Human Research Seminar Series

Humanitarian Devices and Emergency Use Procedures

Monday, May 6, 2013

Presented by:
Melissa A. Epstein, PhD, CIP
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Emergency Use of a Drug or Device and Humanitarian Use Devices

Melissa Epstein, PhD, CIP

Emergency use of a drug or device

The use of an investigational drug or device with a human subject in a life-threatening situation in which no standard acceptable drug or device is available and in which there is not sufficient time to obtain IRB approval.
Emergency use

- The emergency use provision in the FDA regulations is an **exemption from prior review and approval by the IRB** and applies to the treatment of **one subject** per institution.
- If it is anticipated that the drug will be needed again at the institution (for additional subjects), a full protocol must be submitted to the IRB for review and approval at a convened meeting.

Difference between drug and device

- Emergency use of an unapproved investigational **drug or biologic** must be done under an IND (Investigational New Drug). The FDA has special contacts to provide such an IND around the clock if the sponsor or other entity doesn’t already have one.
- Emergency use of an unapproved **device** does not need to be done under an IDE (Investigational Device Exemption).
Conditions to justify emergency use

1. The patient is in a life-threatening or severely debilitating condition that needs immediate treatment;
2. No generally acceptable alternative for treating the patient is available; and
3. Because of the immediate need to use the drug, there is no time to use existing procedures to get IRB approval for the use.

All three conditions must be met.

Definitions

- **Life threatening** means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, *the subjects must be in a life threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.*

- **Severely debilitating** means diseases or conditions that cause major irreversible morbidity, such as blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis, or stroke.
Informed Consent Requirements

1. Even for emergency use, the investigator is required to obtain informed consent of the subject or the subject's legally authorized representative, unless the FDA requirements for exception from informed consent are met [21CFR 50.23(a)].

2. The sponsor/manufacturer will more than likely supply the consent form and the IRB will not be involved in the review or approval of the consent form.

3. In instances where the sponsor’s consent is not available, use the Emergency Use Consent template.

http://www.einstein.yu.edu/docs/irb/forms/eu-device-icd.doc
http://www.einstein.yu.edu/docs/irb/forms/eu-drug-icd.doc

Physician Responsibilities – Prior to use

**Drug**
- Obtain permission from the Department Chairman;
- Obtain approval from the Pharmacy Department. Storage, inventory and dispensing of the investigational agent are generally required through the Pharmacy.
- Obtain IND from the FDA/Sponsor;
- At the manufacturer/sponsor’s request, obtain IRB acknowledgement prior to the use of the drug or biologic;
- Obtain informed consent from the patient or a legal representative.

**Device**
- Obtain an independent assessment by an uninvolved physician;
- Obtain permission from the Department Chairman;
- Obtain authorization from the IDE holder, if an approved IDE for the device exists.
- At the manufacturer/sponsor’s request, obtain IRB acknowledgement prior to the use of the device;
- Obtain informed consent from the patient or a legal representative.
What if the sponsor requires IRB acknowledgement?

- Submit to the IRB
  - Request for Emergency Use of an Investigational Device Form (http://www.einstein.yu.edu/docs/irb/forms/eu-device-req.doc) or Request for Emergency Use of Investigational Drug or Biologic Form (http://www.einstein.yu.edu/docs/irb/forms/eu-drug-req.doc)
  - IDE/IND information
  - Device: Assessment from independent physician
  - Drug: Pharmacy approval
- The IRB Chair or designee will provide written acknowledgment.

Physician Responsibilities – After the use

1. Submit the Request for Emergency Use of Investigational Drug, Biologic/Request for Emergency Use of an Investigational Device to the IRB **within five days** of the emergency use only **when prior IRB acknowledgement is not obtained**.
   1. Include evidence of having met all the physician responsibilities listed in the form and policy
2. **When the clinical outcome is known**, submit to the IRB:
   1. The Final Report for the Emergency Use of an Investigational Drug or Biologic/Final Report for the Emergency Use of an Investigational Device Form,
   2. All adverse event reports, and
   3. A copy of the signed informed consent document.
3. If the enrollment of additional subjects is anticipated in the future, a full protocol must be submitted to the IRB for review and approval at a convened meeting.
Emergency Use – Einstein Policy and Forms

- Policies:

- Forms:
  - [http://www.einstein.yu.edu/administration/institutional-review-board/forms.aspx#emergency](http://www.einstein.yu.edu/administration/institutional-review-board/forms.aspx#emergency)

Refer to both the policy and the form to meet ALL requirements!

