

## **Haverford College Institutional Review Board (IRB) for Human Subject Research**

### **Procedures for Review and Decision on the Proposals for Research Involving Human Subjects**

Haverford College has set up an Institutional Review Board (IRB)<sup>1</sup> for Human Subject Research based on the requirements of the Office of Human Subjects Research Protection (OHRP) to govern research involving human subjects. The jurisdiction of the IRB covers both research performed by employees and students of the College and research by outside individuals or groups involving Haverford students. In order to obtain approval for the IRB the College also obtained a Federal Wide Assurance (FWA)<sup>2</sup> through the National Institutes of Health. Various federal funding agencies mandate approval of funded research by the institution's IRB. In the interest of protecting the safety of Haverford students and personnel, it is expected that all research<sup>3</sup> involving human subjects, whether externally funded or not, be reviewed by the IRB.

### **Membership in the Haverford College IRB**

The membership of the IRB shall be selected in accordance with federal regulations (in particular, with 45cfr46.107 which sets out requirements and guidelines to ensure that the IRB is sufficiently qualified and diverse (in terms of race, gender and cultural backgrounds) to discern community attitudes; among other requirements, this section requires that the IRB not consist completely of scientists or of non-scientists or of members of one-profession). The membership will normally include:

- A Chairperson, who is a faculty member; this member may NOT be the individual with signatory authority for federal grants.
- A faculty member from each academic department from which, in a typical year, at least two research proposals originate (currently psychology and economics). This may be either the chairperson of those departments, or a person designated by the chairperson, in consultation with the Provost.
- The Human Protections Administrator (HPA) (normally the staff member of Institutional Advancement responsible for external grants).

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<sup>1</sup> The official designation of Haverford College's IRB is: IRB00001617 IRB #1 of IORG0001208

<sup>2</sup> Haverford College's assurance identifier is FWA00000916

<sup>3</sup> The term 'Research' is intended to cover any type of systematic investigation that is intended to test hypotheses or gather descriptive data and which is designed to develop or contribute to generalizable knowledge. Often, research investigations are intended for public dissemination, but this intention is not required for an activity to be considered research for the purposes of IRB review. This definition is meant to exclude surveys done by the College solely for institutional purposes. It also excludes class exercises where results are only made available on campus (i.e. the internal web server) or to members of the class (i.e. via Blackboard).

- Either the Director of Athletics or the director's designee as a representative of the Athletics Department.
- An individual with research and/or medical training (M.D. preferred) .
- At least one member who is not otherwise affiliated with Haverford College. Ideally this member should have experience conducting or reviewing human subject research.
- An Executive Assistant (normally an Assistant to the Provost) who maintains IRB records and prepares minutes of IRB meetings. The Executive Assistant may participate in discussions of proposals and is a voting member of the IRB. The Executive Assistant is responsible for maintaining records of IRB proposals, approval letters, continuation requests, IRB correspondence with investigators, end-of-project reports, and IRB meeting minutes.

Each time there is a change in membership of the IRB, the IRB registration must be updated (by the Executive Secretary) at <http://ohrp.cit.nih.gov/efile/>. The Executive Secretary and the HPA should also ensure that the FWA on file is current (this normally needs be renewed every three years).

The IRB evaluates new proposals, monitors approved projects, provides continuing review, receives reports upon conclusion of research projects, and communicates those reports to the Office of the Provost. The committee schedules meetings regularly (usually at least monthly) to provide full review to new proposals, and to review committee functioning and procedures; in the absence of new proposals or committee business, the committee may elect to cancel scheduled meetings. The IRB Chairperson, HPA, and Provost (the signatory official on federal grant proposals although not a member of the IRB) are required to undergo training on the workings of IRBs at URL <http://ohrp-ed.od.nih.gov/CBTs/Assurance>. The Executive Assistant of the Haverford IRB should also undergo this training.

