INSTRUCTIONS FOR FILLING OUT FORM FDA 3926 – INDIVIDUAL PATIENT EXPANDED ACCESS, INVESTIGATIONAL NEW DRUG APPLICATION (IND)

(The field numbers below correspond to the numbered boxes on the Form FDA 3926.)

Field 1: PATIENT'S INITIALS

Enter the patient's initials (not the full name, to preserve confidentiality). The patient need not initial the form.

Field 2: DATE OF SUBMISSION

Provide the date of the submission in the following format: mm/dd/yyyy.

Field 3: TYPE OF SUBMISSION

(3.a.) Initial Submission: If the submission is an initial (original) submission for an individual patient expanded access IND (including for emergency use), select the box provided in field 3.a. and complete only fields 4 through 8, and fields 10 and 11.

(3.b.) Follow-Up Submission: If this is a follow-up submission to an existing individual patient expanded access IND, select the box provided in field 3.b. and complete the items to the right of the checkbox in field 3.b. (Investigational Drug Name and the physician's existing IND Number), and fields 8 through 11. Do not include the commercial sponsor's IND number.

Field 4: CLINICAL INFORMATION

Provide the indication (proposed treatment use) and a brief clinical history of the patient. The clinical history includes age, gender, weight, allergies, diagnosis, prior therapy, response to prior therapy, and the reason for requesting the proposed treatment, including an explanation of why the patient lacks other therapeutic options.

Field 5: TREATMENT INFORMATION

Provide treatment information, including the investigational drug's name and the name of the entity supplying the drug (generally the manufacturer), the applicable FDA review division (if known), and a concise statement regarding the treatment plan. This includes the planned dose, route and schedule of administration, planned duration of treatment, monitoring procedures, and planned modifications to the treatment plan in the event of toxicity. The information should be entered within the space provided.

Field 6: LETTER OF AUTHORIZATION (LOA), IF APPLICABLE

An LOA grants FDA the right to reference another application (IND) for information to satisfy submission requirements, such as a description of the manufacturing facility, chemistry, manufacturing and controls information, and pharmacology and toxicology information.

How to obtain an LOA: The physician is responsible for obtaining the LOA in advance from the entity that is the sponsor of the IND (e.g., commercial sponsor/drug manufacturer) being referenced. Physicians should attach the LOA to Form FDA 3926. The LOA should include the IND number for the application being referenced.

If the LOA is unavailable: In cases where it is not possible to obtain an LOA (e.g., the entity supplying the drug does not have an IND already filed with FDA), physicians should contact the applicable FDA review division (see *http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm429610.htm*) to determine what other sources of information may satisfy the regulatory requirements.

For emergency individual patient expanded access INDs, the physician must submit the LOA (if applicable) and all other paperwork (including Form FDA 3926) to FDA within 15 working days of FDA's initial authorization.

Field 7: PHYSICIAN'S QUALIFICATION STATEMENT

Provide a statement of the physician's qualifications. An appropriate qualification statement includes the medical school attended, year of graduation, medical specialty, state medical license number, current employment, and job title. Alternatively, the relevant portion of the physician's curriculum vitae that includes this information (usually the first few pages) may be attached.

Field 8: PHYSICIAN'S NAME, ADDRESS, AND CONTACT INFORMATION

Enter the physician's name and contact information, including the physical address, email address, telephone number, facsimile (FAX) number, and physician's IND number, if previously issued by the FDA. Do not include the commercial sponsor's IND number here.

Field 9: CONTENTS OF SUBMISSION (FOLLOW-UP/ADDITIONAL SUBMISSIONS ONLY)

This field should only be completed for follow-up/additional submissions to an existing individual patient expanded access IND. Select the appropriate box (or boxes, if more than one apply) and attach the materials indicated for the following categories of follow-up/additional submissions (the relevant FDA regulations are provided in parentheses for additional details).

If none of the following apply to the follow-up/additional communications, use Form FDA 1571 for your submission.