Other mechanisms for drugs

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>Definition/Use</th>
<th>Research</th>
<th>FDA Approval Required</th>
<th>Prior IRB Approval Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment IND</td>
<td>Allows add'l patients to have access to the drug before FDA approval</td>
<td>Yes</td>
<td>Yes – IND</td>
<td>Yes</td>
</tr>
<tr>
<td>Orphan Drug</td>
<td>Treats rare diseases - special funding available</td>
<td>Yes</td>
<td>Yes – 21CFR316</td>
<td>Yes</td>
</tr>
<tr>
<td>Emergency Use</td>
<td>Single patient; life-threatening; before or during clinical trial</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
Other mechanisms for devices

<table>
<thead>
<tr>
<th>Definition</th>
<th>Research</th>
<th>FDA Approval Required</th>
<th>Prior IRB Approval Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compassionate Use IDE</td>
<td>Yes</td>
<td>Yes - IDE supplement</td>
<td>Yes</td>
</tr>
<tr>
<td>Single patient or small group; serious disease or condition, no alternative; during clinical trial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment Use IDE</td>
<td>Yes</td>
<td>Yes – treatment IDE</td>
<td>Yes</td>
</tr>
<tr>
<td>Larger group; serious or life-threatening, no alternative; during clinical trial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Humanitarian Use Device</td>
<td>No</td>
<td>Yes – HDE</td>
<td>Yes</td>
</tr>
<tr>
<td>Treats or diagnoses rare diseases</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency Use</td>
<td>No</td>
<td>No – but IDE can exist</td>
<td>No</td>
</tr>
<tr>
<td>Single patient; life-threatening; before or during clinical trial</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Humanitarian Use Device (HUD)

- HUD definition
  - Title 21 CFR 814.3(n)
  - A device intended to benefit patients in the treatment or diagnosis of a disease or condition affecting fewer than 4,000 individuals in the US per year
- The use of an approved HUD is **not** research but it requires IRB review!
Humanitarian Use Device (HUD)

- Office of Orphan Products Development designates a device as a Humanitarian Use Device (HUD)
  - Verifies that the device is designed to treat or diagnose a disease or condition following the parameters in the definition
  - Reviews a description of the device
  - Reviews a description of the rare disease or condition

Humanitarian Device Exemption (HDE)

- HDE Definition
  - Title 21 CFR 814.2
  - A premarket approval application submitted to FDA seeking a Humanitarian Device Exemption from the effectiveness requirements of sections 514 and 515 of the Food, Drug, Cosmetic Act.
Humanitarian Device Exemption Application to FDA

- FDA approval of HDE application
  - HUD does not pose unreasonable risk of injury to patients
  - That the probable benefit outweighs risk of injury from its use

Humanitarian Device Exemption Application to FDA

- FDA approval of a HDE application allows the HUD to be marketed
HDE-Holder Responsibilities

- Have both HUD designation and approved HDE from FDA before device is shipped to institutions with Institutional Review Board (IRB) oversight
- Responsible for ensuring initial and continuing IRB review
- Responsible for ensuring the HUD is not administered to or implanted in a patient prior to obtaining IRB approval at the health care facility
- Maintains IRB correspondence & reports clinical experience, including safety information, to FDA in annual reports

Physician Responsibilities

- Obtain IRB approval prior to first use and maintain continuing IRB approval
- Give patients HUD information packet
  > Einstein IRB requires the use of the Einstein IRB approved HUD consent template
- Report serious adverse events and deaths to the FDA using the Medical Device Reporting system at 21 CFR 803.
- Report serious adverse events and deaths to the IRB
- Ensure that the device is used only by designated individuals in designated facilities approved for HUD use
- Ensure that the HUD is used within the scope of its labeling
Medical Device Reporting (MDR) and Humanitarian Use Devices

- Applies to all FDA approved devices
- Serious adverse events and deaths must be reported to FDA and the IRB using the Medical Device Reporting system at 21 CFR 803
- HDE-holders and IRBs should ensure that physicians know about this requirement

