Title: Humanitarian Use Device (HUD) Review

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<th>SOP #</th>
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Reviewed/Recommended for Approval:
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Date: 3/7/15

Approved:
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Date: 3/2/15

1 PURPOSE
1.1 This document describes the policies and procedures about medical devices that have been classified by the Food and Drug Administration (FDA) as Humanitarian Use Devices (HUDs).
1.2 This process begins when HRPO staff receive a submission to deploy a humanitarian use device.
1.3 This process ends when the HRRC make a determination regarding the deployment of the HUD, and that determination is communicated to the submitting party.

2 REVISIONS FROM PREVIOUS VERSIONS
None.

3 POLICY
3.1 The HRPO and HRRC applies the regulations of the Food and Drug Administration (FDA) when clinicians use a Humanitarian Use Device (HUD). This includes the requirement to obtain prospective HRRC approval and ongoing review, even though the clinical use of a HUD is not considered to be research.

3.2 The HRRC requires that documented consent be obtained from patients for the use of a HUD whenever possible.

3.3 Policies for different uses of HUDs are summarized here:
3.3.1 Clinical non-emergency use "on label": requires standard HRRC review and approval.
3.3.2 Clinical non-emergency use "off label": requires standard HRRC review and approval.
3.3.3 Clinical single patient non-emergency use "off label": follow the compassionate use procedures (SOP HRP-23).
3.3.4 Clinical single patient emergency use "on label": follow standard single patient emergency use procedures (SOP HRP-23).
3.3.5 Clinical single patient emergency use "off label": follow standard single patient emergency use procedures (SOP HRP-23).
3.3.6 Research on the approved use of a HUD (including the approved population): requires standard HRRC review and approval.
3.3.7 Research on a new use (or population) of a HUD: requires standard HRRC review and approval.
3.4 Continuing review of the use of HUDs may be conducted by Non-Committee Review process, if deemed appropriate by the HRRC and the HUD is being used solely for clinical purposes.

4 RESPONSIBILITIES
4.1 HRPO staff and Designated Reviewers are responsible for carrying out these procedures.

5 PROCEDURES
5.1 HRPO staff use the "WORKSHEET: Criteria for Approval for HUD (HRP-323)" or equivalent to evaluate whether the submission will meet the regulatory and guidance criteria for the review of a HUD and will communicate the results of this determination to the reviewer or convened HRRC.

5.1.1 The HRRC will review the submission at a convened meeting ensuring that appropriate expertise is available either within the membership in attendance or via the use of consultants.

5.1.2 The HRRC will review the risks to patients that are described in the product labeling and other materials, the proposed procedures to ensure that risks are minimized, and will evaluate whether the risks are reasonable in relation to the potential benefits to patients.

5.1.3 The HRRC will evaluate the patient information packet and proposed consent process and will determine if the materials are adequate and appropriate for the patient population.

5.1.4 The HRRC may specify limitations on the use of the device, require additional screening and follow up procedures, require interim reports to the HRRC, require continuing review more often than annually, or set other conditions or requirements as appropriate to minimize risks to patients and ensure the safe use of the device.

5.2 Once use of the HUD is approved, the health care provider is responsible for submitting any modifications to the HRRC-approved plan or patient materials and obtaining approval for those modifications prior to implementation, unless the change is necessary to avoid or mediate an apparent immediate risk to a patient.

6 MATERIALS
6.1 WORKSHEET: Criteria for Approval for HUD (HRP-323)
6.2 SOP: Pre-Review (HRP-021)
6.3 SOP: Post-Review (HRP-052)
6.4 SOP: Emergency Use of a Test Article and Compassionate Use of an Unapproved Device (HRP-023)
6.5 SOP: Emergency Use and Compassionate Use of an Unapproved Device Post-Review (HRP-027)

7 REFERENCES
7.1 Guidance for Industry and FDA Staff - Humanitarian Use Device (HUD) Designations (Jan 24, 2013)
7.2 21 CFR 814.102(a), 21 CFR 814.3(n)