Science Culture & Accountability Plan
Duke University is committed to maintaining the highest quality and integrity of all its scientific enterprise. Because of this commitment, the School of Medicine (SOM) is required to have mechanisms to guarantee the responsible management and critical review of scientific data. This is analogous to the School’s obligation to ensure lab safety, proper clinical study procedures, and the appropriate use of animals in research.

The Marcus Center for Cellular Cures (MC3) is committed to ensuring that departmental policies and procedures are in place to maintain the highest level of professional conduct — to promote a culture in which scientific results are critically reviewed, accountability for data integrity is clearly delineated, concerns can be brought forth without hesitation, and that there are mechanisms by which these concerns can be addressed fairly and expeditiously.

MC3 is the home for 2 cGMP (Clinical Good Manufacturing Practice) laboratories that manufacture cell and tissue product for clinical use. One of these products has been licensed by the FDA since 2012. As such, MC3 is subject to regular external audits and inspections from the FDA, HRSA, FACT, CAP and other agencies, as well as sponsors. MC3 funds a robust Quality Systems Unit (QSU) with 9 dedicated FTEs reporting independently from operations into the Office of Regulatory Affairs and Quality (ORAQ). The QSU oversees all aspects of MC3 operations and is tasked with ensuring quality and compliance with GMP and other federal regulations. QSU and MC3 Leadership meet weekly to review general operations and bi-weekly to discuss quality-specific issues.

In addition to the oversight from QSU, MC3 has in place other mechanisms to ensure the highest level of professional conduct, including:
• Ensuring data integrity and protecting privacy by following standard operating procedures
• Organizing, curating, and disseminating information to improve its usefulness to researchers
• Engaging in ways that allows MC3 to partner effectively with other departments within the Duke and with outside sponsors or vendors
• Developing alliances and partnerships

Promoting a culture of responsibility within MC3 rests with all people who work in this program. All faculty and staff are expected to complete successfully the Responsible Conduct of Research (RCR) training course appropriate to their position.

Creating Our Culture
MC3 is committed to helping create a culture that encourages open and critical discussions in all areas of clinical and laboratory based research. Some of the approaches that the department helps foster are outlined below.

Research team is composed of faculty members, nurse practitioners, cord blood collectors, lab staff and other research staff. The entire team meets approximately
quarterly to update on policies and procedures and to ensure research remains at the forefront of our initiatives.

Laboratories (Carolinas Cord Blood Bank and Robertson GMP Lab):

- Established laboratories conduct regular meetings. These meetings are a forum to update team members on any changes in protocols and policies, and present recent data for group review and evaluation. This helps to ensure transparency within the lab.
- Utilize Master Control, a document control system, for all standard operating procedures, training documentation, change controls and deviations.

Clinical Research Staff:

- Clinical research staff meet at least monthly to discuss new policies, projects and to identify any issues.
- The training coordinator ensures that new staff have adequate training opportunities throughout their orientation and that all required training modules are completed.
- The research manager reviews all monitoring reports in order to identify any issues in the conduct of research. The research manager also reviews the regulatory, consenting, eligibility, protocol compliance and data collection after enrollment of the initial subject and after a new coordinator works on a project.
- Cord blood staff do double review of all data collection.

All Staff:

- Quarterly staff meetings are held, and any important regulation or policy changes are announced and discussed further, if needed, to insure understanding.

- Educating the faculty and staff about available resources and reporting mechanisms for scientific accountability, such as:
  - The responsible PI is always an available party to address concerns.
  - The MC3 administrations are an available resource for reporting concerns.
  - The Research Practice Manager is a point person for any departmental concerns of scientific accountability.
  - The NIH Office of Research Integrity (http://ori.dhhs.gov/)
  - Guidelines for the Proper Handling of Digital Image Data (http://jcb.rupress.org/content/166/1/11.full)
  - Online learning tool for research integrity and image processing (http://ori.hhs.gov/education/products/RlandImages/default.html)
  - The Compliance and Fraud Hotline: To anonymously report a suspected compliance violation or concern at Duke, call 800-849-9793.
  - The department chair is available for private meetings as requested where these matters can be discussed, if desired.
Questions or comments
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