

WORKSHEET: Compassionate Use of an Unapproved Medical Device

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| 8.205 (HRP-325) | 5/1/2024 | 1 of 1 |

The purpose of this worksheet is to provide support for investigators conducting non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use) and to provide support to Designated Reviewers reviewing such uses. This worksheet is to be used when overseeing such uses. It does not need to be completed or retained.
(LAR = "subject's Legally Authorized Representative")

Compassionate Use of an Unapproved Device¹

1 Criteria for Compassionate Use of an Unapproved Device (Check if "Yes." All must be checked.)

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|--------------------------|---|
| <input type="checkbox"/> | The patient is confronted by a serious disease or condition. |
| <input type="checkbox"/> | No generally acceptable alternative for treating, diagnosing, or monitoring the patient is (was) available. |
| <input type="checkbox"/> | The probable risk to the patient is not greater than the probable risk from the disease |
| <input type="checkbox"/> | The patient does not meet the inclusion criteria for an IDE study. |
| <input type="checkbox"/> | The treating physician will document in the medical record that the above findings were met. |
| <input type="checkbox"/> | The treating physician has/will obtain approval from FDA for the use. |
| <input type="checkbox"/> | If an IDE exists for the device, the sponsor has authorized its use. |
| <input type="checkbox"/> | All institutional clearances have been obtained. |
| <input type="checkbox"/> | Concurrence of an IRB Chair has been (will be) obtained. |
| <input type="checkbox"/> | The treating physician will report any problems as a result of the device use to the IRB and sponsor. |
| <input type="checkbox"/> | The treating physician will provide follow-up information (if applicable) of the use and give it to the sponsor, the FDA and the IRB. |
| <input type="checkbox"/> | The use is NOT research subject to DHHS regulation See 3.207 (HRP-310) - WORKSHEET: Human Research Determination. |

2 Consent Criteria (Check if "Yes". All must be checked)

| | |
|--------------------------|--|
| <input type="checkbox"/> | Informed consent will be sought from the patient or the patient's LAR ² |
| <input type="checkbox"/> | Informed consent will be documented using HRP-506 CONSENT DOCUMENT: Informed Consent for Emergency Treatment with an Unapproved Article or Compassionate Use of an Unapproved Medical Device. ³ |

¹ FDA does not consider the compassionate use of an unapproved device to be a clinical investigation, and FDA does not require compliance with 21 CFR §50 and 21 CFR §56. The requirements are based on FDA guidance at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm#compassionateuse>, and <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf>.

² FDA does not require the consent process to follow the informed consent requirements at 21 CFR §50. However, when research involves adults with impaired decision-making capacity, consent must comply with NJ State Statute 26:14.1-5.

³ FDA does not require the documentation of consent to follow the informed consent requirements at 21 CFR §50.27.