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Streamlining Procedures for Single Patient Expanded Access Requests Involving Investigational New Drugs

Four Steps:

1. Revise IRB application procedures so that the treating physician may submit as the application:

    - FDA Form 3926
    - Investigator Brochure or another source of information to determine risks and potential benefits
    - Draft consent document

The above three documents allow the IRB to make the regulatory determinations required to approve the treatment use in 21 CFR 56.111. If you believe it is necessary, add a question to inquire about protecting privacy interests and a question to inquire about maintaining the confidentiality of data, which in this case is the medical record. However, if your IRB understands the practice of your treating physicians to make determinations related to privacy interests and confidentiality, then adding such questions may not be necessary.

2. Revise procedures to ensure that your IRB is able to handle requests in a timely fashion.

    - When a request is made to the IRB office, there is a procedure to handle it (i.e., a process to log it in and decide how it should be handled) within 24 hours.
    - Schedule the request for the next IRB meeting if you have IRB meetings at least weekly.
    - If your IRB meets less frequently than weekly, consider whether you can compose a rapid review IRB. This IRB could be composed of five members, where three must be present for a meeting. Medical expertise could be provided through a consultant, if the experience is not available from the IRB members on the rapid review IRB.
    - If the convened IRB is not able to approve the request because it needs further information, use the expedited review procedure for review of the response, if possible.

3. Provide recommendations or similar guidance to your IRB members about how to review single patient expanded access requests. To determine whether the criteria for approval (21 CFR 56) and the single patient expanded access regulations (21 CFR 312.305 and 312.310) are met, the IRB should:

- Confirm the medical evaluation of the patient's condition based on the information provided by the treating physician. An IRB member or consultant who is a physician and experienced in the condition/disease completes the evaluation. This individual must be able to confirm or deny the claim that there is no comparable or satisfactory alternative available.
- Ensure that informed consent or appropriate permissions will be obtained and documented. Given the compassionate nature of the request and FDA's involvement, consent documents should meet the requirements listed in 21 CFR 50.25, using plain language that is specifically aimed at "patients" who expect direct benefit, as opposed to "subjects" who may not expect benefit.
- Receive documentation that FDA has made its determinations regarding safety and effectiveness and has given clearance for the use.
- Review the physician's treatment plan (or sponsor-provided treatment protocol) and determine that it makes adequate provision for ensuring the safety of the patient including adequate monitoring (timing and type of tests/exams, etc.) and appropriate plans for collecting and reporting the data.
- Confirm that HIPAA requirements will be followed to ensure confidentiality of the medical record. This may be determined by the IRB without any additional information from the treating physician if the IRB knows the practice at your medical facility.
- Confirm that the treating physician will follow standard medical practice to protect the privacy interests of the patient. This may be determined by the IRB without any additional information from the treating physician if the IRB knows the practice at your medical facility.
- When the patient is a child, confirm the provisions of 21 CFR 50.52 are met.
- When the patient is likely to be vulnerable to coercion or undue influence additional safeguards are included in the treatment plan to protect the rights and welfare of the patient.

4. Publish procedures so that they are available to treating physicians and IRB members.