



Lourdes University Institutional Review Board Application for Research Using Human Subjects

Submission Checklist

REMINDER: BEFORE YOU EXIT OR CLOSE THE APPLICATION, BE SURE TO SAVE YOUR WORK TO YOUR COMPUTER FILES.

To the Applicant: Use this checklist to ensure that your submission includes all required items. Reviews may be delayed by incomplete submissions. All documents must be typed. The Application and all related documents must be submitted both in digital format to irb@lourdes.edu and in signed, hard copy to the IRB mailbox, c/o The Welcome Center, McAlear Hall.

Please indicate with a check mark each item that you will include in your submission

1) Application Form (Required)

- Submit the PDF file by clicking the Submit Form button at the top of the page
- Submit a signed copy of the Application along with all related documents to the IRB Mailbox, c/o the Welcome Center, McAlear Hall

2) Investigators

- Principal Investigator Contact Information
- Lourdes students, faculty and staff: Use Lourdes email account only
- Complete required C.I.T.I. training modules (see IRB website, left side)
- Student investigators: Indicate Faculty Advisor and Program Director
- Faculty investigators: Indicate Faculty Supervisor or Department Chair

3) Institutional Permissions (If Applicable)

- Agency Permission Form signed by authorized agency representative
- IRB Approval Letter from other institutions
- Conditional approval for access to Lourdes University Information (*See Section 6D, Research Setting*)

4) Data Collection Instruments

- Survey instrument(s), email surveys, interviews etc. *in final form as participants will see them*
- If an instrument is copyrighted, include permission from author

5) Materials used to approach or recruit research participants

- Written flyer, announcement, brochure, letter etc. *exactly as participants will see them*
- Email: *if email is used, include screen snapshot(s)*
- Script for telephone calls or in person approach (wording may be approximate)

6) Consent documents *in final form as participants will see them*

- For style and content requirements, refer to Sample Consent Forms on IRB Website
- Cover letter(s)
- Adult consent form
- Vulnerable adults with impaired consent capacity

7) Documents to submit if research subjects are children By regulatory definition, children are persons who have not attained the legal age (18 years) for consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted. 45 CFR 46

Subpart A, Office of Human Research Protections (OHRP) Department of Health and Human Services (DHHS)

- Research on Children Form (required)
- Parent/Guardian Permission Form
- Child/Minor Oral Assent Script (non-readers: not able to read or non-proficient at reading)
- Child/Minor Written Assent Form to be signed by child or minor (Proficient readers: Can read and understand a simple assent form)

8) Protocol Assurance Page is signed and dated by appropriate personnel:

- Principal investigator
- Faculty Advisor (student investigators)
- Program Director (student investigators)
- Faculty Supervisor or Department Chair (faculty investigators)

SUBMISSION INSTRUCTIONS: The Application and all related documents must be submitted both in digital format to irb@lourdes.edu and in signed, hard copy to the IRB mailbox, c/o The Welcome Center, McAlear Hall.

1) Submission of Electronic Files

- Submit PDF documents using the Submit Application button at the end of the application
- Submit RTF (Word) documents as email attachments to irb@lourdes.edu

2) Submission of Hard Copy

- Print the entire submission and obtain appropriate signatures. Submit to the IRB mailing address. Submit in standard file folder or large envelope; do not staple or fold.

IRB Mailing Address

Lourdes University Institutional Review Board
c/o The Welcome Center
McAlear Hall
6832 Convent Blvd. Sylvania, OH 43560

Questions?

Shana A. Pyle
Administrative Assistant
Academic Affairs
419-517-8867
spyle@lourdes.edu

IRB Coordinator
irb@lourdes.edu

FOR IRB OFFICE USE ONLY

IRB project # _____ Investigator Name _____

Date received in IRB Office _____ Proposed Start-up Date _____

1) Project Title

Title of Project: _____

2) Request for exempt or expedited review process

- Request for exempt designation: *Include completed [Exempt Designation Request form](#)*
- Request for expedited review: *Include completed [Expedited Review Request form](#)*

3) Project Dates NOTE: Project may not start until the investigator receives the IRB approval letter

a Anticipated starting and completion dates: _____ to _____

b This project may be conducted on an annual basis: Yes

4) Principal Investigator Information

Name: _____

Department or Affiliation: _____

Address: _____

Telephone: Note: use of personal phone numbers should be avoided

Email: Note: Students, faculty and staff at Lourdes University must use Lourdes University email account.

