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## Introduction:

FDA regulations permit an investigational drug to be used for the treatment of an individual patient by a licensed physician, under the following circumstances:

1. The patient has a serious or immediately life-threatening disease or condition;
   1. Immediately life-threatening disease or condition means a stage of disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.
   2. Serious disease or condition means a disease or condition associate with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.
2. There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition;
3. The potential patient benefit justifies the potential risks of the treatment use;
4. The potential risks are not unreasonable in the context of the disease or condition to be treated;
5. The probable risk to the patient from the investigational drug is not greater than the probable risk from the disease or condition;
6. The patient cannot obtain the drug under another IND or protocol; and,
7. Providing the investigational drug for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use.

When a physician would like to submit an Investigational New Drug application (IND) to obtain an unapproved drug for an individual patient, they should first ensure that the manufacturer of the unapproved drug is willing to provide the drug. If the manufacturer agrees to provide the drug, the physician should submit an IND to the FDA.

There are two regulatory pathways depending on the urgency of the use. If drug administration must occur as soon as possible and it is not possible for the BMC/BUMC IRB to approve the request before use, then this is considered an emergency use. Otherwise, this is considered an individual patient IND use.

Emergency Use: In an emergency situation, the request to use the drug may be made via telephone or other rapid means of communication, and authorization to ship and use the drug may be given by the FDA official over the telephone. In these situations, known as emergency INDs (eIND), shipment of and treatment with the drug may begin prior to FDA’s receipt of the written IND submission that follows the initial request. An [emergency IND timeline](https://www.fda.gov/drugs/investigational-new-drug-ind-application/emergency-ind-timeline) from the FDA is available to guide you through the process.

Non-Emergent Use: In a non-emergency situation, a written request (IND) for individual patient use of an investigational drug must be received by the FDA before shipment of and treatment with the drug may begin. These non-emergency requests are known as individual- or single- patient INDs. A [guide to initiate and maintain non-emergency requests](https://www.fda.gov/drugs/investigational-new-drug-ind-application/physicians-guide-non-emergency-single-patient-expanded-access-submissions) from the FDA is available to guide you through the process.

If you have any questions regarding whether an emergency exemption applies, please contact the BMC/BUMC IRB at [medirb@bu.edu](mailto:medirb@bu.edu) or the BMC Investigational Pharmacy Services (IPS) at [IPS@bmc.org](mailto:IPS@bmc.org).

## Steps for Emergency Use of Unapproved Drug(s):

1. **Determine if the proposed use meets the regulatory definition for emergency use of an investigational drug or biologic [21 CFR 56.102(d)]. Emergency uses must meet ALL of the following criteria:** 
   1. The subject has a disease or condition which is life-threatening (e.g., the likelihood of death is high) or severely debilitating (e.g., may cause irreversible morbidity, such as blindness, loss of limb, loss of hearing, paralysis or stroke);
   2. The subject's disease or condition requires intervention with the investigational drug or biologic before review at a convened meeting of the IRB is feasible; and
   3. No standard acceptable treatment is available.
2. **Contact the Drug Manufacturer: The investigator must obtain the manufacturer's agreement to ship the drug or to use part of the drug supply available at BMC as part of another clinical trial.**
   1. Check the drug manufacturer’s website for compassionate use access.
   2. Call drug manufacturer’s medical information phone line to identify appropriate contact.
   3. Complete the initial application requesting drug:
      1. Do not share protected health information (PHI) with the drug manufacturer.
      2. Provide brief clinical description of the patient, and reason for the request.
   4. If the drug manufacturer considers the initial request, they will need additional information such as the treating physician’s license and signed CV (must be Attending or Fellow).
   5. Obtain a Letter of Authorization (LOA) to be able to cross reference the IND number for the FDA. Note: "Piggybacking” onto manufacturer’s existing IND application is usually easier because they will often have a “package” of documents to send you. They must list you as a co-investigator (sub-investigator) on their IND filings.
   6. Some manufacturers require a Confidentiality Disclosure Agreement (CDA) before releasing the Investigator’s Brochure, Pharmacy Manual and the investigational drug. If a CDA is required, contact the Clinical Trial Office (CTO) at [CTO@bmc.org](mailto:CTO@bmc.org).
   7. Check if the drug manufacturer has a treatment protocol and/or a consent template.
3. **Contact the FDA: After the manufacturer has agreed to provide the drug, the FDA must be contacted in order to grant an IND for the emergency use. The FDA maintains 24-hour coverage for emergency INDs (see below).**
4. Request emergency IND for an individual patient with brief history and proposed treatment plan, provide LOA from drug manufacturer (as requested), and describe plans for obtaining informed consent (if applicable).
5. The FDA will ask for the treating physician’s license and CV or other information.
6. The FDA will provide approval verbally and in writing. Provide email ID which is easily accessible.

