Policies and Procedures of the Institutional Review Board

Henderson State University
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Henderson State University
Institutional Review Board
Policies and Procedures Manual

Subject: HSU Institutional Review Board

Applicable Federal regulations: *Federal Policy for the Protection of Human Subjects*, also referred to as the Common Rule. The Policy for the Department of Health and Human Services (HHS) has been codified at 45 CFR 46, Protection of Human Subjects, Subparts A-D

Purpose

When conducting research involving people, consideration for the wellbeing of the individual should be first and foremost. Proper conduct of research involving human research participants (human subjects) has been evolving over the last three-quarters of a century. Guidelines for the protection of human subjects have been shaped through notable instances of disregard for the welfare of human subjects and through responses to these abuses, such as those found in the Nuremberg Code (1947) and the Belmont Report (1979). At universities, the approval of human subjects' research falls to an Institutional Review Board (IRB) for the Protection of Human Subjects. At Henderson State University (HSU) this is called the Institutional Review Board.

Policy:

> All personnel are required to submit, via IRBnet, the HSU Protocol Application when conducting research involving human subjects, and must have successfully completed the required education in the protection of human research participants.

Definitions:
For this document the following definitions, taken from the Common Rule shall apply.

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

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.

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.

(Source: 45 CFR Part 46.102)

Guiding Principles:
At HSU the guiding principles for the protection of human research participants will be based on the *Belmont Report*. The *Belmont Report* establishes three basic principles essential when conducting any human research:

1. **Respect for persons**: individual autonomy through informed consent, and protection for those with reduced autonomy
2. **Beneficence**: through the maximization of benefits and the minimization of harm
3. **Justice**: through an equal selection of subjects and a sharing of risks and benefits

Scope:
To ensure equal and adequate protection of human research participants, and to apply this policy and procedures uniformly, all research conducted at HSU regardless of funding source shall fall under this policy and procedures. In general, HSU will apply 45 CFR 46, Subpart A (the Common Rule) as well as Subparts B, C and D to all research, with the following exceptions:

- Class activities/classes designed to teach research methods, where the purpose is research training and the results will not be disseminated outside of class.

For in-class research methods/training and research projects excluded from review, faculty are strongly encouraged to incorporate materials found at the HSU Human Subjects website into their classroom activities. Instructors should consult with the IRB Chair if any research may be considered greater than minimal risk.

HSU may serve as a point of review of human subjects' research for organizations within the State of Arkansas. These unaffiliated organizations will first sign a memorandum of understanding agreeing to abide by the decisions of the HSU Institutional Review Board. A fee may apply.

After it conducts a review, HSU may accept research from other institutions that has been approved by an IRB registered with HHS Office for Human Research Protections (OHRP). An HSU policy related to the acceptance of research or surveys from other institutions is contained in the Appendix.

Required education in the protection of human research participants:
In accordance with National Institutes of Health (NIH) policy, all HSU personnel listed on an application as investigators (key personnel) conducting human subjects research that is supported by NIH funds are required to complete required education in the protection of human research participants. Although the scope of the policy is limited to research supported by the NIH, to adequately protect all human subjects in research, HSU extends the NIH mandate to all research. The training module chosen by HSU is an on-line training program for researchers developed by the NIH found at http://phrp.nihtraining.com/users/login.php.

Roles and Responsibilities

Principal Investigator:
The principal investigator (PI) is the "first line of defense" in all research. On behalf of the institution, the Principal Investigator is responsible for full compliance with the Common Rule and these policies and procedures. These responsibilities include:

- Consulting with the Chair or compliance coordinator to determine if a project falls under these policies and procedures;
- Submitting a human subjects protocol and application for approval;
- Ensuring that all other key personnel are trained and have completed required education in the protection of human research participants;
- Following approved protocols and notifying the Board of any changes to the research or informed consent prior to making changes (the only changes that can be done without prior consent are those necessary to eliminate apparent immediate hazards to the subjects);
- Immediately filing a report of any unanticipated problems or anticipated, serious adverse events; and
- Reporting on the progress of the research and filing all necessary project extensions.