Co-investigators : (Please list all)

Check box for Student Principal Investigator Undergraduate Graduate Lourdes Other Institution

Research purpose Capstone Project Course Project Personal Scholarship

Faculty Advisor
Name _____
Phone _____ email _____

Program Director
Name _____
Phone _____ email _____

| | | | |
|---|----------------------------------|---|--------------------------------|
| <input type="checkbox"/> Check box for Lourdes faculty or staff Program or Department | <input type="checkbox"/> Faculty | <input type="checkbox"/> Administration | <input type="checkbox"/> Staff |
| Faculty Supervisor or Department Chair | Name | | |
| | Phone | email | |
| <input type="checkbox"/> Check box for Faculty or Staff from other institutions Program or Department | Institution: | | |
| Faculty Supervisor or Department Chair | Name | | |
| | Phone | email | |

5) Funding Information

Is this project being funded? Yes No

If yes, list the funding source: _____

Is this project contingent upon receiving support? Yes No

6) OVERVIEW OF PROJECT:

Directions: It is the IRB's responsibility to determine that your study is designed so as to protect the rights and welfare of human subjects. In order to fulfill this responsibility, the IRB must have a good understanding of the theoretical background, purpose and methodology of your project. Remember that the IRB includes members from a variety of academic areas as well as community representatives. Respond to the following question/statements as completely and concisely as possible and include enough information for the IRB to understand your study procedures.

PLEASE DESCRIBE YOUR PROJECT IN NARRATIVE FORM

A. In brief, what is the theoretical background of your research? Include enough information to orient IRB members to the general area of your study. It is helpful to provide key references and a summary of main ideas.

B. What is the research question or problem that you plan to study?

C. List the research methods that will be used. (For example: survey, experimental, quasi-experimental, action research, participant observation.) Provide a general description of the methods in lay terms.

D. Research Setting: Please list all the organizations where this research has been or will be conducted.

For access to Lourdes University data: Discuss the research with the appropriate administrator and provide email documentation of provisional approval.

Complete the appropriate permission forms, found on the left side of the IRB main page.

- *Agency Permission for Data Collection form signed by authorized person(s) for each agency/organization*
- *IRB Approval Letter from other institutions*
- *Request for Access to Lourdes University Information for Research Form*

E. Who are the people or groups that you plan to include in your research? Why are they appropriate subjects for your study?

F. What means of communication will you use to approach potential research participants? Check all that apply

- | | | | | | |
|--------------------------|--|--------------------------|---------|--------------------------|---------------------|
| <input type="checkbox"/> | Advertisements | <input type="checkbox"/> | Letters | <input type="checkbox"/> | Random Calls |
| <input type="checkbox"/> | Telephone Lists | <input type="checkbox"/> | Notices | <input type="checkbox"/> | Direct Solicitation |
| <input type="checkbox"/> | Lourdes University email lists—specify | | | | |
| <input type="checkbox"/> | Other--specify | | | | |

G. Describe the location of the communication and the order of events.

H. Describe in detail your plan to obtain informed consent, parent/guardian permission and/or child assent.

7) Because research may pose additional and/or unknown risks to vulnerable populations, Federal Regulations require additional safeguards for the protection of pregnant women, children, human fetuses, neonates, prisoners, persons at risk of suicidality and persons with impaired decisional capacity (45 CFR 46 Subpart B, C and D) Other groups, while not specifically mentioned in the Regulations, may also be vulnerable under some circumstances.

a Indicate which, if any of the following groups will be research participants. (check all that apply)

| | | | |
|--------------------------|---|--------------------------|--------------------------------|
| <input type="checkbox"/> | Minors (under 18) <i>Attach Research on Children Form</i> | | |
| <input type="checkbox"/> | Students | <input type="checkbox"/> | Employees |
| <input type="checkbox"/> | Cognitively Impaired | <input type="checkbox"/> | Senior Citizens (over 65) |
| <input type="checkbox"/> | Adults who lack consent capacity | <input type="checkbox"/> | Mentally/Physically Challenged |
| <input type="checkbox"/> | Institutional Residents | <input type="checkbox"/> | No Special Groups |
| <input type="checkbox"/> | Single Subject Populations (by Race, Ethnicity, Sex, or Religion) | | |
| <input type="checkbox"/> | Other (specify): | | |

b If one or more of the above groups is/are selected, state the rationale for using special groups

8) Number of participants

a Approximately how many individuals will you invite to participate?

b What is the maximum number of participants you will include in the study?

