This checklist is for an initial IRB submission. Your IRB may require additional (or fewer) documents to be submitted. Please review your IRB’s submission requirements and customize the checklist as needed.

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| **Initial IRB Submission** | | |
| **General Documents** | **Submitted?** | **Comments** |
| IRB Review Application | Yes  No |  |
| Protocol | Yes  No |  |
| Consent Form | Yes  No |  |
| Assent Form | Yes  No  N/A |  |
| HIPAA Authorization (If reviewed by your IRB and separate from the consent form) | Yes  No  N/A |  |
| Investigator’s Brochure or Product Information | Yes  No  N/A |  |
| Case Report Forms | Yes  No  N/A |  |
| DSMB Charter | Yes  No  N/A |  |
| Other written documents to be provided to subjects that are not part of the protocol:   * QOL instruments * Subject diaries * Equipment instructions for use / device information * Other: *[list here]* | Yes  No  N/A  Yes  No  N/A  Yes  No  N/A  Yes  No  N/A |  |
| Recruitment materials (including screening scripts):  *[list here]* | Yes  No  N/A |  |
| Other: *[list here]* | Yes  No  N/A |  |
| Data and Specimen Banking Consent Form | Yes  No  N/A |  |
| Subject Thank You Letter | Yes  No |  |
| Other: *[list here]* | Yes  No |  |