

Research Involving Human Subjects and/or Anatomical Substances

**Guidelines for Submitting Proposals
for the Conduct of Research Involving Human Subjects**
(including human organs, tissues, cells, body fluids from human subjects
as well as graphic, written, or recorded information derived from human subjects)

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Research Involving Human Subjects and/or Anatomical Substances

1. Introduction

In 1991, the DOD, along with 15 other federal agencies, adopted regulations that are known collectively as the Common Federal Rule. These regulations embody the ethical principles of the Belmont Report. Title 32, Code of Federal Regulations Part 219 (32 CFR 219), “Protection of Human Subjects” applies to all research involving human subjects conducted or supported by the DOD. The Department of Health and Human Services (DHHS) National Institutes of Health (NIH) corollary is 45 CFR 46. Research conducted or funded by the USAMRMC is also governed by Army Regulation (AR) 70-25, January 1990 Office of The Army Surgeon General (OTSG) Regulation 15-2, January 1989. The USAMRMC also adheres to the Food and Drug Administration’s (FDA’s) regulation, Title 21, Code of Federal Regulations for research involving investigational drugs or devices.

The OTSG maintains the overall responsibility for protecting human research subjects for the Department of the Army (DA).

2. Definitions

2-a. Research

32 CFR 219, The Common Federal Rule, defines “research” as 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 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.

21 CFR 312 (FDA) defines “clinical investigation” as “any experiment that involves a test article and one or more human subjects...”

2-b. Human Subjects

32 CFR 219 defines “human subject” as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.” **The regulations extend to the use of human organs, tissues, cells, body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects.**

21 CFR 312 (FDA) defines “human subject” as “an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.”

3. Human Subjects Research Review Process

3-a. Review Levels

In addition to first level of review and approval by the local Institutional Review Board (IRB), the OTSG requires a second level of review and approval by its Human Subjects Research Review Board (HSRRB) of all research involving human subjects. See Section 2-a of this appendix for the definition of a human subject. Approval must be obtained **prior** to initiation of the research protocol.

The HSRRB is functionally similar to a civilian IRB. The HSRRB is supported administratively by the USAMRMC, Office of the Deputy Chief of Staff for Regulatory Compliance and Quality, Human Subjects Protection Division (HSPD).

If your research proposal is recommended for funding and the research involves human subjects, the HSPD, in accordance with 32 CFR 219, will determine that the research:

1. is exempt from HSRRB review,
2. is eligible for expedited review,
3. is no greater than minimal risk and, therefore, can be administratively reviewed and approved by the HSPD, or
4. is greater than minimal risk and, therefore, requires full HSRRB committee review.

3-b. Timelines and Outcomes

In general, research protocols that pose greater than minimal risk to subjects are submitted through the HSPD to the HSRRB for full committee review and approval prior to implementation of the study. Review and approval by the HSRRB is usually accomplished within 45-90 days after submission of the protocol to the HSRRB. Any revisions to the protocol, consent form, advertisements, questionnaires, and other related study documentation recommended by the HSRRB must be reviewed and approved by the HSPD **prior to implementation of the study**.

The HSRRB will make 1 of 4 recommendations to The Surgeon General (TSG):

1. approval without changes,
2. conditional approval contingent upon changes and/or clarification,
3. deferred (Note: Protocols are deferred when the HSRRB has substantive concerns about the conduct of the protocol or the safety of the subjects. The PI will receive written comments from the HSRRB and the investigator's responses will go to full committee for further deliberation.), or
4. disapproved (Note: The PI will be notified in writing. The PI must then notify the HSPD of his or her intention to re-submit the protocol or to terminate consideration of the protocol.).

4. Claim of Exempt Research

4-a. Approval of Exempt Research Involving Human Subjects or Anatomical Substances

Certain categories of research may be exempt from review by the HSRRB. Those categories are specific and follow Federal Guidelines. Your research must fit into one or more of the categories in order to file the Claim of Exemption Form.

4-b. Exempt Categories

The following list details the exemption categories.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - a. research on regular and special education instructional strategies, or
 - b. 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:
 - a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - b. 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 of this section, if:
 - a. the human subjects are elected or appointed public officials or 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.
4. Research involving the collection or study of existing data, documents, records, or pathological 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 that are conducted by or subject to the approval of Department or

Agency heads, and that are designed to study, evaluate, or otherwise examine:

- a. public benefit or service programs
 - b. procedures for obtaining benefits or services under those programs
 - c. possible changes in or alternatives to those programs or procedures or
 - d. 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,
- a. if wholesome foods without additives are consumed, or
 - b. 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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

4-c. Claiming Exemption

Complete the form in Section 9 of this appendix to claim exemption for research involving human subjects or anatomical substances.

