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Overview of the NCBR

Mission:

The mission of the Nebraska CV Biobank & Registry (NCBR) is to promote human subjects cardiovascular research. Human specimens and data are invaluable for basic, translational, and clinical research activities. A robust NCBR that supplies valuable specimens and data for research in a manner that is easily accessible to a broad range of researchers is critical to building our research portfolio and placing UNMC cardiovascular research in competitive positions for extramural funding.

Contributors:

Contributions from many team members are essential to ensure the NCBR remains a valuable resource for UNMC investigators. Contributors include administrators, technical staff, students, faculty, fellows, phlebotomists, nurses, physician assistants, clinical coordinators, clinicians, and surgeons.

Impact:

The NCBR has broad value to investigators in clinical and basic science departments and divisions across the institution. Impact of the NCBR will be measured, in part, by the peer-reviewed publications and grant funding enabled by this unique resource.

Scope of the NCBR Publishing and Funding Guidelines

The purpose of these guidelines is to provide clear expectations regarding publication acknowledgements, publication authorship, and grant funding as it relates to the use of the specimens and data from the NCBR. These guidelines are critical to the long-term viability of the NCBR, and consequently, to the benefit of all investigators who access NCBR resources. These criteria are intended to encourage use of the NCBR without placing unnecessary contingencies related to the use of specimens and data from the NCBR. Similarly, these guidelines are intended to encourage nascent collaborations among individuals with common interests.

Guidelines for Publication Acknowledgement

Acknowledgment of the NCBR:

Any publication the uses specimens or data from the NCBR should include the following statement in the acknowledgments:

> *"Specimens and data used in this study were provided by the Nebraska Cardiovascular Biobank and Registry, which is supported by the Center for Heart and Vascular Research."*

Acknowledgment of NCBR contributors:

Currently, actions from >20 individuals are collectively required to collect a single specimen in the NCBR. Contributions by these individuals to research manuscripts can be recognized either by authorship or by acknowledgement. It is not expected that any individual is included as an author by default simply due to their role in patient care, specimen collection or data retrieval. Rather, authorship or acknowledgement are determined based on total contributions by an individual to the research and manuscript.

Guidelines for Publication Authorship

Standards in the field for defining authorship:

Scholarly journals have clear definitions regarding the contributions required for authorship. These include, but are not limited to the International Committee of Medical Journal Editors (ICMJE):

> https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html
>
> *The ICMJE recommends that authorship be based on the following 4 criteria:*
>
> - *Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND*
> - *Drafting the work or revising it critically for important intellectual content; AND*
> - *Final approval of the version to be published; AND*
> - *Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.*
>
> *Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged. Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are acquisition of funding; general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading. Those whose contributions do not justify authorship may be acknowledged individually or together as a group under a single heading (e.g. "Clinical Investigators" or "Participating Investigators"), and their contributions should be specified (e.g., "served as scientific advisors," "critically reviewed the study proposal," "collected data," "provided and cared for study patients," "participated in writing or technical editing of the manuscript").*

The Nebraska Biobank example:

The Nebraska Biobank (distinct from the NCBR) follows the guidelines stated above. Specifically, when specimens and data from the Nebraska Biobank are used in a research study, the Nebraska Biobank is acknowledged in the publication, but individuals who contributed to specimen collection or provided patient care are not required by default to be included as authors on resulting publications.

Expectations for the Nebraska Cardiovascular Biobank and Registry:

The following expectations are in place for studies that use specimens and data from the NCBR:

1. NCBR specimen and data collection team members are not automatically included as authors on every study that uses specimens from the NCBR. They may be considered for authorship if they also make qualifying contributions to the research and manuscript.

   Example: Dr. Stoller uses 20 tissue samples from the NCBR for studies included in a manuscript. All of the patients were consented by Ryan Ruskamp. All of the samples were collected from the operating room and cryopreserved by Morgan Carpenter. If Ryan and Morgan do not otherwise contribute to the research and manuscript, Ryan and Morgan should be acknowledged in the manuscript. However, if Ryan and Morgan also make other contributions to the research they could be included as authors.

