Appendix II: West Virginia State University Institutional Review Board

WVSU-IRB

Policies Table of Contents

West Virginia State University Institutional Review Board
Human Information and Application/Registration Forms Institutional Assurance Concerning Research

I. GENERAL POLICIES AND RESPONSIBILITIES

All review of research activities involving human subjects covered by this policy shall be carried out by the WVSU-IRB following the procedures set forth in this policy.

A. *UNIVERSITY COMMITMENTS*

West Virginia State University is committed to safeguarding the rights and welfare of all people who participate in research conducted by University faculty, staff, and students. It is also committed to insuring humane care and use of animals in teaching and research. WVSU supports responsible experimentation that promises to increase knowledge and understanding and encourages the highest ethical standards among University researchers.

In addition to assuring compliance with the Department of Health and Human Services (DHHS) regulations 45 CFR 46, as specified in the Office for Protection from Research Risks (OPRR) 1983 report, *Protection of Human Subjects*, the University accepts responsibility for complying with Food and Drug Administration (FDA) regulations (21 CFR 56) and all other applicable state and local laws as they may relate to research covered by the DHHS policy. Categories of research exempted from this policy are those specifically listed in 45 CFR 46.101 (2) (B) 1 through 6. However, the WVSU-IRB requires all research involving human subjects—exempt or non-exempt—to be formally proposed and explained to the IRB.

B. *GENERAL GOALS OF THE WVSU-IRB*

The general goals of the WVSU-IRB are to protect the rights of human participants in research studies, including their rights to give informed consent and to have their safety protected from undue risk;

C. *GENERAL CHARGE TO THE WVSU-IRB*

The WVSU-IRB has the responsibility and authority to review and approve all research projects by WVSU faculty, staff, and students involving human

participants. It will approve only those experiments that conform to the professional standards as understood within the relevant discipline.

D. *RESPONSIBILITIES AND AUTHORITY OF THE WVSU-IRB*

D.1. Review all new and ongoing projects involving human participants at convened WVSU-IRB meetings at which time the majority of the Board's membership constitutes a quorum, with a WVSU-IRB member whose concerns are primarily in non-scientific areas being included in the quorum. Voting on projects is limited to duly appointed Board members. Excluded from this process are those submissions whose researchers are requesting expedited review.

D.2. Notify investigators and other signatories on the research proposal of the results of the WVSU-IRB review.

D.3. Review projects on an annual basis or more frequently as deemed appropriate.

D.4. Require that the informed consent procedure is in accordance with WVSU-IRB policy.

D.5. Observe or have a third party observe the consent process and the research, when appropriate.

D.6. Require written notification by investigators when changes in research activity are proposed.

D.7. Require prompt reporting by investigators when unanticipated problems involving risks to participants occur.

D.8. Suspend or terminate approval of research that has been associated with unexpected serious harm to participants or that is not being conducted in accordance with the WVSU-IRB's decisions. If questions arise concerning legal, moral, or ethical issues involved in research, the WVSU-IRB will meet to discuss the issues, using consultants from the research area or the University General counsel, and meet with the researcher, if possible, before suspension. The privacy rights of research subjects and WVSU students are of paramount importance.

D.9. a. Report to the investigators and their appropriate supervisors (e.g., unit head, department chair, or dean) any suspension or termination of approved research, including the Faculty Senate's Research and Development Committee if that Committee was involved.

D.9.b. Report to the Secretary of DHHS or any applicable funding agency—when the research activity is funded in whole or in part by a DHHS or other government agency grant, contract, or fellowship—regarding (1) serious or continuing noncompliance by investigators with the requirements and determinations of the WVSU-IRB, (2) suspension or termination of approved research that is not being conducted in accordance with the WVSU-IRB's requirements, or (3) any unexpected serious harm to participants associated with research project.

D.10. Advise investigators regarding specific problems associated with protocols involving human subjects.

D.11. Contribute and refer to University guidelines to aid principal investigators in the preparation of their applications for approval of research involving human and animal participants.

