

2018 Common Rule

Information for Investigators

January 18, 2019

Does the 2018 Common Rule impact my research?

Applicability

- Only federally-funded research is required to comply with the Common Rule.
- All existing research will be grandfathered-in under the Pre-2018 Rule.
- Researchers may choose to comply with the 2018 Rule to reduce administrative burden.
- The following agencies have not adopted the 2018 Common Rule. Research funded by these agencies will be continue to be reviewed under the Pre-2018 Rule.

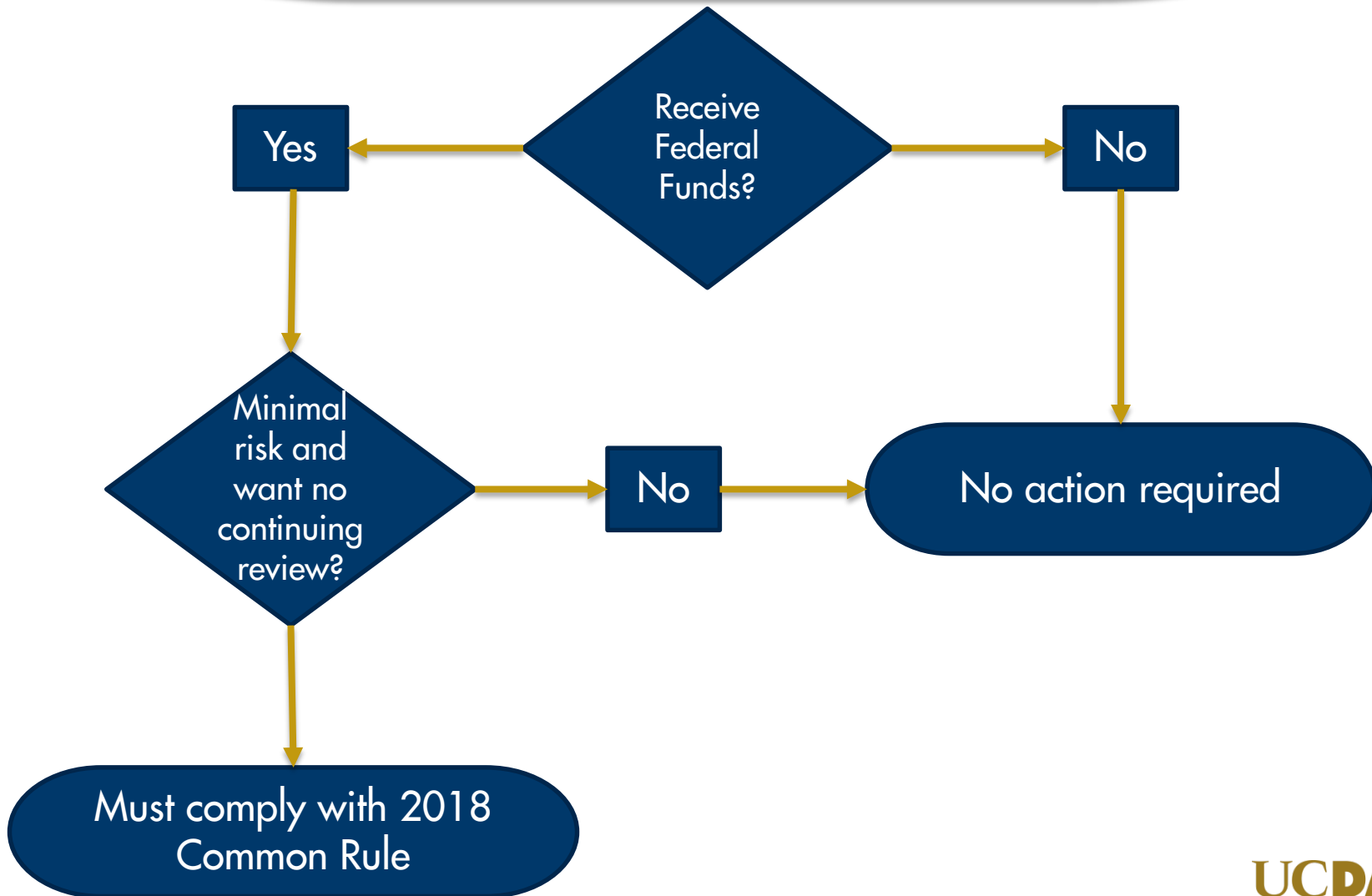
Department of Justice

Office of the Director of National Intelligence

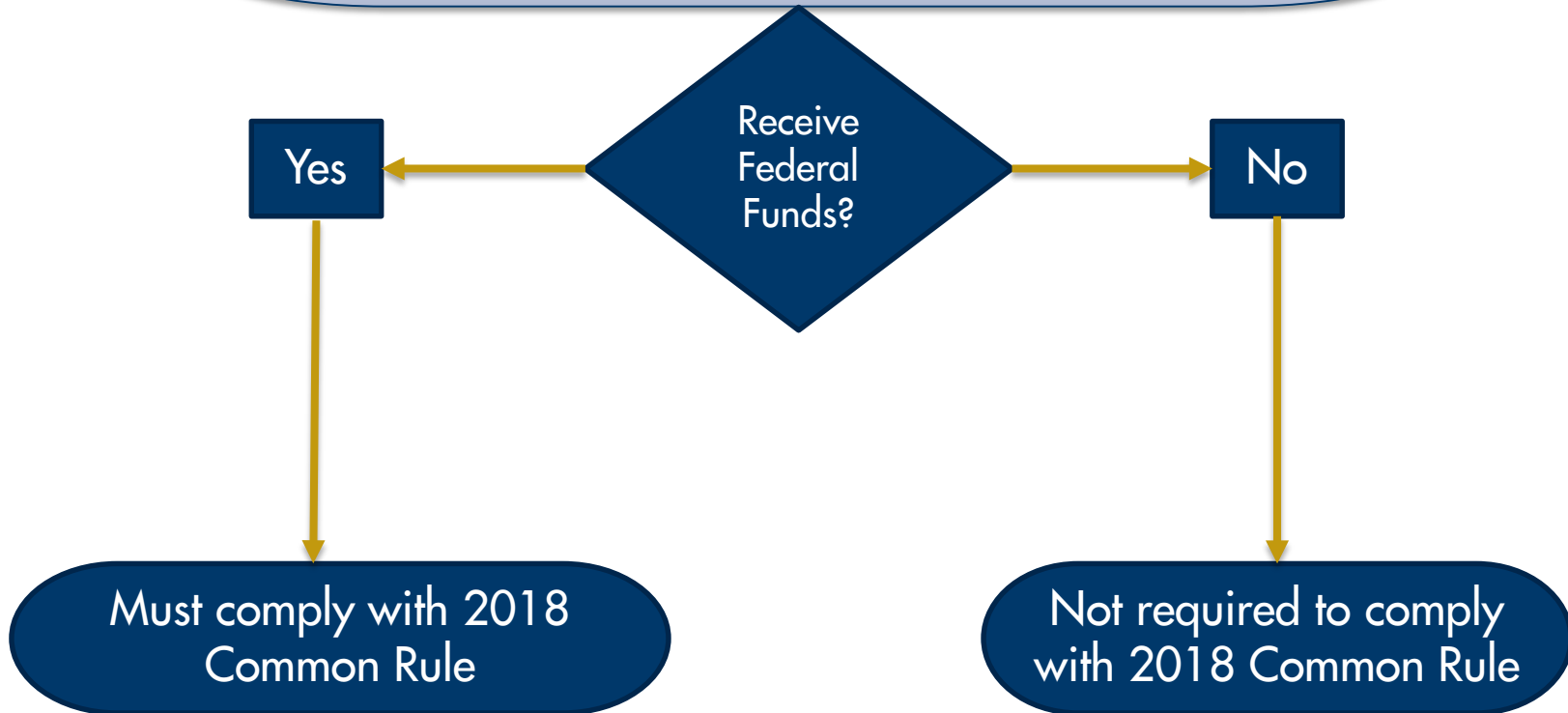
Central Intelligence Agency

Consumer Product Safety Commission

Research initially approved before January 21, 2019



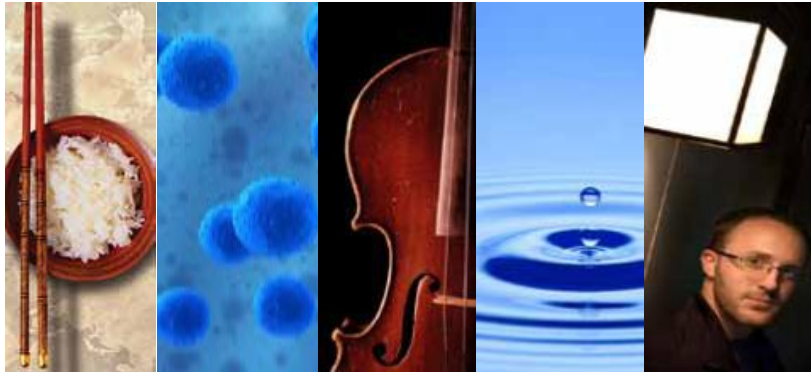
Research initially approved after January 21, 2019



2018 Common Rule

