| **Yes** | | **No** | | **N/A** | **Protocol Checklist** |
| --- | --- | --- | --- | --- | --- |
|  | |  | |  | FDA Documentation of IND/device application in section 11. |
|  | |  | |  | Expanded Access IND FDA 3926/device application in section 11.  **For device expanded access: If there is an existing IDE for the device**, the IDE sponsor (who may be the device manufacturer or a physician who has submitted the IDE to conduct the clinical study for the device) should submit an IDE supplement requesting approval for a compassionate use under section §812.35(a) in order to treat the patient. The IDE supplement should include:   * A description of the patient's condition and the circumstances necessitating treatment; * A discussion of why alternative therapies are unsatisfactory and why the probable risk of using the investigational device is no greater than the probable risk from the disease or condition; * An identification of any deviations in the approved clinical protocol that may be needed in order to treat the patient; * The patient protection measures that will be followed:   + A draft of the informed consent document that will be used;   + Clearance from the institution as specified by their policies;   + Concurrence of the IRB chairperson;   + An independent assessment from an uninvolved physician; and   + Authorization from the device manufacturer on the use of the device.   **If there is no IDE for the device,** the physician or manufacturer submits the above information to FDA, along with a description of the device provided by the manufacturer. |
|  |  | |  | | Remove ALL patient identifiers |
|  |  | |  | | Investigator’s Brochure or Device Manual in section 11. |
|  |  | |  | | Clinical Protocol in section 11, if available |
|  |  | |  | | If the Stanford investigator is the holder of the IND/IDE, complete SIR training. If not completed at time of approval, add an admin note and approval note. |
|  |  | |  | | Consent form: Compensation for Research Related Injury language should be option 2 |
|  |  | |  | | If children is the participant, ask the Chair whether the parental permission signatures should be one or two. |
|  |  | |  | | Add the following after the parental signature lines: The IRB determined that ***one/two*** parental signatures is recommended. |