

# Brittle Bone Disease Consortium

## PUBLICATION POLICY

Version November 12, 2014

### Scope:

This policy addresses the Brittle Bone Disease (BBD) Consortium publication procedures. Refer to the Rare Diseases Clinical Research Network (RDCRN) Publication Policy for Network-wide publication-related policies.

### Objectives:

This policy addresses the coordination, development, and communications related to the orderly and timely release of information generated by the BBD to various audiences, including scientific and medical journals, conferences and meetings, news media, and other public information sources. This policy defines authorship roles and responsibilities - including communications and notifications among co-authors, other investigators, the consortium Principal Investigator, and relevant NIH science and project officers.

### Definitions:

#### ***Publication types***

Scientific and medical journals – The policies listed below apply to publication of data collected by the BBD in scientific and/or medical journals.

Conferences and meetings – BBD PIs can present published data generated by the BBD. Requests to present unpublished data require prior approval from the Consortium PI.

News media – The Consortium PI, study PIs or designee will be responsible for generating press releases and responding to media inquiries.

Other public information sources – The Consortium PI or designee will be responsible for dissemination of BBD data via other public information sources.

#### ***Authorship types and roles***

First author – The first author takes primary responsibility for the integrity of the work as a whole from inception to published article.

Co-authors – Each co-author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Authorship credit should be based only on:

- a. substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; and
- b. drafting the article or revising it critically for important intellectual content; and
- c. final review and approval of the version to be published.

Conditions a, b, and c must all be met.

## **Policies:**

- 1) Preliminary Considerations – Notify the Consortium PIs (Brendan Lee, V. Reid Sutton) of publications under consideration per the BBD Data Use Policy.
  
- 2) Guidelines for Determining Authorship
  - a. Major publications resulting from the study will include all BBD Site PIs, BBD leadership, and project director. Major publications include publications describing the study or reporting on the overall results of the specific aims of the study. In the acknowledgements section, credit will be given to the project coordinators at each site and their names will be listed.
  - b. As we start performing individual or focused analysis of Study data, sites will have the opportunity to take a leadership role in data mining studies and these papers will include only those investigators who have significantly contributed to the analysis and publication as a named author as defined above under Authorship Types and Responsibilities. However, the next to the last author will be listed as “Members of the BBD”<sup>1</sup> and will include the membership listed in 6a. Individual authors need to meet all of the authorship requirements but Members of the BBD do not. Members of the BBD, however, will be provided with a draft of the manuscript for their input prior to its submission. .
  - c. For other site-specific protocols, authorship will be determined by those who have had a significant input in the design, conduct, or analysis of the study data (see 2b).
  - d. Coordinators and others can be included as authors on publication of data from site-specific protocols and individual/focused analysis of Longitudinal Study data when their site has taken a leadership role in the publication and where all authorship requirements are met.
  
- 3) Timeline – The first author will determine the timeline for publication, including Consortium review for quality assurance.
  
- 3) Statistical Support – The first author will notify the DMCC and Baylor College of Medicine of publications under development. DMCC/BCM will determine the need for data/analysis and the degree to which DMCC/BCM review may be required.
  
- 4) Format – The first author will ensure that the manuscript content and format meets accepted scientific standards.
  
- 5) Manuscript Review/Approval

Manuscripts resulting from the Longitudinal Study of BBD will be sent to all “Members of the BBD”<sup>1</sup> prior to submitting to a peer-reviewed journal.

All BBD manuscripts will be submitted to Consortium PI, Brendan Lee (or designee), and to the NIAMS Project Scientist (Scientific Officer) for review prior to submission. The Project Scientist will approve or provide comments within one week of receipt.

Publications that describe the RDCRN and its functions, objectives, and outcomes (that are not focused on a specific protocol or Consortium), require approval of the RDCRN Steering Committee.

- 6) Acknowledgement - The first author will ensure that BBD members, the RDCRN, NIAMS/NCATS/NIDCR/ORDR and sponsors are appropriately acknowledged and that reference is made to the terms and conditions of the individual Consortia Notices of Grant Awards.
- a. Publications resulting from BBD will acknowledge all the PIs that contributed to the dataset as “Members of the BBD”. This will include an asterisk to list all PI names on the first page or include the PI names in the acknowledgements section.  
PIs to be included: Brendan Lee, V. Reid Sutton, Sandesh CS Nagamani, Frank Rauch, David Eyre, Francis Glorieux, Gerald Harris, Tracy Hart, Deborah Krakow, Jeffrey Krischer, Eric Orwoll, Cathleen Raggio, Jay Shapiro, Peter Smith, Laura Tosi, Anne Tsai
  - b. Publications/presentations *must* mention in the beginning of the text or presentation that the consortium is part of RDCRN, an initiative of ORDR, NCATS
  - c. All materials (promotional materials, publications and internet sites) related to the NIH Rare Diseases Clinical Research Network (RDCRN) program must include a statement acknowledging that our consortium is a part of the RDCRN, an initiative of ORDR, NCATS, and an acknowledgement of NIH Cooperative Agreement Award (or grant) support and a disclaimer stating the following:  
  
*“The Brittle Bone Disease Consortium (1U54AR068069-0) is a part of the National Center for Advancing Translational Sciences (NCATS) Rare Diseases Clinical Research Network (RDCRN), and is funded through a collaboration between the Office of Rare Diseases Research (ORDR), NCATS, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), and the National Institute of Dental and Craniofacial Research (NIDCR). The content is solely the responsibility of the authors and does not*

*necessarily represent the official views of the National Institutes of Health.”*

- d. Publications resulting from Longitudinal Study data should also include this language in the acknowledgment section:

*The Brittle Bone Disease Consortium is also supported by the Osteogenesis Imperfecta Foundation*

- 7) Acceptance of Manuscript - The first author or designee will notify the DMCC, the NIH Project Officer, the NIH Project Scientist, and the BBD Program Manager when the manuscript has been accepted for publication.
- 8) NIH Public Access Policy – The first author will ensure that appropriate NIH regulations are followed, including adherence to NIH Public Access Policy, which requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication. The NIH Public Access Policy applies to any manuscript that:
  - d. is peer-reviewed;
  - e. and, is accepted for publication in a journal on or after April 7, 2008;
  - f. and, arises from:
    - i. any direct funding<sup>1</sup> from an NIH grant or cooperative agreement active in Fiscal Year 2008, or;
    - ii. any direct funding from an NIH contract signed on or after April 7, 2008, or;
    - iii. any direct funding from the NIH Intramural Program, or;
    - iv. an NIH employee.

It is the responsibility of the authors to be sure that the publication is submitted to PubMed Central. Instructions related to the submission process can be found at <http://publicaccess.nih.gov/>

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<sup>1</sup> “Directly” funded means costs that can be specifically identified with a particular project or activity. See NIH Grants Policy Statement, Rev. 12/2003

**Revision History:**

12 November 2014: Adopted by the BBD