All faculty and staff may serve as principal investigators. The Institutional Review Board may consider the experience and training of the individual as part of its review, and if deemed necessary, may recommend training above and beyond the required education in the protection of human research participants. When students serve as principal investigators, they must have a HSU faculty advisor serving as a study sponsor.

Institutional Official/IRB Chair:
The responsibility for seeing that an organization is in institutional compliance falls to the Institutional Official (IO). The IO shall maintain registration with HHS, help identify individuals for the Board, review, recommend and report any disciplinary actions taken as a result of non-compliance. Upon consultation with HSU Administration, the IO shall see that all members of the Board are properly trained and knowledgeable in administrative and substantive issues that would come before the Board. The IO will also ensure that sufficient resources, space, and staff are available to support the IRB's review and record keeping duties.

IRB Chair:
The Chair shall convene and preside over meetings, arrange for initial review in order to rule protocols as exempt or arrange for using expedited procedures as outlined in the Common Rule. The Chair may call upon other reviewers from within the Board or non-voting, ad hoc reviewers (consultants) as necessary, to assist in initial and in expedited review. The Chair will provide overall administration, assist in initial and continuing review, assist in making determinations for exempt and expedited applications and will coordinate IRB activities with other compliance activities and committees as needed. In addition, the Chair shall be responsible for overseeing the training of the Institutional Review Board, will file annual updates and other reports to HHS, and will monitor Federal and State regulations and suggest revised policies and procedures to remain in compliance with those regulations.

Graduate Assistant:
The administrative assistant to the Board shall assist in scheduling meetings and arranging for meeting space, take minutes and assist in maintaining records.

Institutional Review Board Members:
The work of carrying out the review of non-exempt research falls to the Institutional Review Board.

Board Membership

Board size and composition:
In keeping with the Common Rule, the HSU Institutional Review Board shall consist of no fewer than five individuals, including one individual whose interests are primarily non-scientific and one individual not affiliated with HSU, except for service on the Board. The Board shall choose an individual as Chair, and in the absence of the Chair, designate an individual to preside over a meeting on her/his behalf.

Board members will have varying backgrounds with respect to experience, gender, race culture and to community attitudes. Board composition shall also be structured to reflect the types of research generally conducted at HSU.

Term of service:
Board members shall generally be appointed to three year terms. Board member terms will be staggered in order that continuity can be maintained. Board members may be reappointed to additional terms, as needed and if willing to continue service.

Consultants/ad hoc reviewers:
The Board, through the Chair or others may seek the advice of experts in other disciplines to review protocols on an ad hoc basis as necessary. These individuals shall not have voting privileges.

Levels of review

Non-Human Subjects Research:
Activity that does not meet the Common Rule definition of research, or research deemed not to be using human subjects will be approved as not human subjects research and is excluded from this policy. It is strongly recommended that all activities that *may* involve human subjects research be brought to the Chair for initial review.

Exempt:
Research involving human subjects that falls under the six categories of research enumerated in 45 CFR 46.101(b) will be deemed to be exempt from the Common Rule. Principal investigators may not make a unilateral determination of a project's exempt status and must submit a protocol or research materials for review. A single trained individual—either the Chair or her/his designee will make the determination as to exempt status. This individual may call on others to provide additional guidance, as needed. If a proposal is determined to be exempt from the Common Rule, no ongoing review will be required, except that the investigator must report any proposed changes to the protocol (such as those that may change the activity so it is no longer exempt) and report any unanticipated or anticipated but serious adverse events.

Expedited:
For research involving no more than minimal risk that appears on the Federal Register list of categories (contained in the Appendix), or for minor changes to previously approved research, an expedited review process may be followed, in accordance with 45 CFR 46.110. At HSU, expedited review will consist of review by a minimum of two members of the Institutional Review Board for new protocols, for continuing review, modifications to a protocol or to accept research approved by another institution's IRB. The level and scope of review will be equivalent to the level of review carried out during full Board review. Under expedited review, the reviewers may agree to approve, approve with modifications, request a resubmission of the protocol, or refer the protocol to the full Board. A protocol may not be disapproved using expedited procedures. All actions approved using expedited review shall be made available via IRBnet to the entire Institutional Review Board.

Full Board review:
Research involving human subjects that is not exempt from the policy and does not meet criteria for expedited review will be reviewed at a duly convened Board meeting.

