Pediatric Blood and Marrow Transplant
Adult Blood and Marrow Transplant
Stem Cell Laboratory

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Inspections by Outside Agencies

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COMM-PAS-019
Inspections By Outside Agencies

1 PURPOSE

1.1 To describe the policies applicable to conducting inspections, assessments, and audits of Stem Cell Laboratory (STCL) and Adult and Pediatric Blood and Marrow Transplant Program (APBMT), hereafter referred to as "the Organization", by external agencies. Throughout this policy, the term inspection will be used to describe any inspection, assessment, or audit activity.

2 INTRODUCTION

2.1 Recognizing the importance of building quality into our products, the Organization wants all staff to feel comfortable, be knowledgeable, and be hospitable during inspections.

2.2 FDA inspections are occasionally scheduled in advance and may be conducted any time the facility conducts operations unless it is a for-cause audit.

2.2.1 21 CFR, Part 600, Subpart C, Section 361, and 21 CFR, Part 1270, Subpart D establish the authorization and procedures for FDA inspections.

2.2.2 Purpose of Inspection

2.2.2.1 To ensure that establishments distributing blood, human cells, tissues, and cellular and tissue-based products are in compliance with the relevant sections of Title 21 of the CFR.

2.2.2.2 To ensure the safety, quality, identity, purity, efficacy, and potency of blood, human cells, tissues, and cellular and tissue-based products.

2.2.2.3 To prevent the distribution of misbranded or adulterated products.

2.2.3 FDA inspectors are not permitted to accept free meals, incentives, etc., and these should not be offered. It is acceptable to offer drinks such as coffee, juice, water, etc.

2.3 Inspections that are usually unannounced include:

2.3.1 FDA

2.3.2 AABB

2.3.3 CAP

2.4 Inspections that are usually scheduled in advance include:

2.4.1 FACT

2.4.2 NMDP

2.4.3 Customers for which Duke Facilities perform contract work or services.

2.5 Organization Employee Conduct During an Inspection:

2.5.1 All employees must demonstrate professional conduct as official representatives of the Organization.

2.5.2 Employees are obligated to give the inspection a top priority.

2.5.3 Employees must cooperate with the inspector.

2.5.4 Employees must answer truthfully the questions asked, being as specific as possible.

2.5.5 Employees must not sign any affidavit presented to them by an inspector without prior review and approval of the Program/Medical Director or designee.

2.5.6 Employees must not discuss work-related matters with an inspector outside of the inspection environment.

3 SCOPE AND RESPONSIBILITIES

3.1 All members of the Duke Organization need to be aware of the process and the guidelines for inspections.

3.2 The Clinical Quality Program (CQP) is responsible for ensuring that all staff who may interact with an inspector are fully trained in their roles and understand the importance of inspections.

3.3 CQP is available to serve as part of the inspection team, with potential cooperation with the Office of Regulatory Affairs.

3.4 Inspection Coordinator

3.4.1 CQP Director/designee will act as the Inspection Coordinator.

3.4.2 If a CQP representative is not available, the highest-ranking employee will serve as Inspection Coordinator.

3.4.3 The responsibilities of the Inspection Coordinator (and team) include, but are not limited to:

3.4.3.1 Asking for and reviewing the inspector's credentials.

3.4.3.2 Reserving a private space in which the inspectors can work.

3.4.3.3 Creating an inspection file.

3.4.3.4 Acting as an escort throughout the inspection, unless the inspector is in the reserved private space or restroom facilities.

3.4.3.5 Providing personal protective equipment, as needed.

3.4.3.6 Being knowledgeable in the procedures on handling any external audits.

4 DEFINITIONS/ACRONYMS

4.1 Affidavit – A voluntary sworn statement of facts, made in writing, before an authorized official, such as an inspector from the Food and Drug Administration

(FDA). Affidavits may be prepared by FDA inspectors to document events, occurrences, or statements made by the Organization employees and presented for signature by these employees during the inspection process.

4.2 AABB – This organization performs accrediting inspections to ensure compliance with the:

4.2.1 Standards for Blood Banks and Transfusion Services

4.2.2 Standards for Immunohematology Reference Laboratories

4.2.3 Standards for Hematopoietic Progenitor Cells

4.3 Center for Biologics Evaluation and Research (CBER) – The branch of the FDA responsible for the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.

