


DukeMedicine


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

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DOCUMENT TITLE:

Inspection Notification List

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COMM-PAS-019 JA1 Inspection Notification List

1. FDA (For 361 Products) or Other External Inspection Agency:

Upon arrival:

- 1.1. Notify the entire Clinical Quality Program (CQP), including the CQP leadership (Director). A member of CQP will serve as the Inspection Coordinator.
- 1.2. If a CQP representative is not available, the highest-ranking employee available will serve as Inspection Coordinator.
- 1.3. The Inspection Coordinator or appropriate leadership will inform applicable personnel of the inspection, including but not limited to the following, using the Email subject line, "FDA IS HERE".
 - 1.3.1. Executive Duke Cancer Institute (DCI) Staff
 - 1.3.2. Division Chiefs
 - 1.3.3. Program and Facility Medical Director(s)
 - 1.3.4. Program and Facility Managers
 - 1.3.5. Other Duke Cancer Institute and/or Duke University Health System Leadership/Offices as applicable based on inspection team (ex., Duke Office of Audit, Risk, and Compliance)
 - 1.3.6. External sponsors, as required

2. CAP Inspection Notification:

Upon arrival:

- 2.1. CAP notifies CQP Director and DUMC Clinical Laboratories.
- 2.2. CQP Director or designated administrative staff, DUMC Clinical Laboratories, notifies designated Laboratory Personnel via phone and email using the Email subject line, "CAP IS HERE".
 - 2.2.1. Program and Facility Medical Directors
 - 2.2.2. Manager-Duke Stem Cell Laboratory
 - 2.2.3. Laboratory Representative(s) report to the designated location and time according to email notification from DUHS
 - 2.2.4. External sponsors, as required

Signature Manifest**Document Number:** COMM-PAS-019 JA1**Revision:** 01**Title:** Inspection Notification List**Effective Date:** 01 Jul 2025

All dates and times are in Eastern Time.

COMM-PAS-019 FRM3 -- COMM-PAS-021 JA3**Author**

| Name/Signature | Title | Date | Meaning/Reason |
|----------------------------|-------|--------------------------|----------------|
| Mary Beth Christen (MC363) | | 26 Jun 2025, 01:24:01 AM | Approved |

Management

| Name/Signature | Title | Date | Meaning/Reason |
|----------------------|-------|--------------------------|----------------|
| Kris Mahadeo (KM193) | | 26 Jun 2025, 10:33:45 AM | Approved |

Medical Director

| Name/Signature | Title | Date | Meaning/Reason |
|----------------------|-------|--------------------------|----------------|
| Kris Mahadeo (KM193) | | 26 Jun 2025, 10:33:57 AM | Approved |

Quality

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| Mary Beth Christen (MC363) | | 26 Jun 2025, 05:15:15 PM | Approved |

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