***Investigational Product (IP)***

1. **PURPOSE**

This Standard Practice Guideline (SPG) describes the regulatory responsibilities, processes, and procedures pertaining to the accountability of the Investigational Product (IP) (including investigational drugs and biologics, placebos, investigational devices, and combination products).

**(MANDATORY LANGUAGE)**

1. **SCOPE**

This SPG applies to all members of the research team including Sponsor-Investigators (SI) involved with the management of the IP for a clinical trial. The process for non-IP (not under study) products is not within scope of this SPG. The responsibilities of UM faculty/staff that act solely as the Sponsor of a clinical trial are also out of scope for this SPG.

 **(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details necessary to further define the scope of this SOP]*

1. **POLICY**

**Good Clinical Practice (ICH GCP)**

This Standard Practice Guideline aligns with the Good Clinical Practice (ICH GCP) guidelines established by the International Council on Harmonization (ICH).

**Principal Investigator (PI):**

**4.6 Investigational Product(s)**

Section 4.6 of the ICH GCP guidelines focuses on the Investigational Product(s), including

4.6.1 which states *responsibility for investigational product(s) accountability at the trial site(s) rests with the investigator/institution.*

Please see additional regulations in Section 4.6, includingSections 4.6 - 4.6.6.

**4.7 Randomization Procedures and Unblinding**

*The investigator should follow the trial's randomization procedures, if any, and should*

*ensure that the code is broken only in accordance with the protocol. If the trial is blinded,*

*the investigator should promptly document and explain to the sponsor any premature*

*unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the*

*investigational product(s).*

**Sponsor-Investigator (SI):**

**5.12 Information on Investigational Product(s)**

**5.13 Manufacturing, Packaging, Labeling, and Coding Investigational Product(s)**

**5.14 Supplying and Handling Investigational Products(s)**

**FDA Regulation(s)** (if applicable)

**Principal Investigator (PI):**

**Per 21CFR part 312.6 - Labeling of an investigational new drug**

**Per 21CFR part 312.7 - Promotion of investigational drugs**

**Per 21CFR part 312.8 - Charging for investigational drugs under an IND**

**Per 21CFR part 312.59 - Disposition of unused supply of investigational drug**

**Per 21CFR part 312.60 - General responsibilities of the investigators**

**Per 21CFR part 312.61 - Control of the investigational drug**

**Per 21CRF part 312.62 - Investigator recordkeeping and record retention**

**Per 21CFR part 312.69 - Handling of controlled substances**

**Per 21 CFR part 812.5 - Labeling of investigational devices**

**Per 21CFR part 812.36 - Treatment use of an investigational device**

**Per 21CFR part 812.100 - General responsibilities of investigators**

**Per 21CFR part 812.110 - Specific responsibilities of investigators**

**Per 21CFR part 812.140 - Records**

**Sponsor-Investigator (SI):**

**Per 21CFR part 312.6 - Labeling of an investigational new drug**

**Per 21CFR part 312.7 - Promotion of investigational drugs**

**Per 21CFR part 312.8 - Charging for investigational drugs under an IND**

**Per 21CFR part 312.50 - General responsibilities of sponsors**

**Per 21CRF part 312.53 - Selecting investigators and monitors**

**Per 21CFR part 312.57 - Recordkeeping and record retention**

**Per 21CFR part 312.59 - Disposition of unused supply of investigational drug**

**Per 21CFR part 312.61 - Control of the investigational drug**

**Per 21CRF part 312.62 - Investigator recordkeeping and record retention**

**Per 21CFR part 312.69 - Handling of controlled substances**

**Per 21CFR part 812.5 - Labeling of investigational devices**

**Per 21CFR part 812.7 - Prohibition of promotion and other practices**

**Per 21CFR part 812.40 - General responsibilities of sponsors**

**Michigan Medicine**

A study involving an Investigational drug or biologic that is conducted using Michigan Medicine facilities must be reviewed by the Research Pharmacy. Per pharmacy Policy, *investigational drugs used in humans in the* UMHHC (University of Michigan Hospitals and Health Centers) must be stored and dispensed by the *Research Pharmacy. Exceptions (waiver of Research Pharmacy involvement) may be allowed in situations where it can be shown that storage or dispensing of the drug by the Research Pharmacy presents a hardship to the investigator, to study subjects or to the conduct of the study. In these cases, Research Pharmacy shall assure storage, dispensing and inventory control criteria are met by auditing these processes. (This was taken from eResearch; however, Research pharmacy policy link is included here.)*

*Policy: 400.05* [PolicyStat :: PolicyStat](https://michmed-clinical.policystat.com/policy/7415063/latest/)

Studies involving controlled substances may be audited by the U-M Controlled Substances in Research Review Committee.

