

Rhode Island Department of Health

INSTITUTIONAL REVIEW BOARD

FOR THE

PROTECTION OF HUMAN SUBJECTS

Guidance for Submitting Applications And Progress Reports to the IRB

Procedures Forms Contacts

Updated: June, 2019

For information contact:

Ernest Julian, PhD, Chair

Telephone (401) 222-2749

E-mail: Ernest.Julian@health.ri.gov

Louis Marchetti, PhD, Vice-Chair

Telephone

E-mail: Louis.Marchetti@health.ri.gov

TABLE OF CONTENTS

1. Jurisdiction of the RIDOH Institutional Review Board	Page 3
2. Procedures for Submitting Proposals to the RIDOH IRB.	Page 4
3. Proposals that may be Exempt from IRB Review	Page 4
4. Proposals that are not Exempt from IRB Review	Page 4
5. Confidentiality, Privacy and Research Risk	Page 6
6. The Informed Consent Process and General Requirements for the Informed Consent Statement	Page 7
7. Sample Informed Consent Form	Page 8
8. Annual Review of Continuing Research	Page 10
9. RIDOH IRB members contact information	Page 11
10. Further Information about Institutional Review Boards	Page 13

JURISDICTION OF THE RIDOH INSTITUTIONAL REVIEW BOARD

The Rhode Island Department of Health (RIDOH) operates an Institutional Review Board (IRB) that reviews proposals for research on human subjects under a Federal Wide Assurance (FWA). The RIDOH IRB's jurisdiction extends to all research proposals that involve RIDOH staff, data, or other resources, specifically where a proposed project has:

- An employee* of the Department serving as Principal Investigator, Co-Investigator or in any role with scientific responsibility in the research project, whether paid or in-kind.
- An employee* of the Department of Health is funded under the grant, contract, cooperative agreement, or other award supporting the research project.
- An employee* of the Department engages directly in recruitment, data collection, or intervention with human research subjects or in any other activity requiring informed consent or assent or for which informed consent is usually required but has been waived as allowed in federal human subjects protection regulations.
- The Department provides confidential data, in which an individual is identified directly or indirectly, to the project.
- The Department provides any financial or in-kind support for the performance of the research project.
- An employee* of the Department will be an author of a manuscript resulting from the research that will be submitted for publication and that will include the employee's affiliation with the Department.

*{*For the purposes of this policy, employees of the Rhode Island Department of Health are (1) full-time and part-time employees in the state personnel system and (2) contract employees.*

PROCEDURES FOR SUBMITTING PROPOSALS TO THE RIDOH IRB

Proposals that may be exempt from IRB Review

If it is determined that human subjects are involved, the Principal Investigator shall consult with the Chair of the IRB to make a preliminary determination of whether the research involved is exempt from IRB review. In situations where the Principal Investigator is a student, the student's faculty sponsor at the institution in which the student is enrolled shall also consult in the decision regarding exempt status. Where it is clear that the project is in the "exempt" category, the research work may proceed *only after* determination of exempt status by the Chair of the IRB. If the IRB Chair cannot assign the status of the project based on preliminary discussions with the Principal Investigator and/or faculty sponsor, the Principal Investigator must make a formal request for IRB review and submit the following information electronically (via e-mail):

1. A letter from the Principal Investigator stating why the exemption should be granted and citing which of the six published reasons for exemption applies (see Appendix D, "Research Exempt from IRB Review"). Where the Principal Investigator is a student, the letter should either be written by or endorsed by the student's faculty sponsor.
2. A completed "Proposal Abstract Cover Sheet."
3. The research proposal, including any informed consent forms to be used. Include survey forms, questionnaires, or interview questions, if applicable.
4. An "Assurance of the Principal Investigator" form. If the Principal Investigator is a student, the student's faculty sponsor should sign the form.
5. If the research involves a cooperating agency, institution, school district, or other organization, a letter of agreement to participate in the research, on official letterhead, is also required. Research that is to be conducted in foreign countries requires a letter of agreement from an appropriate official or cooperating institution.

