



# VCU Office of Research and Innovation

## RAMS-IRB Smartform

### Summary of Changes and Impact

The RAMS-IRB Smartform is changing January 22, 2019 to meet the requirements of the 2018 Common Rule (which goes into effect on January 21, 2019) and will impact all human subjects research at VCU.



## What Changed & Why

### Protocol-like page organization

Improves users' experiences and facilitates compliance with ClinicalTrials.gov requirements

### New questions

Addresses new exempt categories, new institutional requirements for data sharing, and handling of incidental findings

### Fewer pages

Reduces burden and streamlines the smartform

### More hide/show questions

Improves users' experiences by showing additional questions on a topic immediately instead of on subsequent pages

### Rewritten/rephrased questions

Clarifies information sought and includes content previously embedded in help text

### 'Not Human Subject Research' form

Provides researchers with official IRB correspondence for activities that do not meet the regulatory definitions of human subject research

### Contact ORSP



ORSP@vcu.edu



804-828-0868



[research.vcu.edu/human-research](http://research.vcu.edu/human-research)

[wp.vcu.edu/humanresearch](http://wp.vcu.edu/humanresearch)

### **Be prepared:**

1. All new studies reviewed and approved after January 21, 2019 must use the new form.
2. PI's will be asked to convert existing studies to the new RAMS-IRB form either at their next amendment, or 6 months before the study's expiration date.