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| **Instructions** |
| * When use of a Humanitarian Use Device (HUD) is proposed by an individual to whom the Michigan State University HRPP policies and procedures apply as defined by HRPP Manual Section 4-1, Applicability, an HUD application shall be submitted to the MSU Institutional Review Board (IRB) to determine whether MSU IRB review is needed.
* Use this template to complete the HUD application.
* CLICK™ IRB
	+ Include the template with a New Study Submission.
	+ Upload the completed template to the Basic Information SmartForm page, Question 10.
* See HRPP Manual Section 7-7, Humanitarian Use Device.
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| **Complete Questions 1-12.** |
| 1 | Study title.       |
| 2 | Name of responsible physician.       |
| 3 | Name of facility where the HUD will be administered.       |
| 4 | List any other collaborating institutions or entities.       |
| 5 | List the IRB(s) that will be reviewing the activity.       |
| 6 | HUD name.       |
| 7 | What firm(s) or organization(s) manufactures the device(s)?       |
| 8 | HDE#:       |
| 9 | Will the HUD be used in a clinical investigation (e.g. collection of safety or effectiveness data, either for the HDE-approved indication(s) or for a different indication)? | [ ]  No [ ]  Yes |
| Please explain your answer:       |
| 10 | Will the HUD be used in accordance with its approved labeling and indication(s) to treat or diagnose patients? | [ ]  No [ ]  Yes |
| Please explain your answer:        |
| 11 | Will data be submitted to or held for inspection by the FDA in support of a research application or marketing permit? | [ ]  No [ ]  Yes |
| If YES, please explain:       |  |
| 12 | Will you be testing the safety or effectiveness of a device on human samples? | [ ]  No [ ]  Yes |
| If YES, please explain:       |  |