**Expanded Access Request for Use for a Single Patient**

Prior to preparing and submitting documents for an individual patient expanded access investigators should review [Policy 2011-022.2](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPP-CR-Pol-2011-022.2.pdf) - Investigational Drug/Biologic - Expanded Access for Treatment Use, Including Single Emergency Use.

For non-emergency expanded access requests for an individual patient, IRB review and approval is required before treatment begins. However, if prior review and approval is not possible due to an immediate life threatening situation, the emergency use for individual patient expanded access does not require prior IRB review, but the IRB must be notified within five working days of treatment initiation, and any subsequent use of the investigational drug is subject to prior IRB review. Prior approval from the FDA must always be obtained.

Submissions are to be made through the iRIS system and non-emergent use will be reviewed by the convened board. Expedited review may be requested for: 1) Emergency Use for a single patient in a life threatening situation such that there is/was not time for review by the convened IRB, or 2) for a single patient COVID-19 Expanded Access request for which a waiver of the requirement for full board review has been made to the FDA in accordance with the FDA guidance that review by the IRB Chair or designee is sufficient.

Is this an EMERGENCY request such that there is/was not time for the board to convene as the patient is/was in an **immediately** life threatening condition?

YES\_\_\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_\_\_\_

If yes, is this a request for prospective review of emergency use, or the 5-day notification that the use has already occurred?

PROSPECTIVE REQUEST\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 5-DAY NOTIFICATION \_\_\_\_\_\_\_\_\_\_

For a prospective request of emergency use, the investigator should also send an email alert to the IRB such that the submission will be prioritized. The emails should be sent gneiting@uchc.edu, mackinnon@uchc.ed and jblair@uchc.edu

COVID-19 STATUS – is this request for a single patient expanded access related to the COVID-19 pandemic for which a waiver of the request for review be the convened board was made to the FDA?

YES\_\_\_\_\_\_\_\_\_\_ NO\_\_\_\_\_\_\_\_\_\_\_\_

The information provided to the IRB for the use of this investigational drug should include the following information. If a noted element is contained within the FDA form 3926 or 1571, or a protocol, simply add a comment to reference that form (e.g. see form 3926).

**Continuing Review Requirement:** If the use of the drug exceeds the initial approval period the investigator must seek continuing approval using this document as a guideline for submission requirements. If there are no changes to the single-patient consent form it need not be submitted for continuation.

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| **Submission Elements:** | **Check or Add Comment** |
| A summary of the qualifications of the physician submitting the individual patient expanded access request (e.g. c.v. or written summary) |  |
| Assurance from the prescribing person that this use is NOT part of a project that is currently awaiting IRB approval |  |
| Assurance that the use of the drug(s) or biologic is primarily to treat a patient with a specific, clinically urgent, condition; and that the patient is not a research subject |  |
| A brief written statement explaining the rationale for the use of the investigational drug or biologic |  |
| A formal statement from the manufacturer (or distributor) of the investigational drug , that the prescribing person has received approval for use of the investigational agent (e.g. Letter of Authorization from the sponsor of the IND) |  |
| If a submission has been made to the FDA, provide all materials that were sent to the FDA, including* Form FDA 3926 for Individual Patient Expanded Access (or Form 1571 for other types of Expanded Access Requests if that was used in place of Form 3926)
 |  |
| * The rationale for the intended use of the drug, including a list of available therapeutic options that would ordinarily be tried before resorting to the investigational drug or an explanation of why the use of the investigational drug is preferable to the use of available therapeutic options;
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| * The criteria for patient selection or, for an individual patient, a description of the patient's disease or condition, including recent medical history and previous treatments of the disease or condition
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| * The method of administration of the drug, dose, and duration of therapy
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| * A description of the facility where the drug will be manufactured
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| * Chemistry, manufacturing, and controls information adequate to ensure the proper identification, quality, purity, and strength of the investigational drug
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| * Pharmacology and toxicology information adequate to conclude that the drug is reasonably safe at the dose and duration proposed for expanded access use (ordinarily, information that would be adequate to permit clinical testing of the drug in a population of the size expected to be treated)
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| * A description of clinical procedures, laboratory tests, or other monitoring necessary to evaluate the effects of the drug and minimize its risks.
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| * Justification that the probable risk to the person from the investigation agent is not greater than the probable risk from the disease or condition
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| * A thorough patient history
 |  |
| For Emergency Use, if a submission was not made to the FDA, a statement or documentation noting the date of the FDA's verbal authorization. |  |
| Protocol, if one is available. (In the context of an individual patient expanded access request, a protocol may not be necessary to provide the IRB with sufficient information to determine that risks have been minimized and are reasonable in relation to anticipated benefits. This information may be contained in other documents such as the Form 3926) |  |
| For COVID-19 expanded access for single patient, documentation of request/approval for waiver of need for full board review from FDA. |  |
| CONSENT FORMS |  |
| A copy of the consent form that will be used by the prescribing person to obtain informed consent from the patient or the patient’s legally authorized representative. * Such consent form to include: a description of the clinical protocol (length of administration, dosage, method of evaluation of efficacy, side effects, etc.)
* a statement in the informed consent document indicating that although the primary use of the drug is for treatment, the drug is investigational and FDA **has not** determined that the drug is safe or effective for use in treating the patient’s condition can be used to satisfy the requirement that the informed consent provide a statement that the use of the product “involves research.”
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| If consent cannot be obtained, the investigator/clinician and a licensed physician who is not otherwise participating in the intervention must certify in writing that the four criteria for not obtaining consent are met (template available on IRB website): |  |
| When the request is for a pediatric patient, provisions are included for soliciting age-appropriate assent from children (which may require a written assent statement) and permission from a parent or guardian, as required under 21 CFR 50.55  |  |
| **Additional Requirements for Continuing Review:**  |  |
| If the investigator is the sponsor on of the IND, the annual report submitted to the FDA |  |
| A summary of any adverse events experienced by the subject is to be included in the request for CR form.  |  |

**Note**: Investigators are responsible for reporting adverse drug events to the sponsor, and, with the possible exceptions for emergency use noted below, ensuring that informed consent requirements are met and that IRB review of the expanded access use is obtained prior to use of the investigational agent. Investigators are also responsible for maintaining accurate case histories and drug disposition records and retaining records. If the use will extend beyond one year the investigator must seek continuing approval