I. **PURPOSE:**
To provide information for Stanford IRB on principle investigator maintained and dispensed drugs and biologics.

II. **POLICY:**
It is the policy of SHC to provide a process for a principle investigator/protocol director ("PD") that maintains and controls a FDA investigational drug or biologic used in an outpatient setting outside the SHC pharmacy or its monitoring must:

A. Prepare a “Security and Controlled Access Plan” ("Plan") for the drug or biologic, [SEE ATTACHMENT A and B]
B. Submit it for IRB review,
C. After IRB approval, provide a copy to the Stanford Health Care pharmacy,
D. Work with the applicable pharmacy to assure that the storage, handling, and dispensing of the investigational drug or biologic is in compliance with such Plan and applicable FDA regulations (particular 21 CFR 312), applicable Joint Commission requirements, applicable State licensing requirements [SEE ATTACHMENT C and D]
E. Cooperate with any audit of compliance with IRB and SHC policies.

**NOTE:** If the PD either delivers or arranges for the drug or biologic to be stored and dispensed from a SHC outpatient clinic that is subject to audit by the SHC pharmacy, then a Plan is not required. It is considered to be maintained and controlled or monitored by the SHC pharmacy.

III. **DEFINITIONS:**
A. Security and Controlled Access Plan - plan prepared by the PD and approved by the IRB that demonstrates adequate control, security and handling of the investigational drugs and biologics including all of the following:
   1. ensuring the drug or biologic is controlled, used and disposed of in accordance with the IRB approved protocol, any sponsor agreement, applicable FDA regulations (particular 21 CFR 312), applicable Joint

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1 All investigational drugs and biologics administered in the “inpatient” setting at SHC must be maintained and dispensed through their pharmacies, except when the patient brings his or her own investigational drug or biologic because the patient is enrolled in a study at another institution. In that case, the investigational drug or biologic is governed by SHC policies for the patient’s own medication.
Commission requirements, applicable State licensing requirements, and this Policy,
2. administration of the drug or biologic only to participants under the
direct personal supervision of the PI or under the supervision of another
individual listed on the IRB approved protocol directly responsible to the
PI,
3. furnishing of the drug or biologic only to eligible participants under the
IRB approved protocol,
4. maintaining accurate, complete and current records of receipt, use or
disposition of drugs or biologics, including: (i) the dates of receipt, (ii)
dates of dispensing, (iii) quantity currently maintained for dispensing, (iv)
name of participant and amount dispensed received, (iv) amounts
remaining at the end of the trial and method of disposition,
5. providing that if the investigation is terminated, discontinued, or
completed, that any unused drugs or biologics are returned to the
sponsor or disposed of as directed by the sponsor.

IV. **PROCEDURE:**
   A. The Plan should contain the following:
      1. State the name of the PD, and any Study Coordinator.
      2. List all individuals with their job titles who will have access to the drug or
         biologic.
      3. State the drug or biologic name and dosage(s).
      4. Describe the storage location (e.g., building and room number), security
         measures that limit access to those described below, and special storage
         conditions (e.g., to control environmental factors such as temperature,
         light and moisture) that address the following requirements when
         applicable:
         a. Environmental Factors: Medications must be stored at the
            appropriate temperature and in a manner that controls other
            relevant environmental factors (e.g., moisture, light) as specified
            by the manufacturer
         b. Secure Area: Medications must be stored in a locked area and
            access to the medications must be limited to the PD, another
            investigator listed on the IRB protocol, or personnel acting under
5. Describe how the following dispensing requirements will be satisfied:
   a. Labeling: The investigator must comply with following California requirements for labeling information:
      i. Except where the prescriber orders otherwise, either the manufacturer’s trade name or the generic name and the manufacturer’s name.
      ii. Directions for use of the drug
      iii. Subjects Name or Subject Study Identifier
      iv. Investigator or Physician’s Name
      v. Date of Issue
      vi. Strength of Drug Dispensed
      vii. Quantity of Drug Dispensed
      viii. Expiration Date of Drug, if known.
   b. Packaging: The packaging must provide required protection against air, moisture permeability, and light, if appropriate. If the medication is dispensed in a bulk container, that container must have a child-resistant cap, unless the patient does not want one. Alternately, the package may be provided by the manufacturer (i.e., unit dose packaging).