D.12. Maintain complete records.

D.13. Interpret government and University policies pertaining to the protection of human research participants.

D.14. Develop and publish University policies and procedures governing research involving human participants.

D.15. Provide consultation through its Chair to any participant or principal investigator.

D.16. Establish procedures for monitoring implementation of WVSU-IRB action.

D.17. Maintain communication with Federal, State, and local agencies and institutions to insure that the WVSU-IRB procedures are current and consistent.

D.18. Coordinate review of research carried out at off-campus sites.

D.19. Report any changes in WVSU-IRB membership to the University President through the Board Chair.

E. *COMPOSITION OF THE WVSU-IRB*

The WVSU-IRB is sufficiently qualified through the experience, expertise, and diversity of its members, including sensitivity to community attitudes, to command respect for its advice in safeguarding the rights and welfare of research participants.

The WVSU-IRB shall be composed of at least eight members from the University, representing diverse backgrounds and possessing professional competence necessary to review the specific research activities assigned to it. The WVSU-IRB

shall include members of various genders, races, ages, WVSU- professions and departments. It is strongly recommended that at least one member have a background in social science, at least one member have a background in natural science, and at least one member whose primary expertise is in a non-scientific area. In addition, two additional members from the WVSU community are to be included who have no formal affiliation with the University. At any time, consultants may be sought, but these persons may not participate by vote in the WVSU- IRB actions.

Becoming a member shall occur as follows: The Chair of the Faculty Senate shall announce during a Senate meeting that one or more members are needed for the WVSU-IRB. Nominees can put their own names forward or be suggested (with their permission) by others. Potential members of the WVSU-IRB will be then reviewed by the Faculty Senate Executive Committee, then passed on to the University President, who shall appoint the member(s) for a three-year term. The WVSU- IRB shall elect its chair annually. For the purposes of continuity and rotation, initial members of the IRB shall serve staggered one-, two-, and three-year terms.

Responsibility and Authority of West Virginia State University

1. Legal assistance. All requests for legal assistance must be initiated with the University General Counsel. Upon review more specialized consultation or advice maybe sought by external parties, if needed.

2. Liabilities. The University is legally responsible for the acts and omissions of its investigators while acting in the course and scope of their University duties. In the event of a suit against investigators or members of the WVSU-IRB based on their actions in connection with a research activity involving human participants, the University would be obligated to assume their defense if the research project was approved by the WVSU-IRB in accordance with this policy.

It is assumed that a principal investigator has, or should have, knowledge of the applicable University policy requiring that every research activity placing human or animal participants at risk be reviewed by the WVSU-IRB. If an investigator fails to obtain such approval prior to involvement of human or animal participants, the investigator would be acting outside the scope of her/his duties, and the University would not be obligated to defend or indemnify the investigator if legal actions were initiated by a participant.

II. INFORMATION AND INSTRUCTIONS FOR FILING RESEARCH PARTICIPANT PROTECTION PROTOCOLS WITH THE WEST VIRGINIA STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD

II.a. GENERAL INFORMATION

In accordance with Department of Health and Human Services regulations, West Virginia State University recognizes three categories of review for research involving human participants: full, exempt, and expedited. It is anticipated that most research activities carried out at WVSU will fall under the exempt and expedited review categories in that they involve relatively low-risk procedures. The following guidelines will allow the investigator to determine the appropriate application format.

The standard review criteria are used regardless of the risk level of the proposed study. It must be emphasized that WVSU-IRB review concerns research, and thus a project must be clearly defined. The nature of the procedures in the study defines the level of review required.

The following definitions are used by the WVSU-IRB when research projects involve human participants:

II.a.1 HUMAN PARTICIPANT means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (45 CFR 46.102)

II.a.2 RESEARCH a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. (In-class activities conducted by instructors are not automatically subject to WVSU-IRB review unless they constitute "research" as described herein.)

