

OHRS Information Sheet

Single Patient IND and Emergency Use of a Test Article

A. Single Patient IND

FDA regulations at 56 CFR 312.34 permit the use of an unapproved drug in the treatment of a patient, not in a clinical trial, under a treatment protocol or treatment IND, under the following circumstances:

1. The drug is intended to treat a serious or immediately life-threatening disease;
2. There is no comparable or satisfactory alternative drug or other therapy available to treat that stage of the disease in the intended patient population;
3. *The drug is under investigation in a controlled clinical trial under an IND in effect for the trial, or all clinical trials have been completed; and*
4. The sponsor of the controlled clinical trial is actively pursuing marketing approval of the investigational drug with due diligence.

Prior IRB review and approval as well as informed consent are required for a single patient IND.

1. The following documents are required for submission of a single patient IND:
2. Front sheet;
3. Radiation safety screening form;
4. Investigator signature pages;
5. Protocol;
6. Consent;
7. Letter from the sponsor agreeing to request the IND from the FDA;
8. FDA approval or documentation that FDA approval will be pursued and provided to OHRS; and
9. Letter from the investigator explaining why the single patient IND is being sought and addressing the regulatory requirements noted above.

Investigators should submit five copies of the package to OHRS and/or contact OHRS at (617) 632-3029 to arrange electronic submission. The request will be placed on the next available IRB meeting.

PLEASE NOTE:

1. **FDA approval must be provided to OHRS as soon as possible.** Once the FDA approval is received by OHRS, the protocol will be posted on OncPro but the consent will be e-mailed to the investigator since this is a one-time, single use, one-subject protocol.
2. **The consent document must be written for one individual** and must clearly explain that the individual is not otherwise eligible for other open and approved trials.

B. Emergency Use of a Test Article

An exemption under FDA regulations at 21 CFR 56.104 (c) permits the emergency use of an investigational drug on a **one-time basis per institution** without IRB review and approval, but with informed consent, only when all of the following conditions are met:

1. A human subject is in a life-threatening situation;
2. No standard acceptable treatment is available;
3. There is insufficient time to obtain IRB approval; and,
4. The emergency use is reported to the IRB within five working days.
5. **THE SPONSOR OF THE INVESTIGATIONAL AGENT MUST PROVIDE APPROVAL TO USE THE AGENT FOR THIS EMERGENCY USE.**

Procedurally, the following are the first steps that must be taken to start the process for an emergency use of a test article:

1. As soon as possible, an e-mail or other communication must be provided to OHRS with information meeting all of the regulatory conditions stated above.
2. OHRS must provide a protocol number.
3. QACT must be contacted for subject registration.
4. Pharmacy must be contacted for drug distribution.
5. A consent form must be prepared and consent obtained even without IRB review.
6. Please Note: it is the responsibility of the study team to obtain the approval of the sponsor and to obtain drug for the purpose of this emergency use. Any drug in stock can only be transferred from another approved research protocol for use in this emergency setting with the approval of the sponsor.

After the emergency use of the test article, the use must be reported to the IRB within five days. The following items are required to be provided to OHRS after the emergency use of the test article:

1. Front sheet;
2. Investigator signature pages;
3. Protocol;
4. Consent form;
5. Sponsor approval for the use of the test article;
6. Treatment plan/rationale/justification meeting the four regulatory requirements;
and
7. Summary of the progress of the patient.