

**INVESTIGATIONAL DRUG SERVICES**  
**EXCEPTION REQUEST FORM**

Emory University requires the use of a designated pharmacy to provide investigational drug management services (IDS) for trials conducted by Emory faculty. In selected and exceptional circumstances, it may be necessary for the preparation, dispensing and/or management of the investigational drug/material to be performed outside of the designated pharmacy. In those circumstance, the Emory principal investigator for the project should complete this exception form and send it, with any other accompanying documents or information, to: Susan Rogers, RPh at [susan.rogers@emoryhealthcare.org](mailto:susan.rogers@emoryhealthcare.org). Exception requests will be reviewed on a case-by-case basis and shall not set precedence for an investigator or for future trials.

**Exception Request for Use of Investigational Drug Services**

1. Investigator name: \_\_\_\_\_

Investigator contact information (email/phone): \_\_\_\_\_ / \_\_\_\_\_

School/Dept: \_\_\_\_\_

2. Study title: \_\_\_\_\_

Drugs to be used in the study that are investigational (i.e. not approved) OR are approved/marketed products but will be provided for free by a third party/sponsor:

(i) \_\_\_\_\_

(ii) \_\_\_\_\_

(iii) \_\_\_\_\_

3. Study location(s) - (i.e. location at which subjects will be seen and at which study drug(s) will be stored, prepared and dispensed)

(i) \_\_\_\_\_

(ii) \_\_\_\_\_

(iii) \_\_\_\_\_

4. Reason/justification for exception request – please indicate all that apply.

Potential for drug degradation or instability if drug preparation and administration is not immediate or completed within very narrow time window

Study location would require courier delivery of doses and drug is unable to be transported due to documented sponsor or drug labeling restrictions

Advanced scheduling of subject visits is not possible (due to visit criteria) and dose must be prepared for immediate administration or under emergent circumstances

**Other** – Please provide full and complete explanation of study circumstances, timing, location and drug criteria that support the exception request.

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**Please provide a copy of the study protocol and all investigator brochures for each of the study drugs with your signed request form.**

Signed: \_\_\_\_\_

Principal Investigator

NOTE: Exception requests, when granted, are conditional upon the following:  
 (i) certification by IDS that proper drug storage, inventory and preparation conditions and skills are met  
 (ii) annual fee for Emory IDS audits (conducted at least annually but may be more frequent if higher risk or if high enrollment is expected or occurs)  
 (iii) submission of quarterly updates on study enrollment  
 (iv) corrective action and/or withdrawal of exception/waiver may occur if serious deficiencies are noted upon any study audit

IDS: Internal Use Only	Request received	Date Date
	Request decision <input type="checkbox"/> <b>granted</b> <input type="checkbox"/> <b>not granted</b>	