In addition to this required training on the workings of IRBs, all members of the IRB are expected to educate themselves, on an on-going basis, regarding the ethical issues and regulations regarding human subject research. Each member of the IRB should undertake training equivalent to that required for investigators submitting proposals for non-exempt human subject research (for instance, the training course at <http://phrp.nihtraining.com>; see below). Ethical issues and regulations will be discussed at the first convened IRB meeting of each academic year, or following the appointment of any new IRB member.

## **Research that is Exempt from Federal Regulation**

Certain categories of human subject research are exempted from federal regulation (see 45cfr46.101). Researchers wishing to engage in such research should submit to the IRB an exemption request form briefly describing the proposed research and how it satisfies the criteria for exemption in the federal regulations. These requests may be reviewed by the Chairperson of the IRB, by the HPA, or by another IRB member designated by the Chairperson. Should the reviewer agree that the proposed research is exempt, a letter confirming the exempt status will be sent to the researcher. The letter will ask the researcher to renew the request for exempt status on an annual basis.

## **Procedures for submitting proposals for human subject research**

A faculty or staff member wishing to initiate research involving human subjects (and NOT of a type exempt from federal regulation) will be expected to submit a detailed proposal describing the research. The proposal form is downloadable from <http://www.haverford.edu/provost/IRB.htm>. Investigators are required to undertake training in ethical considerations for the conduct of human subject research in order to fully acquaint themselves with the expectations surrounding such research. One such training web-site is the National Institutes of Health Protecting Human Research Participants course available at <http://phrp.nihtraining.com> (on March 1, 2008, this replaced the course formerly offered at <http://cme.nci.nih.gov/>) – or proposers may substitute equivalent training they have received from other sources. Proposals should use a form prepared by the IRB and posted at its web site, and must incorporate the following elements:

- (1) A description of the project including goals, schedule, procedures, and identification of the research subjects
- (2) Copies of any survey instruments to be used
- (3) An explicit evaluation of the risks and benefits of the investigation
- (4) A copy of each type of Informed Consent Form to be used in the study. If an investigator is requesting waiver of informed consent or of documentation of informed consent, he or she must provide a written explanation for the basis for this request.
- (5) Copy of advertisements that will be used to solicit participants.
- (6) When appropriate, ancillary materials establishing the safety (or level of risk) of particular techniques to be employed

Proposals should be submitted to the Executive Assistant, preferably electronically. Proposals will be identified and filed by the submitter's name and date of submission (on page 1 of the proposal form). If a proposer wishes to make changes in a submitted proposal (for instance, to address concerns raised during IRB deliberations), he or she should submit a new version with a later date of submission, and include a cover letter withdrawing the previous version (identified by date). Correspondence and deliberations related to a proposal that is withdrawn or denied, but is replaced by a new, similar proposal, will be filed with the correspondence related to the newer proposal.

During the academic year, the IRB requires 2 or 3 weeks to reach a decision regarding a proposal if it can be approved by expedited review, or 3-5 weeks if it requires full review. During the summer months, decisions may require up to 4-6 weeks. Investigators are asked, whenever possible, to submit their proposals for review at least 6 weeks before the anticipated start of the project.

Outside individuals proposing to perform research involving Haverford College students or taking place on its campus should follow the same procedures as above. Haverford students proposing research involving human subjects must have faculty sponsorship for their projects. The student(s) and sponsoring faculty member must jointly prepare a proposal following the above procedures, and those directly involved in the research must take the training course described above (or document equivalent training).

### **Decision as to possible expedited review of proposals**

Proposal review is governed by federal regulations and occurs as follows. The proposal is first transmitted to the Chairperson of the IRB who makes an evaluation of whether the proposal can be considered under the expedited-review protocol or whether full review is needed. The criteria for that assessment are given in the Appendix. If expedited review is viewed as appropriate, the proposal is transmitted to one or two members of the IRB (usually including the HPA and, if possible, an IRB member from the department from which the proposal was submitted). If the selected IRB members agree that expedited review is warranted, the project is approved and the investigator is notified in writing that the project has been approved. If the Chairperson or one or both of the selected reviewers do not concur that the proposal meets the criteria for expedited approval, then full review by the IRB is undertaken.

