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 |  |