Meetings

The Board shall meet as necessary to conduct business. Minutes of the previous meeting and materials for review will be made available to each member at least three full days prior to the meeting. A quorum, which shall consist of a simple majority (over half of the Board) will be required to be present to review research. The quorum must include one member whose interests are primarily scientific, and one member whose interests are primarily non-scientific. Members with a conflict of interest (abstaining from voting) and non-voting members may not be counted toward a quorum. Members may participate via video or teleconferencing.

Review:
At a minimum, Board review (per the Common Rule) will ensure that:

- Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- 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.
- Selection of subjects is equitable.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, or waived when appropriate, in accordance with and to the extent required by 45 CFR §46.116.
- Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR §46.117.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- Additional considerations for vulnerable populations are evident, as needed.
- The researcher is adequately trained and qualified.

A protocol shall be deemed approved if accepted by a majority of those voting members present. The Board may condition approval subject to modifications to the protocol. These modifications may be provided electronically or in writing; the Chair or her/his designee shall determine if the modifications follow Board requirements. A Board may require the resubmission of a protocol before action is taken, or may disapprove the research, with detailed comments/reasons for disapproval provided to the investigator. The investigator may appeal the decision for disapproval to the Board. The IO may review Board decisions, impose additional modifications or disapprove research activity approved by the Institutional Review Board. The IO or any other official may not approve research that the Board has disapproved.

In accordance with the Common Rule, no member of the Institutional Review Board may be counted towards a quorum or be involved (except to provide information requested by the Board) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.

Confidentiality:
During the process of initial or continuing review of an activity, material provided to the Institutional Review Board shall be considered privileged information and the Board shall assure the confidentiality of the data contained therein.

Minutes and Records:
A current roster of all Board members will be kept on file. Members meeting specific requirements as required by the Common Rule will be identified in the roster.

Files of all projects and all correspondence between the PI and the Board shall be kept. Files shall be destroyed three years after the close/completion of the project.

Minutes shall be kept and made available to the IO and HHS or other agency officials, upon request. Minutes shall generally conform to Roberts Rules of Order and include the following:

- date, time and place of meeting
- those in attendance
- approval of previous meeting's minutes
- movement from open to closed sessions
- motions/including outcomes, and abstentions
- other major points of order
- adjournment

In addition, the level of discussion included in the minutes shall include sufficient detail for others to ascertain the nature of the discussion and the conclusions reached.

Reporting on its Actions

The Board, through the Chair, shall promptly report actions taken at meetings to principal investigators. The reporting shall be done electronically or in writing, and shall consist of either an approval document, request for minor changes to a protocol followed by an approval document, request for major changes and/or resubmission of a protocol in order to secure approval at a subsequent meeting, or notification that a protocol has been disapproved, with reasons for disapproval. This information will be communicated to the investigator in a timely manner, generally within five working days following a meeting.

The institution will be kept informed of Board actions through periodic reports to the IO. Issues necessitating immediate notification to the IO, such as adverse events or noncompliance, will be provided to the IO generally within two working days. Written Board minutes will be provided to the IO at the same time they are provided to the Board. The Board Web Site will be used to provide additional information to the institution regarding human subjects' protection issues. Other informational items will be provided to the HSU community using HSU official means of communications, electronic mail, or MyHenderson.

Disciplinary Action

When a researcher is found to be in noncompliance with Common Rule, other Federal, State or HSU regulations, including this policy and procedures, the Board may recommend sanctions. Such recommendations may include but are not limited to:

- Verbal or written warnings
- Suspension of research activities until all appropriate administrative activities have been corrected or completed
- Re-inspection to substantiate the facility/laboratory is subsequently in compliance
- The inability to use the results of the research in publications

The Board will refer serious issues of noncompliance to the Department Chair/Head, Dean, Institutional Official, OHRP and the appropriate Federal oversight agency, as appropriate. The

University President, upon consultation with other officials as necessary, shall have final authority as to Board recommended sanctions or additional disciplinary action.

