

SOP: EU 1301 Version No: 02 Effective Date: 7/1/08	EMERGENCY SINGLE TIME USE OF A TEST ARTICLE (DRUG, DEVICE, BIOLOGIC)	Supersedes Document Dated: 01/27/04
---	---	--

1. POLICY

An exemption under Food & Drug Administration (FDA) regulations at 21 CFR 56.104(c) allows for the emergency use of an investigational drug, device, or biologic on a one-time basis per institution without Institutional Review Board (IRB) review and approval when all of the following conditions are met:

- A patient (subject) is in a life-threatening situation
- No standard acceptable treatment is available
- There is insufficient time to obtain IRB approval
- The emergency use is reported to the IRB within five (5) working days. (This is not to be construed as an IRB approval for the emergency use).
- The Physician/Investigator obtains informed consent from the patient or legally authorized representative for such emergency use, except when there are circumstances that prevent obtaining consent.

Nothing in this Policy or in the Federal Regulations intends to place a limit on the authority of the physician to provide emergency care to the extent the physician is permitted to do so under applicable federal, state, or local law. This policy does NOT apply when using a marketed product for an indication not in the approved labeling (“off-label use”) when the intent is the practice of medicine.

Department of Health and Human Services (HHS) regulations do not permit the commencement of research activities, even in an emergency, without prior IRB review and approval. However, when requesting a single time emergency use of a test article, IRB approval is not obtained. Therefore, when emergency medical care is initiated without prior IRB review and approval, the patient may not be considered a subject in the HHS supported research. The emergency care cannot be claimed as research nor can any of the data regarding such care be included in any report of a prospectively HHS supported research, except where required by FDA regulations, even if the emergency protocol is identical to that of a research protocol subsequently approved by the IRB.

Any subsequent use of the test article will require full board approval.

Specific Policies

The following definitions are key terms used in this policy. The definition of other terms not defined herein shall have the meaning set forth in the Glossary.

SOP: EU 1301 Version No: 02 Effective Date: 7/1/08	EMERGENCY SINGLE TIME USE OF A TEST ARTICLE (DRUG, DEVICE, BIOLOGIC)	Supersedes Document Dated: 01/27/04
---	---	--

1.1. Definitions

“**Life-threatening**”, for the purposes of section 21. CFR 56.102(d), includes the scope of both life-threatening and severely debilitating, as defined below.

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 patients 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. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

“**Independent Physician**” means a physician not otherwise participating in the single time use of the test article.

1.2. Emergency IND for Drugs and Biologics

The emergency use of an unapproved investigational drug or biologic requires an Investigational New Drug Exemption (IND) from the FDA. If the intended patient does not meet the criteria for an existing study protocol, or an approved study protocol does not exist, the usual procedure is to contact the manufacturer and determine if the drug or biologic can be made available for the emergency use under the company’s IND.

However, if there is not enough time for a submission of an IND, the sponsor should be consulted to verify that an IND exists. If no IND exists, a request must be made to the FDA to authorize shipment of the drug for emergency use in advance of the IND submission. These requests may be made by phone or other communication means (per FDA regulations 21 CFR 312.36).

1.3. Emergency Investigational Device Exemption (IDE) for devices

The Physician/Investigator should contact the sponsor to determine whether an IDE is required. Where an IDE for the device does not exist, and a physician wants to use a device in a way not approved under an existing IDE, or the physician is not an investigator under the existing IDE, the device may be used with the prior approval of the FDA. Follow-up reports must be provided to the FDA that justify the emergency use of the device.

SOP: EU 1301 Version No: 02 Effective Date: 7/1/08	EMERGENCY SINGLE TIME USE OF A TEST ARTICLE (DRUG, DEVICE, BIOLOGIC)	Supersedes Document Dated: 01/27/04
---	---	--

If there is not sufficient time to obtain FDA approval, the device may be used with the following protections in place:

- Informed consent of the patient;
- Clearance from the institution;
- Concurrence of the IRB chair;
- Independent Physician assessment;
- Authorization from the IDE sponsor (if an IDE exists).

1.4. Informed Consent for Any Test Article

In an emergency use situation, the Physician/Investigator is required to obtain informed consent of the patient or the Legally Authorized Representative (LAR) unless both the Physician/Investigator and an Independent Physician certify all of the following in writing:

- The patient is confronted by a life-threatening situation where the use of the test article is necessary;
- Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from the patient;
- Time is not sufficient to obtain consent from the patient's legally authorized representative; and
- No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the patient's life.

