COMPARISON OF THE PROPOSED LIST WITH THE CURRENT LIST—Continued

| Proposed Expedited Review List | 1981 (Current) Expedited Review List |
|---|---|
| (c) Weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography. | Currently number 3; limited to subjects 18 years of age or older; limited echography to ''diagnostic echography''; does not include ''sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography.'' |
| (d) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing involving health subjects. | Currently number 7; limited to ''Moderate exercise by healthy volunteers.'' |
| 7. Collection of data from voice, video, or image recordings made for research purposes where identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. | Currently number 6; stated as: ''Voice recordings made for research purposes such as investigations of speech defects.'' |
| 8. Research on individual or group characteristics or behavior (including but not limited to research involving perception, cognition, surveys, interviews, and focus groups) as follows: | Not included. |
| (a) Involving adults, where (i) the research does not involve stress to subjects, and (ii) identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. | |
| (b) Involving children, where (i) the research involves neither stress to subjects nor sensitive information about themselves, or their family; (ii) no alteration or waiver of regulatory requirements for parental permission has been proposed; and (iii) identification of the subjects and/or their responses would not reasonably place them or their family members at risk of criminal or civil liability or be damaging to the financial standing, employability, or reputation of themselves or their family members. | |
| 9. Research previously approved by the convened IRB as follows: | Not included. |
| (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 the research remains active only for the purposes of data analysis; or | |
| (c) Where the IRB has determined that the research involves no greater than minimal risk and no additional risks have been identified; or | |
| (d) Where no subjects have been enrolled and no additional risks have been identified. | |

Dated: November 4, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97–29651 Filed 11–5–97; 3:51 pm]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Protection of Human Subjects: Suggested Revisions to the Institutional Review Board (IRB) Expedited Review List

**AGENCY:** Office for Protection from Research Risks, National Institutes of Health, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Office for Protection from Research Risks (OPRR), in consultation with the Food and Drug Administration (FDA), is requesting written comments relating to the proposed republication of the list that identifies certain research involving human subjects which may be reviewed by the Institutional Review Board (IRB) through the expedited review procedure authorized in § 46.110 of 45 CFR Part 46. This list was originally published in 1981 and subsequently referenced in the Federal Policy (Common Rule) for the Protection of Human Subjects (56 FR 28003). Pursuant to § 46.110(a), the Secretary, HHS, has the authority to amend and republish the list. In the 16 years since the list was created, significant advances have been made in medicine and biological technology such that it is appropriate to consider revising this list

to include additional procedures or categories of research. OPRR seeks information and suggestions from the research community and public on possible revisions to the expedited review list.

**DATES:** Submit written comments on or before March 10, 1998.

**ADDRESSES:** Comments should be sent to Michele Russell-Einhorn, Director of Regulatory Affairs, Office for Protection from Research Risks, National Institutes of Health, 6100 Executive Blvd., Suite 3B01, Rockville, Md. 20892–7507. Since OPRR and FDA are simultaneously publishing identical lists, comments need not be sent to both agencies.

**FOR FURTHER INFORMATION CONTACT:** Michele Russell-Einhorn at the address above, or telephone (301) 435–5649 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:** The Federal Policy (Common Rule) for the Protection of Human Subjects was published in the **Federal Register** on June 18, 1991 (56 FR 28003) and is employed by 17 Executive Branch agencies. This Federal Policy requires adherence to certain requirements by Federal agencies or institutions receiving Federal support for research activities involving human subjects. The Federal Policy has three cornerstones: review of any research involving human subjects by an Institutional Review Board (IRB); with limited exceptions, informed consent of all research subjects; and formal, written assurance of institutional compliance with the Policy. The Department of Health and Human Services' (HHS) codification of the Federal Policy can be found at 45 CFR Part 46.

Section ____.110 of the Federal Policy provides for expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research. This same section gives the Secretary, HHS, the authority to amend and republish the Expedited Review List as needed after consultation with the departments and agencies that are subject to the Federal Policy. The expedited review list that is referenced in the Federal Policy was originally published by the Secretary, HHS in 1981 as a Notice in the **Federal Register** of a list of categories of research that could be reviewed by the IRB through an expedited review procedure. The Food and Drug Administration (FDA) also references an expedited review list (21 CFR Part 56) for matters under FDA's jurisdiction. The HHS and FDA lists differ slightly, in that item 9 on the 1981 HHS expedited review list regarding certain types of behavioral research is not included in the list referenced in 21 CFR Part 56.110.