Ongoing Project Review and Protocol Changes

Non-exempt projects/protocols will be approved for up to one year. During initial or ongoing review, when the Board discusses the level of risk associated with a protocol, it may also determine that review more frequently than once per year is appropriate. PIs shall submit an extension using the forms approved by the Board that provides information on the status of the project (including information such as percent complete, not yet started, ongoing, temporarily stopped) and certifying that no changes have been made. Ongoing review will use full Board review or expedited procedures, in accordance with the Common Rule and any appropriate OHRP guidance documents.

The Board may conduct or direct others to conduct random audits of any approved project or laboratory facilities for the purposes of post-approval project monitoring or continuing review.

Any changes in protocols shall be reported to the Board electronically or in writing prior to initiation, using forms approved by the Board. The Chair or designee will make a determination as to accept the change using expedited procedures or through Board review, in accordance with the Common Rule. The only exception to this requirement shall be when an investigator initiates a change to eliminate apparent immediate hazards to the subject. Unexpected or serious adverse events shall be reported to the Board following its procedures.

Reporting to Federal Officials

In accordance with the Common Rule and Federal agency policy and guidance, HSU, through the Institutional Official, will promptly report to OHRP and/or the appropriate Federal agency officials any of the following when the activity involves the use of Federal funds:

1. unanticipated problems involving risks to subjects or others;
2. serious or continuing noncompliance with the Federal regulations or the requirements or determinations of the IRB(s); and
3. suspension or termination of IRB approval.

Appendices:

Links:

HSU Institutional Review Board
http://www.hsu.edu/irb/

HHS Office for Human Research Protections
http://www.hhs.gov/ohrp/

Title 45 CFR Part 46- Protection of Human Subjects:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

The Belmont Report
http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

Nuremberg Code
http://www.hhs.gov/ohrp/references/nurcode.htm

The World Medical Association, Inc./Declaration of Helsinki
http://www.wma.net/e/policy/b3.htm

List of other Federal agencies that have adopted the *Federal Policy for the Protection of Human Subjects* (the Common Rule) and their locations in the Code of Federal Regulations

7 CFR Part 1c
Department of Agriculture

10 CFR Part 745
Department of Energy

14 CFR Part 1230
National Aeronautics and Space Administration

15 CFR Part 27
Department of Commerce

16 CFR Part 1028
Consumer Product Safety Commission

22 CFR Part 225
International Development Cooperation Agency, Agency for International Development

24 CFR Part 60
Department of Housing and Urban Development

28 CFR Part 46
Department of Justice

32 CFR Part 219
Department of Defense

34 CFR Part 97
Department of Education

38 CFR Part 16
Department of Veterans Affairs

40 CFR Part 26
Environmental Protection Agency

45 CFR Part 690
National Science Foundation

49 CFR Part 11
Department of Transportation

Steps for the submission of the HSU *Protocol/Application Form*
(See the "Steps for Submission" document for more detail)

1. Create a 'User Profile' in IRBnet (www.irbnet.org)

2. Complete the NIH on-line training for researchers. It can be found at http://phrp.nihtraining.com/users/login.php. The training takes approximately 1-2 hours, but you can save your progress through the training and continue at a later time. At the end of the training you will obtain a certificate. You may save this to your hard drive. A copy will also be available via your NIH account. Upload a copy to your 'User Profile" in IRBnet. All researchers having contact with subjects or having contact with data which has subject identification, need to complete this certificate. Certificates are valid for a period of three years, at which time you may logon to your NIH account to renew. The IRB also accepts CITI training certification.