2. Providers who care for patients are not automatically included as authors on every study that uses specimens from the NCBR. They may be considered for authorship if they also make qualifying contributions to the research and manuscript.

   Example: Dr. Gundry uses 20 tissue samples from the NCBR for studies included in a manuscript. All of the patients were seen by Dr. Stoller in the clinic. All patients were consented by Ryan Ruskamp. All of the samples were collected from the operating room and cryopreserved by Morgan Carpenter. *If Ryan, Morgan, and Dr. Stoller do not otherwise contribute to the research and manuscript, they should be acknowledged in the manuscript. However, if Ryan, Morgan, and Dr. Stoller also make other contributions to the research they could be included as authors.*

3. NCBR team members and clinical providers who contribute to the research and manuscript are considered for authorship based on their contributions.

   Example: Dr. Stoller and Dr. Gundry discuss an idea to conduct a study that uses specimens from the NCBR. Dr. Stoller has identified patients he sees in clinic to include in the study. NCBR team members collect the specimens. Lab members from the Stoller and Gundry groups then contribute to study design, experiment execution, data analysis and preparation of the manuscript. These group members would be considered for authorship based on their contributions. Dr. Anderson would not be included as an author simply because he is the PI of the NCBR, but he would be considered if he contributed to the research and manuscript.

Contributions to Research that are Considered for Authorship

Anyone interested in being included as an author of a scientific study is encouraged to actively participate in research. There are many ways to contribute. Performing a single activity does not rise to the level of authorship, nor are contributions to every aspect of a study required. Listed below are several examples of activities that are considered contributions to research. This is not an exhaustive list of all possibilities, but are examples designed to encourage anyone to identify ways to contribute if they are interested in being authors on scientific publications.

- Contribute to study design by selecting patient population and retrieving appropriate clinical data
- Contribute to study design by planning the experimental design
- Perform experiments and acquire data
- Analyze data and generate figures
- Interpret data in the context of broader physiology or clinical experience and communicate that interpretation verbally or in writing to the study team leader(s)
- Contribute original text to the manuscript draft
- Provide substantive edits to the manuscript (beyond mere grammatical or editorial editing)
- Perform surgery
- Contribute to specimen collection
    - Tissue dissection and/or collection in the operating room
    - Blood collection
    - Processing of specimens in the biobank

Examples of contributions that rise to the level of authorship:

Surgeons:

Perform surgery and crude dissection of tissue collected by NCBR AND contribute to interpretation of research results in the context of clinical experience either through discussions with the other investigators or during manuscript drafting AND provide critical feedback during manuscript preparation.

Surgical Staff:

Contribute to tissue dissection and/or collection in the OR AND contribute to interpretation of research results in the context of clinical experience either through discussions with the other investigators or during manuscript drafting AND provide critical feedback during manuscript preparation.

Clinicians:

Contribute to study design by participating in discussions with other investigators during the planning phase of the study such as identifying patients to include in the study AND review data and provide interpretation in the context of clinical experience either through discussions with the other investigators or during manuscript drafting AND provide critical feedback during manuscript preparation.

Research Staff:

Contribute to study design by participating in discussions with other investigators during the planning phase of the study AND perform experiments and interpret data AND contribute to manuscript writing and editing.

The role of research group meetings:

Surgeons, clinicians, and surgical staff are encouraged to express their interest in participating in research collaborations and publications so they can be included as early in the study process as possible and provided opportunities to contribute to publications. Research group meetings are one of the most effective ways to participate in research in nascent stages of study design.

Grants

If your proposed studies will use specimens or data in the NCBR, it is appropriate to include expenses in the budget to cover costs of specimen collection, processing, archiving, retrieval, and records management.

Following a consultation to discuss project goals, Dr. Anderson will provide materials to support grant applications.

Materials that are prepared for each application include:

1. Letter of Support (customized for the project) stating availability of specimens and overview of consent process / honest broker system
2. Facilities & Resources document for the NCBR
3. Budget justification – descriptions and costs for specimens