Proposals that are not exempt from IRB Review

If the proposal qualifies for expedited or full IRB review (see Appendix E), the Principal Investigator must submit electronically (via e-mail) the complete research proposal,* less any appended material not necessary to a full understanding of the project, plus the following:

1. "Proposal Abstract Cover Sheet" **
2. A completed "Application for Review" **
3. A signed "Assurance of the Principal Investigator" **
4. An "Informed Consent" form, if applicable

5. If the research involves a cooperating agency, institution, school district, or other organization, a letter of agreement to participate in the research, on official letterhead, is required. Research that is to be conducted in foreign countries requires a letter of agreement from an appropriate official or cooperating institution.

- * If the proposal is part of a thesis, dissertation, or sponsored research grant proposal, that proposal should also be submitted.
- ** Forms may be found here: <http://health.ri.gov/forms/proposal/InstitutionalReviewBoard.pdf>

E-Mail all application materials to:

**Ernest Julian, PhD, Chair
Institutional Review Board
Rhode Island Department of Health**

Ernest.Julian@health.ri.gov

CONFIDENTIALITY, PRIVACY AND RESEARCH RISK

Many research proposals submitted to the RIDOH Institutional Review Board involve use of personally identifiable confidential information in the Department's databases, with no intent to contact the individuals whose information is being used. These proposals may be eligible for exemption from informed consent requirements or review under the expedited procedure. Such proposals should address the following issues in their IRB submissions:

- Determine whether the proposed use of the data is research on human subjects as defined in the federal regulations governing human subjects protection. (See Appendix A);
- Specify the risks and benefits of participating in the research for the human subjects. There are often no direct benefits to individuals whose confidential data is accessed. Risks may often include inadvertent and purposeful release of confidential data on an individual. Such release may occur through release of sufficient descriptive information as to allow identification, even when no identifiers are released.
- Minimize the risks to human subjects in the design and conduct of the research. For use of existing data, this means that:
 - The minimum amount of confidential information is requested that is necessary to perform the research.
 - The information is accessible to and handled by the minimum number of personnel possible.
 - Identifiers are removed from the database or the database is returned to the owner as soon as no longer needed.
 - Data that are published or otherwise released are aggregated so that no individual can be identified either directly or indirectly through knowledge of non-confidential data items.
- Specify measures to protect data when on computers and when stored on electronic media. Also describe any data linkages that would result in anonymous data becoming identifiable to an individual.
- If any contact is proposed with an individual identified through access to a RIDOH database, the issues of informed consent become relevant, and all protocols and forms must be reviewed in addition to measures to protect confidentiality.

THE INFORMED CONSENT PROCESS AND GENERAL REQUIREMENTS FOR THE INFORMED CONSENT STATEMENT

- 1. Informed consent should be considered a process that may require continual review; it is not just a legal document.**
2. Informed consent must be obtained only under such circumstances that provide the prospective subject, or the subject's representative, sufficient opportunity to consider participation in the research project and where the possibility of coercion or undue influences is minimized.
3. The Informed Consent Statement
 - a. Must be written in language understandable to the subject or representative;
 - b. Shall not contain any language by which the subject waives any of his or her rights;
 - c. Shall not contain any language that releases the principal investigator or the sponsoring agency from liability for negligence;
 - d. Should include a statement such as, "you are over 18 years of age," if appropriate.
4. The Informed Consent Statement should follow the format and outline given on the next page, as appropriate. When the subject is a minor and the parent or guardian's consent is sought, space for the parent or guardian's signature should be provided. If the subject is an adult requiring guardian consent, space for the guardian's signature should be provided. Alternatively, where it is necessary to separate the consent of the parent/guardian from the assent of the minor or non-consenting adult, separate forms should be used for each.
5. Two copies of the Informed Consent statement must be signed; one copy is to be retained by the individual (or his/her representative/guardian), and one copy is to be kept by the principal investigator. (NOTE: the signature page may not be completely separated from the text of the informed consent.)

N.B. For further guidance, see the "Informed Consent Information" section on the OHRP website.

SAMPLE INFORMED CONSENT FORM

Title of Project _____

Introductory section should begin with words to this effect:

You have been asked to take part in a research project described below. The researcher will explain the project to you in detail. You should feel free to ask questions. If you have more questions later, {P.I.}, the person mainly responsible for this study, { Phone }, will discuss them with you. You must be at least 18 years old to be in this research project (if appropriate).

Description of the project:

You have been asked to take part in the study that {here describe the nature of the study and the purpose of the research}.