II.a.3 MINIMAL RISK. The term "minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Using "minimal risk" as a goal, the WVSU-IRB will

use the "reasonable person standard" to compare the risks of research to those in the daily life of a typical person in the anticipated participant population.

II.a.4 ***WRITTEN, OR IN WRITING*** for purposes of this part, refers to writing on a tangible medium (*e.g.,* paper) or in an electronic format.

II.a.5 ***INTERACTION*** includes communication or interpersonal contact between investigator and subject.

II.a.6 ***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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.,* a medical record).

II.a.7 **EVALUATIONS OF RISK IN RELATION TO BENEFITS.** Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the WVSU-IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapy subjects would receive even if not participating in the research). The WVSU-IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. (45 CFR 46.111(a)(2))

II.B. ACTIONS

Applying the criteria for IRB research review set forth in 45 CFR 46.111, the WVSU-IRB will review each proposal and take one of the following actions:

II.b.1. *Approve the research.* Although the research may involve some risk to the participants, the WVSU-IRB may find that the risk is minimal, and that the investigator has taken all practical steps to minimize the risk.

II.b.2 *Withhold approval of the research with a request for resubmission of the protocol.* This occurs when the WVSU-IRB believes that it has insufficient information to take action, or when it feels the research design contains flaws or characteristics that should be revised to reduce risks to participants. The WVSU-IRB may ask the investigator to provide for emergency back-up medical care, to take further steps to protect the confidentiality of the participants, or to develop a substitute procedure.

II.C INFORMED CONSENT

Except as provided in these documents, legally effective informed consent must be obtained from any research participant or the participant's legally authorized representative who, in the course of a research protocol, is exposed to the risk of physical, psychological, or social injury. Informed consent is defined as the knowing consent of an individual or their legally authorized representative so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The term "participant" shall, where appropriate, mean the participant or the participant's legally authorized representative.

Legally effective informed consent includes at a minimum both the investigator's oral explanation of the research to the participant and the potential participant's expected involvement therein, as well as the investigator's response to any or all questions that the participant may have concerning the research protocol. In certain instances, this will be required documentation of consent using a WVSU-IRB approved consent form, which is signed by the investigator and by the participant.

Informed consent can be sought only under circumstances which

- provide the participant with sufficient opportunity to freely consider whether they wish to be involved in the research and
- minimize any possibility of coercion or undue influence.

In those research settings in which risk to participants may be increased by written records of their names, or in observational studies of naturally-occurring human interaction, the requirement of informed consent must nevertheless be met. The researcher must provide a written explanation to the WVSU-IRB of how the participants' rights to privacy and anonymity will be protected. It is strongly recommended that in such instances, investigators develop an information letter to be given to the participants. This letter should be submitted with the WVSU-IRB application, and it will be subject to committee review.

Any or all of the requirements for obtaining consent may be waived by the WVSU-IRB during its review of a proposal, but only under certain circumstances as specified in 45 CFR 46.101 (b).

The following guidelines are to be used when preparing a Consent Form:

c.1. The consent form is to be written in narrative form and include all information the participant should know in making her/his decision whether to participate.

c.2. Statements must be easily readable and understandable. Technical terminology and abbreviations are not to be used unless clearly defined.

c.3. The consent form must be in the fluent language of the participant. However, translations of consent forms should not be done until the English-language version has been approved by the IRB. Furthermore, translations MUST either be done or verified by a qualified faculty member of the University or someone designated by that faculty member.

c.4. All participants are to be given sufficient time to consider whether they wish to participate before signing the consent form.

c.5. The investigator is reminded that the consent form is simply the written documentation of the consent process. Oral explanations are to be given to each prospective participant, and the participant is to be encouraged to ask questions.

c.6. In reviewing research protocols and consent forms, WVSU-IRB members are particularly cognizant of research involving minors. All research involving minors must conform to the DHHS regulations, as stated in "Additional Protection for Children Involved as Subjects in Research" (45 CFR 46.401-409). The specific requirements are listed in Section II.d below.