IRB Responsibilities

- Conduct initial review
- Conduct continuing review
  > May be expedited
- Ensure that health care providers are qualified through training and expertise to use the device as required in the HDE Approval Order
- Ensure that patients receive the labeling information prepared by the HDE holder or, when safety and effectiveness data is being collected for a PMA, informed consent is obtained (21 CFR 50)
Research for HDE-approved indication

- No Investigational Device Exemption (IDE) required
- IRB review and informed consent required

Research outside approved indication

- Requires an (IDE) 21 CFR 812
- IRB review and informed consent required
Off-label Use of an HUD

- FDA recommends informed consent and reasonable patient protections measures
  > Monitoring and considering the specific needs of the patient and limited information about risks and effectiveness of the HUD
- Summary report to IRB and HDE-holder following the use

FDA Guidance on HUDs

- [http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/DesignatingHumanitarianUseDevicesHUDS/LegislationRelatingtoHUDsHDEs/ucm283517.htm](http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/DesignatingHumanitarianUseDevicesHUDS/LegislationRelatingtoHUDsHDEs/ucm283517.htm)
- List of approved HDEs:
  > [http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm)
Questions?

- Any future questions, please contact the Einstein IRB
- East Campus:
  > Melissa Epstein
  > 718-430-2751
  > melissa.epstein@einstein.yu.edu
- West Campus:
  > Kathleen O’Connor, QM Analyst
  > 718-920-4151 x228
  > koconno@montefiore.org

Einstein IRB Contact Information

<table>
<thead>
<tr>
<th>East Campus IRB</th>
<th>West Campus IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belfer Building, Room 1002</td>
<td></td>
</tr>
<tr>
<td>1300 Morris Park Avenue</td>
<td></td>
</tr>
<tr>
<td>Bronx, NY 10461</td>
<td></td>
</tr>
<tr>
<td>Phone: 718-430-2237</td>
<td></td>
</tr>
<tr>
<td>Fax: 718-430-8817</td>
<td></td>
</tr>
<tr>
<td>3308 Rochambeau Ave</td>
<td></td>
</tr>
<tr>
<td>Bronx, NY 10467</td>
<td></td>
</tr>
<tr>
<td>Phone: 718-798-0406</td>
<td></td>
</tr>
<tr>
<td>Fax: 718-798-5687</td>
<td></td>
</tr>
</tbody>
</table>

Website: [http://www.einstein.yu.edu/irb](http://www.einstein.yu.edu/irb)
Includes: Policies and Procedures, Submission Guidelines, Forms, and Educational Materials
Emergency Use of an Investigational Drug or Biologic Policy and Procedure

Each of the following conditions must exist to justify emergency use:

1. The patient is in a life-threatening condition that needs immediate treatment;
2. No generally acceptable alternative for treating the patient is available; and
3. Because of the immediate need to use the drug, there is no time to use existing procedures to get FDA approval for the use.

I. Definitions

Life threatening includes the scope of both life-threatening and severely debilitating, as defined below.

1. **Life threatening** means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life threatening situation requiring intervention before review at a convened meeting of the CCI/IRB is feasible.
2. **Severely debilitating** means diseases or conditions that cause major irreversible morbidity, such as blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis, or stroke.
3. **Emergency Use** is defined as the use of an investigational drug with a human subject in a life-threatening situation in which no standard acceptable drug is available and in which there is not sufficient time to obtain CCI/IRB approval. (See also Treatment Use (Section I. E.) of the Investigational Drug, Biologic and Device Policy)

   a. Emergency use of an unapproved investigational drug or biologic must be done under an IND (Investigational New Drug).
   b. The emergency use provision in the FDA regulations is an exemption from prior review and approval by the IRB and applies to the treatment of one subject.
   c. If the investigator anticipates the enrollment of additional subjects in the future, a full protocol must be submitted to the CCI/IRB for review and approval at a convened meeting.

ONCE THE ABOVE CRITERIA HAVE BEEN MET, THE FOLLOWING POLICY AND PROCEDURES APPLY

II. Informed Consent
1. Even for emergency use, the investigator is required to obtain informed consent of the subject or the subject's legally authorized representative, unless the FDA requirements for exception from informed consent are met [21CFR 50.23(a)].
2. The sponsor will more than likely supply the consent form and the CCI/IRB will not be involved in the review or approval of the consent form.
3. In instances where the sponsor's consent is not available, use the Emergency Use Consent Template.

