



# Focus On: Expedited Review

Soundia A. Duche, MA, MS  
Program Analyst/PRIDE

**May 15, 2018**

# Objectives

- Categorizing Projects (Recap)
- Expedited Review
  - Eligibility
  - Review Procedures
  - Key Categories
  - Case Studies
  - Common Compliance Findings
  - Expedited Review and the Revised Common Rule

# Categorizing Projects

- Review **all details** of the project
- Address questions in the **following order**:
  - Is it **research**?
  - Is it **human subjects research**?
  - Is the study **exempt** from IRB review?
  - Is my facility **engaged** in human subjects research?
  - Can the IRB use the **expedited** review process?

# Implications of Determinations

- Not Research: Neither the IRB nor R&D Committee is required to review the activity
- Research but not Human Subjects Research: The IRB does not review or approve the activity. Either the R&D Committee or one of its other subcommittees oversees the project.
- Human Subjects Research: Both IRB and R&D Committee must oversee the activity
- Exempt: The IRB Chair or an experienced voting member of the IRB designated by the Chair makes this determination. The R&D Committee or one of its subcommittees assumes oversight if the study is exempt from IRB oversight
- Expedited: The IRB Chair or one or more experienced voting members of the IRB designated by the Chair makes this determination. Both the IRB and R&D Committee oversee the activity

# Poll: Does your IRB Conduct Expedited Reviews?

Does your IRB conduct expedited review and if so how?

- Yes, our IRB Chair conducts all expedited reviews
- Yes, our IRB Chair and designated IRB members perform expedited reviews
- Yes, our IRB Administrator conducts our expedited reviews
- No, we review all actions at a convened IRB meeting
- What's expedited review?

# Expedited Review

# Activities Eligible for Expedited Review

- Must be minimal risk
- Must fit one or more of the expedited review categories **or**
- Minor changes in previously approved research during the period for which the approval is authorized
- Cannot be used if participation in the research activity could place subjects at risk of criminal or civil liability or be damaging to subjects' financial standing, employability, insurability, reputation or be stigmatizing unless appropriate protections are implemented so that such risks are no greater than minimal
- Cannot be used for classified research involving human subjects\*

\*Classified research cannot be conducted at the VA (VHA Handbook 1200.05 Paragraph 3e).

# What is 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

Secretary's Advisory Committee on Human Research Protection (SACHRP)  
cases on understanding minimal risk

[www.hhs.gov/ohrp/sachrp/sachrpminrisk20080131.html](http://www.hhs.gov/ohrp/sachrp/sachrpminrisk20080131.html)



# Expedited Categories

See VHA Handbook 1200.05 Appendix B for full text

1. Some clinical studies of drugs and medical devices
2. Collection of blood (limited by volume and frequency)
3. Noninvasive collection of biological specimens
4. Noninvasive collection of data
5. Materials that have been collected for any purpose, or materials that will be collected solely for nonresearch purposes
6. Collection of voice, video, digital, or image recordings
7. Group characteristics, surveys, interviews, and QA
- 8-9. Continuing review under specific conditions

# What are “Minor Changes”

In the judgment of the IRB Reviewer(s), makes no substantial alteration in:

- The level of risk to subjects
- Research design or methodology
- Subject population
- Qualifications of the research team
- Facilities available to support safe conduct of the research
- Other...

# Expedited Review Procedures

- Conducted by the IRB Chair or an experienced IRB voting member designated by the Chair
- Expedited reviewer cannot disapprove research activity
- Documentation of the specific expedited review category(ies) justifying the approval must be included in both the letter to the investigator as well as the IRB meeting minutes.
- Expedited review approval list must be distributed at the next convened IRB meeting
- All standard IRB approval criteria (38 CFR 16.111) to include requirements for informed consent (or its waiver, alteration, or exception) apply.



# Expedited Review Categories 1-7

\*Note Categories 8 and 9 were covered in our cyberseminar presented on April 24 2018

# Expedited Review Category 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.
- (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 being used in accordance with its cleared/approved labeling.

# Expedited Review Category 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, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, 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.