4.4 CAP – College of American Pathologists – Performs accrediting inspections of the STCL and CCBB Laboratories.

4.5 Code of Federal Regulations (CFR)

4.6 Current Good Manufacturing Practices (cGMPs) – Regulations found within the Code of Federal Regulations (CFR) governing the manufacture of blood and blood components (600 series), drugs and biologics (200 series), and medical devices (800 series).

4.7 Current Good Tissue Practices (cGTPs) – Regulations found within the CFR governing manufacture of human cells, tissues, and cellular and tissue-based products (1271 series).

4.8 Establishment Inspection (EI) – A careful, critical official examination of a facility to determine its compliance with the laws enforced by FDA.

4.9 Establishment Inspection Report (EIR) – A detailed description of the FDA inspection, including the circumstances surrounding observations cited on FDA Form 483.

4.10 Freedom of Information Act (FOI) – An act that allows public access to documents such as the FDA Form 483 and EIR.

4.11 FDA Form 482, Notice of Inspection – The form presented by FDA inspectors upon arrival, announcing the intent to inspect. FDA Form 482 also provides a written explanation of the authority of the inspectors and the rights of the establishment being inspected.

4.12 FDA Form 483, Inspectional Observations – The form on which the FDA records observations noted during an inspection, when the inspector believes that there are processes that are not in compliance with regulations.

4.13 Food and Drug Administration (FDA) – An executive branch of the United States government, within the Department of Health and Human Services, charged with the enforcement of the Federal Food, Drug, and Cosmetic Act of 1938 and the Public Health Service Act of 1944.

4.14 Inspection Coordinator – The individual within an organization assigned to facilitate an inspection, assessment, or audit.

4.15 ISO – International Organization for Standardization – Defines and publishes quality management system and numerous other standards for many industries.

4.16 Most Responsible Individual (MRI) – The person designated to represent the facility being inspected.

4.17 Nonconformance – A term used by the American Association of Blood Banks (AABB) to describe an area of noncompliance with standards. A nonconformance may be classified as Major or Minor, depending on the impact of the noncompliance and the number of times similar non-compliances occur.

4.18 Observation – Verifiable qualitative or quantitative observation, information, record, or statement of failure to conform to a regulation, accreditation requirement, standard, SOP, or policy.

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 N/A

7 SAFETY

7.1 Inspection personnel are provided personal protective equipment if applicable and are to observe all laboratory safety policies.

8 PROCEDURE

8.1 General Inspection Process

8.1.1 When advanced notification and scheduling of an inspection occurs, the Inspection Coordinator will communicate the proposed inspection plans to appropriate personnel. Refer to COMM-PAS-019 JA1 *Inspection Notification List.*

8.1.1.1 Documents can be provided to the inspection team in advance with CQP Director approval.

8.1.2 Upon arrival of the inspector, if not already performed, the Inspection Coordinator will coordinate notification to appropriate personnel. Refer to COMM-PAS-019 JA1 *Inspection Notification List.*

8.1.3 The Inspection Coordinator will ensure that the inspector is credentialed, as applicable, and then escort them to the reserved private area.

8.1.4 If the inspection is being conducted by FDA, an FDA Form 482, Notice of Inspection, must be issued to the Inspection Coordinator, Program/Medical Director, or designated responsible individual.

8.1.5 An opening meeting is typically held to establish the purpose of the inspection and to create a tentative agenda. The Inspection Coordinator or designee should request that the inspector(s) complete COMM-PAS-019 FRM4 *Audit Signature Log.*

8.1.6 The Inspection Coordinator and CQP will work with the inspector to ensure that the appropriate Organization employees are available when needed to gather data and answer questions. The Inspection Coordinator or designee should request that Organization employees attending the opening meeting complete COMM-PAS-019 FRM3 *Audit Attendee Signature Log.*

8.1.7 The Inspection Coordinator must offer the inspector personal protective equipment, such as a lab coat, prior to entering production areas.

8.1.8 All Organization staff must be attentive to the inspection process and be prepared to respond to the questions or requests in a timely manner.

8.1.9 A closing meeting will be held.

8.1.9.1 The Inspection Coordinator will request that the inspector provide as much notice as possible so that the Program/Medical Director/designee, the CQP Director/designee, and other appropriate staff may attend.

8.1.9.2 The inspector will be asked to summarize the inspection, listing any formal citations and other observations or recommendations.