What's new or different?

- Definitions
- Changes to Exempt Categories
- Limited IRB Review
- New Consent Requirements
- No Continuing Review for Some Research
- No IRB Review of Federal Grant Applications
- Single IRB Requirements (effective January, 2020)



2018 Common Rule

Definitions

2018 Common Rule - Definitions

Clinical Trial (new in 2018)

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)

Implications for Investigators

My existing IRB-approved research meets the definition of a clinical trial, how does this impact me?

No action is required. Existing research is grandfathered-in under the Pre-2018 Rule requirements.

Implications for Investigators

My new research meets the definition of a clinical trial, how does this impact me?

You MUST post the informed consent form on a federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

Federal Websites

- [Clinicaltrials.gov](https://clinicaltrials.gov)
- [Regulations.gov](https://www.regulations.gov) (Docket ID: HHS-OPHS-2018-0021)

2018 Common Rule - Definitions

Human Subject (2018)

A living individual about whom an investigator (whether professional or student):

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information/biospecimens.

2018 Common Rule - Definitions

2018

- Intervention includes physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- Interaction includes communication or interpersonal contact between investigator and subject.

Definitions:



Research



Scholarly and
Journalist Activities



Public Health
Surveillance Activities



Criminal Justice
Agencies
Authorized by Law
or Court order for
Investigative Work

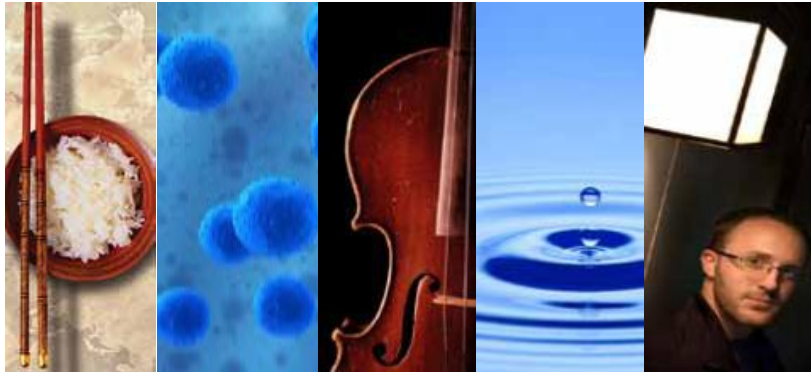


Intelligence,
Homeland
Security, Defense,
National Security
Missions

Implications for Investigators

Is my research still subject to IRB review?