4-d. Final Judgment

The HSPD retains final judgment as to whether a particular activity is covered by this policy.

5. Guidelines for Writing Research Protocols Involving Human Subjects

5-a. The Basic Protocol

A detailed research protocol is required for the HSRRB review of your research. All submissions should include the following information:

1. **Project Title.** The consent form title should match that of the project.
2. **Phase.** For Food, Drug, and Cosmetic Act-regulated medical products, designate as a Phase I, II, III, or IV protocol.
3. **Principal Investigator.** The complete name, address, and phone number of the PI should be listed.
4. **Location of Study.** List all centers, clinics, or laboratories where the study is to be carried out. The complete addresses and site investigator(s) should be listed.
5. **Time Required to Complete.** The month and year of expected start and completion dates should be listed.

6. **Objectives.**
7. **Study Population.** Detail source, number, age range, and sex of subjects along with inclusion/exclusion criteria.
8. **Protocol Design.** Outline the proposed methodology in enough detail to show a clear course of action. Technological reliability and validity of procedures should be indicated. Minimum guidance for the plan includes:
 - a. Subject identification (Describe code system to be used.)
 - b. Subject assignment
 - c. Evaluations prior to entry
 - d. Evaluations to be made during the conduct of the study (i.e., laboratory evaluations, specimens to be collected, schedule and amounts, storage to include where and whether special conditions are required, labeling and disposition)
 - e. Clinical Assessments (i.e., schedule of clinical evaluations and follow-up procedures, and adverse events)
9. **Risks/benefits Assessment.** (Detail benefits of the research to the subject, precautions to be taken to minimize and/or eliminate risks, and specific medical or nursing care that will be needed.)
10. **Reporting of Serious and Unexpected Adverse Events.** (See HSPD Clause 001.02.- Section 5-b.i.)
11. **Description of Protocol Drug(s) or Device(s).** If the protocol uses an investigational drug or device, provide the following information:
 - a. Investigational New Drug (IND)/Investigational Device Exemption (IDE) number and sponsor.
 - b. Complete names and composition of all medication(s), device(s), or placebo(s)
 - c. Source of medication(s), device(s), placebo(s)
 - d. Place where study medication(s) will be stored
 - e. Dose range, schedule, and administration
 - f. Washout period (The washout or pre-drug period must be noted carefully.)
 - g. Duration of drug or device treatment
 - h. Concomitant medications
 - i. Antidotes and treatments available
 - j. Disposition of unused drug
12. **Disposition of Data.** Where will the data be stored and for how long? **Note:** Records for IND studies must be kept until 2 years after a New Drug Application (NDA)/license for the investigational drug is approved/issued, or for 2 years after the IND is withdrawn. Records required for IDE studies should be retained for 2 years after the latter of the following dates: the date that investigation is terminated or completed; or the date that records are no longer required for support of a premarket approval application.
13. **Modification of the Protocol.** Describe the procedure to be followed if the protocol is modified.

14. **Roles and Responsibilities of Study Personnel.** Briefly describe the duties of study personnel.
15. **Signature of Principal Investigator.** Type the following statement, "I have read the foregoing protocol and agree to conduct the study as outlined herein." The PI should sign and date following this statement.

5-b. Requirements Unique to DOD/MRMC-Funded Research

5-b.i. Reporting of Serious and Unexpected Adverse Events

HSPD Clause 001.02

Serious and unexpected adverse experiences will be immediately reported by telephone to the USAMRMC Deputy Chief of Staff for Regulatory Compliance and Quality [(301) 619-2165, during non-duty hours call (301) 619-2165 **and** send information by Fax to (301) 619-7803]. A written report will follow the initial telephone call within three working days. Address the written report to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ-HR, 504 Scott Street, Fort Detrick, MD 21702-5012.

HSPD Clause 007.01

An adverse event temporally related to participation in the study should be documented whether considered to be related to the test article. This definition includes intercurrent illnesses and injuries, and exacerbations of pre-existing conditions. Include the following in all IND safety reports: Subject identification number and initials; associate investigator's name and name of hospital or medical treatment facility; subject's date of birth, gender, and ethnicity; test article and dates of administration; signs/symptoms and severity; date of onset; date of resolution or death; relationship to the study drug; action taken; concomitant medication(s) including dose, route and duration of treatment, and date of last dose.

