



2018 Common Rule:
If, When, and How it
Impacts Your Research

The Road to Implementing the 2018 Common Rule

- Exemption Categories
- Burden Reducing Provisions
- Additional Requirements
- Beyond 2018 – Single IRB
- Compliance Checklist



Terms for today's discussion

- Exempt Research: Human subjects research that is exempt for the requirements of the Common Rule
- Common Rule: Federal regulation governing human subjects research
- New Research: Research initially approved after January 21, 2019
- Existing Research: Research initially approved before January 21, 2019

Exempt Research

What's New?

Pre-2018 Exemption Categories

Research involving normal educational practices

Research involving educational tests, surveys, interviews, or observation of public behavior when the data is anonymous or recording the data poses no risk to subjects

Collection or analysis of existing data, records, or specimens when they are publically available or they are anonymous

Research approved by Dept. or Agency heads to study public services programs, procedures for obtaining benefits from these programs, or changes to these programs.

Taste and food quality evaluation and consumer acceptance studies.

Research that is not federally funded, involves only minimal risk, and does not fall into one of the other exempt categories.

2018 Exemption Categories

Research involving normal educational practices **that do not adversely impact students' opportunity to learn.**

Research involving educational tests, surveys, interviews, or observation of public behavior when the data is anonymous or recording the data poses no risk to subjects, **or when the IRB conducts a limited review.**

Research involving benign behavioral interventions and collection of information from an adult if the subject prospectively agrees and the data is anonymous, or disclosure of the identifiable data poses no risk to subjects, or when the IRB conducts a limited review.

Secondary research using identifiable private information or identifiable specimens if they are publically available or recorded by the investigator in a de-identified format

Research approved by Dept. or Agency heads to study public services programs, procedures for obtaining benefits from these programs, or changes to these programs.

Taste and food quality evaluation and consumer acceptance studies.

What is Limited IRB Review?

IRB Determines there are adequate protections for:

- privacy of subjects
- confidentiality of data



How do I apply for an exemption under the 2018 categories?



New Research: All new projects are automatically evaluated for exemption under the 2018 categories.

Existing Research:
Grandfathered in under 2018 categories. No action required.



2018 Common Rule

Does it apply to my research?

It Depends...



New Research

- Research initial approved after January 21, 2019 is required to comply, unless...

The research is subject to oversight from:

- Department of Justice
- Office of the Director of National Intelligence
- Central Intelligence Agency
- Consumer Product Safety Commission
- FDA, and no federal-funds

Existing Research

- Research initial approved before January 21, is not required to comply, but may elect to comply.

Why would existing research elect to comply?

Burden-reducing provisions

- No IRB review of federal grant applications
- No continuing review for most* minimal risk research

But wait, there's a catch...

New Requirements:

- Waiver of consent justification
- Elements of consent document
- Posting clinical trial consent document
- Single IRB for multisite research

All or Nothing

You must comply with all requirements of the 2018 Common Rule to benefit from the burden-reducing provisions





How many times do I say
“comply”?

2018 Waiver of Consent

How and when do I comply?

Waiver of Consent: Pre-2018 Common Rule Requirements

- Minimal risk research
- Waiver is required to conduct the research
- Will not adversely affect the rights and welfare of subjects
- Subjects will be provided with additional pertinent information

Waiver of Consent: New 2018 Common Rule Requirement

- 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



2018 Waiver of Consent - How do I comply?

HRP-503 Protocol Template-General

Section 8) Data and/or Specimen Management and Confidentiality

If the research will involve BOTH a waiver of consent and use of identifiable private information or identifiable biospecimens, please explain why the research could not be practicably carried out without using identifiable data.

2018 Waiver of Consent - When do I comply?

- New Research: Initial review of research
- Existing Research: If you elect to comply, submit a modification with this new information added to the research protocol and provide the justification you are updating the protocol for compliance with the 2018 Common Rule

Test Your Knowledge: Waiver of Consent

- My medical chart review research involves a waiver of informed consent. It was initially approved in November 2018 and given 1-year approval period. What do I need to do to comply with the 2018 Common Rule?



2018 Elements of Consent

How and when do I comply?

2018 Common Rule Compliant Consent Templates

- HRP-502 Template – General
- HRP-502 Template for Minimal Risk Specimen Research
- HRP-502 Template for Survey/Interview Research
- HRP-502 Template – Exempt Research

Elements of Consent: Pre-2018 Requirements

- Research, purpose, duration and procedures
- Foreseeable risks or Discomforts
- Possible benefits
- Alternative procedures
- Data confidentiality
- Compensation for injury (> min risk)
- Contact information
- Participation is voluntary

Elements of Consent: New 2018 General Requirements

- Begin with Key Information
- Facilitate comprehension
- May not list isolated facts
- Describe future use of de-identified data/specimens



What is Key Information?

Statement that the project is research & participation is voluntary

A research summary: Purpose, Duration, Procedures

Reasonable, foreseeable risks or discomforts

Reasonable, expected benefits

Alternative procedures or treatment, if any

Key Information – How do I comply?

Key Information about This Research Study

You are invited to participate in a research study. The purpose of this research is ***[brief explanation of why the study is being done]***. You are invited to be in this study because ***[briefly explain why the person is being asked to participate in the study, (e.g. have been diagnosed with a certain condition or meeting certain eligibility requirements)]***. Your participation in this research will involve _____ visits and will last about ***[expected duration in hours, days, months, years]***. We expect about [number] people at UC Davis will join and about ***[number]*** people ***[around the U.S./worldwide]*** to participate in this research.