There will be little to no impact from these changes. The scope of IRB review continues to be oversight of research studies involving human subjects. These changes were added as clarification, but do not significantly impact the scope of the IRB's work.



2018 Common Rule

Categories of Exempt Research

Pre-2018 Categories of Exempt Research

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 Categories of Exempt Research

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 disclosure of the identifiable 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

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

2018 Common Rule

Limited IRB Review

When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

45 CFR 46.111(a)(7)

Implications for Investigators

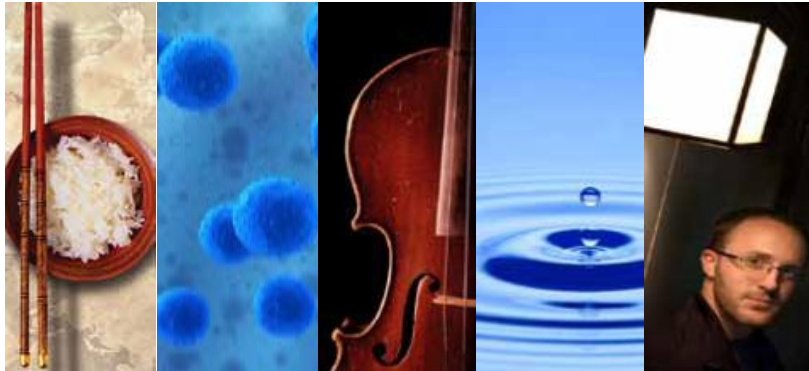
Existing Research

- Research previously determined to be exempt will be grandfathered in.
- Some research previously reviewed under the expedited procedure may now qualify for an exemption determination.
- The IRB will determine if existing research now qualifies for an exemption determinations at the next regular submission (e.g. modification or continuing review progress report)

Implications for Investigators

New Research

- After January 21, 2019, all new studies will be evaluated using the 2018 Common Rule exemption categories
- When necessary, the IRB will conduct limited review as part of the exemption determination. You may be asked to describe how you will protect the privacy of subjects and to maintain the confidentiality of data.



2018 Common Rule

New Consent Requirements

Consent Requirements

The ICF must

- ✓ Provide information that a reasonable person would want to have and an opportunity to discuss that information in order to make an informed decision
- ✓ Begin with a concise and focused presentation of key information most likely to assist in understanding the reasons why one might or might not want to participate in the research.
- ✓ Be organized and presented in a way that facilitates comprehension.

2018 Consent Requirements

The ICF must:

- ✓ NOT merely provide lists of isolated facts.
- ✓ Facilitate the subject/LAR's understanding of the reasons why one might or might not want to participate.

2018 Consent Requirements

When research involves identifiable, private information or biospecimens

Select one:

- ✓ De-identified information or biospecimens may be used for future research studies or distributed to another investigator for future research without additional informed consent; or
- ✓ The information/biospecimens will not be used or distributed for future research studies.

2018 Consent Requirements

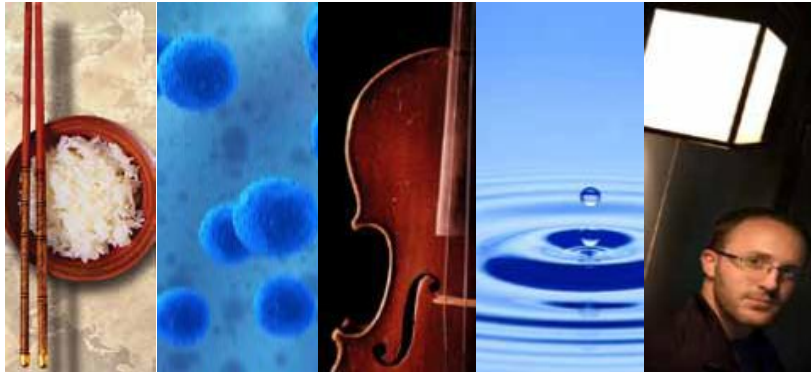
When applicable for research that involves identifiable, private information or biospecimens

