**GUIDANCE 9**

**EMERGENCY USE OF TEST ARTICLE GUIDANCE**

**Rowan University Guidance for Emergency Use of test article is described Article 10 of Rowan University Guidance book:** [**https://research.rowan.edu/officeofresearch/compliance/irb/policiesguidance/index.html**](https://research.rowan.edu/officeofresearch/compliance/irb/policiesguidance/index.html)**.**

The Guidance includes the following:

1. Research Interventions in Emergencies

10.6.1 Scope

10.6.2 Written Approval and Subsequent Report

10.6.3 Emergency Use of Unapproved Medical Devices

10.6.4 Requirements for Emergency Use of an Investigational Device

10.6.5 After-use Procedures

10.6.6 Exception from Informed Consent Requirement

10.7 Emergency Use of an Investigational Drug or Biologic

10.7.1 Obtaining an Emergency IND

10.8 Emergency Exemption from Prospective IRB Approval

10.9 Exception from Informed Consent Requirement

10.10 Exception from Informed Consent for Planned Emergency Research

10.11 Life Threatening Exception to Review

10.12 Emergency Subjects

10.13 Sponsor’s Brochure

Guidance for consenting for the use of test article is provided in Article 5 of Rowan University Guidance book <https://research.rowan.edu/officeofresearch/compliance/irb/policiesguidance/index.html>.

5.28 Special Consent Provisions for Certain Emergency Research

5.29 Criteria for Waiver of Consent for Emergency Treatment for Research