1. PURPOSE

1.1. This procedure establishes the process to assist treating clinicians to comply with FDA requirements for Expanded Access for an individual patient.

1.2. This procedure begins when a clinician/investigator or an IRB staff member notifies an Executive Reviewer of a situation that might involve an Expanded Access for an individual patient that cannot wait for full Board review.

1.3. This procedure ends when the Executive Reviewer informs the clinician and IRB staff members of whether the use complies or complied with FDA requirements; and the full Board has reviewed and approved the subsequent submission for this Expanded Access.

2. POLICY

2.1. Whenever possible, clinicians are to notify the IRB Chair or staff in advance of a proposed Expanded Access for an Individual patient.

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

2.3. Executive 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.

2.4. IRB staff members follow “POLICY: Post Review (HRP-111)” to provide written notification to the submitter of the results of this Policy.

2.5. The expanded access for a single patient of a drug, biologic, or medical device is “research” as defined by FDA, the patient is a “subject” as defined by FDA, and the FDA may require data from such an expanded access to be reported in a marketing application.

3. RESPONSIBILITY

3.1. A Executive Reviewer carries out these procedures.

4. PROCEDURE

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

4.2. Determine whether the situation is in compliance with the Expanded Access for an Individual Patient regulations.

4.3. Notify the clinician who submitted the Expanded Access of the determination or work with the clinician to have the use comply with FDA requirements.

4.4. Notify the clinician that the Expanded Access for an Individual patient must be reported to the IRB within 5 working days of the use of the investigational drug, biologic, or medical device.

4.4.1. If a use was carried out and did not meet FDA requirements, handle this as Noncompliance under “POLICY: Reportable Events (HRP-112).”

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

4.6. Once the required submission is received by the IRB, it may be placed on a future full Board meeting for confirmation.

5. REFERENCES

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

5.2. FDA Guidance: IDE Early/Expanded Access