III. Physician Responsibilities

1. Prior to use of the investigational drug or biologic the treating physician must:
   a. Obtain informed consent from the patient or a legal representative;
   b. Obtain permission from the Department Chairman;
   c. Obtain approval from the Pharmacy Department. Storage, inventory and dispensing of the investigational agent are generally required through the Pharmacy.
   d. Obtain CCI/IRB acknowledgement prior to the use of the drug or biologic when required by the manufacturer/sponsor.
      i. In such instances the physician must submit to the CCI/IRB the Request for Emergency Use of Investigational Drug or Biologic Form. The IRB Chair or designee will provide the physician with written acknowledgment.

2. After use of the drug or biologic the treating physician must:
   a. Submit the Request for Emergency Use of Investigational Drug, Biologic or Device Form to the CCI/IRB within five days of the emergency use only when prior IRB acknowledgement is not obtained.
   b. When the clinical outcome is known, submit to the IRB:
      i. The Final Report for the Emergency Use of an Investigational Drug, Biologic, or Device Form,
      ii. All adverse event reports, and
      iii. A copy of the signed informed consent document.
   c. If the enrollment of additional subjects is anticipated in the future, a full protocol must be submitted to the CCI/IRB for review and approval at a convened meeting.

IV. IRB Contact

1. For Emergency Use at Jacobi Medical Center or North Central Bronx Hospital, contact the Committee on Clinical Investigations of Yeshiva University at 718-430-2237.
2. For Emergency Use at Montefiore Medical Center hospitals contact the MMC Institutional Review Board at 718-798-0406.
Emergency Use of an Investigational Device Policy and Procedure

Each of the following conditions must exist to justify emergency use:

1. The patient is in a life-threatening condition that needs immediate treatment;
2. No generally acceptable alternative for treating the patient is available; and
3. Because of the immediate need to use the device, there is no time to use existing procedures to get FDA approval for the use.

In the event that a device is to be used in circumstances meeting the criteria listed above, the device developer should notify the Center for Devices and Radiological Health (CDRH) Program Operation Staff, by telephone (301-594-1190) immediately. Nights and weekends, contact the Division of Emergency and Epidemiological Operations (202-857-8400).

I. Definitions

Life threatening includes the scope of both life-threatening and severely debilitating, as defined below.

1. **Life threatening** means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.

2. **Severely debilitating** means diseases or conditions that cause major irreversible morbidity, such as blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis, or stroke.

3. **Medical Device**: Defined, in part, as any health care product that does not achieve its primary intended purpose by chemical action or by being metabolized. Medical devices also include diagnostic aids, such as reagents and test kits for in vitro diagnosis.

4. **Emergency Use** is defined as the use of an investigational device with a human subject in a life threatening situation in which no standard acceptable device is available and in which there is not sufficient time to obtain CCI/IRB approval.
   
   a) The emergency use provision in the FDA regulations is an exemption from prior review and approval by the IRB and applies to the treatment of one subject.
   
   b) If the investigator anticipates the enrollment of additional subjects in the future, a full protocol must be submitted to the CCI/IRB for review and approval at a convened meeting.
II. Informed Consent

1. Even for emergency use, the investigator is required to obtain informed consent of the subject or the subject's legally authorized representative, unless the FDA requirements for exception from informed consent are met [21CFR 50.23(a)].

2. The sponsor will more than likely supply the consent form and the CCI/IRB will not be involved in the review or approval of the consent form.

3. In instances where the sponsor's consent is not available, use the Emergency Use Consent template.

III. Physician Responsibilities

1. Prior to use of the investigational device the treating physician must:
   a. Obtain an independent assessment by an uninvolved physician;
   b. Obtain informed consent from the patient or a legal representative;
   c. Obtain permission from the Department Chairman;
   d. Obtain authorization from the IDE holder, if an approved IDE for the device exists.
   e. At the manufacturer/sponsor's request, obtain IRB acknowledgement prior to the use of the device. In such instances the physician must submit to the IRB the Request for Emergency Use of an Investigational Device Form. The IRB Chair or designee will provide written acknowledgment.