**(MANDATORY LANGUAGE)**

 **Additional Regulations or Policies** [ ]  **N/A**

*[Optional: Insert any additional project, department, sponsor, institution, state, or federal policies that apply]*

1. **DEFINITIONS**

COMBINATION PRODUCT: The term includes:

1. A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
2. Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device, and biological products, or biological and drug products;
3. A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
4. Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

GOOD CLINICAL PRACTICE: A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. (Definition is from ICH -GCP R2)

INTERNATIONAL COUNCIL ON HARMONISATION (ICH): A joint initiative involving both regulators and research-based industry representatives of the European Union, Japan, and the USA in scientific and technical discussions of the testing procedures required to assess and ensure the safety, quality, and efficacy of medicines

INVESTIGATIONAL DEVICE EXEMPTION (IDE): Approval by FDA for investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully across state and international boundaries for the purpose of conducting investigations of that device. (FDA 21CRF812)

INVESTIGATIONAL NEW DRUG (IND): a new drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms “investigational drug” and “investigational new drug” are deemed to be synonymous for purposes of this part.

IND means an investigational new drug application. For purposes of this part, “IND” is synonymous with “Notice of Claimed Investigational Exemption for a New Drug.” (FDA part 312)

INVESTIGATIONAL PRODUCT (IP): An investigational product refers to a preventative (vaccine), a therape​utic (drug or biologic), device, diagnostic, or palliative used in a clinical trial. An investigational product may be an unlicensed product or a licensed product when used or assembled (formulated or packaged) differently from the approved form, when used for an unapproved indication, or when used to gain further information about an approved use. (NIH Definition)

PRINCIPAL INVESTIGATOR (PI): A Principal Investigator is a doctor who leads the clinical research team and, along with the other members of the research team, regularly monitors study participants’ health to determine the study’s safety and effectiveness.

SPONSOR: An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial. (ICH-GCP R2 definition)

SPONSOR-INVESTIGATOR: An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject.

 **(MANDATORY LANGUAGE)**

*[Optional: Insert any additional definitions for technical or special terms used within the Standard Practice Guideline that may not be familiar to the lay reader]*

**Note:** Some of the definitions above were obtained from the IRBMed Glossary. These definitions were current as of 01-Oct-2022 and are subject to change. Please see the [IRBMed Glossary](https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/guidance/glossary) for the most current definitions and additional guidance.

**(MANDATORY LANGUAGE)**

1. **ROLES AND RESPONSIBILITIES**

**Principal Investigator**

An individual filling the role of Principal Investigator (PI) is ultimately *responsible* for the management and accountability of the IP in a clinical trial at the site. The Principal Investigator or Designee shall be responsible for the following activities:

* Assigns the duties for investigational drug accountability to the The University of Michigan Research Pharmacy or a similar organization that complies with local, state, and federal laws
* Ensures proper steps are taken to obtain a waiver when not utilizing the University of Michigan Research Pharmacy for the Investigational Drug
* Ensures the clinical research team follows all local, state, and federal requirements when not utilizing the Michigan Medicine Research Pharmacy for the Investigational Drug See Research Pharmacy Policy 400.05:

<https://michmed-clinical.policystat.com/policy/7415063/latest/>.

(Note: This includes audits by the Research Pharmacy.)

