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Research: Investigational Device- AD.0155

PURPOSE

The purpose of this policy is to assure regulatory and operational compliance and efficient management and security of the receipt, storage, dispensing, return, destruction, and billing of investigational devices (**ID**). It is intended that this investigational device policy be consistent with Food and Drug Administration federal regulations, the Common Rule, HIPAA, and good clinical practice, each as amended from time to time. Our policies guide our practices and ensure that we place people at the heart of all we do to deliver the best outcomes and safest care.

APPLICABILITY

This policy applies to Lakeland Regional Health's **Workforce** and personnel engaged in research.

POLICY

I. It is the policy of Lakeland Regional Health to effectively manage and control the receipt, storage, dispensation, return, destruction, and billing of investigational devices pursuant to federal regulations, contractual obligations, and business controls, to ensure the integrity of research practices and the safety of our patients.

II. This policy applies to any device, investigational or not, that has been submitted to the **IRB** in an application for review and approval and that meets one or more of the following criteria:

   A. Has not been approved by the Food and Drug Administration (**FDA**),

   B. Has been approved by the FDA but is being used for purposes other than those stipulated by the FDA,

   C. Is a commercially marketed device, but is being used in a trial for research purposes,

   D. Is being used for Humanitarian purposes [as a Humanitarian Use Device (**HUD**)],

   E. Has received a Humanitarian Device Exemption (**HDE**),

F. Has received an Investigational Device Exemption (**IDE**),

G. Has received a Compassionate Use (**CU**) designation,

H. Has received an In-Vitro Diagnostic (**IVD**) designation or,

I. Has been approved for distribution and use; but, data must continue to be collected for submission to the FDA.

PROCEDURE

I. **Communication**

A. Once the Principal Investigator (PI) receives written approval from the IRB, the **PI** must communicate such approval to the clinical departments involved in the trial prior to any clinical activity related to the trial or use of the IDs.

B. The PI should communicate the following to each ancillary department: general study overview; specific services requested; costs to the ancillary department, along with the availability of grant funding; and logistical considerations, including inventory of IDs, confirmation of billing account, services that are considered investigational, and sources of funding.

C. The process for receipt and distribution of IDs must include efficient and timely notification to:

1. The clinical area where the ID is being used; and
2. The PI, stating that the IDs have been received and are available for use.

II. **Administrative Approvals**

A. Prior to the use of any ID, the PI must receive confirmation of:

i. IRB approval;

ii. a billing account number assignment for charges, when appropriate;

iii. execution of a clinical trial agreement, if applicable;

iv. review and approval by the Investigational Device Review Committee (**IDRC**); and

v. documentation of Medicare billing determination (Medicare Parts A and B) for IDE Devices.

B. The PI must inform Biomedical Engineering about all electrical IDs powered by either external (facility's power supply) or internal (batteries) sources before using such IDs on patients. Biomedical Engineering will determine the level of electrical safety inspection required and ensure that the use of such IDs is consistent with existing standards.

C. If the ID involves laser therapy, the PI must obtain approval from the Laser Safety Officer.

D. If the ID uses diagnostic/therapeutic radiation or involves the use of radioactive pharmaceuticals, the PI must obtain approval from the Radiation Safety Subcommittee.

III. **Finance/Billing**

A. The cost of using the ID will be negotiated and confirmed through a Purchase Agreement, if applicable, and a contract budget will be reviewed with Purchasing and the head(s) of the affected clinical department(s). When negotiating provision of the ID, preferred options are:

i. sponsor provides IDs at no cost; or

ii. sponsor ships IDs on consignment.

B. The clinical trials feasibility committee must approve the use of the ID. Exceptions may be considered on a case by case basis.

C. If the manufacturer or research sponsor provides the ID at no charge, the hospital must not charge the patient or Medicare for the ID. The hospital may bill Medicare for the routine costs of the clinical trial involving the use of the ID so long as the services meet all other Medicare coverage requirements. Also, the hospital must not accept an ID free of charge as a condition of doing business with a manufacturer.