2. After use of the device the treating physician must:
   a. Notify the IRB within five days of the emergency use when prior IRB acknowledgement is not required by submitting to the IRB the Request for Emergency Use of an Investigational Device Form.
   b. When the clinical outcome is known, submit to the IRB:
      i. The Final Report for the Emergency Use of an Investigational Drug, Biologic or Device Form,
      ii. All adverse event reports, and
      iii. A copy of the signed informed consent document.
   c. Evaluate the likelihood of a similar need for the device occurring again, and if future use is likely, immediately initiate efforts to obtain IRB approval and an approved IDE for the device's subsequent use; and
   d. if an IDE for the use does exist, notify the sponsor of the emergency use, or if an IDE does not exist, notify FDA of the emergency use (CDRH Program Operation Staff) and provide FDA with a written summary of the conditions constituting the emergency, subject protection measures, and results.
IV. IRB Contact

1. For Emergency Use at Jacobi Medical Center or North Central Bronx Hospital, contact the Committee on Clinical Investigations of Yeshiva University at 718-430-2237.

2. For Emergency Use at Montefiore Medical Center hospitals contact the MMC Institutional Review Board at 718-798-0406.
REQUEST FOR EMERGENCY USE OF AN INVESTIGATIONAL DRUG OR BIOLOGIC

<table>
<thead>
<tr>
<th>Treating Physician:</th>
<th>Phone:</th>
<th>Fax:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office Address:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Department:</td>
<td>Email:</td>
<td></td>
</tr>
</tbody>
</table>

Please complete the following to determine if Emergency Use is warranted:

- Does an immediate life threatening situation or severely debilitating disease or condition exist in which there is no standard acceptable treatment available? [ ] Yes [ ] No
- What is the time frame within which the drug or biologic needs to be administered?
- Can the patient receive this drug or biologic under an already approved protocol? [ ] Yes [ ] No
- Does the sponsor require an acknowledgement letter from the Institutional Review Board prior to receiving the drug or biologic? [ ] Yes [ ] No

Please complete the following information which is relevant to the emergency situation:

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Age of Patient:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Location:</td>
<td>Moses, Weiler, JMC, NCB</td>
</tr>
<tr>
<td>Medical Record #:</td>
<td></td>
</tr>
</tbody>
</table>

Describe the life threatening situation:

Name of drug or biologic: ___________________________ IND #: ____________________

This drug or biologic will be used according to the following dosage schedule:

<table>
<thead>
<tr>
<th>Treating Physician’s Signature</th>
<th>Date</th>
<th>Department Chairperson’s Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

This form (along with a signed consent form from the subject) must be submitted to the Institutional Review Board (AECOM CCI or MMC IRB) before or within 5 days of the use of the investigational agent.

FOR CCI/IRB USE ONLY:

I have reviewed the emergency request and agree the emergency use meets the requirements of regulation 21 CFR 56.104(c).

<table>
<thead>
<tr>
<th>CCI/IRB Reviewer’s Name</th>
<th>CCI/IRB Reviewer’s Signature</th>
<th>Date</th>
</tr>
</thead>
</table>
# REQUEST FOR EMERGENCY USE OF AN INVESTIGATIONAL DEVICE

<table>
<thead>
<tr>
<th>Treating Physician:</th>
<th>Phone:</th>
<th>Fax:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office Address:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Department:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Email:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Please complete the following to determine if Emergency Use is warranted:**

- Does an immediate life threatening situation or severely debilitating disease or condition exist in which there is no standard acceptable treatment available? [ ] Yes [ ] No

- What is the time frame within which the device needs to be used?

- Can the patient have access to this device under an already approved protocol? [ ] Yes [ ] No

- Does the sponsor require an acknowledgement letter from the Institutional Review Board prior to having access to the device? [ ] Yes [ ] No

**Please complete the following information which is relevant to the emergency situation:**

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Age of Patient:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Location:</td>
<td>[ ] Moses [ ] Weiler [ ] JMC [ ] NCB Medical Record #:</td>
</tr>
</tbody>
</table>

Describe the life threatening situation:

Name and type of device: __________________________ IDE #: __________________________

---

**TREATING PHYSICIAN’S SIGNATURE**

Date

**DEPARTMENT CHAIRPERSON’S SIGNATURE**

Date

---

This form (along with a signed consent form from the subject) must be submitted to the Institutional Review Board (AECOM CCI or MMC IRB) before or within 5 days of the use of the investigational agent.

---

**FOR CCI/IRB USE ONLY:**

I have reviewed the emergency request and agree the emergency use meets the requirements of regulation 21 CFR 56.104(c).