8.1.9.3 Participants at the closing meeting may ask the inspector for clarifications or explanations as necessary.

8.1.9.4 The Inspection Coordinator or designee should request that the Organization employees attending the closing meeting complete COMM-PAS-019 FRM3 *Audit Attendee Signature Log.*

8.2 Retrieving Information and Documents for Review

8.2.1 The Inspection Coordinator evaluates the appropriateness of providing the requested information.

8.2.2 All records, policies, and procedures related to the collection, procurement, processing, testing, and distribution of products as well as documentation regarding the Organization's Quality Program, should be available for review, if requested.

8.2.3 Requests from the inspectors once onsite can be tracked and documented on COMM-PAS-019 FRM2 *Document Request Form.*

8.2.4 Financial and personnel/HR information/documentation should not be shared with the inspector. Redaction of documents is allowed if these documents are requested.

8.2.5 Making Copies of Requested Documents

8.2.5.1 Ensure that each "COPY" is labeled and/or stamped as such, if applicable.

8.2.5.2 Each document given to the inspector should be captured either by making a copy or by noting simply which version

of an SOP was requested. Refer to COMM-PAS-019 FRM1 *Audit Records Log.*

8.2.6 Making Copies of Redacted Documents

8.2.6.1 If the documents requested contain confidential information, the confidential information must be redacted.

8.2.6.2 Redaction is performed by copying the document, obliterating the confidential information with a thick black marker, and then copying the redacted document.

8.2.6.3 If the inspector requests that an un-redacted copy is needed, the CQP Director, Risk Management or the Program/Medical Director must approve. These copies must be stamped "CONFIDENTIAL."

8.2.7 Photography is allowed.

8.2.7.1 If the inspector takes a photograph, notify the CQP Director or designee and the Program/Medical Director.

8.2.7.2 If photographs are taken, the Inspection Coordinator or designee will take photographs as close as possible to those taken by the inspector.

8.2.8 If the inspector requests a sample, the Inspection Coordinator must ensure that:

8.2.8.1 Collection occurs in a manner that maintains the integrity of the sample.

8.2.8.2 The sample is properly labeled.

8.2.8.3 A duplicate sample is maintained by the Organization whenever possible.

8.2.8.4 The Organization obtains a receipt for the sample from the inspector.

8.2.8.5 The Organization obtains a copy of any tests performed on the sample by the auditing agency.

8.3 Content for Note Taking During the Inspection

8.3.1 Personnel associated with the inspection should strive to take comprehensive notes that capture information discussed between the inspector and the Organization. Notes reflecting these exchanges may include, but are not limited to, the following:

8.3.1.1 Key questions that were asked and the answers given.

8.3.1.2 Employees interviewed.

8.3.1.3 Topics discussed.

8.3.1.4 References to the inadequacy of a process/procedure.

8.3.1.5 List of names of key staff present at opening and closing meetings

8.4 Inspection Follow-Up

8.4.1 The Inspection Coordinator or designee will work to address any observations or action items following the audit. One method for completion of this task includes the creation of an inspection summary report that will minimally include:

8.4.1.1 Observations/recommendations presented by the inspector.

8.4.1.2 Observations made by the Organization staff during the inspection.

8.4.1.3 Identification of the responsible department and any corrective actions required.

8.4.2 Obtain and place the original formal inspection report (e.g., EIR), or a copy, from the inspection agency on the shared drive.

8.4.3 Formal responses are usually due within 30 days of the conclusion of the inspection or within 30 days of the receipt of the written report; however, this timeframe may vary.

8.4.4 The CQP Director/designee will prepare formal inspection responses, with input from the applicable departments.

8.4.5 Inspection responses should be reviewed by the CQP Director/designee, the Program/Medical Director/designee, and Regulatory Affairs, as applicable, prior to sending the response.

8.4.6 A copy of the final response, including cover letter, should be maintained in the CQP inspection file.

8.4.7 Corrective actions will be tracked by the CQP, as applicable.

9 RELATED DOCUMENTS/FORMS

9.1 COMM-PAS-019 JA1 Inspection Notification List

9.2 COMM-PAS-019 FRM1 Audit Records Log

9.3 COMM-PAS-019 FRM2 Document Request Form

9.4 COMM-PAS-019 FRM3 Audit Attendee Signature Log

9.5 COMM-PAS-019 FRM4 Auditor Attendee Signature Log

10 REFERENCES

10.1 Code of Federal Regulations, current edition, Title 21, Parts 200, 201, 210, 211, 300, 600, 601, 606, 610, 640,660, 680, 1270 and 1271.

11 REVISION HISTORY

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