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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. | | | | |
| **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: | | |  |