5-b.ii. Volunteer Registry Database Requirements

HSPD Clause 002.01

It is the policy of the USAMRMC that data sheets are to be completed on all volunteers participating in research for entry into this Command's Volunteer Registry Data Base. The information to be entered into this confidential data base includes name, address, social security number, study name, and dates. The intent of the data base is two-fold: first, to readily answer questions concerning an individual's participation in research sponsored by USAMRMC; and second, to ensure that the USAMRMC can exercise its obligation to ensure research volunteers are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at USAMRMC for a minimum of 75 years.

5-b.iii. Sample Donation

HSPD Clause 004.

If the samples donated in this study will be used in other studies, the statement "I understand that there is a possibility that the blood, tissue, body fluid, product, or sample(s) (specify type) which I am providing under this study may also be used in other research studies and could potentially have some commercial applicability" should be included in the consent form. In addition, a donation form must be prepared for signature by the

volunteer and a witness that states “I voluntarily and freely donate any and all blood, tissues, body fluid, product, or sample(s) (specify type) to the study sponsor (insert institution name) and hereby relinquish all right, title, and interest to said items.” The title of the study should be inserted at the top of this donation form. The samples which will be stored, should contain no personal identifiers.

5-b.iv. Title 10 United States Code, Section 980

HSPD Clause 006.01

10 United States Code 980 requires that "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless— (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject."

5-b.v. Medical Monitor

HSPD Clause 008.01

A medical monitor must be assigned to any study involving greater than minimal risk to subjects. The name and curriculum vitae of the medical monitor must be provided. This individual should be a qualified physician, other than the Principal Investigator, not associated with this particular protocol, able to provide medical care to research subjects for conditions that may arise during the conduct of the study, and who will monitor the subjects during the conduct of the study.

5-b.vi. Serum Pregnancy Testing

If pregnant subjects will be excluded from participation in the study, the **method of determining pregnancy** status in women of childbearing potential must be specified. Also, the time that will elapse between the pregnancy test and exposure to research procedures or medical products must be documented. Serum pregnancy tests are required for all clinical medical product studies. For IND studies, serum pregnancy testing is required within 48 hours prior to the start of the study.

5-c. Advertisements, Posters, Flyers, or Press Releases to Recruit Subjects

If subjects will be recruited through an advertisement, newspaper article, or similar process, a copy of the local IRB-approved advertisement must be provided. For studies involving investigational drugs or devices, local IRB review of advertisements is necessary to ensure the information is not misleading to the subjects participating in IND studies. The FDA has established guidelines on advertisements for subjects. General guidance includes: name and address of PI, summary of research purpose, brief eligibility criteria, truthful list of benefits, and the person to contact for further information.

5-d. Surveys, Questionnaires, or Other Instruments

If the research involves surveys, questionnaires, or other instruments, include copies of the instruments in the Human Use Appendix.

5-e. Investigational Drugs or Devices

For research that involves an investigational drug or device:

1. Submit a copy of the Investigator's Drug Brochure and/or device manual and associated case report/data collection forms.
2. For IND products, specify the IND number, name of the sponsor, and the procedure by which the IND sponsor will monitor the protocol in accordance with 21 CFR 312.
3. For Investigational Devices, include your local IRB's assessment of the risk of the investigational device you plan to use in your study. If the device poses significant risk to research subjects, specify the IDE number obtained from the FDA, the name of the sponsor, and the procedure by which the IND sponsor will monitor the protocol in accordance with 21 CFR 812.
4. Contact your local IRB and/or the FDA if you have questions regarding IND or IDE submission requirements.

6. Informed Consent Requirements

The information that is given to the subject, or his or her representative shall be in language understandable to the subject or the representative. No informed consent may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

6-a. Elements of Informed Consent

The following information is essential for informed consent documents:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others that may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

6. For research involving more than minimal risk, include the following explanation of medical care available for research-related injury, (HSPD Clause 003.01):

Should you be injured as a direct result of participating in this research project, you will be provided medical care, at no cost to you, for that injury. You will not receive any injury compensation, only medical care. You should also understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigator before you enroll in this study.