6. Documentation of Dispensing: An appropriate record must be made in the subject’s medical record and should include:
   a. Drug name
   b. Quantity dispensed
   c. Educational material given

7. Describe your method of inventory control and record keeping that will show how the drug or biologic is used or disposed of including:
   a. Receipt date and quantity of each shipment with the batch, lot or code number of the drugs or biologics within the shipment
   b. Dates of dispensing, quantity dispensed, batch, lot or code number of drug or biologic dispensed, and method of identifying each individual patient to whom the drug or biologic is dispensed
c. That any unused portion is returned to manufacturer or disposed of in a manner that does not expose any individuals to risks

NOTE: (The inventory control and recordkeeping for the last two sub-points may be satisfied by inclusion in the Plan and utilization of the attached form of record or of a similar type of recordkeeping form modified, if necessary, to satisfy these requirements, e.g., one provided by your sponsor, the NIH investigational drug accountability record.)

Refer to ATTACHMENT E (Investigational Agent Accountability Record)

8. State that you will maintain such records for 2 years from FDA marketing approval or form shipment and delivery to you if not approved.
9. Provide emergency contact information.
10. No controlled substance will be dispensed outside of the investigational pharmacy control. All controlled substances will be stored in the investigational study secure area and dispensed from the investigational pharmacy per the protocol.

B. If you have any questions or need additional information on preparing a Plan contract:

Investigational Drug Services
Stanford Health Care
Mail Code: 5616
or Fax: 725-6262

Also, after IRB approval of your Plan, file a copy with the Investigational Pharmacy as listed above.

V. COMPLIANCE:

A. All workforce members including employees, contracted staff, students, volunteers, credentialed medical staff, and individuals representing or engaging in the practice at SHC are responsible for ensuring that individuals comply with this policy;

B. Violations of this policy will be reported to the Department Manager and any other appropriate Department as determined by the Department Manager or in accordance with hospital policy. Violations will be investigated to determine the nature, extent, and potential risk to the hospital. Workforce members who
violate this policy will be subject to the appropriate disciplinary action up to and including termination.

VI. RELATED DOCUMENTS / PROCEDURES:
   A. Patients’ Own Medications Policy
   B. Controlled Substances Policy
   C. SHC Chemical Waste Management Program
   D. Patient Care Area Medication Storage Inspections Policy
   E. Medication Error Quality Assurance Program
   F. Investigational Drugs Look Alike Sound Alike Medications

VII. APPENDICES:
   A. Attachment A: Letter to the Principal Investigator
   B. Attachment B: Sample Form for Plan
   C. Attachment C
   D. Attachment D: Notification/Registration of Investigational Drugs Stored/Dispensed by Principal Investigator
   E. Attachment E: Investigational Agent Accountability Record

VIII. DOCUMENT INFORMATION:
   A. Legal References / Regulatory Requirements:
      1. Title 22:70263 (O) Investigational Drugs
      2. Joint Commission Comprehensive Accreditation Manual for Hospitals
      3. 21 CFR 312.59; 312.62; 312.61; 312.60; 312.69; 50:23a
      4. California State Board of Pharmacy Law
      5. Guideline for Industry E6 Good Clinical Practice: Consolidated Guidance
   B. Original Document:
      1. Owner:
      2. Author and date: 9/1989
   C. Distribution and Training Requirements:
      1. New documents or any revised documents will be distributed to Department Manual holders. The department/unit/clinic manager will be responsible for communicating this information to the applicable workforce members.
D. Review and Renewal Requirements:
   1. This policy will be reviewed and/or revised every three years or as required by change of law or practice.

E. Review and Revision History:
   1. Bruce Lepley, RPh: 1/14
   2. Esther Kimm, Pharm.D: 1/2018

F. Approvals:
   1. Pharmacy and Therapeutics Committee 1/2018

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< Date >

Dear Principal Investigator:

The 2004 JCAHO Medication Management Standard 7.40 mandates that the pharmacy have a process for reviewing, approving, supervising and monitoring all investigational medication use in the institution.

We realize that studies are currently being conducted in clinics and these investigational new drugs (IND) are stored in doctor’s offices. These IND are directly dispensed to the subjects by the principal investigator.

To ensure that all investigators are handling drugs in compliance with the JCAHO Medication Management standard and with California State Law, the SHC Pharmacy Department has developed the following policy and set of procedures in order for you to continue your current study protocol(s).

