corticalmetrics

SOP: EMERGENCY AND COMPASSIONATE USES

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1. PURPOSE

1.1. This procedure establishes the process to assist treating physicians to comply with FDA requirements for <Emergency Uses> and <Compassionate Uses>.

1.2. This procedure begins when an HRPP staff member notifies a <Designated Reviewer> of a situation that might involve an <Emergency Use> or a <Compassionate Use>.

1.3. This procedure ends when the <Designated Reviewer> informs the submitter and HRPP staff members of whether the use complies or complied with FDA requirements.

2. POLICY

2.1. Whenever possible, physicians are to notify the IRB in advance of a proposed <Emergency Use>.

2.2. Physicians are to notify the IRB in advance of a proposed <Compassionate Uses>.

2.3. Data obtained from uses covered by this SOP cannot be used in a non-exempt systematic investigation designed to develop or contribute to generalizable knowledge.

2.4. <Designated Reviewers> can inform submitters of whether a proposed use, if carried out as described, will meet FDA requirements or whether a use already carried out met FDA requirements. The IRB has no authority to prospectively or retrospectively approve or disapprove a use.

2.5. HRPP staff members follow “SOP: Post Review (CM-127)” to provide written notification to the submitter of the results of this SOP.

2.6. The emergency use of a drug or biologic is “research” as defined by FDA, the patient is a “subject” as defined by FDA, and the FDA may require data from an emergency use to be reported in a marketing application.

3. RESPONSIBILITY

3.1. A <Designated Reviewer> carries out these procedures.

4. PROCEDURE

4.1. Review the information provided and if needed contact the submitter or physician.

4.2. Determine whether the situation is:

- 4.2.1. <Emergency Use> of a drug or biologic.
- 4.2.2. <Emergency Use> of a device.
- 4.2.3. <Compassionate Use>.
- 4.2.4. None of the above. If so, stop all processing under this SOP and notify the submitter and the HRPP staff member.

4.3. Determine whether the use meets or met FDA requirements.

4.4. Notify the submitter of the determination or work with the submitter to have the use comply with FDA requirements.

- 4.4.1. If a use was carried out and did not meet FDA requirements, handle this as <Noncompliance> under “SOP: New Information (HRP-128).”

4.5. Notify the HRPP staff member handling the submission of the decision and the reasons.

5. REFERENCES

5.1. 21 CFR §56.102(d) 21 CFR §56.104(c)

5.2. FDA Guidance: IDE Early/Expanded Access