1 PURPOSE

1.1 This procedure establishes the process to review notifications of:

1.1.1 Emergency use of an unapproved drug, biologic, or device in a life-threatening situation.

1.1.2 Compassionate use of an unapproved device without an investigational device exemption (IDE) for a serious condition.

1.1.3 Emergency use of a humanitarian use device (HUD) when a humanitarian device exemption (HDE) has been issued.

1.2 The process begins when the Office of IRB Administration (OIA) receives a notification of a proposed or actual use.

1.3 The process ends when a designated reviewer has:

1.3.1 Determined whether the proposed or actual use will follow or has followed Food and Drug Administration (FDA) regulation and guidance; and

1.3.2 Notified the physician and OIA staff of the determination.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 REQUIREMENTS

3.1 Whenever possible, physicians are to notify the IRB of a proposed emergency use of an unapproved drug, biologic, or device in a life-threatening situation in advance of the use.

3.2 Physicians are to notify the IRB of a proposed compassionate use of an unapproved device without an IDE for a serious condition.

3.3 Physicians are to notify the IRB of a proposed emergency use of an HUD when an HDE has been issued for a serious condition.

3.4 Data obtained from uses covered by this procedure can only be used in a systematic investigation designed to develop or contribute to generalizable knowledge if a separate application for research is submitted to and approved by the IRB.

4 RESPONSIBILITIES

4.1 A designated reviewer carries out these procedures.

5 PROCEDURE

5.1 The designated reviewer uses the *OIA-322 WORKSHEET: Emergency Use*, or equivalent, to determine whether the circumstances will meet regulatory and guidance criteria and indicate the results of this determination to the physician.

5.1.1 If met, inform the physician that the physician can proceed with the use.

5.1.1.1 If the advance notification of the use is made in the electronic submission system, also request an updated submission following the emergency use to provide data on treatment outcomes.

5.1.2 If not met, inform the physician that if the physician proceeds with the use, the IRB will consider that action to be non-compliance.

5.2 For notifications after the emergency use of a test article in a life-threatening situation, the designated reviewer uses the *OIA-322 WORKSHEET: Emergency Use*, or equivalent, to determine whether the circumstances met regulatory and guidance criteria.

5.2.1 The designated reviewer communicates with the physician directly as needed to resolve any outstanding questions to assess whether the criteria have been met.

5.2.2 The designated reviewer informs OIA staff of the results of the evaluation.

5.2.3 If notification was made outside of the electronic submission system, OIA staff confirm that a submission has been made in the electronic submission system within 5 days after the date of the use of the test article.

5.2.4 OIA staff send the results of the evaluation to the physician by preparing and sending *OIA-526 TEMPLATE LETTER: Acknowledgment of Emergency Use*, or equivalent.

6 MATERIALS

6.1 *OIA-001 SOP: Definitions*
6.2 *OIA-322 WORKSHEET: Emergency Use*
6.3 *OIA-526 TEMPLATE LETTER: Acknowledgment of Emergency Use*

7 REFERENCES

7.1 21 CFR 50.23
7.2 21 CFR 56.104(c)