- *Initial Written IND Safety Report:* A report of potential serious risks to be submitted as soon as possible but no later than 15 calendar days after the sponsor (i.e., the physician, who is considered a sponsor-investigator) determines that information qualifies for reporting, or, a report of unexpected fatal or life-threatening suspected adverse reactions, submitted no later than 7 calendar days after the sponsor's initial receipt of the information (21 CFR 312.32(c))
- *Follow-up to a Written Safety Report:* A follow-up report to an IND safety report, to be made as soon as the information is available but no later than 15 calendar days after the sponsor receives the information (21 CFR 312.32(d))
- *Annual Report:* A brief report of the progress of the investigation, submitted within 60 days of the anniversary date that the IND went into effect (21 CFR 312.33)
- *Summary of Expanded Access Use (treatment completed):* A written summary of the results of the expanded access use, including adverse effects, at the conclusion of treatment (21 CFR 312.310(c)(2))
- *Change in Treatment Plan:* Also known as protocol amendments; a submission describing changes in the IND, including changes of investigators (21 CFR 312.30)
- *General Correspondence:* Any other communication between the sponsor and FDA pertinent to the investigation (21 CFR 312.41)
- *Response to FDA Request for Information:* A submission containing responses to clinical information requests (21 CFR 312.41)
- *Response to Clinical Hold:* A submission correcting deficiencies previously cited in a FDA Clinical Hold letter (21 CFR 312.42(e))

Field 10.a: REQUEST FOR AUTHORIZATION TO USE FORM FDA 3926 FOR INDIVIDUAL PATIENT EXPANDED ACCESS

Select this box to request under 21 CFR 312.10, that FDA accept the completed Form FDA 3926 to satisfy FDA's requirements for submitting an individual patient expanded access IND.

~~Generally, an IND submission for purposes other than individual patient expanded access includes additional information, beyond that included in Form FDA 3926. Therefore, consistent with 21 CFR 312.10, FDA intends to considers a completed Form FDA 3926 with the box in Field 10.a checked and the form signed by the physician, to be a request for a waiver of any additional requirements in 21 CFR part 312 for an IND submission.~~

Field 10.b: REQUEST FOR AUTHORIZATION TO USE ALTERNATIVE IRB REVIEW PROCEDURES

~~Select this box for the IRB review to be conducted by a single person (the IRB chairperson or a designated IRB member).~~ Select~~ing~~ this box ~~will~~ to request under 21 CFR 56.105, authorization to obtain concurrence by the IRB chairperson or by a designated IRB member, instead of at a convened IRB meeting, before the treatment use begins, in order to comply with FDA's requirements for IRB review and approval.

~~Consistent with 21 CFR 56.105, FDA considers a Form FDA 3926 with the box in Field 10.b. checked and the form signed by the physician to be a request for a waiver of the requirements in 21 CFR 56.108(c), which relate to IRB review and approval at a convened IRB meeting at which a majority of the members are present. FDA concludes that such a waiver is appropriate for individual patient expanded access INDs when the physician obtains concurrence by the IRB chairperson or another designated IRB member before treatment use begins.~~

Field 11: CERTIFICATION STATEMENT AND SIGNATURE OF THE PHYSICIAN

The licensed physician identified in Field 8 must sign this field. By signing this field, the physician certifies that treatment will not begin until 30 days after FDA receives the completed application and all required materials unless the submitting physician receives earlier notification from FDA that the treatment may proceed. The physician agrees not to begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold. The physician also certifies that informed consent will be obtained in compliance with F~~ederal~~DA requirements (~~including~~see ~~FDA's regulations in~~ 21 CFR part 50) and that an Institutional Review Board (IRB)
~~that complies with all Federal requirements (including FDA's regulations in 21 CFR part 56)~~ will be responsible for initial and continuing review and approval of the expanded access use, consistent with applicable FDA requirements (see 21 CFR part 56). ~~If the Form FDA 3926 is completed, signed by a physician, and has the box in Field 10.b. checked, IRB review and approval would involve concurrence by the IRB chairperson or by a designated IRB member in lieu of review and approval at a convened meeting at which a majority of the IRB members are present.~~ The physician also acknowledges that in the case of an emergency request, treatment may begin without prior IRB approval provided the IRB is notified of the emergency treatment within 5 working days of treatment. The physician agrees to conduct the investigation in accordance with all other applicable regulatory requirements.