SOP: All Emergency Use, Compassionate Use (Device Only) and IRB Waiver for Individual Patient Expanded Access (Drug Only) Post-Review

1 PURPOSE

1.1 This procedure establishes the process to communicate the review of:

1.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation.

1.1.2 Non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use).

1.1.3 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested.

1.1.4 The use of an investigational drug, agent, or biologic as part of the Right to Try (RTT) Act.

1.2 The process begins when the Designated Reviewer has notified IRB staff of whether an actual or proposed use has followed or will follow FDA regulations and guidance.

1.3 The process ends when the IRB staff has communicated the results to the physician and if necessary initiated the non-compliance process.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 None

4 RESPONSIBILITIES

4.1 IRB staff carry out these procedures.

5 PROCEDURE

5.1 For emergency use of a drug, biologic, or device in a life-threatening situation:

5.1.1 If the Designated Reviewer has indicated that the proposed use will follow FDA regulations:

5.1.1.1 Complete HRP-570 - LETTER - Pre-Rev EU - Crit Met and send to the physician.

5.1.1.2 Set a 5 day deadline for receipt of the 5 day report.

5.1.2 If the Designated Reviewer has indicated that the proposed use will NOT follow FDA regulations, complete HRP-571 - LETTER - Pre-Rev EU - Crit Not Met and send to the physician.

5.1.3 If the Designated Reviewer has indicated that the actual use described in the 5-day report followed FDA regulations, complete HRP-572 - LETTER - Review of EU - Crit Met and send to the physician.

5.1.4 If the Designated Reviewer has indicated that the proposed use did NOT follow FDA regulations:

5.1.4.1 Complete HRP-573 - LETTER - Review of EU - Crit Not Met and send to the physician.

5.1.4.2 Manage under HRP-024 - SOP - New Information as Non-Compliance.

5.2 For compassionate use of a device, complete HRP-574 - LETTER - Device Compassionate Use.

5.3 For non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested, complete HRP-575 - LETTER - Rev of IRB Waiver for Indiv Pt Drug Exp Access.

5.4 For RTT use the HRP-510 - LETTER – Approval. Letter to be customized in accordance with RTT. See prior RTT cases in HRP Shared Folder or WIKI for reference.

5.4.1 Biannually, via email, the HRP will report the following status as required to the State Department of Public Health, the Medical Board of California, and the Osteopathic Medical Board of California:

5.4.1.1 The duration of the treatment.

5.4.1.2 The costs of the treatment paid by eligible patients.

5.4.1.3 The success or failure of the investigational drug, biological product, or device in treating the immediately life-threatening disease or condition from which the patient suffers.

5.4.1.4 Any adverse event for each investigational drug, biological product, or device

6 MATERIALS

6.1 HRP-024 - SOP - New Information

6.2 HRP-570 - LETTER - Pre-Rev EU - Crit Met

6.3 HRP-571 - LETTER - Pre-Rev EU - Crit Not Met

6.4 HRP-572 - LETTER - Review of EU - Crit Met

6.5 HRP-573 - LETTER - Review of EU - Crit Not Met

6.6 HRP-574 - LETTER - Device Compassionate Use

6.7 HRP-575 - LETTER - Rev of IRB Waiver for Indiv Pt Drug Exp Access

7 REFERENCES

7.1 21 CFR §50.23; 21 CFR §50.24; 21 CFR §56.102(d); 21 CFR §56.104(c); 21 CFR §56.105/ FDA Form 3926

7.2 21 CFR §812.36; 21 CFR §812.47.

7.3 (FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors) Frequently Asked Questions About Medical Devices: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf.

7.4 UC Office of the General Counsel Health Sciences Research Advisory: *Clinical Use of Investigational Drugs, Devices and Biologics under Federal and California Law*, November 2018