### **Circulation of proposals for full (non-expedited) IRB review**

If the research is judged to require full review, the proposal is circulated in entirety to all IRB members via email or regular mail, at least one week in advance of a scheduled meeting. Each member is requested to reply with a written evaluation at least one day prior to the meeting. The basic standard of evaluation is that the benefits of carrying out the research must outweigh any apparent risks to the subjects. The evaluation should include a recommendation for “minimal risk” approval (see below), basic approval, or non-approval of the proposal, and commentary justifying that judgment. In cases of a negative recommendation, the IRB member is expected when possible to offer suggestions for altering research procedures to gain approval. These evaluations should be submitted via email to the Chairperson of the IRB.

The “minimal risk” approval category indicates that the IRB certifies that the proposed research involves no more than minimal risk. This is a more stringent restriction on risk than required for basic approval, which allows for more than minimal risk if they are outweighed by the benefits of the research (and other conditions outlined in federal regulations are satisfied). The practical distinction between these two types of approval is that “minimal risk” approved proposals may (at the discretion of the Chairperson) undergo expedited continuing review, whereas basic approval requires that any continuing review of the proposal be undertaken by the full IRB.

### **Convened meetings for decisions on non-expedited proposals.**

The Chairperson will prepare a summary of the reviews of the written evaluations he or she received from members of the IRB regarding the proposal. This summary will be distributed at a convened meeting at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. Convened meetings may be conducted by telephone conference call or with involvement of one or two members by speaker phone as long as each participating IRB member can actively and equally participate in the discussion of the proposal. The Executive Assistant should record minutes showing which members are present and summarizing the discussion. The discussion should follow the questions of the “Questionnaire for Reviewers” found in the Appendix, and consensus or divergent views about these questions should be documented in the minutes. By federal regulations, the minutes must

contain a vote total of supporting vs. dissenting members for all decisions supporting approval of a proposal, and to be approved the proposal must receive the votes of a majority of those present at the meeting. For proposals that are approved by the “minimal risk” approval category, a separate vote should be taken and recorded to document that decision. If approval is subject to stipulations (specific required changes to procedures), these must be agreed upon and entered into the minutes, and then read back to the IRB members prior to the vote for approval. The Executive Assistant will maintain minutes for at least five years for all convened meetings; this ensures that minutes are maintained for at least three years after the expiration date of any approved proposal.

The Chairperson of the IRB will send a letter to the proposal investigators giving approval to the project (if necessary with changes stipulated by the IRB) or denying approval for the proposal as submitted. If the proposal is approved under the “minimal risk” category (see below), the letter must explicitly indicate this. Especially in the case of a negative decision, the letter should summarize (preserving confidentiality) the written evaluations received and the discussion of the proposal during the convened IRB meeting.

The IRB must decide to deny approval to any proposal that would be inconsistent with federal regulations governing human subject research. But it may also deny approval based on other ethical concerns or because the proposed research would be detrimental to Haverford College or its community. The IRB may send proposals to, and seek comments from other College officials when needed. Proposals involving athletes are sent for comment to the Athletic Director and proposals from outside individuals to perform research on Haverford students are sent to the Dean of the College. When a proposal comes from a department that is not represented in the IRB deliberations (including cases when the proposer is a member of the IRB and so is not participating in the IRB deliberations), the IRB Chairperson may invite a member of that department to participate in preliminary review and the discussions at the convened meeting. Other on-campus expertise and authority are drawn upon on an as-needed basis. By federal regulations, those who are not members of the IRB may attend meetings but may not vote to approve or deny proposals.