| **Type of Request** | **Weekday M-F 8:00 – 4:30 pm ET** | **After hours, weekends, and holidays** |
| --- | --- | --- |
| Emergency Requests | Contact the Division of Drug Information:  855-543-3784, or 301-796-3400 301-431-6353 (fax) [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov) | Emergency Coordination Staff:  866-300-4374, or 301-796-8240 fax: 301-431-6356 [CDER-EIND@fda.hhs.gov](mailto:CDER-EIND@fda.hhs.gov) |

**Note:** From past experience, there may be difficulties with file sharing with the FDA as the files may be too large for the network. You may need to use a non-BMC email system to send required information to the FDA.

1. **Contact the BMC/BUMC IRB: When there is sufficient time, the investigator should contact the IRB as soon as possible to determine whether or not the IRB can issue concurrence or convene and approve the emergency use.**
   1. While prior IRB approval before emergency use is not required, the BMC/BUMC IRB should be alerted to the situation, if possible. This notification should not be considered IRB approval.
   2. Contact:
      1. Jamie Merrill, IRB Director at 617-942-0312 or [jcm57@bu.edu](mailto:jcm57@bu.edu)
      2. Matt Ogrodnik, OHRA Director at 617-358-6559 or [maogrodn@bu.edu](mailto:maogrodn@bu.edu)
   3. A formal submission in INSPIR is required within 5 days of drug administration.
2. **Notify BMC Investigational Pharmacy Services (IPS): The unapproved drug must be shipped to the Pharmacy to maintain the appropriate chain of custody.**
   1. Supply IPS with:
      1. A copy of the FDA's letter or email indicating its approval for the Emergency IND.
      2. The manufacturer's approval to ship drug.
      3. Notice that the investigator is exercising the Emergency Exemption and the BMC/BUMC IRB has been or will be notified.
   2. Provide drug manufacturer with Investigational Pharmacist’s contact information and drug shipment address:

Contact Info:

Investigational Pharmacy Service

[IPS@bmc.org](mailto:IPS@bmc.org)

Phone # 617-638-6774; Pager# 2809

Drug Shipment Address:

Boston Medical Center

Investigational Pharmacy Services (ME-B378)

840 Harrison Ave

Boston, MA 02118

1. **Notify Clinical Trial Office (CTO)**

Contact Info:

Clinical Trial Office

[CTO@bmc.org](mailto:CTO@bmc.org)

1. **Obtain Written Informed Consent from the Patient or Legally Authorized Representative (LAR):**
   1. Craft an informed consent to be utilized.
      1. You are encouraged to seek out a consent template from the drug manufacturer. If time allows, the IRB can assist in modifying the consent to be site- and patient-specific.
      2. If the drug manufacturer does not have a consent template available, you may use [the BMC/BUMC IRB Single Patient Expanded Access Consent template](https://www.bumc.bu.edu/irb/files/2023/07/Single-Patient-Expanded-Access-Consent-Template.docx). If time allows, the IRB can assist in modifying the consent to be site- and patient-specific. Please contact Jamie Merrill or Matt Ogrodnik using the contact information provided above.
      3. If there is no time to modify the IRB’s template, a clinical consent form can be used. Physicians should discuss with the patient, or legally authorized representative, the investigational nature of the proposed emergency treatment, the risks and benefits, and document these discussions in the medical record, in clinical notes, and in a clinical consent form.
   2. Consent the Patient or their LAR. The consent form must be signed and dated appropriately as the FDA doesn’t allow verbal consent. Ideally, the consent discussion takes place in-person; however, if that is not possible, particularly if an LAR is needed, there are other options to obtaining a signature, including fax and email. The BMC/BUMC IRB is available to answer any questions relating to consent or allowable documentation.
   3. Provide IPS Pharmacy with a copy of the signed consent.
   4. **Informed Consent Exception**: An exception to the requirement for informed consent may be made if both the investigator and an independent physician who is not otherwise participating in the clinical investigation certify in writing all of the following:
      1. The subject is confronted by a life-threatening (or severely debilitating) situation necessitating the use of the investigational drug or biologic;
      2. Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from the subject;
      3. Time is not sufficient to obtain consent from the subject's legal representative; and
      4. No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life.

