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| **GENERAL INSTRUCTIONS** – delete this box from the completed form. Red text represents instructions to you – to be deleted from the final version.**NOTE: This form is designed to be a starting point on an IRB Submissions Tracking Log. Update it as necessary for your specific study.** * This log tracks submissions to the IRB. Maintaining such a log helps the study team easily track the status of IRB submissions and show when submissions become active or were acknowledged by the IRB. Maintain this log in the Regulatory Binder.
* If the study is ceding review to an outside IRB, complete the IRB of Record Name and IRB of Record #. If the study is not ceding review and the only IRB is the local Boston University Medical Campus/BMC IRB, delete the entire header row with External IRB information.
* Note that if the study is ceding review to an outside IRB, there may still be some required submissions to the BMC/BUMC IRB. See [HRPP Policy 2.5.4](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#2.5.4) for full details. For ceded studies, if the submission should be made to both the IRB of Record and the BMC/BUMC IRB, describe these submissions on separate lines of the table.
* If there are submissions to an external IRB that are made on behalf of the local study team and are *only* concerning the local study team or participants, those can be tracked on this log. Overarching IRB submissions made to an external team that impact the study as a whole should not be tracked on this log. For example, protocol amendments submitted to the IRB of Record by the Lead Team and distributed after approval to a local site should not be tracked on this log.
* In the column “Description of Submission” describe the submission and provide sufficient detail so it is clear what was the purpose of the submission and the documents submitted for review. For example, “Initial Submission” or “Amendment: update to protocol, consent form, screening process and form to add additional study risks.”
* Information on stipulations or response to stipulations, including receipt and re-submission dates can be included in the comments column, if applicable.
* If there are no comments on a specific submission, study teams should include a “n/a” or “no comments” type response to prevent any concerns that this is missing data rather than no actual comments.
* Additional pages should be printed or rows added as required for study needs.
* Page numbers do not automatically update as it is unknown how many pages will be necessary for the entire study. The page information in the footer should be added when the study is complete and no IRB submissions are expected to occur.
* Delete the CRRO template version date and add in the study-specific version date of this document.
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| Description of Submission | IRB | IRB Submission Date | IRB Approval Date | Comments |
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