What will be done:

If you decide to take part in this study here is what will happen: {explanation of what will happen to the subject; how long the subject will be involved in the study; and state what portions, if any, are considered experimental. Explain alternative procedures, if any}.

Risks or discomfort:

{Explain any risks or discomfort that might reasonably be expected to happen. If there are no risks or discomforts, state that here}.

Benefits of this study:

{Describe benefits to the subject, or to others, of this study. If of no direct benefit to the subject, include a sentence to the following effect:} Although there will be no direct benefit to you for taking part in this study, the researcher may learn more about { }. (NOTE: payment given to the subject for participation in the study is not a benefit, it is a recruitment incentive.)

Confidentiality:

{Describe the way confidentiality of records identifying the subject will be maintained. Use words to the following effect, if appropriate:} Your part in this study is confidential. No information will be released that identifies you by name. All records will {describe how records are to be maintained}. {Or, if the study involves information that legally must be reported to government agencies, then include the following:} My part in this study is confidential within legal limits. The researchers and the sponsoring agency will protect your privacy, unless they are required by law to report information to city, state or federal authorities, or to give information to a court of law. Otherwise, none of the information will identify you by name. All records will be {describe how they are to be maintained}. {Alternatively, if the study is anonymous, then this should be stated here. Indicate to the subject how anonymity will be preserved.}

In case there is any injury to the subject: (If applicable)

{Explain whether any medical or other treatment is available if injury occurs, and who to contact; use words to this effect:} If this study causes you any injury, medical treatment will be provided to you through { }, and this treatment will be paid for by { }. To report any injury that happens because you agreed to be in this study, you should write or call { }.

Decision to quit at any time:

{Use words to the following effect:} The decision to take part in this study is up to you. You do not have to participate. If you decide to take part in the study, you may quit at any time. Whatever you decide will in no way {penalize you} {affect your benefits, medical care} {etc.} {insert appropriate language}. If you wish to quit, you simply inform {name and phone number of principal investigator} of your decision.

Rights and Complaints:

{Use words to the following effect:} If you have any questions later about your rights as a participant in this research, or if you are not satisfied with the way this study is performed, you may speak with {P.I.'s Name} or with {name and phone of individual}, anonymously, if you choose. In addition, you may contact { }, who is the Administrator of the Institutional Review Board of the Rhode Island Department of Health, at { }.

You have read the Consent Form. Your questions have been answered. Your signature on this form means that you understand the information and you agree to participate in this study.

Signature of Participant

Signature of Researcher

Typed/printed Name

Typed/printed name

Date

Date

CONSENT FORM
(Name of Project)

TEAR OFF AND KEEP THIS FORM FOR YOURSELF

Dear Participant:

1. You have been asked to take part in the research project described below. If you have any questions, please feel free to call (PI, *phone number*), the person mainly responsible for this study.
2. The purpose of this study is to (*state purpose*). Responses to these items will be (*state how responses will be collected and how confidentiality will be maintained*).
3. **YOU MUST BE AT LEAST 18 YEARS OLD** to be in this research project or to consent to your child's participation.
4. If you decide to take part in this study, your participation will involve (describe procedures) pertaining to (*state appropriate information*).
5. The possible risks or discomforts of the study are minimal, although you may feel some embarrassment answering questions about private matters (*delete last phrase if it is not appropriate for your project*).
6. Although there are no direct benefits of the study, your answers will help increase the knowledge regarding (*state appropriate information*).
7. Your part in this study is confidential. That means that your answers to all questions are private. No one outside the project can know if you participated in this study or know any information about your participation. Scientific reports will be based on group data and will not identify you or any individual as being in this project.
8. The decision to participate in this research project is up to you. You do not have to participate and you may quit at any time.
9. Participation in this study is not expected to be harmful or injurious to you. However, if this study causes you any injury, you should call the "IRB Administrator" at the Rhode Island Department of Health, {phone #}.

If you have any more questions or concerns about this study, you may contact _____ at _____.

You are at least 18 years old. You have read the consent form and your questions have been answered to your satisfaction. Your filling out the survey implies your consent to participate in this study.

If these questions are upsetting and you want to talk, please use the phone numbers below: (*appropriate in cases where questions are of a sensitive nature*):

(Names and phone numbers of resources available, e.g., Counseling Center, Women's Resource Center, AA, etc.).

