

INVESTIGATIONAL DRUG SERVICES
EXCEPTION REQUEST FORM

Emory University requires the use of Emory's Investigational Drug Service (IDS), to provide investigational drug management services for trials conducted by Emory faculty. In certain specific circumstances, it may be necessary for the preparation, dispensing and/or management of the investigational drug/material to be performed outside of IDS; provided, however, that a request to do so must be approved in advance. To make such a request, the Emory principal investigator for the project should complete this Exception Request Form and send it, with the protocol and investigator brochure, to: sy.quoc.tran@emory.edu. Exception requests will be reviewed on a case-by-case basis and shall not set precedence for an investigator or for future trials.

Request for Exception

1. Investigator name: _____

Investigator contact information (email/phone): _____ / _____

School/Dept: _____

2. Study title: _____

Exception from use of IDS requested for the following drugs used in this study:

(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 –

- ☐ Emergent circumstances
- ☐ Potential for drug degradation or instability if drug preparation and administration is not immediate or completed within very narrow time window
- ☐ Schedule 1 Controlled Substance: submit completed Investigator Checklist for the Use of Schedule (DOCX)1 Controlled Substances to oric@emory.edu
- ☐ Other –

Please provide full and complete explanation of criteria that support the exception request. Include study circumstances, timing, location and description of drug storage and preparation conditions.

Exception requests, when granted, are conditional upon the following:

- proper drug storage, inventory and preparation conditions and skills are met
- agreement of investigator to undergo audit by Emory IDS, with any associated costs to be borne by the site.
- implementation of corrective action if any deficiencies are noted upon audit. Withdrawal of the exception may occur if serious deficiencies are noted.

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

IDS: Internal Use Only	Request received	Date: _____
	Request decision	<input type="checkbox"/> granted <input type="checkbox"/> Proper drug storage, inventory and preparation conditions and skills are met
		<input type="checkbox"/> not granted
	Signature: _____	Date: _____