- ✓ A statement that the subject's biospecimens (even if de-identified) may be used for commercial profit and whether the subject will/will not share in the profit;
- ✓ A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- ✓ Whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

2018 Common Rule – Consent Requirements

2018 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



2018 Common Rule

No Continuing Review



WARNING

If your federally funded research is subject to FDA oversight, FDA regulations still apply.

FDA-regulated studies must have continuing review.

2018 Common Rule – No Continuing Review

2018 Common Rule compliant research does not require continuing review, if:

- Research is eligible for expedited review (except for research which was initially reviewed at full committee or which is being expedited only because there was no enrollment in the previous year), or
- Research has progressed to the point it involves only:
 - (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 - (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Implications for Investigators

My active research study is minimal risk, requires informed consent, what should I do?

You can either:

- Do nothing and continue to submit annual continuing review progress reports, or
- Update consent forms to comply with the new rule. Once the research is compliant with the 2018 Common Rule, continuing review will no longer be required.

Implications for Investigators

My research is minimal risk, involves a waiver of informed consent, and I am still accessing identifiable private records, what should I do?

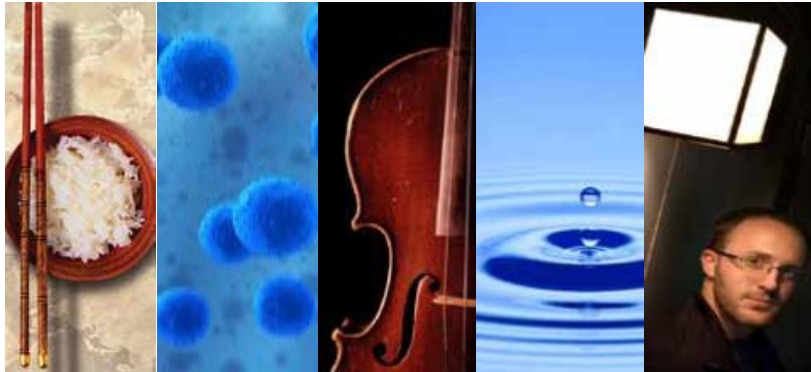
You can either:

- Do nothing and continue to submit annual continuing review progress reports, or
- Update the protocol to explain why the research cannot practicably be conducted using anonymous or coded data or specimens. Once approved, continuing review will no longer be required.

Implications for Investigators

My research is in long-term follow-up or data analysis, what should I do?

Your research may no longer require continuing review. Contact the IRB for information about removing the expiration date for IRB approval.



2018 Common Rule

No IRB Review of Federal Grant

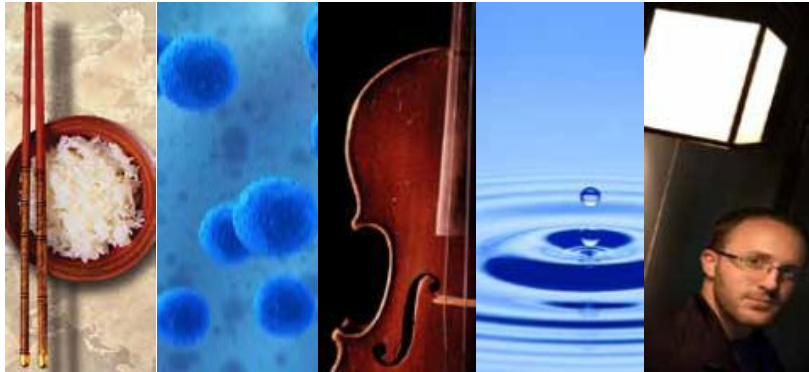
2018 Common Rule – Federal Grant Applications

For 2018 Common Rule compliant research, IRBs are no longer required to review federal grant applications in conjunction with the application for IRB approval

Implications for Investigators

My new research project is federally funded, do I include the grant in my submission to the IRB?