Thank you, (Name of Investigator)

ANNUAL REVIEW OF CONTINUING RESEARCH

The Code of Federal Regulations empowers the Institutional Review Board (IRB) to "conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year, and to observe or have a third party observe the consent process and the research." (45 CFR 46.109(e)).

Approved projects are assigned a monitoring date. A "Human Subjects Research Progress Report" form must be completed and returned electronically to the RIDOH IRB ten days before the designated date.* In addition, investigators will be asked to submit electronically (1) the project's current informed consent document, if appropriate, and (2) a summary progress report for the project covering the period since the last review by the RIDOH IRB, including any recent literature, findings, or information that has become available concerning risks associated with the research. The IRB will review these documents to ensure that your research protocol continues to be in compliance with federal and state regulations. **It is the responsibility of the investigator to ensure that the investigator's project remains compliant in the continuing review requirement.**

Continuing research must be monitored and approved for continued IRB approval. If you do not respond to our request for review within the specified time frame, your project will no longer have IRB approval.

Please refer also to the Rhode Island Department of Health IRB Operating Policies and Procedures, Section XII. Procedures for Continuing Review.

* Progress Report Forms may be found here:
<http://health.ri.gov/forms/reporting/InstitutionalReviewBoardProgress.pdf>

Rhode Island Department of Health IRB Members

CHAIR

Ernest Julian, PhD, Chief, Office of Food Protection

R.I. Department of Health – Room 203 Capitol Hill,
Providence, RI 02908
401-222-2749// Ernest.Julian@health.ri.gov

VICE-CHAIR

Louis Marchetti, PhD, Chief Administrative Officer, Board of Medical Licensure

R.I. Department of Health - 3 Capitol Hill, Providence, R.I. 02908
//Louis.Marchetti@health.ri.gov

FULL BOARD MEMBERS

Internal – Department of Health Staff

- **Roseann Giorgianni, State Registrar**
Office of Vital Records
- **Siena Napoleon, MPH,**
Center for Health Data and Analysis
- **Ernest Julian, PhD, Chief**
Office of Food Protection
- **Louis Marchetti, PhD, Supervisor**
Biochemistry Lab, Public Health Laboratory

External – Community Members

- **Colleen Fontana, BA**
- **John Fulton, PhD, Epidemiologist**
- **Bruce McIntyre, JD, Attorney**
- **Vivian Weisman, MSW**

(updated June, 2019)

FOR ADDITIONAL INFORMATION

For general information involving human subjects protection, visit the website for the Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services:

<http://www.hhs.gov/ohrp>

For documents relating to human subjects protection, including -

- The "Belmont Report"
- Regulations for the Protection of Human Research Subjects (45 CFR 46)
- Informed Consent Information

visit the following website:

<https://www.hhs.gov/ohrp/regulations-and-policy/index.html>

For guidance with human subjects protection issues in public health, see the human subjects protection website at the Centers for Disease Control and Prevention:

<http://www.cdc.gov/od/ads>

For information on federal certificates of confidentiality, which protect confidential information collected on research subjects from access through most federal, state, and local legal actions, such as subpoenas, see the following website:

<http://www.hhs.gov/ohrp/policy/index/html>

For Rhode Island's Confidentiality of Healthcare Communications and Information Act (Rhode Island General Laws Chapter 5-37.3) and specifically for requirements relating to the release of medical records (Section 5-37.3-4(d)) see:

<http://www.rilin.state.ri.us/Statutes/TITLE5/5-37.3/INDEX.HTM>

APPENDICES

- A. Does the Project Include Research Involving Human Subjects?**
- B. Research Involving Human Subjects Who Are Afforded Special Protections**
- C. Minors as Research Participants**
- D. Research exempt from IRB review**
- E. Research eligible for expedited review**

APPENDIX A

DOES THE PROJECT INCLUDE RESEARCH INVOLVING HUMAN SUBJECTS?

The Rhode Island Department of Health (RIDOH) Institutional Review Board (IRB) is established to review the procedures for protection of human subjects in all research projects that involve RIDOH staff, data, or other resources. The principal purpose of IRB review is to assure that the procedures for obtaining informed consent from human research subjects are properly established and administered.