D. The hospital must review the clinical trial contract to determine which services are the responsibility of the sponsor and which services may be billed to Medicare. Items/services provided solely to satisfy data collection and analysis needs and that are not used in direct clinical management of the patient are not covered by Medicare and are generally the responsibility of the sponsor. Items/services reimbursed by the sponsor of the clinical trial must not be billed to Medicare.

E. The hospital must develop a process to store and maintain documentation that the IDE study was reviewed during the study planning phase and was listed as approved on the CMS Coverage Website, including the date of verification, prior to enrolling a Medicare patient. Once approval has been verified with Medicare and all other coverage requirements have been met, it is appropriate to bill routine care items and services in Category A IDE studies or Category B device (when the ID is not received free-of-charge) and routine care items and services in Category B IDE studies to Medicare.

F. The PI must submit a billing and payment service agreement to the Hospital's Patient Accounting Office. Prior to the study start date, the PI must verify with Hospital's Patient Accounting Office that the billing and payment service agreement has been approved and a hospital account number has been assigned.

IV. **Device Ordering/Shipment/Receiving**

A. IDs are ordered or received as determined by LRH Purchasing policies and by the sponsor and research protocol. Receiving dock personnel or PI will generate a requisition / purchase order to document the ordering of, receipt and distribution of IDs to the appropriate department. The PI is responsible for notifying the clinical department(s) of any ID not directly received by the receiving dock personnel. The PI must request sponsor notification of shipment of IDs. The receiving and ancillary department must record the receipt of all IDs that come through that department. The PI is responsible for notifying the clinical departments of any IDs not directly received by the ancillary department.

B. The PI is responsible for all documentation required by the sponsor. The sponsor will

require the following information, at a minimum:

i. Sponsor name;
ii. Study/Protocol title;
iii. PI name;
iv. Type of ID received;
v. Quantity received;
vi. Date of receipt;
vii. Batch number or code mark of each individual ID;
viii. Name of person receiving ID (associated with the unique identifier); and
ix. Implantation date.

C. Upon receipt of the ID shipment, the PI must inventory the shipment to ensure the information on the packing slips match exactly what has been received. Promptly notify sponsor of any discrepancies. If sponsor includes an "acknowledgement of receipt" form the PI will obtain the appropriate signatures and date (most order acknowledgements are now electronic with no copy given to the receiving dock copy form and packaging slips for study records) and forward the original form to the sponsor. If the sponsor does not provide "acknowledgement of receipt forms, the packaging slip should be signed and dated with the date of receipt at the site. Packaging slips should be filed in the study records and a copy should be forwarded to the receiving department for LRH record retention. If requested, a copy may be faxed to the sponsor. IDs must be tagged, individually, to indicate investigational status. Ensure any supplies required for blinding of the ID are available. Ensure the randomization code has been received, if appropriate.

D. An ID accountability log is maintained by the PI, documenting receipt, use, disposition, type and quantity of the ID, dates of receipt, batch number or code mark; names of all persons who received, used, or disposed of each ID; and why and how many units ID have been returned to the sponsor, repaired, or otherwise disposed.

E. IDs should not be used until delivered to the PI after IRB and all other approvals are secured. The IRB approved protocol should describe how the ID will be managed. This includes education on the ID and who will have access to the ID and how the ID will not be used in place of approved devices for non-research subjects.

V. Device Storage

A. IDs should not be received on site, nor stored in patient care areas, prior to IRB approval. All IDs will be stored in the appropriate ancillary department in a secure, locked, location with limited access, separate from other devices. IDs are labeled to reflect "Investigational Device—Research Use Only".

B. Off-site storage is not allowed. Store IDs according to the sponsor requirements. If climate control is required, temperature checks are documented in a temperature log.

VI. Device Distribution

A. The ancillary department will record the use/dispensing of each ID. The record shall include at a minimum: date dispensed, name of person dispensing, name of person receiving, name/MR# of research subject as recipient of ID.