- No. Your research is required to comply with the 2018 Common Rule. Because it complies with the 2018 Common Rule, the IRB does not need to review the grant.



2018 Common Rule

Single IRB Requirement

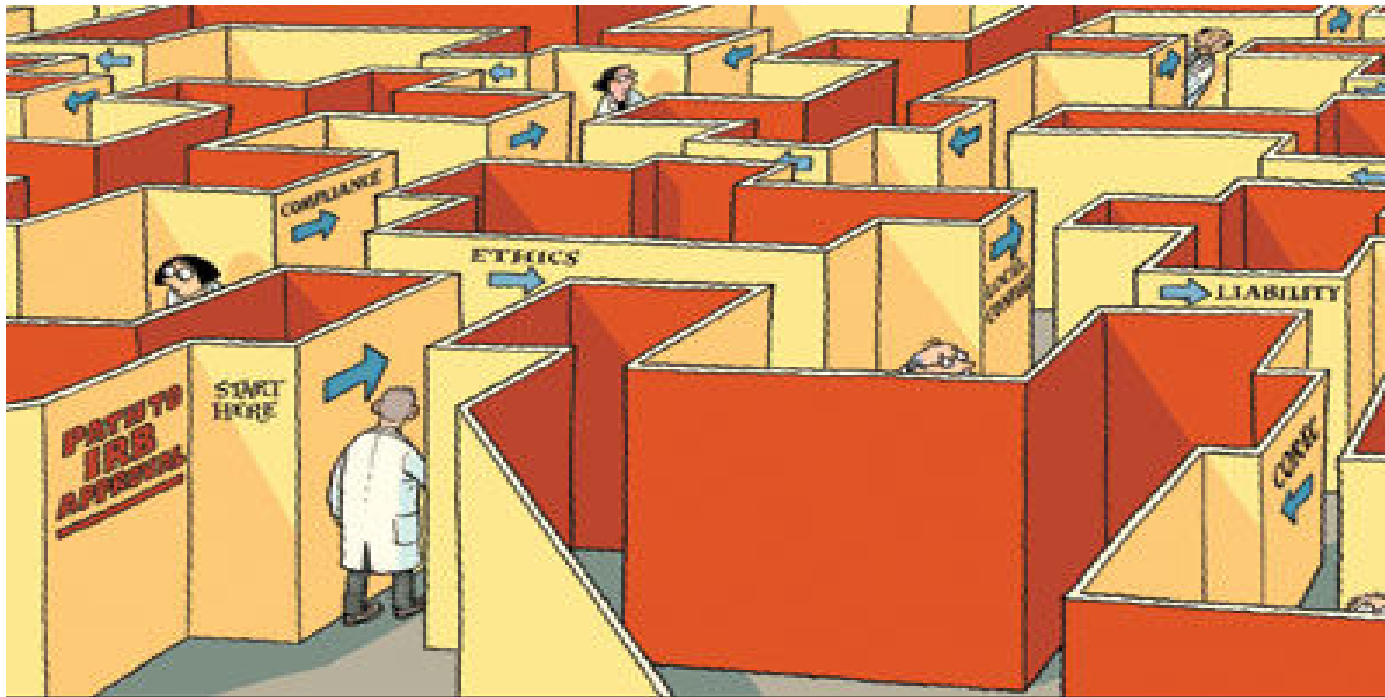
2018 Common Rule – Single IRB Requirement

Takes effect January 20, 2020

- No action is required at this time. More information will be shared as the date approaches.

Need help? Contact the IRB

IRB Help Desk
hs-irbeducation@ucdavis.edu



Website
research.ucdavis.edu/irbadmin