Emergency Use Report Form
Attachment 1

Please refer to SYS-RES-103, Emergency Use, for more detailed information about Emergency Use.

Sections A & B of this form should be completed and emailed to the IRB Office (IRB@integrisok.com) with a copy to the IRB Chair or his/her designee (the Director of Research and Grants) and discussed **before the use, whenever possible**. The fully completed form **must** be submitted to the INTEGRIS IRB within **5 working days after initiation** of the Emergency Use.

A. Physician Information

Treating Physician's Name:	Date:
Department, Division:	Phone/Pager:
Email address:	Preferred method of contact:

B. Confirm that Emergency Use is Appropriate (all boxes must be checked)

☐ 1. Patient has a **life-threatening** or **serious disease or condition** (*see* SYS-RES-103 for the definitions of these terms, which differ for drugs/biologics vs. devices)	**Describe the patient's condition (noting why it is life-threatening/serious)**:
☐ 2. **No generally acceptable alternative** for treating the patient is available	**Explain why available alternatives are not acceptable** (*e.g., standard therapies have been exhausted; patient does not qualify for research study; research study is not approved at INTEGRIS*): **Explain the proposed therapy** (*also attach any available materials, protocols, investigator's brochures provided from the manufacturer*):
☐ 3. Patient's condition **requires immediate treatment**, such that there is not sufficient time to obtain IRB review and approval at a convened meeting.	**Explain timing considerations**:
☐ 4. Depending on whether the test article is a drug/biologic or device, the treating physician has made the **additional determinations** specified in SYS-RES-103.	**For Drugs/Biologics,** determine that the **probable risk** to the person from the investigational test article is not greater than the probable risk from the disease or condition. See SYS-RES-103 for the additional determinations to be made by FDA. **For Devices,** assess the **potential for benefit** from the use of the unapproved device, and to have substantial reason to believe that benefits will exist.

→ **(1) Email:** After completing parts A & B above, **email this form** to the IRB Office (IRB@integrisok.com) as directed in SYS-Res-103.

→ **(2) Follow-up by Phone:** Next, **call the IRB Office at 405-949-4184 or 405-713-7762** to discuss the Emergency Use.

→ **(3)** IRB Office sends **confirmation letter** to treating physician and the IRB Coordinator.

While seeking IRB concurrence, you may simultaneously work through the other steps in the process, per SYS-RES-103.

→ Contact the **manufacturer** of the investigational agent about their willingness to make the test article available to your patient.
→ Refer to SYS-RES-103 for information about the necessary approvals from the **sponsor** and/or **FDA** for the emergency use.

C. Test Article Information

Name of Test Article:	Name of Manufacturer:	
Who holds the IND (*for drugs/biologics*) or IDE (*for devices*)?	☐ Treating Physician	☐ Manufacturer/Sponsor
For Drug or Biologic, include emergency **IND#** (*from FDA*):	For Device, include applicable **IDE#** (*usually from sponsor*):	

D. Patient Protection Measures. Complete as many as possible *before* using the investigational article:

☐ Written informed consent from patient or their legally authorized representative.

☐ Concurrence of the IRB Chair or designee, confirmed by email

☐ *DEVICES ONLY*: independent assessment from uninvolved physician that emergency use criteria are satisfied.

E. Follow-up Report.

This completed form must be submitted to the INTEGRIS IRB (IRB@integrisok.com) within **5 working days after the initiation** of the investigational article. See SYS-RES-103 for information about follow-up reporting to **FDA** and/or **sponsor**.

Date of emergency use:	**Date this follow-up report submitted to IRB:**	
Provide patient outcome information **as of the date when this report is submitted** to the IRB.	**Patient's current condition**:	
☐ No adverse events have occurred.	**OR**	☐ Adverse events have occurred and the report is attached.
☐ Attached copy of the **signed** emergency use consent form	**OR**	☐ Written informed consent could not be obtained → See waiver criteria: **Submit** written documentation from the **treating** physician and a **second** independent/uninvolved physician that the emergency situation fulfills the following criteria: 1) The patient was confronted by a life-threatening situation that necessitated the use of the test article; 2) Informed consent could not be obtained because of an inability to communicate with or obtain legally effective consent from the patient; (3) There was insufficient time to obtain consent from the patient's legally authorized representative; **and** (4) No alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the patient's life.
☐ Attached email confirmation of IRB concurrence	**OR**	☐ It was not possible to obtain prior IRB concurrence; please **explain**:
☐ For Drugs/Biologics, obtained emergency IND from FDA	**OR**	☐ For Devices, obtained prior authorization from IDE sponsor. If sponsor authorization not obtained, **explain**:
☐ No additional uses of the investigational agent are anticipated	**OR**	☐ Additional uses of the investigational agent are anticipated. **Explain** whether there is a research study available that could be opened at INTEGRIS:
☐ DEVICES only: attached second opinion of an uninvolved physician that the patient meets the ***criteria for emergency use*** (part B above)	**OR**	☐ DEVICES only: Second opinion that patient met criteria for emergency use was not obtained prior to the emergency use; please **explain** why it was not possible to obtain a second opinion:

F. Signatures and Approvals

Physician Signature: _____ Date: _____
(Optional Signature if submitted from physician's e-mail account.)

G. Final IRB Follow-Up Report on Completion of Treatment. This section must be completed upon completion of treatment. If treatment of the drug/biologic or use of the device continues beyond an initial use, indicate "indefinite use" on the form and submit a continuing review report at six (6) months, one year, and annually until either completion of treatment or approval by the FDA.

Date of Completion of Treatment:	Indefinite Use?: ☐ Yes ☐ No
Status of Patient upon Completion of Treatment:	
Outcome of Treatment:	Any Adverse Effects of Treatment:

IRB Final Review of Follow-Up Emergency Use Report	
IRB Chairperson Signature:	Date Noted:

☐ All requirements for Emergency Use are satisfied; no further action is required. Retain documentation in your files.
☐ Subject to the additional requirements detailed in IRB correspondence dated: _____

Additional requirements met on: _____

☐ Physician (or member of appropriate Department/Division) must request an IRB consultation about the need for a new IRB application.