

# Revision to the Common Rule: Factsheet for DVAHCS Investigators

The revision to the Common Rule (45 CFR 56) becomes effective **January 21, 2019**. The Common Rule is the federal policy for the protection of human subjects and the revision will affect both you and the functions of the research oversight committees. All studies approved on or after January 21, 2019 must follow the Revised Common Rule (also referred to as the **2018 Requirements**).

## SUMMARY OF CHANGES

- Changes to the informed consent form (ICF) meant to facilitate participant understanding
- Requirement that key information be presented first in the consent discussion
- Requiring ICFs for certain federally funded clinical trials be posted on the public website
- Requiring single Institutional Review Boards (sIRB) review for multisite cooperative research
- Eliminating continuing review requirements for minimal risk research eligible for expedited review and for studies that have completed study interventions
- Elimination of IRB requirement to review grant applications
- Revising and establishing new exempt categories of research
- Adopting the definition of “Clinical Trial” that includes behavioral health-related outcomes
- Revising criteria for waiver of informed consent and waiver of documented consent
- Included a provision for screening, recruiting, and determining eligibility without informed consent or waiver of informed consent

**\*\*ALL FORMS ARE BEING UPDATED AND ARE NOT CURRENTLY AVAILABLE FOR USE. YOU WILL BE INFORMED WHEN NEW DOCUMENTS ARE AVAILABLE AND REQUIRED FOR USE\*\***

**\*\*THIS FACT SHEET IS SUBJECT TO CHANGE AS MORE INFORMATION IS PROVIDED BY THE OFFICE OF RESEARCH AND DEVELOPMENT (ORD)\*\***

## 16 Common Rule changes that may affect how you prepare and conduct research studies as an investigator:

### 1. Studies approved on or after January 21, 2019: Informed Consent Forms (ICFs) must include an introductory overview paragraph.

**Policy:** The ICF must begin with a concise and focused presentation of the key information most likely to assist a prospective participant in understanding why he/she should or should not participate.

**What you will do:** Include an introductory paragraph on ICFs following the instructions on the ICF template.

***For studies also under the jurisdiction of FDA***<sup>1</sup>: FDA has issued guidance stating the provisions of the 2018 Requirements (Revised Common Rule) are not inconsistent with FDA's current policies and guidance. Studies under HHS and FDA do not need 2 separate consent forms and may follow the 2018 Requirements of informed consent.

## **2. Studies approved on or after January 21, 2019: Other Informed Consent Form (ICF) changes are mandated.**

**Policy:** Changes to required elements and additional elements of informed consent (as applicable).

**What you will do:** Use the updated template and follow the ICF instructions, which will include new required elements such as information on future use of collected biospecimens, whether whole genome sequencing is a procedure, and others.

***For studies also under the jurisdiction of FDA:*** See item 1 above. Studies under HHS and FDA do not need 2 separate consent forms and may follow the 2018 Requirements of informed consent.

## **3. Studies approved on or after January 21, 2019: Exempt Human Subjects Research.**

**Policy:** There are now eight categories of exempt human subjects research. Four exempt human subjects research categories have been revised; one exempt category has been replaced; two new exempt categories have been added; one exempt category is unchanged. Certain categories of exempt human subjects research now allow for access, collection, and use of identifiable private information or identifiable biospecimens (see Item 9 below). All exempt human subjects research proposals must be submitted to IRB initially for review; this is current practice.

***Note: Data and biospecimens no longer have to be in existence prior to the start of the study. For example, a research study that proposes to analyze samples or information that will be collected for clinical purposes in the future may qualify for exemption.***

**What will you do:** Review the new and revised categories of exempt human subjects research. If you believe your protocol meets criteria for one or more categories of exempt human subjects research, submit the *Application for Initial Review of Exempt Human Subjects Research* with the application packet.

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<sup>1</sup> FDA Regulated Research: 1) Drugs, biologics, and devices used to diagnosis, cure, mitigate, treat, or prevent disease; and 2) Clinical investigations that evaluate safety and effectiveness of FDA-regulated products (IND/IDE regulations).

#### 4. Studies approved on or after January 21, 2019: Exempt Category 4.

**Policy:** This category covers secondary research uses of identifiable private information or identifiable biospecimens. Data do not need to be existing (“on the shelf”) at the time of the research study. The data can be collected prospectively for non-research purposes and still be used for exempt research under Category 4.

**What will you do:** Complete the *Application for Initial Review of Exempt Human Subjects Research*. Include a *Request for Waiver or Alteration of HIPAA Authorization* if individually identifiable health information is being accessed, collected or used because this exempt category is subject to Privacy Act requirements. Do not include a *Waiver of Informed Consent* because exempt research is not subject to the Revised Common Rule informed consent requirements.

#### 5. Broad Consent and Exempt Categories 7 and 8. We will not implement the provision for broad consent to store, record, and conduct secondary research on identifiable private information and identifiable bio-specimens.

**What you will do:** This precludes the use of two new exemption categories #7 and #8. However, you may still conduct secondary research on identifiable information and identifiable bio-specimens under another exempt category, if applicable, or through expedited review that includes the appropriate waiver of informed consent and HIPAA requests (**this is current practice and the exclusion of broad consent does not exclude any category of research**).

