**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...

<table>
<thead>
<tr>
<th>SIRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>• sIRB functionality will permit document sharing and visibility amongst various institutions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Researcher Profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>• User Profiles for CV storage</td>
</tr>
<tr>
<td>• CITI information integration for visibility of active and expired certifications</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Enhanced Functionality</th>
</tr>
</thead>
<tbody>
<tr>
<td>• IRB Inbox display of items that require action</td>
</tr>
<tr>
<td>• Current process of uploading both clean and tracked document versions will be eliminated, tracked changes and comments will be removed automatically</td>
</tr>
<tr>
<td>• File name consistency</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Revised Data Capture</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Smartform questions regarding the scope of your research have been modified to capture the information required for the revised common rule.</td>
</tr>
</tbody>
</table>

**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
Revised Federal Regulations – Original Effective January 19, 2018- Delayed until July 19, 2018

The Department of Health and Human Services - OHRP has revised the existing set of regulations known as “the Common Rule”. The revised regulations were revisited in an effort to better protect human subjects, better facilitate research, reduce ambiguity and ease regulatory burden. These revisions apply to research covered by the Common Rule. **FDA-regulated research is NOT subject to the Common Rule.** The revised regulations apply ONLY to research reviewed and approved after July 19, 2018. 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
- Limited IRB review applies to exempt research involving identifiable information or specimens.
- Request for waivers of authorization may apply

### Expedited Research
- The requirement for continuing review (for initial studies approved post 1.19.2018) may be waived for:
  - Studies approved via expedited review
  - Non-FDA regulated full board studies that remain open for data analysis and/or long term follow up only.
  - The IRB has the authority to require continuation if expedited studies meet certain criteria*

### 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
- Broad consent (will not be implemented at NYU Langone Health at this time)

### 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

*Continuing review of an expedited study will be required when studies include the following: vulnerable populations (LIST include students); deception research, multiple phases/compartments and not all are available/developed at the time of initial review; Interventional studies with the FDA approved drug or device; sensitive information that presents increase risk to employability, insurability, social stigmatization, criminal and civil liability; Interventional studies deemed category 9 at a fully convened IRB meeting.*
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. In addition, the new common rule require sIRB review for collaborative research. With the requirement of sIRB, the goal is to better facilitate research and protect human subjects by eliminating the multiple IRB reviews. If you intend to carry out multi-site research you should know the following information...

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

NIH sIRB Required Applicability (1.25.2018)
- Human Subjects Research
- Multi-Site
- Studies that will be NIH-sponsored

Cooperative Research Applicability (1.20.2020)
- 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
- NYUSom IRB will act 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