



Focus On: Exempt and Expedited Review

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Welcome

The mission of VA's Program for Research Integrity Development and Education (PRIDE) is to protect participants in VA human research. In support of that mission, PRIDE:

- contributes to policy and guidance in human subject protection
- provides training and education
- manages VA Human Subject Protection Program (HRPP) accreditation
- implements the VA Central IRB
- promotes awareness of VA Research Principles and Professionalism

Objectives

- Categorizing Projects (Recap)
- Exempt Determinations & Expedited Review
 - Eligibility
 - Determination/Review Procedures
 - Key Categories
 - Case Studies
 - Common Compliance Findings

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?

Definitions

- Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- Human subject means a living individual about whom an investigator conducting research obtains
 - (1) Data through intervention or interaction with the individual, or
 - (2) Identifiable private information.

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



Exempt Determinations

Activities Eligible for Exemption

- Research activities in which the only involvement of human subjects will be in one or more of the six categories outlined in the Common Rule (38 CFR 16.101(b)) may be exempt from IRB review
- Refer to handout for a list of exempt categories

38 CFR 16.101(b) and VHA Handbook 1200.05 par 16

Exempt Determination Procedures

- The IRB Chair or an experienced IRB voting member designated by the Chair conducts the exempt review
- The IRB records must include documentation of the specific exempt category(ies) justifying the exempt status
- Once the IRB has deemed a study to be exempt, the R&D Committee or one of its subcommittees will oversee the study



Key Exempt Categories

2, 4, 5 and 6

Exempt Category 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.**

38 CFR 16.101(b)(2)

Exempt Category 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.

38 CFR 16.101(b)(4)

Exempt Category 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; and (iv) possible changes in methods or levels of payments for benefits or services under those programs.

38 CFR 16.101(b)(5)

Exempt Category 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.

38 CFR 16.101(b)(6)

Case Study 1

- In June 2011, Dr. See submits a protocol to the IRB to conduct human research on patients treated for hepatitis at the hospital between 2005-2010
- He will use a list of subject medical record numbers to cross reference patient's microscopic images, lab reports, and medical records and analyze the data as part of his research study
- Data will be published in aggregate form once his analysis is complete

Case Study 1 - Poll

Does this study qualify for exemption?

1. No
2. Yes – Category 2
3. Yes – Category 4
4. Yes – Category 5
5. Yes – Category 6

Case Study 1 – Poll Correct Answer

Does this study qualify for exemption?

- ✓ 1. No
- 2. Yes – Category 2
- 3. Yes – Category 4
- 4. Yes – Category 5
- 5. Yes – Category 6

Case Study 2

- A VA Researcher is investigating the efficacy of radiation treatment on various forms of cancer
- The investigator receives coded clinical data where all subject identifiers have been removed prior to his receiving the data
- The data provider's only role in the study is to provide the investigator with the coded data
- The investigator enters into an agreement with the data provider specifying that the investigator will never have access to the key to the code

Case Study 2 - Poll

Is this research study subject to the Common Rule (38 CFR Part 16):

1. Yes
2. No – it does not involve human subjects research
3. No – it is eligible for Exempt Category 4
4. Insufficient information provided

Case Study 2 – Poll Correct Answer

Is this research study subject to the Common Rule (38 CFR Part 16):

1. Yes
- ✓ 2. No – it does not involve human subjects research
3. No – it is eligible for Exempt Category 4
4. Insufficient information provided

Case Study 3

A VA Researcher wants to study diet and obesity in Veterans trying to lose weight

- The study involves an in person or telephone interview and administration of a behavioral questionnaire every month for the next six months
- The questionnaire asks subjects' questions about their diet and weight gain/loss
- Patient name and contact information will be retained

Case Study 3 - Poll

Does this study qualify for exemption?

1. No
2. Yes – Category 2
3. Yes – Category 4
4. Yes – Category 5
5. Yes – Category 6

Case Study 3 – Poll Correct Answer

Does this study qualify for exemption?

1. No
- ✓ 2. Yes – Category 2
3. Yes – Category 4
4. Yes – Category 5
5. Yes – Category 6

Common Compliance Findings: Exempt Determinations

- Inappropriate application of exempt categories of research
- Inappropriate application of Exempt Category 4
- R&D Committee did not conduct initial and/or continuing review of protocols deemed exempt by the IRB



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 4g).

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

Expedited Categories

See VHA Handbook 1200.05 par 19 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.
- All standard IRB approval criteria (38 CFR 16.111) to include requirements for informed consent (or its waiver, alteration, or exception) apply.
- R&D Committee approval is required



Key Expedited Review Categories*

1, 5 and 7

*Note Categories 8 and 9 will be covered in a webinar focusing on continuing review.

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 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 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 Study 4

- In 2012, 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 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 2012-2015.
- He submits an amendment to the IRB expanding the date range.

Case Study 4 - Poll

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...

Case Study 4 – Poll Correct Answer

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...

Case Study 4 – Poll 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

Case Study 4 – Poll Part 2 Correct Answer

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

Case Study 5

- 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

Case Study 5 - Poll

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 5 – Poll Correct Answer

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

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
- Use of expedited review to approve amendments involving procedures that do not fall within the list of categories that may be reviewed by expedited review
- 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
- Expedited review conducted by someone other than a voting IRB member

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Questions?