9) INFORMED CONSENT *Sample forms available on the left side of the IRB website.*

Which forms of consent will be used in your study? (check all that apply):

| | | |
|---|--------------------------|------------------------------------|
| a | <input type="checkbox"/> | Adults who have ability to consent |
| b | <input type="checkbox"/> | Adults who lack ability to consent |

If your study will include children (under 18 years of age)

| | | |
|---|--------------------------|--|
| c | <input type="checkbox"/> | Parent/Guardian Permission |
| d | <input type="checkbox"/> | Child/Minor Oral Assent Script (Non-readers: Not able to read or not proficient at reading) |
| e | <input type="checkbox"/> | Child/Minor Written Assent to be signed by the child or minor (Proficient readers: Can read & understand a simple assent form) |

10) DATA & CONSENT COLLECTION

a. Data collection methods (check all that apply):

| | | | |
|--------------------------|------------------------------|--------------------------|-------------------------|
| <input type="checkbox"/> | Archival Data | <input type="checkbox"/> | Observation |
| <input type="checkbox"/> | Computer Collected Task Data | <input type="checkbox"/> | Physical Tasks |
| <input type="checkbox"/> | Focus Groups | <input type="checkbox"/> | Questionnaire or Survey |
| <input type="checkbox"/> | Instruction/Curriculum | <input type="checkbox"/> | Testing/Evaluation |
| <input type="checkbox"/> | Intervention | <input type="checkbox"/> | Video or Audio Taping |
| <input type="checkbox"/> | Interview | <input type="checkbox"/> | Web or Internet |
| <input type="checkbox"/> | Other: | | |

b. What are the origins of the instrument(s) you plan to use? If you did not design your own instrument, do you have permission of the author to use the instrument in research? Please include permission in your submission.

| | | | | | |
|----|--|--------------------------|-----|--------------------------|----|
| c. | Will the data collected be anonymous? <i>(The data are anonymous if there are no identifiers connected to the data and the researcher is unable to link data to any one individual. See Privacy and Confidentiality on the IRB website for more information)</i> | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| d. | Will the data be collected with identifiers? <i>(Identifiers include but are not limited to names, student numbers, email addresses, birthdates, social security numbers or small sample size.)</i> | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| | If Yes: Will identifiers be removed for analysis? | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| | Will identifiers be removed for reporting? | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |

e. Describe how the consent forms and other study material (e.g., data instruments, computer task data, interview questions) will be distributed and collected to protect the privacy of the participants.

f Describe the security of the data. Where will the consent forms and other study material be stored? Who will have access? How and when will study data be destroyed?

g Signed consent forms must be retained for three years after the end of the study. For student projects, faculty/staff advisors should retain the original or a copy of the signed consent forms for three years.

Name of the person who will retain the consent forms for the specified three years

11) RISK FACTORS: A research participant is considered to be at risk if the research procedures expose the participant to possible physical or mental harm, coercion, deceit or loss of privacy. The most obvious examples of placing participants at risk of harm include administration of unusual physical exertion, deceit and public embarrassment or humiliation. Coercion may be present when the potential participants are not able to exercise their right to decline participation, particularly when the researcher is in a relationship of greater power over the participants. The Public Health Service Act 301(d), 42U.S.C. 241 (d), Office for Human Research Protections (OHRP) Department of Health and Human Services (HHS).

a Risk Criteria

| Risk Criteria | CHECK ONE | | | |
|--|--------------------------|-----|--------------------------|----|
| Concerns about employment and/or workplace | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| Deceit, coercion or pressure | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |

| | | | | |
|---|--------------------------|-----|--------------------------|----|
| Loss of privacy or possible embarrassment/humiliation | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| Participants will be tape recorded, photographed, or videotaped | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| Participants may experience mental discomfort. | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| Participants may experience physical discomfort. | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| Peer issues at school. | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| Electrical equipment will be used. | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| Experimental drugs will be used. (From H.R.S.A.) | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| Other: | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |

- b. What is the likelihood of any deceit, coercion or pressure? Low Moderate High
- c Explain and describe the potential deceit, coercion or pressure and proposed safeguards.
- d Explain the likelihood and seriousness of any other risks to the participants (physical, mental, or other) Describe alternative methods that would not entail comparable risks and why these were not used.

e If the research participants will be compensated or rewarded, indicate the type and amount of compensation. Indicate whether students are receiving course credit (regular or extra credit) and, if so, what alternatives are offered to those students who do not wish to participate in the research.

f Describe any anticipated benefits to participants. Describe any contributions to general knowledge in the field of inquiry.

g. Indicate which of the following categories accurately describes this research study:

| | |
|--------------------------|--|
| <input type="checkbox"/> | Not greater than minimal risk |
| <input type="checkbox"/> | Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects |
| <input type="checkbox"/> | Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition |
| <input type="checkbox"/> | Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects |

12) INVESTIGATOR ASSURANCE STATEMENTS**Principal Investigator (All investigators)**

In making this application, I certify that I have read and understood Lourdes University's policies and procedures governing research with human participants, in particular Institutional Review Board policies. I shall comply with the letter and spirit of these policies and will not undertake the research without Institutional IRB approval. I further acknowledge my obligation to: (1) obtain written Institutional Review Board approval prior to making any changes from the originally approved protocol; (2) report immediately all adverse effects of the study on the participants to the Chairperson of the Institutional Review Board and if I am a student investigator, to my Faculty Advisor; and (3) to supply the Institutional Review Board with a completed Statement of Project Completion Form at the close of this research, and all other reports/information as requested.