Participation in this study will involve ***[briefly provide a description of any procedures, drugs, and/or devices that the participant will experience as a part of this study]***. All research studies involve some risk. Risks of this study are ***[significant/minimal]***. These risks are described in detail later in this document. There ***[is/is not]*** the possibility that you may benefit from participation in this study.

Here are some reasons you may not want to participate in this research: ***[List the reasons a reasonable person might not want to enroll such as a requirement for frequent visits to the research site, likelihood of receiving placebo, risks of the study, compliance with study requirements (e.g. completion of diaries, only being allowed to eat certain foods, etc.)]***.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include ***[briefly describe any alternatives the participant will have aside from participating in this study]***. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

De-identified Data/Specimens – How do I comply?

[Include the following if the research involves collection of identifiable information or specimens, otherwise delete]

While this study *[does/does not]* involve banking the data and/or specimens we collect with your identifiable information (e.g., your name, medical record number, or date of birth) for future use, we may still use your data or specimens to answer additional research questions or share them with other investigators for additional research. If we do so, we will remove all identifiable information before use or sharing. Once identifiers have been removed, we will not ask your consent for the use of sharing of your data or specimens in additional research.

Additional Elements of Consent: Pre-2018 Requirements

- Unforeseeable risks to the subject, embryo or fetus
- When participation can be ended by the investigator
- Costs the subject may incur
- Consequences of early withdrawal and procedures for early termination
- Subjects will be told of new findings that may affect willingness to continue
- Approximate number of subjects to be enrolled

Additional Elements of Consent: 2018 Requirements

| When your project involves | The consent form must include |
|--------------------------------------|--|
| Use of biospecimens | <p>A statement that the subject's biospecimens (even if identifiers are removed)</p> <ul style="list-style-type: none">• May be used for commercial profit• Whether the subject will or will not share in the commercial profit |
| Clinically relevant research results | <p>A statement regarding whether the clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under which conditions</p> |
| Whole genome sequencing | <p>A statement indicating that the research will (if known) or might include whole genome sequencing</p> |

2018 Biospecimens Requirement

[Always include:] Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

Clinically Relevant Research Results – How do I comply?

Will I receive any results from this research?

[Use this section to inform subjects whether they will receive any study results. Caution: if results of testing are experimental or are not performed at a CLIA certified lab, you cannot provide results to subjects.]

Whole Genome Testing – How do I comply?

[Include the following for whole genome testing:]

We will do whole genome testing for this study. Your “genome” is the complete DNA instruction book. “Whole genome testing” means making a list of the entire order, or sequence, of the DNA in your genome.

Consent Requirements – How do I comply?

New Research

Use a 2018 Compliant Consent Template with your initial submission.



Consent Requirements – How do I comply?

Existing Research – Open to Enrollment

If you elect to comply, submit a modification of the consent documents and provide the justification you are updating the protocol for compliance with the 2018 Common Rule.

Note: You may be required to re-consent all subjects with the new consent document.

Consent Requirements – How do I comply?

- Existing Research - Data analysis or long term follow-up

If you elect to comply, submit a modification notifying the IRB of the study status and provide the justification you are updating the protocol for compliance with the 2018 Common Rule.

Test Your Knowledge: Consent Requirements

- My greater than minimal risk research was initially approved in June 2017. The research is open to enrollment. Should I update my consent documents to comply with the new requirements?

Test Your Knowledge: Consent Requirements

- I'm developing a new federally funded minimal risk research study. Should I use a 2018 compliant consent document?



2018 Clinical Trials Consent

How and when do I comply?

What is a clinical trial?

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

45 CFR 46.102(b)



Posting of Clinical Trials Consent Documents

For each clinical trial, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee on a publicly available Federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject.



Posting of Clinical Trial Consent – How do I comply?

Clinicaltrials.gov

Regulations.gov

(Docket ID: HHS-OPHS-2018-0021)

 U.S. National Library of Medicine

ClinicalTrials.gov

Find Studies ▾

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Submi

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Posting of Clinical Trial Consent – When do I comply?

- After the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject.

Test your knowledge: Posting of Clinical Trials Consent Documents

- My research was initially approved in July 2017. My project randomizes children to one of two behavioral modification interventions to compare their effectiveness. Do I need to post a consent document to a federal website?

Test your knowledge: Posting of Clinical Trials Consent Documents

- My research was initially approved in February 2019. My project requires adult participants who have diabetes to eat a specific diet for 12 weeks. Do I need to post a consent document to a federal website after closing to enrollment?

Beyond 2018 - Single IRB

How and when to comply

Cooperative Research

- Federally-funded projects that involve more than one institution.
- Must rely upon approval by a single IRB.
- The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

Single IRB – How do I comply?

- **IRB Authorization Agreement (IAA):** A formal, written agreement in which the reviewing IRB agrees to serve as the IRB of record for a relying Institution, also referred to as a reliance.
- IRB Administration facilitates the agreement
- Contact hs-irbreliance@ucdavis.edu to begin the process

Single IRB – When do I comply?

- New Research: All federally-funded cooperative (multi-site) research must have a single IRB of record by January 20, 2020
- Existing Research – Contact the Reliance Team to determine if a reliance agreement is appropriate for your project

Test Your Knowledge: Cooperative Research

- My NIH-funded multisite clinical trial is renewing its grant next year. Do I need a Single IRB for this project?

Let's Review

How do I comply with the 2018 Common Rule?

2018 Compliance Checklist

- ✓ Justification for waiver of consent
- ✓ New consent requirements
- ✓ Post clinical trial consent documents
- ✓ Use Single IRB for multi-site research





Thank you!
(comply)