The current (1981) list allows an IRB to utilize the expedited review procedure for research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods):

(1) Collection of hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction. (2) Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor. (3) Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves). (4) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant. (5) Collection of both supra-and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques. (6) Voice recordings made for research purposes such as investigations of speech defects. (7) Moderate exercise by healthy volunteers. (8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens. (9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects. (10) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

OPRR, in consultation with FDA, is proposing to revise the expedited review list to include additional procedures or categories of research that may be reviewed under the expedited review procedure. Since 1981, OPRR has received some suggestions to this effect and has incorporated several into the proposed revision of the list that is published herein. OPRR seeks additional comments from the public on procedures or categories of research involving human subjects that may be amenable to review by the IRB chairperson or other designated IRB member instead of review by a convened meeting of the IRB.

The following is a proposed revision of the current expedited review list found at 46 FR 8392 (Jan. 26, 1981) and 46 FR 8980 (Jan. 27, 1981). FDA is simultaneously publishing an identical list. Judgment is reserved on whether OPRR and FDA will publish identical lists after comments are received and reviewed. OPRR welcomes and encourages comments from the research community and public.

### Research Activities Which May Be Reviewed Through Expedited Review Procedures [1]

Research activities (carried out through standard methods) which involve (1) no more than minimal risk, and (2) appear in one or more of the following categories may be reviewed by the Institutional Review Board through the expedited review procedure authorized in 45 CFR 46.110 and 21 CFR 56.110. The activities that appear on this list should not be deemed to be of minimal risk simply because they are included on this list. Appearance on this list merely means that the activity is eligible for review through the expedited process when the specific circumstances of the proposed research involve no more than minimal risk to the human subjects. The categories in this list apply regardless of the age of subjects, except as noted.

(1) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

(2) Collection of blood samples by finger stick or venipuncture as follows:

(a) From healthy, nonpregnant adults [2] who weigh at least 110 pounds, in

[1] The 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 Section ____.110.

[2] Throughout this document, when OPRR refers to ''adult,'' OPRR defers to state law for determining the age of majority.

amounts not exceeding 550 ml in an 8 week period and no more than 2 times per week.

(b) From healthy, pregnant adults who weigh at least 110 pounds, in amounts not exceeding 100 ml in an 8 week period and no more than 2 times per week.

(c) From healthy children, in amounts not exceeding 3 ml/kg in an 8 week period and no more than 2 times per week.

(d) From medically vulnerable adults who weigh at least 110 pounds, in amounts not exceeding 50 ml in an 8 week period and no more than 2 times per week.

(3) Prospective collection for research purposes of the following biological specimens:

(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) Stool cultures obtained by rectal swab.

(j) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings.

(k) Sputum collected after saline mist nebulization.

(4) Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens) where these materials, in their entirety, have been collected prior to the research, for a purpose other than the proposed research.

(5) Research involving solely (a) prospectively collected identifiable residual or discarded specimens, or (b) prospectively collected identifiable data, documents, or records, where (a) or (b) has been generated for nonresearch purposes.

(6) Collection of data through use of the following procedures:

(a) Noninvasive procedures routinely employed in clinical practice and not involving exposure to electromagnetic radiation outside the visible range (i.e., not involving x-rays, microwaves, etc.).

(b) 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.

(c) Weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography.

(d) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing involving healthy subjects.

(7) Collection of data from voice, video, or image recordings made for research purposes where identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(8) Research on individual or group characteristics or behavior (including but not limited to research involving perception, cognition, surveys, interviews, and focus groups) as follows:

(a) Involving adults, where (i) the research does not involve stress to subjects, and (ii) identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(b) Involving children, where (i) the research involves neither stress to subjects nor sensitive information about themselves, or their family; (ii) no alteration or waiver of regulatory requirements for parental permission has been proposed; and (iii) identification of the subjects and/or their responses would not reasonably place them or their family members at risk of criminal or civil liability or be damaging to the financial standing, employability, or reputation of themselves or their family members.

(9) 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 the research remains active only for the purposes of data analysis; or

(c) Where the IRB has determined that the research involves no greater than minimal risk and no additional risks have been identified; or

(d) Where no subjects have been enrolled and no additional risks have been identified.