* Ensures Investigational Product (IP) is properly labeled according to regulatory requirements
* Provides authorization to begin and discontinue distribution of the Investigational Product (IP) to participating sites
* Authorizes and delegates to individuals the authority to prescribe IP
* Ensures that the IP is only dispensed according to the approved protocol and to participants that are appropriate
* Follows all applicable randomization procedures, including unblinding/unmasking of IP
* Ensures that participants understand the correct use of the IP and provides IRBMED approved patient education material when necessary
* Maintains a record of the Investigational Product (IP) returned from participants, and ensures (when necessary) they are delivered to the appropriate department i.e. research pharmacy or Sponsor
* Ensures Investigational Products (IP) including investigational devices are properly stored and managed by the clinical research team including receipt of shipment, inventory at the site, dispensation/use by each participant, final dispensation, number of devices that have been repaired, returned to the sponsor or otherwise disposed of and the reason for the return, repair or disposal. (Note: The Research Pharmacy does not provide accountability for devices, however, they may provide accountability for combination products)
* Receives and provides necessary training prior to using Investigational Products
* Ensures that the applicable University department/unit/organization or the Sponsor/Manufacturer has assessed all devices for safety and tagged or registered them prior to use on clinical trial subjects
* Delegates responsibilities as appropriate

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the Primary Investigator/Designee*]

**Sponsor-Investigator**

An Investigator filling the role of the Sponsor-Investigator assumes the responsibilities of the Principal Investigator as described above and ***in addition***, is responsible for the following:

* Consults with appropriate regulatory specialists (MIAP at MICHR, etc.) to determine whether or not an IND and/or IDE application must be filed with the FDA prior to use of an IP in a clinical trial
* Submits the IND and/or IDE application to the FDA with assistance from MICHR IND/IDE Investigator Assistance Program (MIAP)
* Oversees the management of IP product supply (procurement, distribution, accountability, and disposition
* Ensures Investigational Product (IP) is properly labeled according to regulatory requirements
* Consults with the University of Michigan Research Pharmacy to ensure appropriate processes and related documentation are in place including processes for multi-site trials

*Note: The UM Research Pharmacy does not generally provide centralized services for Investigational Product (IP) using multi-site clinical trials. Consult with the Research Pharmacy prior to designating them as a central hub to ensure they are able to provide this service.*

* Arranges and provides randomization and unblinding/unmasking procedures regarding the IP
* Ensures randomization, blinding and unblinding procedures are harmonized with procurement, distribution, accountability, and disposition procedures for the IP
* Selects appropriate qualified, prescribing investigator(s)
* Provides investigational site(s) with all necessary materials to run the clinical trial (i.e. Instructions for the IP, the Investigator’s Brochure, etc.) and coordinates additional training as needed
* Ensures investigational site(s) have the appropriate approvals prior to shipping drug or devices to the site(s)
* Ensures monitoring is in place to review drug and device accountability at the site(s) during the life of the clinical trial
* Supplies tracking tools to participating sites and/or pharmacies (when needed) to facilitate management of inventory, shipping, storage, dispensing, disposal and return of IP
* Follows all local, state, federal, and international laws (including ICH GCP when applicable) for the clinical trial
* Delegates responsibilities as appropriate

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the Sponsor- Investigator/Designee*]

**Study Coordinator(s)/Designee**

An individual filling this role shall be responsible for the following activities:

* Maintains documentation of participants given IP
* Records details of the IP (e.g. dispensing, administration, return and/or disposal dates, etc.)
* Discusses with the PI concerns regarding the storage, use, safety, disposal or return of the IP that may arise during the clinical trial
* Reviews IP for expiration date and other issues that could affect the safety or quality of the IP
* Collaborates with the Research Pharmacy for the life of the investigational drug clinical trial (if applicable)
* Ensures proper information is recorded and documentation stored regarding IP
* Assists study team with the storage and management of the investigational device
* Creates additional guidance or SPGs to help facilitate the management of the IP

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the Study Coordinator(s)/Designee*]

**Co-Investigator(s)**

An individual filling this role may be responsible for the following activities:

Ensures that the IP is only dispensed according to the approved protocol and to participants that are appropriate

Notifies the PI and applicable research team members of any concerns regarding the IP

Follows all applicable randomization procedures regarding IP and unblinding/unmasking of IP

* Ensures that participants understand the correct use of the IP and provides IRB approved patient education material when applicable
* Maintains records of the return of IP product from participants and returns investigational product back to the Research Pharmacy or Sponsor as needed
* Receives and provides necessary training prior to using investigational product, as needed

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the Co- Investigator(s)]*

**Additional Roles and Responsibilities** [ ]  **N/A**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional role(s) and responsibilities that apply to this SPG]*

1. **PROCEDURE**

**Non-University of Michigan, Sponsor Initiated Clinical Trial Regulatory Obligations**

*[Describe the process for collecting and storing the IP documentation necessary to complete the IRB application (i.e. IB brochure, package insert, manufacturing information, etc.)]*