If, in the investigator’s opinion, immediate use of the investigational drug or biological product, or unapproved medical device is required to preserve the subject’s life, and if time is not sufficient to obtain an independent physician’s determination that the four conditions above apply, the investigator should make the determination and, within 5 working days after the use of the investigational drug or biological product, or unapproved medical device, have the determination reviewed and evaluated in writing by a physician who is not participating in the clinical investigation. NOTE: This process should only be used in truly exceptional cases and the IRB should be consulted, if at all possible.

1. **IPS will provide drug to be administered:**
   1. IPS will receive the drug and determine compounding/dispensing requirements. A protocol from any institution or manufacturer, or any other information regarding drug use, indication, administration, dispensing instructions (dose, route, frequency, etc), and preparation instructions must be sent to the pharmacy.
   2. IPS will pend the order in Epic for the treating physician. Physician signing the order must be the MD who requested the FDA approval.
   3. IPS will deliver drug to floor.
2. **Treat patient with unapproved drug under an Emergency Use IND.**
3. **Report Treatment to the BMC/BUMC IRB, FDA, and Drug Manufacturer (as required): There are important and time-bound reporting requirements that need to be addressed after drug administration.**
   1. **BMC/BUMC IRB:**
      1. An investigator must submit the IRB within 5 working days after use of the investigational drug. [See Policies for more information](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#12.3).
         1. Submit completed Emergency Use Application through INSPIR. The Application must include as PI or supervising PI the staff physician that requested to use the drug or biologic.
         2. Log into INSPIR with username and password (either BMC or BU). <https://inspir.bu.edu/>
         3. Go to “Add a New Study”, and complete new study application. For instructions on how to submit, please see here: https://www.bumc.bu.edu/irb/files/2016/10/How-to-create-a-new-protocol-draft.pdf
         4. After completing Sections 1-3 (Study Title, Department, Key Personnel), in the Review Pathway (Section 4.1), select the last option “None of the above…” and in Section 4.2, select “Yes” to generate the Emergency Use application. The application will request brief clinical information, a description of the consent process, and other information.
         5. The following documents should be attached:
            1. Documentation of FDA correspondence and approval
            2. FDA Form 3926 (with Box 10b checked)
            3. Documentation of Drug Manufacturer’s approval
            4. Consent form (NOTE: All patient identifiers must be removed)
            5. The treatment protocol provided by the manufacturer, if applicable
            6. Bias in Research word document required to submit application. Mention on document this is a “individual patient IND” or as appropriate
         6. After submission, contact the IRB via [medIRB@bu.edu](mailto:medIRB@bu.edu) or Jamie Merrill at [jcm57@bu.edu](mailto:jcm57@bu.edu)
   2. **The FDA:**
      1. The FDA will communicate to the holder of the eIND regarding subsequent submissions, which can be found in the [Emergency IND Timeline](https://www.fda.gov/drugs/investigational-new-drug-ind-application/emergency-ind-timeline); however, in brief:
         1. Mandatory Safety Reports – Unexpected Fatal or Life-Threatening Adverse Reactions: As soon as possible but no later than 7 calendar days.
         2. Mandatory Safety Reports – Other: As soon as possible but no later than 15 calendar days after determining the suspected adverse reaction qualifies for reporting.
         3. Follow-up to a Written Safety Report: As soon as the information is available but no later than 15 calendar days after the sponsor receives the information.
         4. IND Application Amendments (as needed due to changes in treatment plan): Throughout the IND application life cycle.
         5. Results Summary: Following completion of the treatment for emergency use.
         6. IND Application Annual Reports: Within 60 days of the anniversary of FDA’s original authorization date (so long as the application remains active).
   3. **The Drug Manufacturer: Adhere to any requirements imposed by the manufacturer.**
4. **Retain Records:** The individual holding the IND is responsible for recordkeeping and record retention. At a minimum, the following documents should be maintained and readily accessible (e.g. in a regulatory binder):
   1. Copies of all FDA correspondence, such as:
      1. Completed FDA Form 3926
      2. Treatment Plan
      3. SAE Reports
      4. Annual Reports
      5. Amendments
   2. Copy of the signed Consent Form
   3. Either IRB Concurrence or Approval Letter
   4. Manufacturer Agreement to ship drug (as applicable)
   5. Investigator’s Brochure (if applicable)
   6. Case Report Forms (if applicable)
   7. Drug Accountability Records
   8. Documentation of Adverse Events and Protocol Deviations
   9. Monitoring Reports (if applicable)

