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Home > IRB Town Hall Meetings on Policy Changes

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## IRB Town Hall Meetings on Policy Changes

Jan 9, 2019

Human Research Protection Program

January 8, 2019

To: Investigators and Staff

### **Town Hall Meeting: New Common Rule for Human Subjects Research**

The HRPP is hosting two Town Hall meetings to discuss the changes to the federal policy for research involving Human Subjects on:

- **Monday January 14<sup>th</sup> @ 10-11am, MB Rock Hall 102 (Auditorium)**
- **Tuesday January 15<sup>th</sup> @ 3-4pm, Parnassus Nursing N225**

These sessions will be live streamed and recorded if you are unable to attend in person. Go to the IRB website at [irb.ucsf.edu](http://irb.ucsf.edu) [1] on the Town Hall days for a link to the live streams.

### **Overview**

The federal policy for the protection of Human Research Subjects promulgated in 1991 has been updated to better protect human subjects involved in research while facilitating valuable research by reducing burden, delay, and ambiguity for investigators.

### **What studies are affected?**

The Revised Common Rule only applies to **new federally-funded and federally-conducted studies approved on or after January 21, 2019**. If your study is federally-funded/conducted and is already approved, or receives IRB approval prior to January 21, the revised policy does not apply.

### **What are the changes?**

Below is a brief outline of the main changes to the Common Rule:

- Continuing Review ? Some new, minimal risk studies will no longer require annual review. The IRB is currently identifying applicable studies and will reach out to researchers who are eligible for this in January.
- Informed Consent ? Several new standard statements are required in the consent form. New consent form templates will be available on the IRB website by January 15th.
- Exemptions ? Several exempt categories will be broadened, and one new category will be added: Benign behavioral interventions. The IRB application and website guidance will be updated to reflect the changes in January.

### **What to Expect**

The IRB will release an updated application, consent form templates, and FAQs prior to January 21, 2019.

### **Resources**

To learn more about the upcoming changes, visit CITI Program's Final Rule Resources [2]. This page offers a comprehensive overview of the revised regulations, but please note that UCSF may implement some of the changes differently than described by CITI.

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### **Links**

[1] <http://irb.ucsf.edu/>

[2] <https://about.citiprogram.org/en/final-rule-resources/>