If immediate use of the test article is required to preserve life and there is insufficient time to obtain an Independent Physician's determination that the four conditions above apply, the Physician/Investigator should make the determination and within 5 working days after use of the test article, have the use reviewed and evaluated in writing by an Independent Physician. The Physician/Investigator must notify the IRB within 5 working days after the use of the test article [21 CFR 50.23 (c)]. All documents will be maintained.

1.5. IRB Notification and Review of Emergency Use Request

If full IRB approval cannot be obtained and use of the investigational drug, biologic or device meets the criteria for emergency use, the following steps must be completed prior to the use:

SOP: EU 1301 Version No: 02 Effective Date: 7/1/08	EMERGENCY SINGLE TIME USE OF A TEST ARTICLE (DRUG, DEVICE, BIOLOGIC)	Supersedes Document Dated: 01/27/04
---	---	--

1. The Aurora IRB requires notification prior to the single time emergency use of a test article whenever possible. This notification should not be considered IRB approval. Notice must be made by calling or paging the IRB Chair or RSPP Manager before the investigational article is administered or used in the patient. The IRB Chair or RSPP Manager will use Form EU 1301-A to determine that the regulatory criteria will be met.

Notification is used to track the use in order to ensure that the Physician/Investigator submits a report within the five day time-frame required by 21 CFR 56.104(c).

2. The IRB Chair or the RSPP Manager shall notify the Chief Medical Officer, the Site Administrator, the Institutional Official, or Vice President of Medical Affairs, as appropriate. This notification is to prohibit such use if the patient's condition does not qualify for Emergency Use or the risk to the patient outweighs any benefit related to the Emergency Use.
3. Unless immediate use of investigational article is required to preserve the life of the patient, verbal or written acknowledgement from the IRB Chair or the RSPP Manager of the acceptance of the one-time use should be secured prior to use.
4. Regardless of whether the RSPP Office was notified prior to use, the Physician/Investigator is always required to submit a written report to the RSPP Office within 5 working days after emergency use of the investigational article. The report must document compliance with the specific FDA requirements for emergency use, indicating that a life-threatening situation existed in which no standard acceptable treatments were available, and that the investigational article needed to be used expeditiously, meaning insufficient time was available to convene a quorum for full board IRB approval. If informed consent was not obtained prior to the use, the report should indicate that the requirements in section 1.4 were satisfied.
5. If a test article was used in a life-threatening situation without full committee approval, or prior notification of the IRB Chair or RSPP Manager, an Independent Physician must certify in writing that all of the criteria for single time emergency use were met. All documentation must be reviewed by the IRB Chair to determine/verify that the circumstances of the emergency use followed FDA regulations.

Any subsequent use of the test article will require submission of a research protocol for full IRB review and approval.

1.6. Use Of Data Generated Prior To IRB Approval

Whenever emergency use is initiated without prior IRB review and approval, the patient may not be considered to be a research subject. HHS regulations do not permit research activities

SOP: EU 1301 Version No: 02 Effective Date: 7/1/08	EMERGENCY SINGLE TIME USE OF A TEST ARTICLE (DRUG, DEVICE, BIOLOGIC)	Supercedes Document Dated: 01/27/04
---	---	--

to be started, even in an emergency, without prior IRB review and approval. The physician may, without prior IRB approval, treat the patient using a investigational article (if the situation meets the FDA requirements as noted in this policy), but the patient may not be considered a research subject and data derived from use of the investigational article may not be used in the study.

1.7. Aurora Compliance Department Notification of Emergency Use

The RSPP office will notify the Specialty Patient Accounts Representative of the emergency use as soon as possible so appropriate billing procedures may be followed.

2. SCOPE

This policy/procedure **applies only** to single time emergency use of FDA regulated test articles without IRB review and approval and with or without informed consent. This policy/procedure **does not apply** when using an **approved** agent/device for a non-marketed (off-label) purpose when the goal is medical treatment or “compassionate use” for drugs or devices. The RSPP Office should be consulted when “compassionate use” is being considered to ensure compliance with federal regulations.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.23 (a), (b) & (c)

21 CFR 56.102 (d)

21 CFR 56.104 (c)

21 CFR 312.36

FDA IRB Information Sheets 1998

4. REFERENCES TO OTHER APPLICABLE SOPS

None