The following tabulation of changes is included to enable readers to more easily compare the categories of research included in both lists.

| Proposed expedited review list | 1981 (Current) expedited review list |
|---|---|
| 1. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required. | Unchanged; currently number 9. |
| 2. Collection of blood samples by finger stick or venipuncture as follows: | Currently number 4, limited to venipuncture; ''finger stick'' not included |
| (a) From healthy, nonpregnant adults, in amounts not exceeding 550 ml in an 8 week period and no more than 2 times per week. | Amounts currently limited to 450 ml |
| (b) From healthy, pregnant adults, in amounts not exceeding 100 ml in an 8 week period and no more than 2 times per week. | Not included. |
| (c) From healthy children, in amounts not exceeding 3 ml/kg in an 8 week period and no more than 2 times per week. | Not included. |
| (d) From medically vulnerable adults, in amounts not exceeding 50 ml in an 8 week period and no more than 2 times per week. | Not included. |
| 3. Prospective collection for research purposes of the following biological specimens: | ''Prospective'' and ''for research purposes'' currently not included. |
| (a) Hair and nail clippings in a nondisfiguring manner ..... | Currently part of number 1; unchanged. |

| Proposed expedited review list | 1981 (Current) expedited review list |
|---|---|
| (b) Deciduous teeth at time of exfoliation, or if routine patient care indicates a need for extraction. | Currently part of number 1; ''deciduous teeth'' included without qualifiers. |
| (c) Permanent teeth if routine patient care indicates a need for extraction. | Currently part of number 1; ''routine'' not included. |
| (d) Excreta and external secretions (including sweat) | Currently part of number 2; unchanged. |
| (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. | Currently part of number 2; ''uncannulated saliva'' included without qualifiers. |
| (f) Placenta removed at delivery | Currently part of number 2; unchanged. |
| (g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor. | Currently part of number 2; unchanged. |
| (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. | Currently number 5; ''procedure'' was not qualified with the word ''collection.'' |
| (i) Stool cultures obtained by rectal swab | Not included. |
| (j) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings. | Not included. |
| (k) Sputum collected after saline mist nebulization | Not included. |
| 4. Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens) where these materials, in their entirety, have been collected prior to the research, for a purpose other than the proposed research. | Currently number 8; stated as: ''The study of existing data, documents, records, pathological specimens, or diagnostic specimens.'' |
| 5. Research involving solely (a) prospectively collected identifiable residual or discarded specimens, or (b) prospectively collected identifiable data, documents, or records, where (a) or (b) has been generated for nonresearch purposes. | Not included. |
| 6. Collection of data through use of the following procedures: | Currently number 3; ''recording'' instead of ''collection.'' |
| (a) Noninvasive procedures routinely employed in clinical practice and not involving exposure to electromagnetic radiation outside the visible range (i.e., not involving x-rays, microwaves, etc.). | Currently number 3; limited to subjects 18 years of age or older. |
| (b) 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. | Currently number 3; limited to subjects 18 years of age or older. |
| (c) Weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography. | Currently number 3; limited to subjects 18 years of age or older; limited echography to ''diagnostic echography''; does not include ''sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography.'' |
| (d) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing involving healthy subjects. | Currently number 7; limited to ''Moderate exercise by healthy volunteers.'' |
| 7. Collection of data from voice, video, or image recordings made for research purposes where identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. | Currently number 6; stated as: ''Voice recordings made for research purposes such as investigations of speech defects.'' |
| 8. Research on individual or group characteristics or behavior (including but not limited to research involving perception, cognition, surveys, interviews, and focus groups) as follows: | Currently number 9, stated as follows: Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.'' |
| (a) Involving adults, where (i) the research does not involve stress to subjects, and (ii) identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. | |
| (b) Involving children, where (i) the research involves neither stress to subjects nor sensitive information about themselves, or their family; (ii) no alteration or waiver of regulatory requirements for parental permission has been proposed; and (iii) identification of the subjects and/or their responses would not reasonably place them or their family members at risk of criminal or civil liability or be damaging to the financial standing, employability, or reputation of themselves or their family members. | |
| 9. Research previously approved by the convened IRB as follows: | Not Included. |
| (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 the research remains active only for the purposes of data analysis; or | |

| Proposed expedited review list | 1981 (Current) expedited review list |
|---|---|
| (c) Where the IRB has determined that the research involves no greater than minimal risk and no additional risks have been identified; or<br>(d) Where no subjects have been enrolled and no additional risks have been identified | |

Dated: October 31, 1997.

**Gary B. Ellis,**

*Director, Office for Protection from Research Risks.*

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