

Potential Procedure for Institutional Implementation of the Final Rule

- 1 Outline the Final Rule by section
- 2 IRB staff reviews each section and determines which of the institution's documents require revision
- 3 IRB staff edits affected documents
- 4 Another IRB staff reviews the revised documents
- An IRB director or institutional leader reviews each revision and develops the training tools as needed

Examples of Institutional Documents:

- SOPs
 IRB Minutes Templates
- Policies
 IRB Determination Letters
- Checklists
 Informed Consent Templates
- Worksheets Investigator Manual
- Forms IRB Applications



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