**University of Michigan Sponsor-Initiated Clinical Trial Regulatory Obligations**

*[Describe the process to collect and distribute all necessary information regarding the IP (i.e. IB brochure, package insert, manufacturing information, etc.) to all participating research staff.]*

**Investigational Drug Accountability**

*[Describe the process to document drug accountability (i.e. clinical trials will be managed by Research Pharmacy)]*

*[When not using the Research Pharmacy, (waiver required) describe the process that the research team will follow in order to manage all necessary regulations (i.e. where will the drugs be kept, what type of logs will be maintained, etc.)]*

*[For multi-site trials, describe the process used at the site(s) to document additional steps in the drug accountability trail (i.e. delivery of study medications to participants and returns.)]*

*[For multi-site trials, describe the process used when a non-UM pharmacy has agreed to be the central hub for shipping study drugs to other sites.]*

*[Describe the process for authorizing and discontinuing the distribution of IP to study sites. Include a description of any relevant documentation associated with the process (i.e. pharmacy manual) and how it will be managed.]*

**Investigational Device Accountability**

*[Describe the processes to store and manage the device used including the receipt of shipment, inventory at the site, dispensation/use by each participant, and final dispensation, (why and how many units of the device have been returned the sponsor, repaired, or otherwise disposed of.) Records of these should include dates, quantities, batch, serial numbers, and expiration date (if applicable).]*

**Additional Procedures** [ ]  **N/A**

*[Optional: Insert any additional relevant procedures. Provide enough detail to ensure the procedure is consistently carried out, without providing so much detail that violations occur due to normal or expected variations in the work.]*

1. **REFERENCES**

FDA [Title 21 CFR 312.6 - Labeling](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.57) of an investigational new drug:

<http://www.ecfr.gov/cgi-bin/text-idx?SID=16349f1e2bfb166ffd2aa2932b8262d8&mc=true&node=se21.5.312_16&rgn=div8>

FDA Title 21 CFR 312.7 - Promotion of investigational drugs:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=16349f1e2bfb166ffd2aa2932b8262d8&mc=true&n=sp21.5.312.a&r=SUBPART&ty=HTML#se21.5.312_17>

FDA Title 21 CFR 312.8 - Charging for investigational drugs under an IND:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=16349f1e2bfb166ffd2aa2932b8262d8&mc=true&n=sp21.5.312.a&r=SUBPART&ty=HTML#se21.5.312_18>

FDA Title 21 CFR 312.50 - General responsibilities of sponsors:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=16349f1e2bfb166ffd2aa2932b8262d8&mc=true&n=pt21.5.312&r=PART&ty=HTML#se21.5.312_150>

FDA Title 21 CFR 312.53 - Selecting investigators and monitors:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=16349f1e2bfb166ffd2aa2932b8262d8&mc=true&n=pt21.5.312&r=PART&ty=HTML#se21.5.312_153>

FDA [Title 21 CFR 312.57 - Recordkeeping and record retention](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.57):

<http://www.ecfr.gov/cgi-bin/text-idx?SID=0095923a55b9a25c4ae656e596e0c6ad&mc=true&node=se21.5.312_157&rgn=div8>

FDA [Title 21 CFR 312.59 - Disposition of unused supply of investigational drug](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.59):

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=22498ff22b4c67a9d8f3a0ee60c3a58d&mc=true&n=pt21.5.312&r=PART&ty=HTML#se21.5.312_159>

FDA [Title 21 CFR 312.60 –](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.59) General responsibilities of investigators:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=22498ff22b4c67a9d8f3a0ee60c3a58d&mc=true&n=pt21.5.312&r=PART&ty=HTML#se21.5.312_160>

FDA [Title 21 CFR 312.61 - Control of the investigational drug](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.61):

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=22498ff22b4c67a9d8f3a0ee60c3a58d&mc=true&n=pt21.5.312&r=PART&ty=HTML#se21.5.312_161>

FDA [Title 21 CFR 312.62 - Investigator recordkeeping and record retention](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62):

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=22498ff22b4c67a9d8f3a0ee60c3a58d&mc=true&n=pt21.5.312&r=PART&ty=HTML#se21.5.312_162>