**BMC/BUMC HRPP Policies and Procedures Related to Emergency Use:**

[12.3.1      Emergency Use of Drugs and Biological Agents](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#12.3.1)

[12.3.3      Informed Consent for Emergency Use](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#12.3.3)

[12.3.4      Processing of Reports for Emergency Use](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#12.3.4)

INSPIR Application Information - Emergency use – Sections [7.2.2.2](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#_Required_Basic_Information) and [7.2.2.21](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#_Emergency_Use_Information)

## Steps for Individual Patient Use of Unapproved Drugs (Non-Emergency Use):

1. **Determine if the proposed use meets the regulatory definition for use of an investigational drug or biologic including:** 
   1. Patient has a serious disease or condition, or whose life is immediately threatened by their disease or condition.
   2. There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
   3. Patient enrollment in a clinical trial is not possible.
   4. Potential patient benefit justifies the potential risks of treatment.
   5. Providing the investigational medical product will not interfere with investigational trials that could support a medical product’s development or marketing approval for the treatment indication.
   6. Confirm there is sufficient time to obtain prior IRB approval before drug administration. If not, please follow emergency use procedures found above.
2. **Contact the Drug Manufacturer: The investigator must obtain the manufacturer's agreement to ship the drug or to use part of the drug supply available at BMC as part of another clinical trial.**
   1. Check the drug manufacturer’s website for compassionate use access.
   2. Call drug manufacturer’s medical information phone line to identify appropriate contact.
   3. Complete the initial application requesting drug:
      1. Do not share PHI with the drug manufacturer.
      2. Provide brief clinical description of the patient, and reason for the request.
   4. If the drug manufacturer considers the initial request, they will need additional information such as the treating physician’s license and signed CV (must be Attending or Fellow).
   5. Obtain a Letter of Authorization (LOA) to be able to cross reference the IND number for the FDA. Note: "Piggybacking” onto manufacturer’s existing IND application is usually easier because they will often have a “package” of documents to send you. They must list you as a co-investigator (sub-investigator) on their IND filings.
   6. Some manufacturers require a Confidentiality Disclosure Agreement (CDA) before releasing the Investigator’s Brochure, Pharmacy Manual and the investigational drug. If a CDA is required, contact the Clinical Trial Office (CTO) at [CTO@bmc.org](mailto:CTO@bmc.org).
   7. Check if the drug manufacturer has a treatment protocol and/or a consent template.
3. **Contact the FDA: After the manufacturer has agreed to provide the drug, the FDA must be contacted in order to grant an IND.**
4. In a non-emergency situation, [a written request (IND) for individual patient use](https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/physician-request-single-patient-ind-compassionate-or-emergency-use) of an investigational drug must be submitted to the FDA. However, you may want to first consider calling the FDA to discuss.
5. Complete FDA [Form 3926](https://www.fda.gov/media/98616/download). This form is designed specifically for individual patient IND requests, and should be used by physicians when submitting requests for individual patient expanded access to investigational drugs, including in emergencies. It can also be used for certain submissions to FDA after the initial application is filed. For instructions on how to complete the 3926, see [here](https://www.fda.gov/media/98627/download).
   1. **In the Form 3926, be sure to check the box in 10.b. titled: Request for Authorization to Use Alternative IRB Review Procedures.** This will allow for IRB chairperson concurrence rather than require review by the full convened IRB, which could potentially add time delay.
6. Email the FDA a Patient Treatment Plan ([completed Form 3926](https://www.fda.gov/media/98616/download)) containing:
   1. Request for single subject IND in the header of the letter;
   2. Clinical history of subject;
   3. Proposed treatment plan;
   4. Drug supply reference statement, with Letter of Authorization (LOA);
   5. Statement that informed consent and IRB approval will be obtained prior to treatment;
   6. Investigator qualification statement, CV or biosketch;
   7. Treating physician contact email and phone number
   8. Again, check box in Section 10.b. to request IRB chairperson concurrence
7. If the request is approved, an IND number will be issued by the FDA and the treating physician will be contacted typically by phone or other electronic means of communication, with a letter to follow. The IND is considered active upon issuance of the number. Treating physician will then contact the drug supplier and provide the IND number. The supplier may then ship the drug directly to the treating physician.

| **Type of Request** | **Weekday M-F 8:00 – 4:30 pm ET** | **After hours, weekends, and holidays** |
| --- | --- | --- |
| Non-Emergency Requests | Contact the Division of Drug Information:  855-543-3784, or 301-796-3400 301-431-6353 (fax) [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov) | Emergency Coordination Staff:  855-543-3784, or 301-796-8240 fax: 301-431-6353 [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov) |

**Note:** From past experience, there may be difficulties with file sharing with the FDA as the files may be too large for the network. You may need to use a non-BMC email system to send required information to the FDA.

1. **Submit to the BMC/BUMC IRB:**
   1. An investigator must obtain IRB approval prior to drug administration. [See Policies for more information.](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#7.2.2.22) 
      1. Submit completed Individual patient IND Application through INSPIR. The Application must include as PI or supervising PI the staff physician that requested to use the drug or biologic.
      2. Log into INSPIR with username and password (either BMC or BU). <https://inspir.bu.edu/>
      3. Go to “Add a New Study”, and complete sections. For instructions on how to submit, please see here: https://www.bumc.bu.edu/irb/files/2016/10/How-to-create-a-new-protocol-draft.pdf
      4. After completing Sections 1-3 (Study Title, Department, Key Personnel), in the Review Pathway (Section 4.1), select the last option “None of the above…” and in Section 4.3, select “Yes” to generate the Individual patient (single use) IND application. The application will request brief clinical information, risks profile of the drug, a description of the consent process, and other information.
      5. If a consent template is provided by the drug manufacturer, it can be used but needs to be modified to be BMC/BUMC-specific, including the addition of our template HIPAA authorization language. The IRB can help facilitate these revisions. If you do not have consent template to use, please use the [BMC/BUMC IRB Single Patient Expanded Access Consent Template.](https://www.bumc.bu.edu/irb/files/2023/07/Single-Patient-Expanded-Access-Consent-Template.docx)
      6. The following documents should be attached:
         1. Documentation of FDA correspondence and approval;
         2. FDA Form 3926 (with Box 10b checked)
         3. Documentation of Drug Manufacturer’s approval;
         4. Consent form (NOTE: All patient identifiers must be removed)
         5. The treatment protocol provided by the manufacturer, if applicable
         6. Bias in Research word document required to submit application. Mention on document this is a “individual patient IND” or as appropriate
      7. After submission, contact the IRB via [medIRB@bu.edu](mailto:medIRB@bu.edu) or Jamie Merrill at [jcm57@bu.edu](mailto:jcm57@bu.edu)
2. **Notify BMC Investigational Pharmacy Services (IPS): The unapproved drug must be shipped to the Pharmacy to maintain the appropriate chain of custody.**
   1. Supply IPS with:
      1. A copy of the FDA's letter or email indicating its approval for the Individual patient IND
      2. The manufacturer's approval to ship drug;
      3. Notice that the investigator has or will submit to the BMC/BUMC IRB for review and approval. NOTE: IPS will require documentation of IRB approval prior to releasing the drug for administration.
   2. Provide drug manufacturer with Investigational Pharmacist’s contact information and drug shipment address:

Contact Info:

Investigational Pharmacy Services

[IPS@bmc.org](mailto:IPS@bmc.org)

Phone # 617-638-6774; Pager# 2809

Drug Shipment Address:

Boston Medical Center

Investigational Pharmacy Services (ME-B378)

840 Harrison Ave

Boston, MA 02118

1. **Notify Clinical Trial Office (CTO).**

Contact Info:

Clinical Trial Office

[CTO@bmc.org](mailto:CTO@bmc.org)

1. **Obtain Written Informed Consent from the Patient or Legally Authorized Representative (LAR):**

Consent the patient or their LAR using the IRB-approved consent form. The consent form must be signed and dated appropriately as the FDA doesn’t allow verbal consent. Ideally, the consent discussion takes place in-person; however, if that is not possible, particularly if an LAR is needed, there are other options to obtaining a signature, including fax and email. The BMC/BUMC IRB is available to answer any questions relating to consent or allowable documentation. Please contact Jamie Merrill or Matt Ogrodnik using the contact information provided above.

* 1. Provide IPS Pharmacy Services with a copy of the signed consent.

1. **IPS will provide drug to be administered:**
   1. IPS will receive the drug and determine compounding/dispensing requirements. A protocol from any institution or manufacturer, or any other information regarding drug use, indication, administration, dispensing instructions (dose, route, frequency, etc), and preparation instructions must be sent to the pharmacy.
   2. IPS will pend the order in Epic for the treating physician. Physician signing the order must be the MD who requested the FDA approval.
   3. IPS will deliver drug to floor.
2. **Treat patient with unapproved drug under an individual patient IND.**
3. **Report Treatment to the FDA, and Drug Manufacturer (as required): There are important and time-bound reporting requirements that need to be addressed after drug administration.**
   1. **The FDA:**
      1. The FDA will communicate to the holder of the individual patient IND regarding subsequent submissions, which can be found in the [non-emergency IND guidance from the FDA](https://www.fda.gov/drugs/investigational-new-drug-ind-application/physicians-guide-non-emergency-single-patient-expanded-access-submissions); however, in brief:
         1. Mandatory Safety Reports – Unexpected Fatal or Life-Threatening Adverse Reactions: As soon as possible but no later than 7 calendar days
         2. Mandatory Safety Reports – Other: As soon as possible but no later than 15 calendar days after determining the suspected adverse reaction qualifies for reporting
         3. Follow-up to a Written Safety Report: As soon as the information is available but no later than 15 calendar days after the sponsor receives the information
         4. IND Application Amendments (as needed due to changes in treatment plan): Throughout the IND application life cycle.
         5. Results Summary: Following completion of the treatment
         6. IND Application Annual Reports: Within 60 days of the anniversary of FDA’s original authorization date (so long as the application remains active).
   2. **The Drug Manufacturer: Adhere to any requirements imposed by the manufacturer.**
4. **Retain Records:** The individual holding the IND is responsible for recordkeeping and record retention. At a minimum, the following documents should be maintained and readily accessible (e.g. in a regulatory binder):
   1. Copies of all FDA correspondence, such as:
      1. Completed FDA Form 3926
      2. Treatment Plan
      3. SAE Reports
      4. Annual Reports
      5. Amendments
   2. Copy of the signed Consent Form
   3. Either IRB Concurrence or Approval Letter
   4. Manufacturer Agreement to ship drug (as applicable)
   5. Investigator’s Brochure (if applicable)
   6. Case Report Forms (if applicable)
   7. Drug Accountability Records
   8. Documentation of Adverse Events and Protocol Deviations
   9. Monitoring Reports (if applicable)

**BMC/BUMC HRPP Policies and Procedures Related to Individual Patient IND Use:**

[12.1.1      Requirements for Research Involving a Drug or Biological Agent](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#12.1.1)

INSPIR Application Information - Individual patient IND: Sections [7.2.2.2](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#_Required_Basic_Information), [7.2.2.4](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#_Investigator_Training_Information), [7.2.2.5](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#_Conflict_of_Interest), [7.2.2.8.1](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#_Drug_and_Biological), and [7.2.2.22](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#_Individual_Patient_IND)