#### 6. Studies approved on or after January 21, 2019: Continuing review.

**Policy:** Continuing review will not be required for research that is reviewed by **expedited** review. Additionally, research that has progressed to data analysis only or clinical follow-up that includes data obtained only from clinical care does not undergo continuing review.

**What you will do:**

**1) Minimal Risk Expedited Research:** Minimal risk research eligible for expedited review will not require a continuing review by IRB or R&D committee. All amendments, notifications, event reports, and study closures will continue be submitted to IRB.

**2) Greater than minimal risk studies that have progressed to data analysis or clinical care:** For protocols approved on or after January 21, 2019, submit the *Application for Continuing Review of Research* with the change in study status noted. IRB correspondence will dictate how your protocol is reviewed or is not reviewed in future cycles. All amendments, notifications, event reports, and study closures will continue to be submitted to IRB.

**3) FDA Regulated Research:** Studies under the jurisdiction of FDA and HHS must continue with the current FDA requirements, which includes conducting a continuing review no less than once a year. Continue with current practice.

**\*\*For protocols approved prior to January 21, 2019 await further guidance from the Research Office or correspondence from IRB.\*\***

**7. Studies approved on or after January 21, 2019: Continuing Review for greater than minimal risk research with participants engaged in interventions:**

**Policy:** Continuing review by the convened IRB is required.

**What you will do:** You will receive notification of continuing review submission deadlines from the Research Office. Submit all required continuing review documents to the IRB. This has not changed from current practice.

**8. Studies approved on or after January 20, 2020: Cooperative research and the use of a single IRB.**

**Policy:** The compliance date for this provision is January 20, 2020 but it can be adopted prior. This will mandate the use of a single IRB of record for U.S. institutions for multi-site research (with some rare exceptions). However, current VHA Handbooks do not address this practice.

**What you will do:** The DVAHCS cannot participate in multi-site or cooperative trials that utilize a single IRB until or unless VHA Handbooks and Directives are updated. Contact the IRB if you are part of a study that proposes to use a single IRB.

**9. Studies approved on or after January 21, 2019: Limited IRB review.**

**Policy:** Limited IRB review is a revision to the requirements of an exemption request.

**Note:** *It will now allow research that otherwise meets exempt criteria to include the use of identifiable private information or identifiable bio-specimens.*

**What you will do:** The *Application for Initial Review of Exempt Human Subjects Research* form has been modified to make you aware that use of identifiable information or identifiable bio-specimens does not exclude an exemption request from being granted, provided all other exempt criteria are met. As always, you will receive correspondence from the IRB regarding all requests to review research. IRB reviews all exempt human subjects research requests and determines if the project meets exempt human subjects research status, this is not changed from current practice.

## 10. Studies approved on or after January 21, 2019: Posting of clinical trial consent form on a Federal Website.

**Policy:** For clinical trials funded or supported by a **Federal** agency, one IRB approved consent form used to enroll subjects must be posted by the awardee or Federal department on a publicly available Federal website (e.g., ClinicalTrials.gov). The form must be posted after recruitment closes, and no later than 60 days after the last study visit.

**Revised Definition of Clinical Trial:** Research studies in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of the intervention on biomedical or behavioral health-related outcomes.

**Consent forms must be posted on either:** <https://clinicaltrials.gov> or a docket folder on <http://Regulations.gov> (Docket ID: HHS-OPHS-2018-0021).

### What you will do:

- (1) **For a clinical trial funded by VA ORD**, ORD is responsible for posting a consent form.
- (2) **For a clinical trial funded or supported by a Federal agency other than VA**, the awardee is responsible for posting a consent form.
- (3) **For a clinical trial funded or supported by a non-Federal agency (e.g., university, industry, private nonprofit organizations) or not funded**, the VA investigator conducting the clinical trial is responsible for posting a consent.

## 11. Studies approved on or after January 21, 2019: Waiver of Documented Consent Criterion added.

**Policy:** **RED** font denotes new criterion for waiving the requirement to obtain a signed informed consent form.

- (1) The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from breach of confidentiality; or
- (2) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context; or
- (3) **The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.**

**What you will do:** Complete and submit the revised *Request for Waiver of Documented Consent*, following all instructions on the form.

## **12. Studies approved on or after January 21, 2019: Waiver of Informed Consent Criterion added.**

**Policy;** **RED** font denoted new criterion for waiving informed consent.

1. The research involves no more than minimal risk to the subjects.
2. The research could not practicably be carried out without the requested waiver or alteration.
3. **If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.**
4. The waiver or alteration will not adversely affect the rights and welfare of subjects.
5. Whenever appropriate, the subjects or LARs will be provided with additional pertinent information after participation.

**What you will do:** Complete and submit the revised *Request for Waiver or Alteration of Informed Consent Process*, following all instructions on the form.