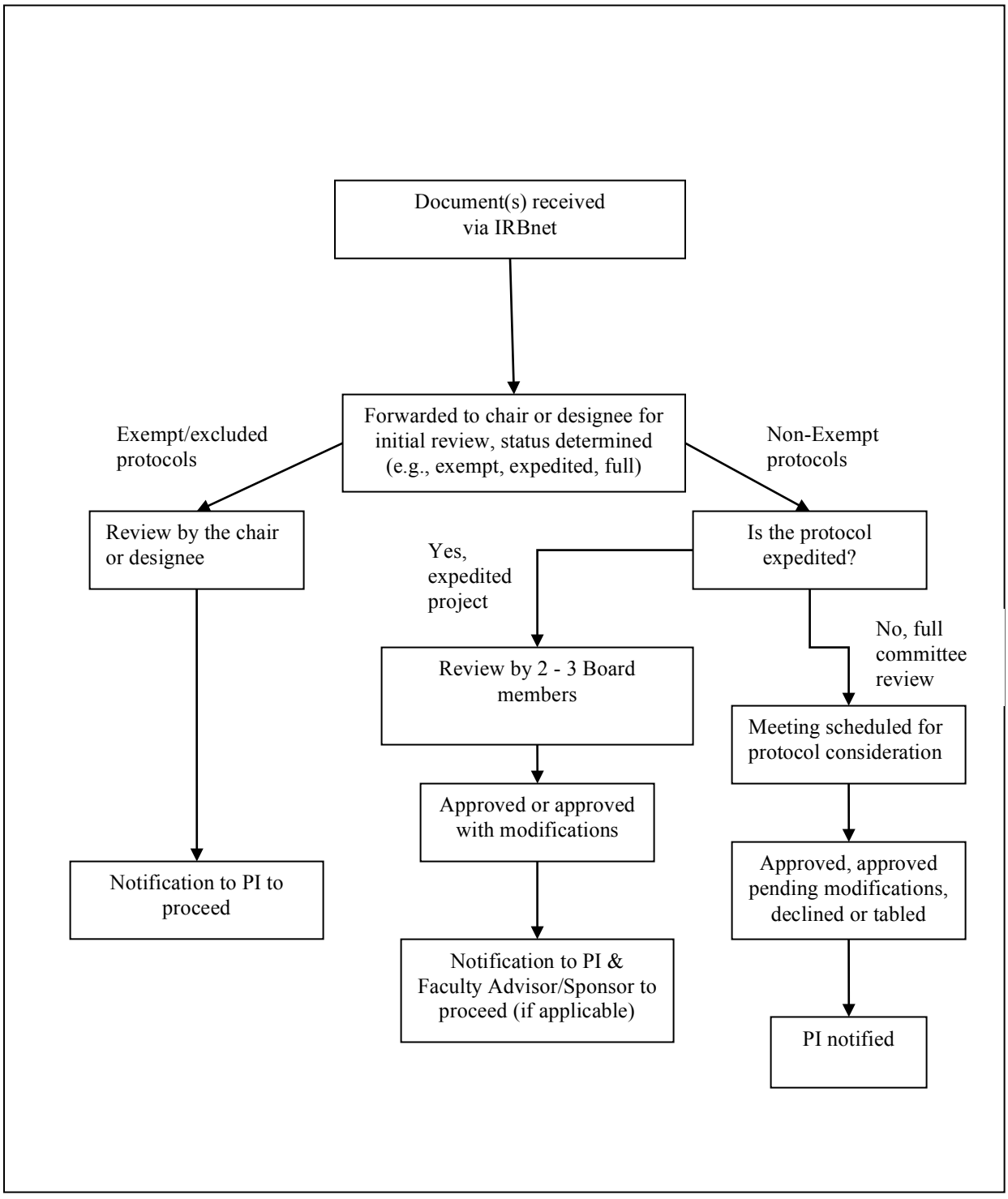
3. Complete the Protocol/Application Form and upload it as part of your project in IRBnet. The IRB Chair will forward the proposal to other Board members as needed. If your proposal requires full Board review, you MUST submit at least one week prior to the monthly IRB meeting date.

4. Electronic signatures of ALL researchers (PI and Co-investigators) are required in IRBnet on the proposal submission. In the case of student research (graduate or undergraduate) the faculty advisor must also sign.

5. You will be notified via IRBnet if any modifications to the proposal are needed. If you are submitting an exempt research proposal, you will receive an email regarding the disposition of your proposal. If you are submitting an expedited research proposal, your proposal will be forwarded to two to three Board members for review. This usually requires one to two weeks. If you are submitting a proposal for full Board review, please submit the proposal no less than one week prior to the scheduled meeting times. The full Board meets once per month as needed.

6. You may proceed with your project only when you have received the final approval letter from the Board.

Human Subjects Approval Process Flowchart for Initial Review:



Exempt Protocols/45 CFR 46.101 (b)*

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

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

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

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or
(ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

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

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

*The exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners.
**The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research

involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure[1]

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 children[2], 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.

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[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 FR 60364-60367, November 9, 1998.