# Expedited Review Category 3

Prospective collection of biological specimens for research purposes by noninvasive means. Examples include, but are not limited to:

- (a) hair and nail clippings in a non-disfiguring manner;
- (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- (c) permanent teeth if routine patient care indicates a need for extraction;
- (d) excreta and external secretions (including sweat);
- (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- (f) placenta removed at delivery;
- (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- (h) supra- and 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.

# Expedited Review Category 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 include, but are not limited to:

- (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.



# Expedited Review Category 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).

# Expedited Review Category 6

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

# Expedited Review 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.

# Case Studies

# Case Study 1

- An Investigator wants to study gay and lesbian Veterans who were victims of bullying, harassment and discrimination while on active duty in the military
- The research involves administration of a survey that will query the Veterans about sexuality and illegal drug use
- The researchers obtain a Certificate of Confidentiality to protect the subjects

# Poll: Case Study 1

Is this study eligible for expedited review?

1. No
2. Yes – Expedited Review Category 5
3. Yes – Expedited Review Category 7
4. Insufficient information to make a determination

## Case Study 2

A research study is evaluating cytokine levels in subjects diagnosed with Rheumatoid Arthritis.

- 50 subjects will be enrolled per year over the next five years.
- 20ml of blood will be collected by venipuncture 4 times per week for 6 weeks.
- Subjects will also be asked to complete a survey assessing their pain
- The research study is not conducted under an IND or IDE
- The PI states that the study involves no greater than minimal risk and the reviewer agrees with that assessment

## Poll: Case Study 2

- Is the study eligible for expedited review? If yes, which category?
  - a) Expedited Review Category 2
  - b) Expedited Review Category 3
  - c) Expedited Review Category 7
  - d) Expedited Review Category 2 and 7
  - e) Straight to the convened board please!



# Case Study 3

- A research study is evaluating memory function and cardiac fitness in healthy adults taking part in a 3-month exercise regimen
- Subjects will undergo the following:
  - Monthly surveys regarding memory, cardiac, and lung fitness
  - Baseline and three-month blood pressure and body mass index measurements
  - Baseline and three-month MRIs (Magnetic Resonance Imaging) with contrast to assess cerebral blood flow
  - A single chest x-ray at baseline
- The PI states that the study involves no greater than minimal risk

## Poll: Case Study 3

- Is the study eligible for expedited review? If yes, which category?
  - a) Expedited Review Category 4
  - b) Expedited Review Category 5
  - c) Expedited Review Category 7
  - d) Expedited Review Categories 4 and 7
  - e) Straight to the convened board please!

# Case Study 4

(For those looking for something more advanced)

- In 2015, a study was deemed exempt by the IRB under Exempt Category 4 – Used existing clinical data recorded in such a manner that subjects could not be identified by the Investigator.
- The Investigator realizes today (May 15,2018) that he does not have sufficient data in the cohort for his analysis and wants to expand the date range to include new cases of clinical data collected between 2015 to April of 2018.
- He submits an amendment to the IRB expanding the date range.

# Poll: Case Study 4

The amendment constitutes a:

1. Minor change in previously reviewed research
2. More than a minor change in previously reviewed research
3. There's more to this story...

# Poll: Case Study 4 (Part 2)

What should be the outcome of the review?

1. Study still qualifies for Exempt Category 4
2. Study now qualifies for Expedited review, Category 5

## Poll: Case Study 4 (Part 3)

If this same Investigator decided to submit a new protocol instead of an amendment for analyses of existing clinical data recorded in such a manner that subjects could not be identified by the Investigator for the period of 2015 to April of 2018, the investigator should submit this for:

- Evaluation as an Exempt activity, Category 4
- Evaluation as an Expedited Review activity, Category 5
- No evaluation. It cannot be done.

## Poll: Case Study 4 (Part 3)

The Investigator should submit the protocol for review by:

- a) Evaluation as an Exempt activity, Category 4
- b) Evaluation as an Expedited Review activity, Category 5
- c) No evaluation. It cannot be done.

