish to obtain further information regarding your rights as a research subject, you may contact the Institutional Review Board by telephoning 251-460-6308. You also understand that if you have any questions pertaining to your participation in this particular research study, you may contact the investigator by calling the telephone number(s) listed at the top of page one. You have been given the opportunity to ask questions and have had them answered to your satisfaction.

**CONCLUSION:** You have read and understand the consent form. You agree to participate in this research study. Upon signing below, you will receive a copy of the consent form.

_____ Name of Subject	_____ Signature of Subject	_____ Date
_____ Name of Witness	_____ Signature of Witness	_____ Date
_____ Name of Investigator	_____ Signature of Investigator	_____ Date
_____ Person obtaining consent	_____ Signature of person obtaining consent	_____ Date

(number all pages)

## IRB Checklist for Review Categories

**EXEMPT REVIEW CATEGORIES: (46.101)** *Certain low-risk research is considered to qualify for exempt review. Exemption does not imply that researchers have no ethical responsibilities to subjects, nor does it mean that the research does not have to be reviewed.*

**Category 1:**

- a) research conducted in established or commonly accepted educational settings, involving normal educational practices
- b) research on regular/special educational instructional strategies

**Category 2:**

- a) involves educational tests, surveys, interviews or observation of public behavior
- b) data recorded to prevent identification of subjects
- c) prevention for risk of disclosure of subjects' responses outside the research (placing subjects at risk of criminal civil liability, or damage financial standing, or reputation)

**NO EXEMPTION AVAILABLE IF:**

- a) minors are involved in survey or interview procedures
- b) minors are involved in observation of public behavior and the observers participate in the activities observed.

**Category 3:**

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2 but involves:

- a) human subjects who are elected/appointed public officials, candidates for public office or
- b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

**Category 4:**

Research involving the collection or study of existing archival data, documents, (publicly available or recorded to prevent identity of subjects, anonymous data)

**Category 5:**

Research and/or demonstration project, subject to approval of department/agency head, designed to study, evaluate:

- a) public benefit or service programs
- b) procedures for obtain benefits or services
- c) changes/alternatives to programs/procedures
- d) changes in methods/levels of payment for benefits or services

**Category 6:**

Involves taste and food quality evaluation and consumer acceptance studies

- a) wholesome foods without additives are consumed
- b) food consumed is at or below safe level; agricultural chemical, environmental contaminant at or below safe levels (established by FDA, EPA or USDA)

**EXPEDITED REVIEW CATEGORIES: (46.110)**

**Category 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. (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.

**Category 2: Collection of blood samples by finger, heel or ear stick/venipuncture as follows:**

- (a) from healthy, nonpregnant 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.

## IRB Checklist for Review Categories

	<p><b>Category 3: Prospective collection of biological specimens for research purposes by noninvasive means.</b> Examples:</p> <ul style="list-style-type: none"> <li>(a) hair and nail clippings in a nondisfiguring manner</li> <li>(b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction</li> <li>(c) permanent teeth if routine patient care indicates a need for extraction</li> <li>(d) excreta and external secretions (including sweat)</li> <li>(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</li> <li>(f) placenta removed at delivery</li> <li>(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor</li> <li>(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</li> <li>(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings</li> <li>(j) sputum collected after saline mist nebulization.</li> </ul>
	<p><b>Category 4: Collection of data through noninvasive procedures</b> (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. <b>Where medical devices are employed,</b> 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:</p> <ul style="list-style-type: none"> <li>(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</li> <li>(b) weighing or testing sensory acuity</li> <li>(c) magnetic resonance imaging</li> <li>(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography</li> <li>(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.</li> </ul>
	<p><b>Category 5: Research involving materials</b> (data, documents, records, or specimens) <b>that have been collected, or will be collected solely for nonresearch purposes</b> (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.)</p>
	<p><b>Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.</b></p>
	<p><b>Category 7: Research on individual or group characteristics or behavior</b> (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.)</p>
	<p><b>Category 8: Continuing review of research previously approved by the convened IRB:</b></p> <ul style="list-style-type: none"> <li>(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</li> <li>(b) where no subjects have been enrolled and no additional risks have been identified; or</li> <li>(c) where the remaining research activities are limited to data analysis.</li> </ul>
	<p><b>Category 9: Continuing review of research, not conducted under an investigational new drug application or investigational device exemption</b> 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.</p>
<p><b>FULL BOARD REVIEW:</b> If there is a physical risk or potential for injury to harm subject's dignity/well being, full board review is required. Full Review covers all research not falling into the category of Expedited Review or Exempt.</p>	
	<p><b>Examples of projects requiring review by the full board include the following:</b></p> <ul style="list-style-type: none"> <li>- Studies involving an FDA-approved drug/device for a new indication or use.</li> <li>- Studies involving investigational new drugs, medical devices or procedures.</li> <li>- Any study involving vulnerable populations such as: children, prisoners, pregnant women, mentally incompetent, etc.</li> </ul>