### **Approval, Continuing Review, and Final Reports**

Proposals are approved for a period of up to one year from the date of the meeting at which the proposal was approved. Stipulated in approval letters are procedures for investigators to follow in the event of unanticipated problems involving risks to subjects or others. Investigators are required to report these unforeseen risks and/or negative consequences, immediately, to the IRB Chairperson, who will then report to the Provost. If any member of the IRB, including the HPA, receives a report of non-compliance with IRB procedures, or a significant unforeseen risk or negative consequence involving a human subject, this should be relayed to the IRB Chairperson, who will then immediately discuss the concern with the investigator and also report to the Provost.

Following a report of unanticipated problems involving risks to human subjects or others, or of serious or continuing noncompliance with IRB regulations, the IRB must decide on a corrective action, which may include suspension or termination of the IRB approval for a particular proposal. Temporary corrective actions (including suspension of approval)

may be taken by the IRB Chairperson in consultation with the Provost, but final corrective actions should be determined by the IRB at the next convened meeting, which should take place within two weeks of the report of problem or noncompliance. Promptly after the decision on corrective action is finalized, and also after any suspension or termination of IRB approval for any reason, the IRB Chairperson must make an incident report to the Office of Human Research Protections (OHRP) of the Department of Health and Human Services. Details on the contents of incident reports may be found at [http://www.hhs.gov/ohrp/policy/incidreport\\_ohrp.html](http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html).

The approval letter will also specify that the investigators must make a request to the IRB before making any changes to the approved protocol. Such changes may not be implemented during the approval period without re-review and approval by the IRB, except as necessary to eliminate apparent immediate hazard to the subjects. Change requests deemed minor by the IRB chairperson may be handled by expedited review, even if the initial proposal required full review.

The proposers of each approved IRB proposal are required to submit either a final report or request for continuation (which includes a progress report) on or before the expiration date of approval. At or before the conclusion of the approval period, the IRB Executive Assistant will send a letter to the faculty/staff investigator or sponsor, reminding them to submit either a request for continuation or a final report. It is appropriate for final reports from previous proposals by an investigator to be considered as part of IRB deliberations on new proposals from the investigator. Investigators who wish to continue a project for more than one year must submit a request for continuation of approval. This must include a progress report (including reports of any adverse effects on participants, whether expected or not, and any changes in procedures made relative to the original proposals), and may also include minor proposed modifications to the original protocols, consent forms or survey instruments; these should be attached to the continuation request.

Requests for continuation of approval will receive the same type of review (full or expedited) as the original proposal, except that proposals approved in the “minimal risk” category and for which no additional risks have been identified may be given expedited continuing reviews (see paragraph (9) in the Appendix). Final reports should be available for perusal at the next face-to-face meeting of the IRB.

The IRB, at a convened meeting of a new proposal involving more than minimal risk, may decide to grant approval for a shorter than a one-year period. Conditions triggering a shortened approval period are those in which a new procedure (never before approved by the IRB) is proposed, that is deemed by the IRB to carry acceptable risk, but for which the experience of initial human subjects may better inform the judgment of acceptable risk. The IRB reserves the right to require re-review of a proposal after a first stage of a multistage protocol, or after a data collection has begun involving a certain number of human subjects, in order to allow the investigator to report any problems or unanticipated consequences that arise from such procedures. The IRB may decide to appoint one or more of its members and/or a disinterested third party to provide research oversight to a particular experimental protocol, in order to minimize risks to human subjects and/or to verify that no material changes are made to the approved procedures.

Upon the conclusion of research projects, investigators are required to submit a final report to the IRB. The report summarizes the conclusions obtained and evaluates the measures taken to protect the safety of research subjects, suggesting improvements when appropriate for future projects of the same nature. This final report must include an indication of the secure location of the original signed Informed Consent Forms from all subjects participating in the research. The faculty investigator is responsible for keeping Informed Consent forms available for inspection for 3 years after the conclusion of the project. The Provost's Office will keep these forms in cases of research by outside investigators, or when the faculty investigator or sponsor leaves the college. Each Spring, the IRB chair submits to the Office of the Provost a summary statement on the findings and actions of the committee during the prior academic year, including copies or summaries of final reports and progress reports that are submitted by investigators.

