VUMC Cores and Shared Resources
Guidelines for Scientific Rigor & Transparency

Purpose:

Research cores and shared resources have an institutional role in supporting researchers in the responsible conduct of research through training, informal mentorship and service provided by the core. Cores are particularly well suited to facilitating good experimental design via well-developed, implemented and defined standard operating procedures (SOPs) and application of quality control/quality (QC/QA) assurance best practices. Cores are also uniquely positioned within VUMC to offer and promote authentication services for key biological and/or chemical resources to help achieve compliance with NIH policies and guidance related to rigor and reproducibility. Finally, cores play an institutional role for defining and establishing rigorous methods for acquiring and analyzing data; effectively transmitting these methods and concepts to users of a core; and producing large, complex experimental data sets.

The purpose of these guidelines is to support the research community in promoting intellectual and scholarly rigor, and appropriate transparency to encourage and enable reproducibility in science and practice, while balancing the needs for autonomy across the range of hypothesis-driven discovery and learning-based practice.

Guidelines:

VUMC cores and shared resources will work to provide research services and products using validated experimental methods that employ the highest level of rigor, reproducibility and transparency. Through the implementation and sharing of these best practices, cores will also provide evidence to users of the effectiveness of a more rigorous approach to the conduct of science, enabling individual investigators to better incorporate these practices into their own research programs. VUMC cores will be guided by the following principles:

- Methods are documented and systematically defined by use of peer-reviewed, consistently applied SOPs.
- Reagents are validated and properly maintained (i.e. inventory controls and proper storage)
- Software tools are validated
- Instrumentation is maintained and calibrated
- Positive/negative controls are justified, used and appropriately interpreted.
- Batch effects are defined and reported
- Statistical tests are appropriate to the data type and experiment
- QC and sample data delivered to core user is clearly annotated including interpretation of false positive/negative results. Results should be supplied in full unadulterated form for future analysis
- Education provided to researchers for the purposes of accurate reporting of results
- Core staff are appropriately trained on new instrumentation/methods
- Where applicable, limitations on the interpretation of resulting data are explained.

Each core is encouraged to develop resources that support best practices of scientific rigor and transparency as applicable and appropriate to the core scope of work, including a website page for sharing grant- and manuscript- ready text, development/maintenance of technical SOPs, internal

oversight to ensure adherence to written guidelines, compliance reporting guidelines and other educational/training materials, with reciprocal links to OOR website.

Glossary:

SOP
Standard Operating Procedure, a document outlining the most detailed procedures for effective conduct of an experiment or process.

Mentorship
For cores, defined as an informal approach where core experts model best practices to the students, trainees and/or junior faculty that make up the majority of actual core users.

Data
Recorded information, regardless of form or the media on which it may be recorded that is created or acquired in the process of performing research. It includes original observations and activities of a study that are necessary for reconstruction and evaluation of the report of the study.

Rigor
The strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation, and reporting of results.

Reproducibility
"… refers to the ability of a researcher to duplicate the results of a prior study using the same materials as were used by the original investigator…Reproducibility is a minimum necessary condition for a finding to be believable and informative."
Excerpted from: *K. Bollen, J. T. Cacioppo, R. Kaplan, J. Krosnick, J. L. Olds,* Social, Behavioral, and Economic Sciences Perspectives on Robust and Reliable Science *(National Science Foundation, Arlington, VA, 2015).*

Transparency
Approach to sharing of knowledge and data that is as open, accessible and unbiased as possible to enable broad dissemination, understanding and utility.

Core
A core is a shared laboratory resource that provides equitable access to services that facilitate users' scientific research activity; scientific services may include specialized products, expertise, modern equipment and/or advanced technology.

References:

VUMC policy on Sharing, Retention and Ownership of Research Data
https://vanderbilt.policytech.com/docview/?docid=11448

VUMC SOP for Managing Data Retention Requirements in Core Facilities
See draft SOP in Appendix 1.