# Case Study 5

## (This one's really complex)

The Old Glory VA has begun offering Hot Yoga on site to all veterans who receive care at the facility. A researcher is interested in assessing stress in veterans suffering from PTSD who have enrolled in the Hot Yoga program or have expressed interest in it. The study will involve:

- Completion of written surveys and participation in a focus group on Hot Yoga and stress
- Collection of identifiable saliva and hair samples that will be processed through a bioassay device to determine cortisol levels pre- and post-Hot Yoga sessions.
- Bioassay analyses will be done using the device in the Hot Yoga room (90 to 96 degrees Fahrenheit) and at normal room temperatures (70 to 77 degrees Fahrenheit) to evaluate whether there are difference in the bioassay device function using duplicate samples.
- The bioassay device has approved labeling for operation in temperatures between 40 degrees and 98 degrees Fahrenheit.
- The study is exempt from the IDE regulations
- The PI feels the study is minimal risk and the IRB reviewer agrees with that determination



## Poll: Case Study 5

Is the study eligible for expedited review? If yes, which category?

- a) Expedited Review Category 1
- b) Expedited Review Category 3
- c) Expedited Review Category 7
- d) All of the above (a, b, and c)
- e) Straight to the convened board please!



# Common Compliance Findings

# Common Compliance Findings: Expedited Review

- Applying expedited review to minimal risk research not appearing in the list of categories eligible for expedited review
- Use of expedited review procedures to review changes that are substantive
- Failure to advise IRB members of expedited approvals
- Failure to consistently document expedited review decisions and relevant categories in the IRB minutes and approval letters
  - University of Illinois was cited by OHRP for using expedited review category 9 to verify minor changes approved by the convened IRB (see December 1, 2014 determination letter)
- Expedited review conducted by someone other than a voting IRB member



# Expedited Review and The Revised Common Rule

# Expedited Review and the Revised Common Rule: What Has Not Changed

- The following continue to be eligible for expedited review:
  - Research appearing on the Secretary's expedited review list
  - Minor changes in previously approved research
- IRB Chair and/or designated members of the IRB conduct expedited review
- The expedited review route cannot be used to disapprove research
- All IRB members must be advised of research proposals approved via expedited review

# Expedited Review and the Revised Common Rule: What Has Changed

- List of activities on the Secretary's expedited review list are now presumed to be minimal risk
  - The IRB must now document the rationale for determining an activity on the list is greater than minimal risk and subject to convened board review
  - Secretary of HHS will review the expedited review list every 8 years and amend it as appropriate
- Continuing review is no longer required for studies reviewed by expedited review
  - The IRB must document the rationale for conduct continuing review of research that otherwise would not require continuing review

# Expedited Review and the Revised Common Rule: What Has Changed (cont.)

- Research for which limited IRB review is a condition of exemption is eligible for expedited review (i.e. certain research eligible for exempt review)
  - Applies to 4 specific categories of Exempt Research
  - IRB does not have to ensure that all of the 111 approval criteria are met
  - IRB review is limited to (1) determining that adequate provisions to protect the privacy of subjects and maintain the confidentiality of their data exist and/or (2) Broad consent is appropriately obtained and documented (or waiver of documentation is appropriate)

# Limited IRB Review by Expedited Review

Research reviewed by the IRB using limited IRB review

- Applies to 4 specific categories of Exempt Research
- IRB does not have to ensure that all of the 111 approval criteria are met
- IRB review is limited to (1) determining that adequate provisions to protect the privacy of subjects and maintain the confidentiality of their data exist and/or (2) Broad consent is appropriately obtained and documented (or waiver of documentation is appropriate)



# Exempt Research Requiring Limited IRB Review: 38 CFR 104d(a)(2)(iii) and 104d(a)(3)(i)(c)

- Research involving educational tests, surveys, interviews, or observation of public behavior if the information obtained is recorded such that the identity of human subjects can be readily ascertained and the IRB conducts a limited IRB review to ensure that adequate provisions exist to protect the privacy of subjects and maintain the confidentiality of their data (38 CFR 104d(a)(2)(iii))
- Research involving benign behavioral interventions when identifiable information is collected from an adult through verbal, written, or audiovisual recordings and the subject prospectively agrees to both the intervention and data collection and the IRB conducts a limited IRB review to ensure that adequate provisions exist to protect the privacy of subjects and maintain the confidentiality of their data (38 CFR 104d(a)(3)(i)(C))