II.D. RESEARCH INVOLVING MINOR PARTICIPANTS

The Department of Health and Human Services issued regulations, effective June 6, 1983, giving additional protection to children involved as participants in research. The regulations contained in "Additional Protection for Children Involved as Subjects in Research" (45 CFR 46.401-409) must be applied to all research involving minors which is reviewed by the WVSU-IRB.

A minor is a person under age 18 who does not have the legal authority to consent. Emancipated minors, whom the state gives the right to consent and contract as adults, are to be treated as adults. The regulations governing children in research dictate that investigators consider the age, maturity, and psychological state of the participating children and obtain the legal consent from the responsible parent or

guardian. If the legal consent is provided by the parent or guardian, in addition, the children's assent is required. Regulations define "assent" as the child's affirmative agreement to participate. Further, the regulations dictate that "mere failure to object should not, in the absence of affirmative agreement, be construed as assent."

The assent procedure may be represented by an assent form or by a prepared script of the explanation to be tendered by the investigator. The following areas must be addressed in the assent procedure, utilizing language appropriate to the child's age and/or developmental level:

d.1. The rationale for asking the child to participate
d.2. From the child's point of view, description of what is to occur
d.3. The risk to the child
d.4. The benefit to the child
d.5. Identification of the researcher by name and telephone number in case questions should arise before and after participation
d.6. A statement that the child has a choice to participate in or to withdraw from the research at any time without any negative consequences
d.7. A statement that the child can retain a copy of the assent form
d.8. Date and signature lines for the investigator and, if appropriate, for the child.

II.E. PROCEDURE FOR FULL REVIEW

Review of all IRB proposals will be conducted through the use of an electronic submission protocol. The faculty member submitting a proposal will need to acquire a username and password through the Office of Sponsored Programs. The Chair of the Committee or the Administrative Support Staff can create the login information. Once completed the proposal will automatically be sent to relevant administrators for approval. Once approved IRB will begin evaluation. A committee representative will evaluate the proposal to determine if it qualifies for Full, expedited, or exempt review. The review process will begin once that determination is made. Approval may take up to 3 weeks. Any missing paperwork, misunderstandings, or lack of clarity in the proposal can add to that review time. All investigators and other personnel in the proposal will need to complete the Responsible Conduct in Research training and attach the certificate of completion before the IRB evaluation will begin.

A written decision, with explanation where necessary, will be sent to the investigator and to the signatories on the application.

II.F. CATEGORIES OF HUMAN RESEARCH EXEMPT FROM FULL WVSU-IRB REVIEW:

In accordance with 45 CFR 46.104, the following research activities may be exempt from full review by the WVSU-IRB:

f.1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

f.2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

f.3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

f.4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

1. (i) The identifiable private information or identifiable biospecimens are publicly available;

2. (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the

investigator does not contact the subjects, and the investigator will not re-identify subjects;

3. (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

4. (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

f.5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the

department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

f.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.

f.7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

f.8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

II.G. CATEGORIES OF RESEARCH SUBJECT TO EXPEDITED REVIEW

In accordance with DHHS guidelines (63 FR 60364), research activities with human participants involving no more than minimal risk and involving one or

more of the following categories (carried out through standard methods) may be reviewed by the WVSU-IRB through an expedited review procedure:

g.1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:

a. Research on drugs for which an investigation 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.

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

a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amount drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

b. From other adults and children, considering the age weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

g.3. Prospective collection of biological specimens for research purposes by non-invasive means. Examples:

(a) hair and nail clippings in a non-disfiguring 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 subgingical dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and

(i) the process is accomplished in accordance with accepted prophylactic techniques;

(j) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth;

(k) sputum collected after saline mist nebulization.

g.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.

g.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.)

g.6. Collection of data from voice, video, digital, or image recordings made for research purposes.

g.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 DHHS 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.)

g.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.

g.9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 2 through 8 do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater that minimal risk and no additional risks have been identified.