**CCI/IRB REVIEWER’S SIGNATURE**

Date
### FINAL REPORT FOR THE EMERGENCY USE OF AN INVESTIGATIONAL DRUG, BIOLOGIC, OR DEVICE

<table>
<thead>
<tr>
<th>Treating Physician:</th>
</tr>
</thead>
</table>

You are required to report the clinical outcome of the emergency use of an investigational drug, biologic, or device. Please complete this form as required and return it to the CCI or IRB:

<table>
<thead>
<tr>
<th>Name of drug, biologic, or device:</th>
<th>IND/IDE #:</th>
</tr>
</thead>
</table>

Indication Treated: 

Patient Name: 
Age of Patient: 

Period of Treatment: From: To: 
Sex of Patient: 

Patient Location:  

<table>
<thead>
<tr>
<th>Moses</th>
<th>Weiler</th>
<th>JMC</th>
<th>NCB</th>
</tr>
</thead>
</table>

Medical Record #: 

Clinical Outcome: 

Additional Comments: 

<table>
<thead>
<tr>
<th>Treating Physician’s Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

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Informed Consent for Emergency use of an Investigational Drug or Biologic

WHAT IS THIS NEW MEDICINE ABOUT?

- You have …… , and have been told that you are not getting better with medicines that are commonly used to treat your condition ……

OR

- You have …… , and have been told that there are no medicines that are approved by the U.S. Food and Drug Administration (FDA) for general use in the United States to treat your illness.

- You are being offered a new investigational medicine called [Click here to enter the Name of the Drug]. This means that the medicine is an experimental drug not approved by the U.S. Food and Drug Administration (FDA) for general use in the United States.

- The new medicine is being studied at other hospitals under a research study known as:

- The new medicine is being given under the supervision of your doctor:

  Doctor: [Click here to enter the Name and Title.]
  Address: [Click here to enter the Address, including City, State and Zip.]
  [Click here to enter the Phone Number.]

- Your decision to receive this medicine is voluntary. This means that you decide whether or not you want to take this medicine after talking with your doctor.

- There may be words that you do not understand about your illness and this new medicine. Your doctor will answer all of your questions.

WHAT IS REQUIRED OF YOU and HOW WILL THE DRUG BE GIVEN?

- [Click here to begin typing. Press Enter for a new bullet]

WHAT ARE THE POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES TO YOU?

- [Click here to begin typing. Press Enter for a new bullet]

  In addition to the risks listed above, there is always the possibility that you will have a reaction that is currently not known and not expected.
ARE THERE ANY BENEFITS TO YOU?

- There may or may not be direct medical benefit to you from this new medicine.
  - Possible benefits are

WHAT OTHER CHOICES DO YOU HAVE?

- There are currently no other medicines that will improve your illness.
- You may choose not to take this medicine.

WHAT IF SOMETHING GOES WRONG?

- If there is a physical injury as a result of receiving this new medicine, only immediate, essential, short-term medical treatment as determined by the participating hospital will be available for the injury without charge to you personally.
- No monetary payment will be offered.

WILL THERE BE ANY COSTS TO YOU?

- There is no cost to you.
  - OR
  - Receiving this new medicine may lead to added costs to you or your insurance company.

CAN THE NEW MEDICINE BE STOPPED?

- [Click here to begin typing. Press Enter for a new bullet]

WHAT HAPPENS WHEN YOU FEEL BETTER?

- Once you are feeling better your doctor will discuss your future treatment plan with you.

WHAT IF NEW INFORMATION BECOMES AVAILABLE?

- Your doctor will tell you if there is new information that may lead you to change your mind about continuing to receive the medicine.
- If you decide to stop receiving the medicine your doctor will continue to care for you.

WHO DO YOU CALL FOR QUESTIONS?

- Doctor's Name: [Click here to enter the Name and Title.]
- Office Address: [Click here to enter the Address, including City, State and Zip.]
If you have any questions about this medicine, or you believe you have any injury related to the medicine, you should call the doctor named above.

You may also call the Administrator of the Committee on Clinical Investigations of Yeshiva University at (718) 430-2253, Monday through Friday between 9 AM and 5 PM, or the Montefiore Medical Center Institutional Review Board at (718) 798-0406, Monday through Friday between 9 AM and 5 PM.

WHO WILL KNOW THAT YOU HAVE TAKEN THIS NEW MEDICINE?

Your medical records and information about the new medicine will be kept private and your name will not be used in any written or verbal reports.