FDA [Title 21 CFR 312.69 - Handling of controlled substances](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.69):

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=22498ff22b4c67a9d8f3a0ee60c3a58d&mc=true&n=pt21.5.312&r=PART&ty=HTML#se21.5.312_169>

FDA [Title 21 CFR 812.5 - Labeling of investigational devices](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.5):

<http://www.ecfr.gov/cgi-bin/text-idx?SID=22498ff22b4c67a9d8f3a0ee60c3a58d&mc=true&node=se21.8.812_15&rgn=div8>

FDA Title 21 CFR 812.7 - Prohibition of promotion and other practices:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=22498ff22b4c67a9d8f3a0ee60c3a58d&mc=true&n=sp21.8.812.a&r=SUBPART&ty=HTML#se21.8.812_17>

FDA Title 21 CFR 812.36 - Treatment use of an investigational device:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=22498ff22b4c67a9d8f3a0ee60c3a58d&mc=true&n=pt21.8.812&r=PART&ty=HTML#se21.8.812_136>

FDA Title 21 CFR 812.40 - General responsibilities of sponsors:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=22498ff22b4c67a9d8f3a0ee60c3a58d&mc=true&n=pt21.8.812&r=PART&ty=HTML#se21.8.812_140>

FDA Title 21 CFR 812.100 - General responsibilities of investigators:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=22498ff22b4c67a9d8f3a0ee60c3a58d&mc=true&n=pt21.8.812&r=PART&ty=HTML#se21.8.812_1100>

FDA Title 21 CFR 812.110 - Specific responsibilities of investigators:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=22498ff22b4c67a9d8f3a0ee60c3a58d&mc=true&n=pt21.8.812&r=PART&ty=HTML#se21.8.812_1110>

FDA Title 21 CFR 812.140 - Records:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=22498ff22b4c67a9d8f3a0ee60c3a58d&mc=true&n=pt21.8.812&r=PART&ty=HTML#se21.8.812_1140>

FDA Title 21 CFR 812.140(b) - Sponsor Records:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=22498ff22b4c67a9d8f3a0ee60c3a58d&mc=true&n=pt21.8.812&r=PART&ty=HTML#se21.8.812_1140>

FDA Combination Products: <http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm118332.htm>

International Council for Harmonisation:

<http://www.ich.org/>
<https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>

University of Michigan - Michigan Institute for Clinical and Translational Research (MICHR) - IND/IDE (MIAP):

<https://www.michr.umich.edu/rdc/2016/4/22/indide-lifecycle-maintenance>

University of Michigan - Michigan Institute for Clinical and Translational Research (MICHR) - MIAP - For Investigator-Initiated Medical Device Clinical Investigations - IND DECISION WORKSHEET (**IND requirement or exemption determinations):**

[IND/IDE Decision Worksheets — MICHR (umich.edu)](https://michr.umich.edu/resources/indide-decision-worksheets?rq=worksheet)

University of Michigan - Michigan Institute for Clinical and Translational Research (MICHR) – MIAP - For Investigator-Initiated Medical Device Clinical Investigations - IDE DECISION WORKSHEET (**IDE requirement or exemption determinations):** [IND/IDE Decision Worksheets — MICHR (umich.edu)](https://michr.umich.edu/resources/indide-decision-worksheets?rq=worksheet)

University of Michigan Medical School Policy on Requirement to use MICHR MIAP Services: <https://az.research.umich.edu/medschool/glossary/michr-indide-investigator-assistance-program-miap>

U-M Controlled Substances in Research Review Committee

<https://research-compliance.umich.edu/controlled-substances-research>

[**Michigan Medicine - Department of Pharmacy Services - Research Pharmacy**](http://ummcpharmweb.med.umich.edu/i/DepartmentSections/ResearchPharmacyService/tabid/78/Default.aspx)**:**

<https://pharmwebsp.med.umich.edu/SitePages/Home.aspx>

[**Michigan Medicine - Department of Pharmacy Services - Research Pharmacy**](http://ummcpharmweb.med.umich.edu/i/DepartmentSections/ResearchPharmacyService/tabid/78/Default.aspx) **Policies:**

<https://pharmwebsp.med.umich.edu/SitePages/Policies.aspx#IDS>

1. **APPENDICES**

*[Optional: Insert any additional SPG appendices]*