In general, templates are an efficient way to build study documents but care needs to be taken that edits are made that are relevant and appropriate for each study. Study teams can use the CRRO templated tools and edit for each new study or can build their own templates based on their usual needs to use for all future studies.

During planning and operationalization stages, before enrollment starts, research teams should discuss what forms will be needed for their study. These could be data collection forms, source documentation, even forms or logs for study management like visit checklists and progress notes.

CRRO templated tools are built upon a mix of institutional policies, federal regulations, ICH Good Clinical Practice, and current best practices. Where appropriate, the relevant guidance has been provided in either instructional text or comments. As it is impossible to include or address all policies, regulations, and best practices, study teams should use their own discretion and knowledge of which policies and regulations apply to their specific study. When something on a template is in direct conflict with a policy or regulation that a study may be governed by, study teams must follow that policy or regulation. If there are questions about this, please [contact the CRRO team](mailto:crro@bu.edu). The CRRO cannot make any guarantee that these templated tools follow current policy or regulations as those may change without warning or announcement. These templated tools are not meant to be used as a policy or guidance document.

Study teams should understand how they will be using these tools and that can inform where and how the tools are built. Some tools can be built in REDCap or within Excel in Box, for example, using the template to provide ideas on what needs to be included while some study teams might find it more comfortable to maintain a tool on paper. A study does not need to only use paper forms or REDCap forms, a mix of documentation is always acceptable. Generally, a tool should not be updated with actual study data or information within Word but be either paper handwritten documents or completed as a REDCap form. The templated tools are provided as Word documents but study teams may build their own study-specific forms and logs in any format, including any institutionally-allowed and HIPAA-compliant system as appropriate.

Complementary to using templated tools are completing reviews of data or information documented on a tool or form. This process, known as self-assessment, can be used to verify protocol adherence and compliance to policy and regulations. Conducting this internal self-assessment review of study procedures and documentation is a recommended best practice and supports participant safety and rights protection as well as increasing data integrity and reliability. [Self-Assessment Tools](https://www.bumc.bu.edu/crro/resources-library/self-assessment-tools/) are available to assist study teams with the following reviews.

* Informed Consent
* Participant Eligibility
* Protocol Adherence

Additional resources for many of the topics covered in these tools are available within the [Standard Operating Procedure guidance document](https://www.bumc.bu.edu/ohra/required-training/institutional-standard-operating-procedures-sops/).

How to Use Templated Tools

The CRRO templated tools are not meant to be static, unchanging documents, but *must be edited* for each study to align with IRB-approved procedures that are in the INSPIR application, protocol, or other study document. However, not all templated tools that are available will be required or should be used on every study. Study teams should review all available tools and what will be needed for compliant and complete documentation and set up tools prior to starting recruitment and enrollment. Once it is decided that a templated tool will be used for a study, the following steps can be followed:

* Download the tool to a study team folder, making sure to update the file name to something appropriate for the study.
* Read all red-text instructions and comments very carefully – there is information on how to use the tool, to ensure compliance with institutional policy, and guidance on documentation best practices. It is recommended that comments and instructions are not deleted until the tool has been finalized and all study-specific edits have been completed.
* Template tool version dates should be deleted and study team version information should be added.
* Review and make all changes necessary to align with study procedures. This could include deleting rows or information that is not applicable or adding rows, columns, or information that is relevant.
* Making the tool relevant and applicable to the specific study procedures must be carefully done. These tools will form some of the source documentation required for compliant research and could be used during auditing or monitoring. If the tool is wrong, it is very likely that a study team member could miss a required procedure or step or do it incorrectly which will result in a protocol deviation.
* It is recommended that, if possible, more than one study team member is reviewing these tools for accuracy and relevancy prior to finalizing. This will help minimize errors that lead to deviations.
* Once the tool is final and reviewed, it is recommended that the tool is saved with final version information. It can be helpful to mark it as “final” or something similar within the file name or file folder where stored.
* If study or protocol amendments are submitted to the IRB, the tool must be updated if procedures are changed that are documented on the form. This is, in part, why proper versioning is useful so that it is clear when changes are made and can be tracked by auditors or monitors.

The [CRRO team](mailto:crro@bu.edu) is available for [consultations and to provide training](https://www.bumc.bu.edu/crro/research-and-regulatory-consultations/) on editing and using these templated tools.

Resources and Links

* [Human Research Protection Program (HRPP) Policies and Procedures](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/)
* [Institutional Standard Operating Procedures](https://www.bumc.bu.edu/ohra/required-training/institutional-standard-operating-procedures-sops/)
* [Summer Session](https://www.bumc.bu.edu/crro/training-education/summer-sessions-library/): Everything You Always Wanted to Know But Were Afraid to Ask: A Focus on Study Documents
* [Clinical Research Seminar](https://www.bumc.bu.edu/crro/training-education/past-seminars/): Quality Management: Taking a Proactive Approach and Using Self-Assessments to Ensure High Quality Research