Four possible mechanisms are available to offset the costs of this requirement:

- a. The proposed recipient may absorb such costs into the institution's operating budget.
 - b. The proposed recipient's liability insurance, if available, may be sufficient to cover any medical care costs. The proposed recipient's business office and/or legal advisor must ensure that there is adequate coverage under this liability insurance.
 - c. The proposed recipient could negotiate an additional amount of funds, if available, into the award that will cover such medical care cost (such as liability insurance).
 - d. Third-party payers may be billed for such medical expenses. If this method is used, the subject must be informed, in the consent document, that his/her insurance company will be billed.
7. A contact for answers to questions about the research and research subjects' rights, and a contact in the event of a research-related injury to the subject.
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

6-b. Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.

6. The approximate number of subjects involved in the study.

6-c. Requirements Unique to DOD/MRMC-Funded Research

6-c.i. Certification of Translation

HSPD Clause 005.01

Provide documentation that the foreign language version of the consent form is an accurate translation.

Documentation should include the following statement, “I certify that this is an accurate and true translation” as well as the signature, name, address, phone number and, if available, Fax number of the translator.

6-c.ii. Payment for Study Participation: Active Duty Military Personnel

Under 24 CFR 30, payment for participation is limited to blood donation and may not exceed \$50 per blood draw. Active duty research subjects may not receive any other payment for participation in a research study.

6-c.iii. Confidentiality: Military Personnel

The following statement is **MANDATORY** for studies utilizing military personnel:

All data and medical information obtained about you as an individual will be considered privileged and held in confidence; you will not be identified in any presentation of the results. Complete confidentiality cannot be promised, particularly to subjects who are military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities.

6-c.iv. Pregnant Women

If pregnant women will be excluded, the following statement, HSPD Clause 009.01 (or equivalent), must be included:

I should avoid becoming pregnant for at least (time period in days, weeks, or months) after participation in the study. To avoid becoming pregnant, I should either abstain from sexual relations or practice a method of birth control. Except for surgical removal of the uterus, birth control methods such as the use of condoms, a diaphragm or cervical cap, birth control pills, IUD, or sperm-killing products are not totally effective in preventing pregnancy.

6-c.v. Volunteer Registry Data Base

For all studies involving greater than minimal risk, HSPD Clause 002.01, Volunteer Registry Data Base, must be included in the consent form. See Section 5-b.ii. of this appendix.

7. Assurances

If an institution has filed a Multiple Project Assurance (MPA) with the DHHS Office for Protection from Research Risks (OPRR), that assurance number should be documented on the Optional Form 310 (OF 310,

Protection of Human Subjects Assurance/Certification/Declaration, page A-53), which replaced DHHS Form 596.

If the institution has not filed a MPA with OPRR, a written Assurance of Compliance should be filed with the USAMRMC Office of the Deputy Chief of Staff for Regulatory Compliance and Quality, Human Subjects Protection Division. A DOD Assurance number will be issued for the research project. There are three different assurance applications: (1) for institutions that have an IRB but no MPA; (2) for overseas institutions; and (3) for institutions using another institution's IRB. Sample assurance documents and the OF 310 can be downloaded from the USAMRMC Congressionally Directed Medical Research Programs website (<http://mrmc-rad6.army.mil/documents.html>).

The OF 310 should be completed and signed by the Chairperson of the IRB. If another agent signs this document, verification of authority should be included in the remarks column (individual's signature authority). The OF 310 **must** include the level of risk that the project poses to the subject. These risk levels are: exempt, minimal risk, and greater than minimal risk. The HSPD reserves the right to determine whether the assigned risk level is in compliance with all applicable regulations.

8. Inclusion of Women and Minorities in Research

Consistent with the Belmont Report and recent Congressional legislation, special attention is given to inclusion of women and minorities in research funded by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. If women and/or minorities will be excluded, a justification must be included.

9. Where to Go for Help and Information

If your research involves human subjects, you should first contact your local IRB for institutional requirements.

If you have questions regarding the USAMRMC protocol and consent form requirements or the review and approval process, contact the Office of the Deputy Chief of Staff for Regulatory Compliance and Quality, Human Subjects Protection Division at the address or phone number listed below.