Your records may be inspected by the U.S. Food and Drug Administration (FDA), the agency for regulating drugs.

Your records may also be inspected by the company who makes the medicine and who have given the medicine to us.

Members of the human research committee at Montefiore Medical Center and Yeshiva University may also review your records.

All of these groups have been requested to keep your name private.

MAY YOU STOP TAKING THE MEDICINE AT ANY TIME?

YES. You may tell your doctor at any time that you do not want to continue to take the new medicine.

Your decision to receive the new medicine is voluntary.

Your treatment by your doctor and hospital staff now and in the future will not be affected in any way if you refuse to receive this new medicine, or if you change your mind.
SUMMARY

• You have read and listened to an explanation of the information about this new medicine.

• You have been given the opportunity to ask questions and have your questions answered.

• A copy of this consent document has been given to you whether or not you agree to receive the medicine.

SIGNATURE PAGE

Kindly check each box below as a way of making sure that these points were discussed with you and that your questions have been answered:

☐ I have decided to voluntarily receive the new medicine.

☐ Information about the new medicine has been explained.

☐ The doctor has told me what I must do when I receive the medicine.

☐ I have been given the name of the doctor and others to contact if I have any questions or if there is a any injury from receiving the medicine.

☐ I have been told about any costs and payments to me.

☐ I can discontinue taking the medicine at any time without penalty

☐ The doctor has told me about other treatment options.

☐ My name will not appear on any published reports.

☐ I will be given a schedule explaining how the medicine is to be taken.

__________________________________________  _______ __________
Signature of Patient       Date

__________________________________________  _______ __________
Signature of Guardian or Family Member    Date

__________________________________________  _______ __________
Signature of Physician obtaining consent    Date
WHAT IS THIS NEW DEVICE ABOUT?

- You have ……, and have been told that ……
- The device is investigational. This means that the device is experimental and not approved by the U.S. Food and Drug Administration (FDA) for general use in the United States.
- The new device is being studied at other hospitals under a research study known as:

Doctor: [Click here to enter the Name and Title.]
Address: [Click here to enter the Address, including City, State and Zip.]
Phone Number: [Click here to enter the Phone Number.]

- Your decision to be treated with this device is voluntary. This means that you decide whether or not you want to be treated with the device after talking with your doctor.
- There may be words that you do not understand about your condition and the new device. Your doctor will answer all of your questions.

WHAT IS REQUIRED OF YOU and HOW WILL THE DEVICE WORK?

- [Click here to begin typing. Press Enter for a new bullet]

WHAT ARE THE POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES TO YOU?

- [Click here to begin typing. Press Enter for a new bullet]

In addition to the risks listed above, there is always the possibility that you will have a reaction that is currently not known and not expected.

ARE THERE ANY BENEFITS TO YOU?

- There may or may not be direct medical benefit to you from this new device.
  - Possible benefits are

WHAT OTHER CHOICES DO YOU HAVE?
• There are currently no other devices that will improve your illness.

• You may choose not to be treated with this device.

WHAT IF SOMETHING GOES WRONG?

• If there is a physical injury as a result of being treated with the new device, only immediate, essential, short-term medical treatment as determined by the participating hospital will be available for the injury without charge to you personally.

• No monetary payment will be offered.

WILL THERE BE ANY COSTS TO YOU?

• There is no cost to you. OR

• Receiving this new device may lead to added costs to you or your insurance company.

CAN THE NEW DEVICE BE STOPPED?

• [Click here to begin typing. Press Enter for a new bullet]

WHAT HAPPENS WHEN YOU FEEL BETTER?

• Once you are feeling better your doctor will discuss your future treatment plan with you.

WHAT IF NEW INFORMATION BECOMES AVAILABLE?

• Your doctor will tell you if there is new information that may lead you to change your mind about continuing to use the device.

• If you decide to stop using the device your doctor will continue to care for you.

WHO DO YOU CALL FOR QUESTIONS?

• Doctor’s Name: [Click here to enter the Name and Title.]

• Office Address: [Click here to enter the Address, including City, State and Zip.]

• Office Phone: [Click here to enter the Phone Number.]

• If you have any questions about the device, or you believe you have any injury related to the device, you should call the doctor named above.