Title of Project _____ IRB# _____

Principal Investigator's Signature _____ Date (mm/dd/yyyy) _____
(On printed hard copy only)

Faculty Advisor (for research conducted by students)

By my signature on this research application, I certify that the student is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accordance with the research protocol. In addition, I confirm that:

- I have thoroughly reviewed this IRB application, including the protocol narrative, and verify that it is complete and the research is appropriate in design.
- I agree to meet with the Investigator on a regular basis to monitor study progress.
- I assure that the investigator will promptly report unanticipated problems and will adhere to all requirements for continuing review.
- If I will be unavailable, e.g. sabbatical leave, vacation or resignation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the Lourdes University IRB, in writing, of such changes.
- If the student leaves the college, I will provide all necessary documents for terminating the study or continuing review.

Student Name _____

Title of Project _____ IRB# _____

Faculty Advisor Signature _____ Date (mm/dd/yyyy) _____
(On printed hard copy only)

Program Director (for research conducted by students)

I certify that the Faculty Supervisor is qualified to mentor the student in this research project and that there are adequate resources (financial, support and facilities) available. I support this application, and hereby submit it for further review.

Student Name _____

Title of Project _____ IRB# _____

Program Director Signature _____ Date (mm/dd/yyyy) _____

(On printed hard copy only)

Faculty Supervisor or Department Chair (for research conducted by faculty)

I acknowledge that I have reviewed the faculty application for research and confirm that the resources required to conduct and complete this project are available.

Faculty Supervisor Signature _____ Date (mm/dd/yyyy) _____

(On printed hard copy only)

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IRB Mailing Address

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Questions?

Shana A. Pyle
Administrative Assistant
Academic Affairs
419-517-8867
spyle@lourdes.edu

IRB Coordinator
irb@lourdes.edu

Request for Exempt Review Designation

Background: All human subjects research protocols must be submitted to the IRB for review. After initial review, the IRB may determine that a protocol is ***Exempt from additional IRB review or oversight***. However, the Federal government requires that IRB's retain files of ALL human subjects research proposals that have been reviewed, whether they have been determined to be *Exempt, Expedited or Full Board Review*. (45 CFR §46.115, IRB records)

If you believe that your protocol may qualify as Exempt, you may check the exemption category and include this document with your application. The IRB will use the information to help decide whether your protocol meets Exempt criteria.

45 CFR 46.101(b) Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(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 paragraph (b)(2) of this section, if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) 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.

Limited Application to Research on Children: (b) Exemptions at §46.101 (b)(1) and (b)(3) through (b)(6) are applicable to research on children. The exemption at §46.101 (b)(2) regarding educational tests is also applicable to research on children.. However, the exemption at §46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, **except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.** (Subpart D of Federal regulations. 45 CFR 41:402(b))

If your research subjects are children, does your research involve observation of public behavior when the investigator(s) do not participate in the activities being observed?

Yes No (If you have checked No, your research does not qualify as Exempt)

For questions or further information, please contact:

IRB Coordinator
irb@lourdes.edu

or

Shana Pyle, Administrative Assistant
spyle@lourdes.edu
419-517-8867

Lourdes University Institutional Review Board
Application for Research Using Human Subjects

Request for Expedited Review

Background: All human subjects research protocols must be submitted to the IRB for review. The IRB will determine whether a protocol is to be **Exempt from additional IRB review, reviewed through an expedited process, or reviewed by the full IRB committee.** The Federal government requires that IRB's retain files of ALL human subjects research proposals that have been reviewed, whether they have been determined to be *Exempt or reviewed by an Expedited or Full Board Review procedure.* (45 CFR §46.115, IRB records)

If you believe that your protocol may qualify for **Expedited Review**, please check the expedited category(ies) and include this document with your application. The IRB will use the information to help decide whether your protocol meets **Expedited Review** criteria. **Source:** 63 FR 60364-60367, November 9, 1998
<http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>

**Categories of Research That May Be Reviewed by the
Institutional Review Board (IRB) through an
Expedited Review
Procedure¹**

Applicability

(A) 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 involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) 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 no greater than minimal.

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

(E) 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.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Check the Research Category(ies) Applicable to your Research

(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.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

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(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 children², 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.

(3) Prospective collection of biological specimens for research purposes by noninvasive 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 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. 45 CFR 46.101(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. 45 CFR 46.101(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:

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(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) 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.

¹ 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.

² 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).