**DOCUMENT NUMBER:** COMM-QA-040

**DOCUMENT TITLE:**
Inspections by Outside Agencies

**DOCUMENT NOTES:**

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**Document Information**

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COMM-QA-040
INSPECTIONS BY OUTSIDE AGENCIES

1 PURPOSE

1.1 To describe the policies applicable to conducting inspections, assessments, and audits of Carolinas Cord Blood Bank (CCBB), Stem Cell Laboratory (STCL), CT2-GMP Facility, Adult and Pediatric Blood and Marrow Transplantation Programs (APBMT) and other Programs, 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 usually scheduled in advance and may be conducted any time the facility conducts licensed operations unless it is a for-cause audit.

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

2.2.2 Section 351(c) of the Public Health Service Act and Sections 702 and 704 of the Federal Food, Drug, and Cosmetic Act provide authority for FDA inspectors to conduct inspections.

2.2.3 Purpose of Inspection

2.2.3.1 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.

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

2.2.3.3 To prevent the distribution of misbranded or adulterated products.

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

2.3 Some inspections that are usually unannounced include:

2.3.1 AABB

2.3.2 State of Florida, Agency for Health Care Administration, Division of Managed Care and Health Quality

2.3.3 CAP

2.4 Other inspections that are usually scheduled in advance include:

2.4.1 FACT

2.4.2 ASHI
2.4.3 ISO
2.4.4 EU

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 work 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 QSU Director is responsible for ensuring that all staff that may come in contact with an inspector are fully trained in their roles and understand the importance of inspections.
3.3 Duke Translational Medicine Institute Regulatory Affairs (DTMI RA) is available to serve as part of the inspection team.
3.4 Inspection Coordinator
3.4.1 QSU Director/designee will act as the Inspection Coordinator.
3.4.2 If a QSU representative is not available, the highest-ranking employee or their designee will serve as Inspection Coordinator.
3.4.3 The responsibilities of the Inspection Coordinator 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

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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 ASHI – American Society for Histocompatibility and Immunogenetics. Perform
   accrediting inspections for the HLA and Molecular labs to ensure compliance with
   standards set forth by the organization.

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

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

4.6 Code of Federal Regulations (CFR)

4.7 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 (200 series), and medical devices (800 series).

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

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

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

4.11 European Union (EU)

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

4.13 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.

4.14 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.

4.15 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.

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

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

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

4.20 Observation – Verifiable qualitative or quantitative observation, information, record, or statement of failure to conform to a regulation, accreditation requirement, standard, SOP, or policy, identified or occurring one or two times out of a total of 3-12 examples during the assessment.

4.21 Office of Regulatory Affairs – The department within FDA responsible for overseeing the inspection, surveillance, and enforcement activities of all the FDA operational divisions. Field inspectors from this office perform routine inspections of all blood establishments inspected by FDA.

4.22 European Union (EU) – European Communities that have established standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. Representatives from the EU have the authority to inspect US centers that supply blood or tissues to European agencies.

4.23 Quality Systems Unit (QSU)

5 MATERIALS
5.1 NA

6 EQUIPMENT
6.1 NA

7 SAFETY
7.1 Inspection personnel are provided personal protective garments/wear and are to observe all laboratory safety policies.

8 PROCEDURE

8.1 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 Inspection Notification List, COMM-QA-040 JA1.

8.1.2 Upon arrival of the inspector, the Inspection Coordinator will coordinate notification to appropriate personnel. Refer to Inspection Notification List, COMM-QA-040 JA1.

8.1.3 The Inspection Coordinator will ensure that the inspector is credentialed and then escort them to the reserved private area.
8.1.4 An opening meeting will be held to establish the purpose of the inspection and to create a tentative agenda.

8.1.5 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.

8.1.6 The Inspection Coordinator must work with the inspector to ensure that the appropriate Organization employees are available when needed to gather data and answer questions.

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 inspector's and/or the Inspection Coordinator's questions or requests in a timely manner.

8.1.9 Photography is allowed.

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

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

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

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

8.1.10.2 The sample is properly labeled.

8.1.10.3 A duplicate sample is maintained by the Organization, whenever possible.

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

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

8.1.11 A closing meeting will be held.

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

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

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

8.2 Inspection Follow-Up

8.2.1 The Inspection Coordinator or designee will create an inspection summary report that will minimally include:
8.2.1.1 Observations/recommendations presented by the inspector.
8.2.1.2 Observations made by the Organization staff during the inspection.
8.2.1.3 Identification of the responsible department and any corrective actions required.

8.2.2 Obtain and place the original formal inspection report (e.g., EIR), or a copy, from the inspection agency in the inspection file.

8.2.3 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.

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

8.2.5 Inspection responses must be reviewed by the QSU Director/designee, the Program/Medical Director/designee, and Regulatory Affairs, as applicable, prior to sending the response.

8.2.6 A copy of the final response, including cover letter, must be maintained in the QSU inspection file.

8.2.7 Corrective actions will be tracked by the QSU.

8.3 Retrieving Information/Documents for Review

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

8.3.2 All records, policies, and procedures related to GMP manufacturing, collection, procurement, processing, testing, and distribution of blood components and tissue grafts and/or documentation required as part of the organization’s Quality Program must be available, and when requested by the inspector, documented on Document Request Form, COMM-QA-040 FRM2.

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

8.3.4 Making Copies of Requested Documents

8.3.4.1 Ensure that each “COPY” is stamped as such.

8.3.4.2 A copy of each document given to the inspector must be maintained in the Organization inspection file and documented when provided to the inspector and when returned to Document Control Operations. Refer to Audit Records Log, COMM-QA-040 FRMI.

8.3.5 Making Copies of Redacted Documents

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

8.3.5.2 Redaction is performed by copying the document, obliteratoring the confidential information with a thick black marker, and then copying the redacted document.
8.3.5.3 If the inspector requests that un-redacted copy is needed, the QSU Director, Risk Management or the Program/Medical Director must give approval. These copies must be stamped “CONFIDENTIAL.”

8.4 Content for Note Taking
8.4.1 Key questions that were asked and the answers given.
8.4.2 Employees interviewed.
8.4.3 Topics discussed.
8.4.4 References to the inadequacy of a process/procedure.
8.4.5 List of names of key staff present at opening and closing meetings

9 RELATED DOCUMENTS/FORMS
9.1 COMM-QA-040 JA1 Inspection Notification List
9.2 COMM-QA-040 FRM1 Audit Records Log
9.3 COMM-QA-040 FRM2 Document Request Form
9.4 COMM-QA-040 FRM3 Audit Attendee Signature Log
9.5 COMM-QA-040 FRM4 Auditor Attendee Signature Log

10 REFERENCES
10.3 Public Health Services Act, Section 351(c), 42 U.S.C., Section 262.

11 REVISION HISTORY

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<td>John Carpenter</td>
<td>Add revised name of FRM1 (Audit Records Log) and new FRM4 Auditor Attendee Signature List.</td>
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## Signature Manifest

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