Records of the discussions and actions of the Committee and final reports received from investigators will be maintained in the Provost's Office for at least three years following completion of projects. They are available for inspection by any member of the IRB (except for records of discussions from which the IRB member was, or would have been recused; the IRB members are responsible for avoiding inspection of such records, and should ask the IRB Chairperson if in doubt).

### **Changes to this document**

This IRB procedures document may be amended by consensus of the IRB committee. Consensus for changes should normally be obtained at a regular (in-person) meeting of the IRB, although proposed changes will normally be distributed in advance and prior email discussion is encouraged to facilitate consensus-building. The President and Provost of the College should be consulted about any changes that could conceivably adversely affect the college's interests, and even if there are no such concerns, should be notified of any changes that are approved. The current IRB procedures document should also be posted at IRB web page at the Provost's Office web site (currently <http://www.haverford.edu/provost/IRB>).

### **Appendix A. Questionnaire for Reviewers**

The following questionnaire may be used by the chair to obtain opinions from other members of the IRB for expedited proposal review, and also (with the exception of question 10) should form a minimal basis for discussion of proposals during full committee review. Questions 1 – 7 are based on the criteria specified in federal regulations, section 45 CFR 46.111.

- 1) Is the proposed research design scientifically sound & does it minimize risks to subjects (i.e. not unnecessarily expose subjects to risk)?
- 2a) Is the level of risk to human subjects minimal? (Regulatory definition of minimal risk: 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 (45 CFR 46.102(h)(i).))

- 2b) If the level of risk is more than minimal, how much of an increase in risk is it over minimal risk (refer to the regulatory definition above)?
- 2c) Whether the risk is minimal or more than minimal, is the risk reasonable in relation to any possible anticipated benefits to subjects and to the importance of knowledge that may reasonably be expected to result?
- 3a) Is subject selection equitable (cf. question 3 on the last page of the proposal form)?
- 3b) If human subjects for this study are likely to include members of vulnerable groups, such as children, prisoners, pregnant women, mentally disabled persons, or economically- or educationally disadvantaged persons, are there appropriate additional safeguards included in the study to protect the rights and welfare of these subjects (from, for instance, coercion or undue influence)?
- 4) Is informed consent obtained from research subjects or their legally authorized representative(s)? If not, does the proposal meet the requirements for waiver of informed consent in 45 CFR 46.116(c) or (d)?
- 5a) See checklist on our proposal form for the eight required elements of informed consent. If not all eight elements are present, is it reasonable that we waive any informed consent requirements as requested on the page before the checklist?
- 5b) Will the informed consent be obtained with a signed written consent form, with a copy given to the person signing the form? If not, does the proposal satisfy the requirements for waiver of documentation in 45 CFR 46.117(c)?
- 6a) Should this project be reviewed more often than annually (i.e. should the approval we give at this time be for less than one year), and/or should we require that any continuation proposal contain verification from sources other than the investigators that no material changes have occurred since previous IRB review?
- 6b) Would use of a data & safety monitoring board or other research oversight process enhance subject safety?
- 7) Are there adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data?
- 8) Is this domestic/international collaborative research? If so, are federal-wide assurances in place at the other institutions, and is there IRB approval from the other institutions?
- 9) Do you have any ethical or procedural concerns related to the treatment of human subjects by the investigators other than those raised in your answers to questions 1-8?
- 10) For expedited review only: In which of the categories 1-9 (from those at [www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm)) does this proposal fall? (NOTE: for Haverford's IRB, the most common category is category 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.)

**Appendix B. Categories of Research That May Be Reviewed by the  
Institutional Review Board (IRB) through an  
Expedited Review Procedure<sup>1</sup>**

(From <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm>)

**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<sup>2</sup>, 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.