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NIH Grants Policy
https://grants.nih.gov/policy/reproducibility/index.htm

VUMC Guidelines for Research Shared Resources and Core Facilities
https://www.vumc.org/oor/system/files/160510_2016_VUMC_Core_Guidelines.pdf

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Appendix 1:
DRAFT - SOP for Managing Data Retention Requirements in Core Facilities

The Vanderbilt University Medical Center Policy on Ownership of Research Data details the institutional and investigator responsibilities related to ownership, sharing and storage of primary research data, regardless of the technology used to create, preserve or record it. **The Principal Investigator (PI) has primary responsibility for archiving and maintaining data as required by the Policy.**

The purpose of the following **SOP for Managing Data Retention Requirements in Core Facilities** is to ensure consistent best practices for Cores, which may provide data management and storage services to PIs. Cores are not required to provide data management and storage services, and PIs may also "opt-out" of such services that are provided by a Core facility. In these cases, the PI should take possession, or provide instructions for transfer, of data at the end of the minimum operational data retention period (see item 1, below).

Note: Unless otherwise qualified, the term data refers to original, primary research data as defined in the institutional Policy on Ownership of Research Data.

1. Each Core should define what constitutes original, primary research data and additional valuable derivatives that may be stored by the Core, as appropriate to its technology platforms, applicable regulatory requirements and in consultation with institutional advisory structures (for example ISROC, faculty advisory committees, or other etc.). This definition may vary by Core and by service type.

2. Cores should establish and consistently adhere to a minimum operational data retention period. This is defined as the timeframe immediately following collection of data necessary for processing and releasing results to the PI. This minimum period may vary by Core and by service type.

3. Cores should create a written **Data Management SOP**, which should be readily available to PIs by website or other means, especially at the initiation of a project. The Core SOP should include as applicable:
   a. The Core-specific minimum data storage period, including schedule or timetable.
   b. Other data storage options provided by the Core.
   c. Cost of storage options.
   d. Any restrictions on types of data that can be stored by the Core (e.g. personal protected information; encryption; formats).
   e. Information about alternative storage options if available, e.g. public repositories – these may vary by Core and by service type.
   f. Additional considerations may include export compliance, confidentiality or non-disclosure agreements, patent protection and IP standards as applicable to Core and/or service type.

   Note: Each Core's Data Management SOP should be reviewed and approved by the Office of Research. It is expected that each SOP will apply to any *ad hoc* or "legacy" data storage going forward.

4. Cores may opt to offer data storage and management services for all, part or none of the required data retention time frame – provided this is clear to the PI at the initiation of work. Cores may contract with internally or externally managed data storage services, or may provide other appropriately managed environments for storage.

5. If Cores offer data storage and management services the following guidelines apply:

    a. Cores should establish the minimum operational data retention, which by definition ends at the point when data are finally transferred to the PI or other storage facility as directed by the PI.

    b. Cores should use best practices to ensure that data is managed in an appropriate, safe and accessible environment. Criteria for data safety include (1) regularly verifying data integrity and (2) avoiding single points of failure (e.g., storage device, computer, or server room).

    c. The costs associated with data storage services may be charged back to the PI. Costs for commonly used storage solutions such as the central storage repository (e.g. cost per terabyte in BlueArc) should be consistent across all Cores. As for all other Core services fees, data storage fees are subject to review and approval by the Office of Research.

    d. Cores should establish a notification process that includes a brief reminder to investigator of his/her responsibilities (reference Policy).

    e. Cores should send timely reminders to PIs regarding deadlines for discarding data. Before any data is destroyed, the Core should document the PI's acknowledgement of the planned data destruction. If the PI is not available (e.g., is not responsive or has left Vanderbilt), the Core should work with the Office of Research to contact the PI's department chair for guidance before any action is taken.

    f. Cores should maintain a log to document all communications and actions related to data storage, including:
        - PI request for data storage services
        - PI "opt-out" from Core-based data storage services
        - PI or departmental requests to destroy data
        - Actions taken by Core

For additional guidance, contact Susan Meyn in the Office of Research: s.meyn@vumc.org

References:

From PolicyTech: https://vanderbilt.policytech.com/

- *Sharing, Retention and Ownership of Research Data*
- *Acceptable Use Policy*

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