Research Navigator – IRB Module Upgrade

The IRB module of the Research Navigator submission system will undergo an upgrade. Expected to deploy **Mid-February 2018**, the upgraded system will have a new look and feel and include the following updated or new features:

### Personal Profile
- User Profiles for CV storage
- CITI information integration for visibility of active and expired certifications
- Electronic FDs

### Enhanced Functionality
- Inbox display of items that require action
- sIRB functionality will permit document sharing and visibility amongst various institutions
- New document management enhancement will remove all tracked changes and comments from documents automatically when finalized, eliminating the need to upload both clean and tracked document versions
- File names integration will also take place.

### Revised Data Capture
- Smartform questions regarding the scope of your research have been modified to capture the information required for the revised common rule.

**Implementation and Support**

**Over the next few months please look for:**
- Hands-on FAQ/Training Session – Post Go-Live
- Updated On-Demand Submission Instruction Modules
- Updated IRB Fundamental and Advanced Sessions
- Updates regarding implementation via IRB Website and OSR Announcements

Last updated: December 2017
Revised Federal Regulations
The Department of Health and Human Services - Office of Human Research Protection has revised the existing set of regulations known as “the Common Rule”. The revised set of regulations was revisited in an effort to better protect human subjects, better facilitate research, reduce ambiguity and ease regulatory burden. The New Common Rule will be effective January 19, 2018 and the following changes may impact your research...

Definitions
• Revised definitions
• Human subjects
• Legally Authorized Representative
• Research
• Newly added definitions
• Clinical Trial
• Public Health Authority
• Written or In-Writing

Exempt Research
• New Categories
• Clarification of existing categories
• Implementation of the new Limited IRB will eliminate the requirement for waivers of consent request for exempt research involving identifiable information or specimens

Expedited Research
• The requirement for continuing review may be waived for:
  • Studies previously approved via expedited research
  • Full board studies that remain open for data analysis and/or long term follow up only
  • The IRB has the authority to waive this requirement at their discretion

Informed Consent
• Inclusion of a “Key Information” sheet which provides a high level overview of major details that may impact a potential subjects decision to participate
• Additional elements that must only be included when relevant to study activities
• New for option for broad consent that is not going to be implemented at NYU Langone Health Immediately

Implementation and Support
Over the next few months please look for:
• Q/A sessions regarding regulation and policy revisions
• Updated Forms, Templates and Guidance Documents
• Updated IRB Fundamental and Advanced Sessions
• Updates regarding implementation via IRB Website and OSR Announcements

Last updated: December 2017
**Single IRB for Multi-Site Research**

The National Institute of Health (NIH) has a new policy requiring the use of a single IRB for all multisite research projects. The goal of this policy is to better facilitate research and protect human subjects by eliminating the current requirement multiple IRB reviews. If you intend to carry out multi-site research you should know the following information...

### Implementing and Support

Over the next few months please look for:

- Q/A sessions regarding regulation and policy revisions
- Updated Forms, Templates and Guidance Documents
- Updated IRB Fundamental and Advanced Sessions
- Updates regarding implementation via IRB Website and OSR Announcements

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**Applicability**

**Human Subjects Research**

**Multi-Site**

**Studies that will be NIH-sponsored in the future**

**Applicability**

**IRB oversight for most federally-funded collaborative research projects located in the U.S. will be required to use a single IRB (commercial, academic, or hospital-based)**

**NYU SoM IRB as an sIRB**

**RNav upgrade includes Cloud based system that will permit document sharing and communication across institutions**

**Alert the IRB BEFORE submitting your grant**