



Implementing the Revised Common Rule Sample Research Status Report

The revised Common Rule eliminates* the requirement for continuing review (unless the IRB determines otherwise) for research that:

- is eligible for expedited review in accordance with §__.110;
- requires limited IRB review in accordance with §__.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);
- has progressed to the point that it involves only one or both of the following:
 - data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 - accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Organizations may choose to adopt more stringent standards and continue to require continuing review when it is not required by regulation. Organizations may also establish procedures to ensure ongoing knowledge and oversight of research when continuing review by the IRB itself is not required. AAHRPP - accredited organizations are required to have an alternate process, such as staff review, to maintain oversight of research when continuing review by the IRB is not required.

HRP provides this sample Research Status Report as an example of study information that organizations may want to capture on an annual basis when continuing review by an IRB is not required. As with all HRP templates, organizations should customize this sample document to capture local requirements and to best meet their needs.

HRP has developed numerous resources and sample documents to assist clients with the implementation of the revised Common Rule. Please contact us at 347-862-9321 or info@hrpconsultinggroup.com if you would like to learn more about our Common Rule Services.

*Organizations should be cognizant of other regulations or requirements that may trigger the need for continuing review even when research is conducted or supported by a Common Rule agency or department. For example:

- when the research is also FDA-regulated (e.g., a NIH-supported clinical trial of an FDA-regulated test article);
- when the research is supported by the Dept. of Justice/National Institute of Justice (as of 10/30/18, DoJ is not a signatory on the revised Common Rule);
- when a study was IRB-approved prior to the compliance date of the revised Common Rule and has not been transitioned to comply with the revised Common Rule;
- When continuing review by the IRB is a term of a grant or contract.

For additional information, visit our website or contact us at:

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Research Status Report

PI Name:	IRB Number:
Protocol Title:	

1. Estimated study completion date:
2. Current status of the research:
 - Open to enrollment but no subjects have been enrolled to date
 - Open to enrollment and subjects have been enrolled
 - Closed to enrollment, but subjects are still “active” on the protocol regimen or undergoing procedures or interventions for the research
 - Closed to enrollment, but follow-up of subjects (or data collection) continues
 - Closed to enrollment, but analysis of identifiable or coded data continues
 - Suspended or on hold. Explain:
 - Other. Explain:

3. Have there been any changes in funding for this study?

- No
- Yes. Please explain:

4. Are any changes in funding planned for or anticipated in the next 12 months?

- No
- Yes. Please explain:

Please Note: Changes in funding must be reported to the IRB using [FORM NAME] before expending any of the new funding. Changes in funding sometimes trigger additional regulatory requirements that have to be addressed before moving forward with the research. Likewise, the loss or end of funding may remove requirements.

5. How many subjects have been enrolled in this study since inception?

The following questions are intended as examples of information that organizations may want to capture for QA purposes.

6. Have there been any changes to investigators or other research team members that have not yet been submitted to the IRB?

- No
- Yes. Please explain:



7. Have there been any changes made to the research or research materials that have not yet been submitted to the IRB?
- No
 Yes. Please explain:
8. Are there any interim reports (e.g., DSMB report, sponsor or coordinating center report, audit or inspection report, etc.) that have not yet been submitted to the IRB?
- No
 Yes. Please explain:
9. Is there any new information or literature that suggests a change in what was previously understood about the research by the IRB, or that may impact the rights, welfare, or willingness of subjects to continue in the research, that has not yet been submitted to the IRB?
- No
 Yes. Please explain:
10. Have there been any problems or complaints associated with the research that have not yet been reported to the IRB?
- No
 Yes. Please explain:

Please submit the following with this form:

- **Current human subjects training and COI training documentation for each investigator and research team member**
- **Any changes or reports identified in items 6-10 above that have not previously been submitted to the IRB**
- **Copies of any publications or presentation resulting from this research that have not previously been submitted**

PRINCIPAL INVESTIGATOR'S STATEMENT

By entering my name and the date below, I certify that the information provided in this report is, to the best of my knowledge, accurate.

Name

Date