To that end, the RIDOH IRB is mandated to review only those projects and programs that, in whole or part, meet the definition of research on human subjects, as presented in the federal regulations governing protection of human subjects (Title 45, Code of Federal Regulations, Part 46). The definitions are as follows:

"Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities." [45 CFR 46.102(d)]

"Human subject means 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. *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects." [45 CFR 46.102(f)]

If a project or program, or any component of a project or program, does not meet both of these definitions, it is not subject to IRB review. It is the responsibility of the principal investigator (PI) of a project to obtain IRB review in all cases where appropriate. The PI may choose not to submit a project to the IRB if he/she believes it does not meet the federal definitions. However, the consequences of failing to obtain human subjects review of a project where it is required are such that it is advisable to submit any questionable projects for review. The chair, members, and staff of the RIDOH IRB are available to investigators for consultation on the necessity of submitting specific projects for IRB review.

APPENDIX B

RESEARCH INVOLVING HUMAN SUBJECTS WHO ARE AFFORDED SPECIAL PROTECTIONS

Certain categories of human research subjects are afforded special protections under federal regulations because they are at greater risk of adverse consequences and/or because they require special consideration in the informed consent process. These categories are -

- (1) Fetuses, pregnant women, and human *in vitro* fertilization,
- (2) Prisoners, and
- (3) Children.

The special protections afforded each of these categories of human subjects are detailed in Subparts B, C, and D of the federal regulations regarding the protection of human subjects, 45 CFR 46. .

[Note: The National Institutes of Health (NIH) have instituted policies supporting diversity in the selection of human research subjects, for the purpose of maximizing the applicability of research results to all relevant populations. Investigators performing NIH-sponsored research projects should be aware of these policies and, for some groups, the impact of the policies on informed consent procedures. The policies are "Inclusion of Children in Research" and "Inclusion of Women and Minorities in Research" and can be found at the NIH web site "grants.nih.gov/grants/oprr/library_human.htm" under the heading "National Institutes of Health (NIH) Information."]

APPENDIX C

MINORS AS RESEARCH PARTICIPANTS

Children are more vulnerable than other research participants "...because of their more limited cognitive competencies and experiential backgrounds, which constrain their capacities to understand and defend their rights as research participants and to make responsible decisions concerning research participation. They are also vulnerable because of their limited social power, which impairs their ability to exercise independent decision making concerning research participation..." (Thompson, 1990). Because of these limitations, special caution is advised in the preparation and review of protocols involving children as subjects. These include:

Consideration of the developmental level of the individual in the determination of "minimal risk": It is usually assumed that vulnerability in children decreases with age. However, there are conditions in which vulnerability increases or peaks at certain ages. For example, children's increasing self-awareness or adolescents' sensitivity to their changing bodies may make older children more vulnerable than younger children.

Considerations in obtaining informed consent or assent: It is clear that consent is required from the parent or guardian. Less clear are the requirements for the child's assent. Although children cannot consent to research, they do have the right to refuse to participate. It is recommended that the following be delineated in obtaining assent from children:

1. That assent be required and obtained in writing from the child unless there is a clear, written justification for not obtaining assent.
2. That there be a clear means of documenting how assent is obtained, and by whom. Where appropriate, a separate form should be drafted with language appropriate to the child's developmental level.

Explanation of and process for quitting or withdrawal from the research: Since children tend to be acquiescent to adult wishes and are often reluctant to speak up when uncomfortable, special attention must be given to processes for quitting or withdrawal from research. Along with the usual statements in the informed consent form, the researcher is advised to:

1. Be cognizant of signs of discomfort shown by the child throughout the interview or testing procedures, and periodically inquire about the child's reactions or feelings.
2. Include procedures for withdrawal that address the above considerations.

APPENDIX D

RESEARCH EXEMPT FROM IRB REVIEW

Projects that do not meet the definition of research or do not involve human subjects as defined in Appendix A are exempt from IRB review. For projects that do involve research on human subjects, the following categories are exempt from review, per 45 CFR 46.101(b).

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, qualifies as exempt *unless*:

(i) Information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects (*information must be anonymous*); **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 2, 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 or procedures; or

(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.

APPENDIX E

RESEARCH ELEGIBLE FOR EXPEDITED IRB REVIEW

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.

Research Categories

(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:

(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:

(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).

Source: 63 Federal Register 60364-60367, November 9, 1998.