We are asking the principal investigator(s) or study coordinator(s) to read and educate any involved staff on this new procedure, complete the investigational drug storage notification/registration form for pharmacy records, and to utilize the attached dispensing log sheet.

Please return the completed notification/registration form and necessary attachments within two weeks of receipt of this letter. Feel free to contact me for further questions or information.

Investigational Drug Services
Stanford Health Care
650-736-1990
Fax: 650-725-6262
ATTACHMENT B: SAMPLE FORM FOR PLAN

Stanford Health Care
Security and Controlled Access Plan
For PI Maintained and Dispensed Investigational Drug or Biologic

Name of PI/ PD: ________________________________________________

Name of Study Coordinator (if applicable): ________________________

Room #/Location of Storage Area: _________________________________

Drug/ Biologic name and dosage(s):
____________________________________________________________________________

Individuals with job titles who will have access:
____________________________________________________________________________

____________________________________________________________________________

Special storage conditions followed: _____________________________________________

____________________________________________________________________________

Recordkeeping of dispensing and disposing: I will utilize the attached form for recording the
dispensing and other disposition of the drug/ biologic. I will maintain such records for 2 years
from the date of FDA marketing approval or from shipment and delivery to me if not approved

Emergency Contact Information: _____________________________________________

I agree that: (1) the procedures described in this Plan will be followed for the storage,
dispensing, and recordkeeping for the named investigational drug or biologic, and (2) a copy of
the Plan as approved by the IRB will be filed with the SHC Investigational Pharmacy.

PD Signature: _______________________________ Date: _________________
ATTACHMENT C

I. Notification of Pharmacy
   A. Notification/Registration Form: Complete the notification/registration forms and send to pharmacy.
   B. IRB approval letter: Attach copy of IRB approval letter to 1a.

II. Storage
   A. Temperature: Medications must be stored at the appropriate temperature specified by the manufacturer.
   B. Secure Area: Medications must be stored in a locked area and access to the medications must be limited to study personnel only.

III. Inventory Control
   A. Records: A running inventory of material received, issued, and destroyed should be maintained. Use the attached inventory form titled: NIH, Investigational Drug Accountability Record

IV. Dispensing
   A. Labeling: The investigator must comply with California State Law. The medication must be labeled with the following information:
      1. Except where the prescriber orders otherwise, either the manufacturer’s trade name or the generic name and the manufacturer’s name.
      2. Directions for use of the drug
      3. Subjects Name or Subject Study Identifier
      4. Investigator or Physician’s Name
      5. Date of Issue
      6. Strength of Drug Dispensed
      7. Quantity of Drug Dispensed
      8. Expiration Date of Drug, if known

V. Packaging: The packaging must provide required protection against air and moisture permeability. If the medication is dispensed in a bulk container, that container must have a child-resistant cap, unless the patient does not want one. Alternately, the package may be provided by the manufacturer (i.e., unit dose packaging).

VI. Documentation of Dispensing: An appropriate record must be made in the subject’s chart and should include:
   A. Drug Name
   B. Quantity dispensed

Educational material given
<table>
<thead>
<tr>
<th>Policy Title: Security and Controlled Access Plan for Investigational Drugs and Biologics Maintained and Controlled by a Protocol Director</th>
</tr>
</thead>
<tbody>
<tr>
<td>Departments Affected:</td>
</tr>
<tr>
<td>Key Words:</td>
</tr>
</tbody>
</table>
ATTACHMENT D: Notification/Registration of Investigational Drugs Stored/Dispensed by Principal Investigator

Copy of Approval Letter from IRB: ____________________(please attach)

Name of Principal Investigator: ____________________________________________

Name of Study Coordinator (if applicable): _________________________________

Room #/Location of Drug Storage Area: _________________________________

Drug Name and dosage(s):
____________________________________________________________________

List all individuals and job title who will have access to medication:
____________________________________________________________________
____________________________________________________________________
____________________________________________________________________

Special Storage conditions (refrigerate, protect from light):
____________________________________________________________________

Emergency Contact Information:
____________________________________________________________________

I agree that the appropriate procedures will be followed for storage and dispensing of Investigational Drugs.

Date: ___________________________ Principal Investigator Signature: ______________________

Return form to: Investigational Drug Services
Stanford Health Care
Mail Code: 5616
Or Fax: 725-6262
ATTACHMENT E: Investigational Agent Accountability Record