Step-by-Step Process to Obtain a Single Patient IND (Non-emergency)

1. Discuss available treatment options with the patient and decide, along with your patient, whether a clinical trial or treating with an investigational drug, biologic, or device outside a clinical trial is appropriate. This will be dependent upon the patient's medical history, whether there are approved therapies available with which the patient has not been treated, and whether they are eligible to enter a clinical trial for the product. Only patients with a serious or life-threatening disease or condition are eligible for expanded access consideration.

2. Select the investigational product that you want to use for treatment. This may occur in several ways: the patient brings information about the investigational product to you, you consult clinicaltrials.gov or RUF Navigator to find which investigational products are available through a company's expanded access program, you contact the drug, biologic or device company.

   Every company is mandated by the 21st Century Cures Act to publish its policy regarding expanded access, and provide contact information for requests.

   A company that does not have a listed expanded access program may be willing to provide its product outside of its ongoing clinical trial(s) and, therefore, you should contact the company.

3. Follow the company's instructions for requesting a single patient IND (treatment use).

4. After you receive the company's decision, if the company agrees to provide the product, they will provide a Letter of Authorization (LOA), allowing FDA to cross-reference their Investigational New Drug Application (IND). This signals FDA that the company will make their product available outside of the clinical trial setting.

   See FDA's Expanded Access Contact Information website for physicians to locate the appropriate review division to file the request. You will need to complete FDA Form 3926 (you may need to open the page in Internet Explorer or save the document as a PDF to your desktop by selecting "save page as" under your browser's file menu before opening it) describing the patient's medical history and current status, proposed treatment protocol (such as dose, treatment duration, concomitant conditions/medications, etc., and rationale for the proposed treatment). You will also need to attach your curriculum vitae to confirm medical qualification, and provide any background information about the product, regarding known safety or efficacy, and the letter of authorization (LOA) from the company. You will also confirm on the application that treatment will not begin without prospective IRB review and documentation of informed consent, once you receive confirmation from FDA.

5. FDA has up to 30 days to make a determination, and usually will respond sooner. If the determination is to proceed, FDA will send you a letter with the IND number and any concerns, recommendations, or stipulations.

6. While you are waiting for FDA's determination, contact the IRB office in your institution or the IRB that your institution uses to make them aware that the expanded access request will be coming to them shortly for review. If you don't have access to an IRB, contact WCG Foundation at info@wcgfoundation.org or call 404.386.8982 to find an IRB that will conduct the review for you.

   After you receive FDA approval, submit Form 3926, a draft informed consent document, and any other documents required by the IRB for review. Be sure to check the box on Form 3926 requesting a waiver of the requirement for the full IRB to review the request. The IRB chair or a designee will review the request.

7. Once you have received IRB approval, and the patient has reviewed and signed the informed consent document, you may begin to treat the patient.

8. Review FDA's requirements for physicians who treat patients under a single patient IND. They are listed below:

   - Seek IRB approval for continuing review if the treatment use extends longer than one year or a second dose is needed.
   - Maintain accurate case history records and observations related to provision of product, including adverse events.
   - Report adverse events as required by FDA.
   - Maintain accurate documentation of the disposition of investigational product, including dates, quantity and use.
   - Adhere to reporting obligations of IRB, FDA, and sponsor.
   - Prepare and send summary report of treatment use to sponsor and FDA.
   - Maintain confidentiality of the information both about the patient and the condition.