REAGAN-UDALL FOUNDATION
FOR THE FOOD AND DRUG ADMINISTRATION

SINGLE-PATIENT EA DOCUMENT CHECKLIST

The process for obtaining single-patient expanded access (EA) has several steps and documents to organize. This checklist offers a brief overview of the documents a licensed physician must fill out or obtain from the pharmaceutical company, the FDA, or the IRB.

PHARMACEUTICAL COMPANY

DRUG REQUEST FORM

Some pharmaceutical companies may ask the physician to provide a drug request form. Contact the company to find out about their process for requesting expanded access and what information you will need to provide. You can find a pharmaceutical company's contact information and requirements for expanded access requests in the EA Navigator **Company Directory**. If the company is not listed in the Directory, search clinicaltrials.gov for information. If a company requires a drug request form, it will likely include:

- The patient's clinical history
- The rationale for why this treatment may be effective
- The physician's regulatory knowledge of the product and experience using experimental treatments
- A proposed treatment plan (which may be determined in concert with the pharmaceutical company).

REQUIRED DOCUMENTATION

If the pharmaceutical company decides to grant the request to use the investigational drug, the company's representative will provide required documentation such as a **Letter of Authorization (LOA)**. The physician will submit a copy of the required documentation to the FDA and Institutional Review Board (IRB) later in the application process in order to verify the company has approved the physician's use of the investigational treatment for single-patient EA. If a LOA is unavailable, the FDA still needs sufficient information to assure the product's quality.

THE FDA

FORM FDA 3926

The FDA requires that **Form FDA 3926,** or Individual Patient Expanded Access Investigational New Drug Application, is submitted by the physician or physician's representative. Form FDA 3926 includes:

- A brief clinical history of the patient
- Proposed treatment plan using the investigational treatment
- The name of the pharmaceutical company
- Indication that the physician will obtain informed consent from the patient

- Commitment that the physician will receive approval from an Institutional Review Board (IRB)
- Information concerning the physician's training, experience, and licensure

Instructions for filling out Form FDA 3926 are available **here**. Contact information and procedures for the submission of Form FDA 3926 can be found **here**.

INSTITUTIONAL REVIEW BOARD

IRB TREATMENT PROTOCOL

Once the pharmaceutical company has agreed to provide the investigational treatment and Form FDA 3926 has been submitted to the FDA, the physician must submit an expanded access treatment protocol to an Institutional Review Board (IRB). An IRB can be found through the **HHS Registry of IRBs**, or the physician's medical institution. Physicians who aren't affiliated with an institutional IRB can also use an independent IRB that is familiar with reviewing EA requests, including **Western IRB**, **Quorum Review IRB**, **Chesapeake IRB**, and **Sterling IRB**. For more information, questions or assistance with IRB procedures, visit the **WCG Foundation.**

INFORMED CONSENT FORM

The informed consent form provides patients with information about a protocol, including patient expectations and known possible outcomes and risks. The informed consent must be submitted to the IRB for review. Following the IRB's approval, the treating physician must review the informed consent form with the patient. The FDA also may ask to see the informed consent form.

REPORTING DOCUMENTS

As the patient undergoes treatment with the investigational treatment, the physician must follow the treatment protocol agreed upon with the IRB and the pharmaceutical company. The physician must report the following to the FDA and IRB:

- Serious and unexpected adverse events (view guidelines for determining adverse events **here**)
- Changes to the treatment plan
- End of treatment