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| The purpose of this checklist is to provide support for PIs and study personnel when submitting an expanded access for devices (compassionate use) application for IRB Review. This checklist must be used for all expanded access reviews. This checklist must be included in the submission. | |
| **IRB Number:**  **Study Name:**  **Primary Investigator:**  **Entity:** |  |
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| **Each expanded access submission must include the following items/forms:** | |
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|  | Cover Letter, including:   * 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; and * An identification of any deviations in the approved clinical protocol that may be needed to treat the patient |
|  | Informed Consent |
|  | Independent assessment of a physician who is not participating in the study or in the care of the patient that concurs with the planned usage |
|  | Authorization from the device manufacturer on the use of the device |
|  | An appropriate schedule for monitoring the patient to detect any possible problems arising from the use of the device, taking into consideration the investigational nature of the device and the specific needs of the patient. |
|  | Evidence of FDA approval of the compassionate use |
|  | Confirmation of the IDE by the sponsor **OR** a description of the device provided by the manufacturer |
|  | PI’s CV |
|  | Research Personnel List |
|  | Conflict of Interest (for each member of study personnel) |
|  | Confidentiality Agreement (for each member of study personnel) |
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| Notes: | |
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