# Exempt Research Requiring Limited IRB Review: 38 CFR 104(d)(7)

- Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research if the IRB conducts a limited IRB review and determines that broad consent is appropriately obtained and documented (or waiver of documentation is appropriate) and adequate provisions exist to protect the privacy of subjects and the confidentiality of their data (38 CFR 104(d)(7)).

# Exempt Research Requiring Limited IRB Review: 38 CFR 104(d)(8)

- Research involving the use of identifiable private information or identifiable biospecimens for secondary research if (i) broad consent was appropriately obtained; (ii) documented (or documentation is waived if appropriate); (iii) the IRB conducts a limited IRB review and determines that adequate provisions exist to protect the privacy of subjects and maintain the confidentiality of their data and the research to be conducted is within the scope of the broad consent; and (iv) there are no plans to return individual research results to subjects (38 CFR 104(d)(8)).

# References

- Federal Policy for the Protection of Human Subjects ('Common Rule'): 38 CFR Part 16 (Dept of Veterans Affairs)
- Department of Veterans Affairs, Veterans Health Administration handbooks:
  - VHA Handbook 1200.05, Requirements for the Protection of Human Subjects Research ([https://www.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=3052](https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3052))
- Office of Human Research Protections (OHRP), Department of Health and Human Services (HHS):
  - Categories of Research That May Be Reviewed by the IRB through an Expedited Procedure (<http://www.hhs.gov/ohrp/policy/expedited98.html>)
  - Determination Letter to University of Illinois, December 1, 2014 (<https://www.hhs.gov/ohrp/compliance-and-reporting/determination-letters/2014/december-01-2014-university-of-illinois-at-chicago/index.html>)

# Contacts

Soundia Duche, MA, MS

Program Analyst, PRIDE

[soundia.duche@va.gov](mailto:soundia.duche@va.gov)

- Email questions to [vhacoORDregulatory@va.gov](mailto:vhacoORDregulatory@va.gov)
- Website: <http://www.research.va.gov/PRIDE/>

# ORD/ORO Collaborative Training on the Revised Common Rule: Tentative Schedule

Date	Topic	Department Lead
24-Apr-18	Continuing Review	ORD
15-May-18	Expedited Review	ORD
16-May-18	Overview of the Revised Common Rule	ORO
19-Jun-18	Working with the VA CIRB	ORD
17-Jul-18	Waivers: Common Rule, Privacy Rule, and FDA Regulations	ORD
18-Jul-18	Informed Consent: ICFs; Broad Consent; and Posting of ICFs	ORO
21-Aug-18	Myth Busters: Common Misperceptions re. VA Research	ORD
18-Sep-18	IRB Approval Criteria	ORD
19-Sep-18	Exempt Review and Limited IRB Review	ORO
16-Oct-18	Transition Provisions and Overview of the revised VHA Handbook 1200.05	ORD
20-Nov-18	In-depth Focus on the revised VHA Handbook 1200.05	ORD
21-Nov-18	External IRBs and FWAs	ORO
18-Dec-18	In-depth Focus on the revised VHA Handbook 1200.05	ORD

Questions?

### § 16.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in § 16.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in § 16.102(e) must be reviewed and approved, in compliance with §§ 16.101, 16.102, and §§ 16.107 through 16.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(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.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures.<sup>1</sup>

<sup>1</sup> Institutions with HHS-approved assurances on file will abide by provisions of title 45 CFR part 46 subparts A-D. Some of the other Departments and Agencies have incorporated all provisions of title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. 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, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

# Office for Human Research Protections (OHRP) - Categories of Research

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

### 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. (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. (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.

---

<sup>1</sup> 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](#).

<sup>2</sup> 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.