## **13. Studies approved on or after January 21, 2019: Screening, Recruiting, and Determining Eligibility**

**Policy:** An IRB may approve a proposal for the investigator to obtain information or biospecimens to screen, recruit, or determine eligibility of prospective subjects for a research study without informed consent and without granting a waiver of informed consent, if one or both of the following criterion are met:

(1) the information is obtained through oral or written communication with the subject or the subject's legally authorized representative, **or**

(2) identifiable private information or identifiable biospecimens are obtained by accessing records or stored identifiable biospecimens.

**What you will do:** You **WILL NOT** submit a *Request for Waiver of Informed Consent* for screening/recruiting. You are **STILL REQUIRED** to submit a *Waiver of HIPAA Authorization* for screening/recruiting purposes. The protocol must indicate that screening/recruiting/determining eligibility will occur under one or both criterion listed above.

#### **14. Transitioning studies approved prior to January 21, 2019 to the Revised Common Rule.**

**Policy:** Studies approved prior to January 21, 2019 have the option to remain under the prior Common Rule or to transition to the Revised Common Rule.

**What you will do:** If your study is eligible, you may request a transition to the Revised Common Rule as PI. The IRB may also request that you transition a study to the Revised Common Rule. This may occur at the time of Continuing Review, the submission of an amendment or with other submissions to the IRB. Transitioning to the Revised Common Rule may require use of a new Informed Consent Form and/or waiver of informed consent documents.

**Note:** *Re-consent will not be required unless other significant are made to the Informed Consent Form and IRB determines re-consent is necessary.*

**\*\*FDA regulated studies cannot be transitioned to the 2018 Requirements/Revised Common Rule. See item 15 below.\*\***

**15. FDA Regulated Research Approved prior to January 21, 2019<sup>2</sup>:** FDA has not revised its regulations (21 CFR 50 and 21 CFR 56) and all FDA regulated research must comply with current FDA requirements, including for clinical investigations that are subject to both HHS (Revised Common Rule) and FDA jurisdiction. This includes FDA regulated research eligible for expedited review.

**What will you do:** Continue with current practice. FDA regulated research cannot be transitioned to the Revised Common Rule and all current requirements, including continuing review of research occurring no less than once a year, must continue.

#### **16. FDA Regulated Research Approved On or After January 21, 2019:**

**What will you do:** Follow all current FDA requirements. Studies under the jurisdiction of FDA must continue with all current FDA requirements (21 CFR 50 and 21 CFR 56), which includes conducting a continuing review no less than once a year. Studies that fall under the jurisdiction of FDA and HHS regulations may follow the 2018 Requirements of informed consent (see items 1 and 2 above).

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<sup>2</sup> FDA Regulated Research: 1) Drugs, biologics, and devices used to diagnosis, cure, mitigate, treat, or prevent disease; and 2) Clinical investigations that evaluate safety and effectiveness of FDA-regulated products (IND/IDE regulations).

## Effective January 21, 2019: Exempt Human Subjects Research Categories

Category	Criteria
<b>Category 1</b>	Research conducted in established or commonly accepted educational settings, that specifically involves normal educational settings, that specifically involves normal educational practices that are not likely to adversely impact the students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and the research on the effectiveness of or the comparison among instrument techniques, curricula, or classroom management methods.
<b>Category 2</b>	Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior (including visual or auditory recording) if at least one of the following criteria are met: 1) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; 2) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; or 3) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.
<b>Category 3<sup>3</sup></b>	Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audio visual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criterial is met: 1) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; 2) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or 3) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.
<b>Category 4</b>  <i>*A HIPAA Authorization (VA Form 10-0493) or Request Waiver of HIPAA Authorization is required for this category</i>	Secondary research for which consent is not required: Secondary uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: 1) The identifiable private information or identifiable biospecimens are publicly available; 2) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not reidentify subjects; 3) The research involves only information collection and analysis involving the investigator's use of identifiable health information when the use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" or for "public health activities and purposes" as described in 45 CFR 164.512(b); or 4) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subjects to and in compliance with section 208(b) of the E-Government Act of 200, 44

<sup>3</sup> Benign behavioral interventions are defined as brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing (HHS, 2017)

	U.S.C 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C> 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, et seq.
<b>Category 5</b>	Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency, or otherwise subject to the approval of department or agency heads, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs procedures, or possible changes in methods or levels of payment or benefits or services under those programs.
<b>Category 6</b>	Taste and food quality evaluation and consumer acceptance studies: 1) If wholesome food without additives are consumed; 2) 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 FDA, EPA or the Food Safety and Inspection Service.
<b>Category 7</b>	<i><b>Durham VAHCS is not pursuing broad consent at this time and exempt category 7 cannot be used. The proposal may qualify for exemption under another category, or this proposal will be reviewed using expedited or convened IRB procedures.</b></i> Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use.
<b>Category 8</b>	<i><b>Durham VAHCS is not pursuing broad consent at this time and exempt category 8 cannot be used. The proposal may qualify for exemption under another category, or this proposal will be reviewed using expedited or convened IRB procedures.</b></i> Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: 1) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 116(a)(1) through (4), (a)(6), and (d); 2) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 117; 3) the investigator does not include returning individual research results to the subjects as part of the study plan.