Investigational Drug Service Pharmacy | MC001
100 Michigan St NE, Grand Rapids MI 49503
SH-PharmacyResearch@Spectrum-Health.org
Phone: 616.486.6113 Fax: 616.391.1083
Monday – Friday 7 am – 3:30 pm

Research Request for Investigational Pharmacy Services

This request form should be used to request any pharmaceutical services related to the study that will not be provided by investigators. Please contact the Investigational Drug Service (IDS) pharmacy with any questions.

Protocol Title:	
Protocol Number:	**Protocol Short Name:**
Sponsor:	**IRB Number:**
Estimated Number of Patients Enrolled:	
Timeframe of Study (approx.):	
Department Coordinating Study: ☐ **SHOR** ☐ **CRCWM** ☐ **BCC** ☐ **Other: _____**	

Principle Investigator (PI):	
Address:	
Phone:	
Email:	
PI Specialty Office **(i.e. Peds Nephrology, etc):**	
Study Coordinator (Regulatory)	**Study Coordinator (Clinical)**
Name:	**Name:**
Phone:	Phone:
Email:	Email:
Sponsor Contact:	
Email:	

Clinical Trial Details

Please provide a brief description of the research study and requirements:

Will this study involve after hours enrollment and/or require 24/7 on call IDS services? ☐ **Yes** ☐ **No**
If yes, please explain:

Investigational Agent

What is/are the investigational agent(s) for this study?
_____

Is this a controlled substance? _____

Storage requirements for study drug _____

Who is responsible for randomization? _____

What is the estimated total number of dispenses **per patient** for each agent?

Agent 1 _____ # of dispenses _____
Agent 2 _____ # of dispenses _____
Agent 3 _____ # of dispenses _____
Agent 4 _____ # of dispenses _____
Agent 5 _____ # of dispenses _____
Agent 6 _____ # of dispenses _____

Will this study require drug transportation from IDS to an offsite location? If yes, please explain _____
_____

Are there sponsor required trainings (webinar, conference call, **SIV, IXRS**, etc)?_____
_____

Are there ancillary medications needed from the IDS pharmacy that are not provided by the sponsor? Please describe
_____
_____

Agent Procurement

Are shipments automated (IXRS) or ordered by non-IDS staff? ☐ Yes ☐ No

If drug shipments are not automated, what is the sponsor's process for ordering study drug?
☐ Drug order form ☐ Email
☐ Telephone ☐ Other _____

Inpatient Areas: (please specify)

☐ Butterworth _____ ☐ Blodgett _____ ☐ HDVCH _____

☐ Meijer Heart Center _____ ☐ Other _____

Outpatient Areas: (**on campus**, i.e. LHCP, on campus clinic) _____

Where will the study agent(s) be dispensed?

Outpatient Areas: (**off campus**, requiring research staff transportation; please provide address)

_____

Electronic Medical Record Resources

Note: IDS will now be assessing need for EPIC contraindicated medication groupers for RSH records and/or EPIC medication builds. If your study requires either item, IDS will inform you and discuss the process after review of this document. If you have any questions or are unsure of how to answer the below questions, please reach out to IDS or an RSH record builder.

Will the sponsor provide a specific list of prohibited medications? ☐ Yes ☐ No ☐ N/A or not sure

Is there a significant safety or clinical reason to build the contraindicated meds functionality or other medication alert as determined by PI or study team?

☐ Yes ☐ No **Explain:**_____

Billing and Reimbursement

Who is funding the study?

☐ Sponsor/Industry ☐ Government ☐ Grant ☐ Other_____

Is reimbursement for IDS costs provided? ☐ Yes ☐ No

Other

Will there be a pharmacy manual provided? ☐ Yes ☐ No

Will a pharmacy binder be provided? ☐ Yes ☐ No

Submitted by: _____

Date: _____

Please send the research protocol, pharmacy manual, and investigator brochure along with this request form to: **SH-PharmacyResearch@spectrum-health.org**

Study team is required to contact IDS when submitting final trail intake/IRB to confirm trial is moving forward

IDS Pharmacy Departmental Use Only

Study Approved: ☐ Yes ☐ No

Approval Signature/Date:_____

EPIC Build being considered: ☐ Yes ☐ No

Contraindicated meds grouper being considered: ☐ Yes ☐ No

Follow up: