

**DUKE****DOCUMENT NUMBER:** COMM-QA-040 JA1**DOCUMENT TITLE:**

Inspection Notification List

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COMM-QA-040 JA1 INSPECTION NOTIFICATION LIST

1. FDA or Other External Inspection Agency:

Upon arrival:

- 1.1. Notify the Office of Regulatory Affairs and Quality MC3 Quality Systems Unit (QSU) including the QSU leadership (Director(s), Managers, etc.). A member of QSU will serve as the Inspection Coordinator.
- 1.2. If a QSU representative is not available, the highest-ranking employee available or their designee will serve as Inspection Coordinator.
- 1.3. The Inspection Coordinator or appropriate leadership will inform applicable personnel of the inspection, which may include but not be limited to the following:
 - 1.3.1. Executive Staff
 - 1.3.2. Program/Medical Director
 - 1.3.3. Supervisor(s)/Manager(s)
 - 1.3.4. Duke University Office of Regulatory Affairs and Quality leadership
 - 1.3.5. Director Quality Management Systems, DUMC Clinical Laboratories
 - 1.3.6. Other School of Medicine Leadership/Offices as applicable based on inspection team (ex. SOM Dean's Office, Duke Office of Audit, Risk, and Compliance)
 - 1.3.7. External sponsors, as required

2. CAP Inspection Notification:

- 2.1. CAP notifies (calls) Director Quality Management Systems, DUMC Clinical Laboratories.
- 2.2. Director Quality Management Systems or designated administrative staff, DUMC Clinical Laboratories notifies designated Laboratory Personnel via phone and email. Email subject line typically reads: "CAP IS HERE".
 - 2.2.1. Medical/Program Directors- CCBB and APBMT/STCL programs
 - 2.2.2. Manager-Duke Stem Cell Laboratory
 - 2.2.3. ORAQ MC3 QSU Staff
 - 2.2.4. Carolinas Cord Blood Bank Processing Laboratory Management (Director(s), Managers, etc.).
- 2.3. Laboratory Representative(s) report to the designated location and time according to email notification from DUMC.
- 2.4. Director Quality Management Systems or designated administrative staff will notify external sponsors, as required

Signature Manifest**Document Number:** COMM-QA-040 JA1**Revision:** 09**Title:** Inspection Notification List**Effective Date:** 15 Jan 2021

All dates and times are in Eastern Time.

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Document Release

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