HRP-325 | 2/2/2024

WORKSHEET: Compassionate Use of an Unapproved Medical Device

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 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")[1]

Compassionate Use of an Unapproved Device[2]

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

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

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

- ☐ Informed consent will be sought from the patient or the patient's LAR.[3]
- ☐ Informed consent will be documented using HRP-506 - TEMPLATE CONSENT DOCUMENT – Expanded Access.[4]

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[1] This document satisfies AAHRPP element I.7.C

[2] 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 https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm#compassionateuse, and http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf.

[3] FDA does not require the consent process to follow the informed consent requirements at 21 CFR §50.

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