Phone: (301) 619-2166

Mail: Commander

U.S. Army Medical Research and Materiel Command

ATTN: MCMR-RCQ-HR

504 Scott Street

Fort Detrick, MD 21702-5012

References:

- Title 32 Code of Federal Regulation, Part 219, Protection of Human Subjects
- Title 21 Code of Federal Regulation, Part 50, Protection of Human Subjects
- Title 21 Code of Federal Regulation, Part 56, Institutional Review Boards
- Title 21 Code of Federal Regulation, Part 312, Investigational New Drug Application
- Title 21 Code of Federal Regulation, Part 812, Investigational Devices

- Army Regulation 70-25, Use of Volunteers as Research Subjects
- Army Regulation 40-7, Use of Investigational Drugs and Devices in Humans and the Use of Schedule I Controlled Drug Substances
- Office of The Surgeon General Regulation 15-2, Human Subjects Research Review Board
- Title 45 Code of Federal Regulation, Part 46 (45 CFR 46), Subparts B, C, and D, Protection of Human Subjects
- Title 10 United States Code, Section 980
- Department of Defense Directive 3216.2 (when using organs or tissues obtained at autopsy)
- Department of Defense Directive 6465.2

Copies of the preceding references can be obtained from either the U.S. Government Printing Office or the National Technical Information Service at:

Phone: (202) 512-1800

Mail: U.S. Government Printing Office
North Capital & G Street, NW
Washington, DC 20401

Phone: (703) 487-4650 or 4684

Mail: National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161

10. Claim of Exemption from Review by the Human Subjects Research Review Board

United States Army Research and Materiel Command
Office of the Deputy Chief of Staff for Regulatory Compliance and Quality
Human Subjects Protection Division

PROTOCOL TITLE
PI'S NAME
INSTITUTION

EXEMPT CATEGORY CLAIMED (Please refer to Exempt Categories - Section 4-b.)

1. Will existing or archived data, documents, records, or biological specimens be used? Yes No
 - a. Will any data or biological specimens be collected from subjects? Yes No
 - b. What is the source(s) of existing or archived data/biological specimens? (all that apply)

_____ existing data	publicly available?
_____ archived data	publicly available?
_____ biological specimens	publicly available?
 - c. Will the information be recorded in such a manner that subjects cannot be identified, directly or indirectly through links? Yes No
2. Will data be recorded
 - a. by audiotape? Yes No
 - b. by videotape? Yes No
3. If survey instruments are used, will sensitive or private topics be explored? Yes No
4. Will the subjects be identifiable either by name or through demographic data? If yes, describe on a separate sheet how the confidentiality of a subject's identity will be maintained and plans for maintaining or destroying identifying links to subjects after the study is completed.

PI's Signature

**Protection of Human Subjects
 Assurance Identification/Certification/Declaration
 (Common Federal Rule)**

Research activities involving human subjects may not be conducted or reported by the Departments and Agencies adopting the Common Rule (28003, June 18, 1991) unless the activities are exempt from or reported in accordance with the common rule. See section 101(b) the common rule for exemptions. Institutions submitting applications or proposals for support must submit certification or appropriate Institutional Review Board review and approval to the Department or Agency in accordance with the common rule.

Institutions with an assurance of compliance that covers the research to be conducted on file with the Department, Agency, or the Department of Health and Human Services (HHS) should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency. Institutions which do not have such an assurance must submit an assurance and certification of IRB review and approval within 30 days of a written request from the Department or Agency.

1. Request Type ORIGINAL LOW PRIORITY EXEMPTION	2. Type of Mechanism o GRANT o CONTRACT o FELLOWSHIP o COOPERATIVE AGREEMENT o OTHER: _____	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
4. Title of Application or Activity		5. Name of Principal Investigator, Program Director, Fellow, or Other

6. Assurance Status of this Project (*Respond to one of the following*)

- This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance identification no. M-_____ IRB identification no. _____
- This Assurance, on file with (*agency/dept*) _____, covers this activity.
Assurance identification no. _____ IRB identification no. _____ (*if applicable*)
- No assurance has been filed for this project. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph _____.

7. Certification of IRB Review (*Respond to one of the following IF you have an Assurance on file*)

- This activity has been reviewed and approved by the IRB in accordance with the common rule and any other governing regulations or subparts on (*date*) _____ by: Full IRB Review or Expedited Review
- This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the common rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed and certification will be provided.		10. Name and Address of Institution	
11. Phone No. (<i>with area code</i>)	12. Fax No. (<i>with area code</i>)		
13. Name of Official		14. Title	
15. Signature		16. Date	