B. Ensure that all key research personnel involved in ID accountability are listed on the IRB application, and performing activities appropriate to their job categories and licensures. The ancillary department will record the use/dispensing of each ID. The PI is responsible for ensuring accurate inventory and notifying study monitor or sponsor when additional inventory is needed. The PI is responsible for informing sponsor and IRB if emergency breaking of the ID blind is medically necessary. The PI will follow the procedures outlined in the protocol and document all circumstances appropriately.

C. IDs may only be used by an IRB approved PI in accordance with an IRB approved protocol, and for subjects who have consented to participate in the approved research study. The PI is responsible for verification of research subject's signature on an IRB approved informed consent document that is maintained in the medical record.

VII. Documentation and Record Keeping

A. Each department maintains a current inventory log of stored IDs by study.

B. The department must maintain documentation of the specific use of each ID by individual study subjects, consistent with federal regulations, sponsor instructions, and hospital policies.

C. The department and the PI are responsible for documenting the return of unused IDs to the sponsor, or destruction of the ID, with written authorization from the sponsor at completion of the clinical trial, or IDE/IVD/HDE/CU project.

D. Documentation of device destruction should be retained in the study record and a copy sent to the sponsor.

VIII. Device Returns

A. The ancillary department and PI are jointly responsible for returning all unused IDs to the sponsor upon completion of the clinical trial, unless the sponsor authorizes otherwise. Unless otherwise provided in a clinical trial agreement, IDs are returned at sponsor's expense.

B. When returning IDs, PIs will record the following information, at a minimum:

i. Sponsor name;

ii. Study/Protocol title;

iii. PI name;

iv. Type of ID;

v. Date received;

vi. Batch number or code mark;

vii. Date of return; and

viii. Name of person returning ID.

C. This may be accomplished by separately recording all necessary information or obtaining copies of the ancillary department's inventory logs. The ancillary department will make this information available for the Purchasing Supply Chain Department, if necessary to work out arrangements and obtain **RGA** if needed for return of unused IDs.

D. If the IDs have been designated for destruction (in writing by sponsor) the PI may destroy the IDs as designated by sponsor and in accordance with Occupational Safety and **OSHA** requirements. Destruction of IDs should be documented and verified by two (2) qualified personnel.

E. The PI (or sponsor/manufacturer) must provide direction for the disposition of unused, damaged or faulty IDs and for the disposition of all stock and/or equipment at the termination of the research study. IDs cannot be maintained after conclusion of the study, unless they have FDA marketing approval and the PI has secured hospital approval to maintain the ID for clinical research.

DEFINITIONS

CU: Compassionate Use

FDA: Food and Drug Administration

HDE: Humanitarian Device Exemption

ID: Investigational Device

IDE: Investigational Device Exemption

IDRC: Investigational Device Review Committee

IRB: Institutional Review Board

IVD: In-Vitro Diagnostic

OSHA: Occupational Safety and Health Administration

PI: Principal Investigator

RGA: Return Goods Authorization

Workforce: All LRH employees, volunteers, trainees/students, contractors, and medical staff

REFERENCES

https://research.unc.edu/wp-content/uploads/sites/61/2012/11/CCM3_034228.pdf.

https://www.unmc.edu/academicaffairs/_documents/compliance/NE_Medicine_MI29_InvestigationalDevices.pdf.

https://www.research.uci.edu/compliance/human-research-protections/docs/control-of-investigational-devices.pdf.

https://hcahealthcare.com/util/forms/ethics/policies/regulatory-compliance-support/regsbill007-a.pdf.

Additional resources:

https://research.ucdavis.edu/policiescompliance/irb-admin/researchers/project-guidance/investigational-drugs-or-devices/devices/.

https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/fda50_1.html.

https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/fda814_1.html.

Approval Signatures

Step Description	Approver	Date
	Danielle Drummond: 0001 President & Chief Executive Officer - LRHS	07/2023
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