New Submission Checklist

This checklist provides guidance on what documents may need to be uploaded as part of your new IRB submission. Please note that this is only a general list and attachments may not be limited to those listed in this checklist.

☐ **Protocol**
If you were provided a protocol from a sponsor or lead site, be sure to attach it to the submission. If you are authoring the protocol, please be sure to use the protocol template on our website.

☐ **Children's Addendum for Multisite Studies**
This form should only be completed when a protocol is provided by a sponsor or lead site. The form should include CHOA-specific study information.

☐ **External Staff Spreadsheet**
If you would like to add external study staff (those who are not affiliated with Children's or those without a CHOA login), please be sure complete and upload the external staff spreadsheet. It can be found by clicking the question mark icon next to the "External Team Member Information" section or on our website.

☐ **Drug Attachments**
If your study involves an investigational drug, please be sure to upload any associated documents. This may include, but is not limited to, an investigator brochure, FDA 1572, FDA correspondence, and sponsor correspondence.

☐ **Device Attachments**
If your study involves an investigational device, please be sure to upload any associated documents. This may include, but is not limited to, an investigator brochure, FDA correspondence, and sponsor correspondence.

☐ **Consent Documents**
All consent, assent, and waiver of documentation templates can be found on our website. We ONLY accept consent documents on our templates.

☐ **Recruitment Documents**
Recruitment documents may include, but are not limited to, phone scripts, emails, letters, brochures, and flyers.

☐ **Radiation Safety Submission Form**

If radiation is involved in the study, please complete the radiation safety submission form found on our website and upload it to the "Other Attachments" section on the Local Site Documents page of the submission.

☐ **Genetic Testing Appendix**
If your study involves the collection of specimens for genetic research or testing, please complete and upload the genetic testing appendix. Genetic specimens include blood, saliva, solid tumors, and any other tissues or body fluids used for genetic testing.

☐ **Department Approval**
Every study submission should include department approval from the area or division medical director. If you are the director of your department, please obtain approval from your direct supervisor. If your research involves departments outside of your own, you will also need to obtain department approval from all outside departments.

☐ **Surveys and Questionnaires**
If applicable, please include all surveys and questionnaires.

☐ **Data Safety Monitoring Board or Committee Charter**
Please include the charter if applicable.