• You may also call [Click here to enter the Name and Title.] at [Click here to enter the Phone Number.]
• You may also call the Administrator of the Committee on Clinical Investigations of Yeshiva University at (718) 430-2253, Monday through Friday between 9 AM and 5 PM, or the Montefiore Medical Center Institutional Review Board at (718) 798-0406, Monday through Friday between 9 AM and 5 PM.

WHO WILL KNOW THAT YOU HAVE BEEN TREATED WITH THIS NEW DEVICE?

• Your medical records and information about the new device will be kept private and your name will not be used in any written or verbal reports.

• Your records may be inspected by the U.S. Food and Drug Administration (FDA), the agency for regulating devices.

• Your records may also be inspected by the company who makes the device.

• Members of the human research committee at Montefiore Medical Center and Yeshiva University may also review your records.

• All of these groups have been requested to keep your name private.

MAY YOU STOP BEING TREATED WITH THE DEVICE ANY TIME?

• YES. You may tell your doctor at any time that you do not want continue to use the device.

• Your decision to be treated with the new device is voluntary.

• Your treatment by your doctor and hospital staff now and in the future will not be affected in any way if you refuse to receive this new device, or if you change your mind.

SUMMARY

• You have read and listened to an explanation of the information about this new device.

• You have been given the opportunity to ask questions and have your questions answered.

• A copy of this consent document has been given to you whether or not you agree to be treated with the device.
Kindly check each box below as a way of making sure that these points were discussed with you and that your questions have been answered:

☐ I have decided to voluntarily be treated with the new device.

☐ Information about the new device has been explained to me.

☐ The doctor has told me what I must do when I receive the device.

☐ I have been given the name of the doctor and others to contact if I have any questions or if there is any injury from using the device.

☐ I have been told about any costs and payments to me.

☐ I can discontinue using the device at any time without penalty.

☐ The doctor has told me about other treatment options.

☐ My name will not appear on any published reports.

☐ I will be given a schedule explaining how to use the device.

__________________________________________  _________________
Signature of Patient       Date

__________________________________________  _________________
Signature of Guardian or Family Member    Date

__________________________________________  _________________
Signature of Physician obtaining consent    Date

EMDVCON
1.28.03
A humanitarian use device (HUD) is a device intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States per year.

(Name of Device) has been approved by the Food and Drug Administration (FDA) as a Humanitarian Use Device for the treatment of (Name of Condition). The safety and effectiveness of this device has not been proven through research testing.

Purpose:

You are being asked to give your consent for use of a HUD by your physician because you have (name of condition) and your doctor does not think other available treatments will help your condition. No comparable device is available to treat (name of condition). The (device/product) use will be used under the direction of (Name of treating physician), in the department of (Department Name). There may be other physicians and professional staff persons who may assist (him/her) in the use of this (device/product)

This is not a research study. However, because of the limited experience with the device, the FDA requires that the Institutional Review Board for the protection of human subjects approve its use.

Include:

- an explanation of the postulated mechanism of action of the HUD in relation to the disease or condition,

Procedures:

Include:

- a description of the use of the HUD
- a description of any ancillary procedures associated with the use of the HUD
Risks:
Potential risks are….

Include:
  • a description of all known risks or discomforts.

There may be other significant or even life-threatening risks that we do not know about.

Benefits:
The possible benefits are…

Include:
  • A description of possible benefits.

Alternatives:
If you do not consent to the use of this product, the alternatives are…

Include:
  • A list of alternative treatments.

Costs:
This device is being used for clinical care and is the most appropriate device for your situation in the judgment of your treating physician. As a result, you or your insurance company will be charged or held responsible for the costs of your care. Your individual insurance or government health insurance program may not cover certain services, items or procedures. You may want to discuss this with your insurance carrier in advance. You will be responsible for any co-payments and/or deductibles for services rendered.

If you have any questions about the device, please contact Dr. (Name of Doctor) at (MD Phone Number).

If you have a complaint or question regarding the use of this device in your medical care, please contact the Einstein Institutional Review Board, West Campus at 718-798-0406.

I have read the above explanations and have received answers to any questions I have about treatment with this product. I consent voluntarily to the use of this device.
☐ I have received the manufacturer’s patient information booklet.

Comment [k1]: If a manufacturer’s patient information booklet is available, include this checkbox.

Printed Name of Participant or Legal Representative
Signature of Participant or Legal Representative
Date

Printed Name of Person Obtaining Consent
Signature of Person Obtaining Consent
Date

Obtaining Consent