Final

EDRN PUBLICATION POLICY

TABLE OF CONTENTS

I. EARLY DETECTION RESEARCH NETWORK PUBLICATION REVIEW GROUP (PRG)

A. Duties and Responsibilities:

The overall responsibilities of the EDRN Publications Review Group (PRG) is to oversee the compliance to the guidelines governing authorship, cooperative alliances, credit for scientific input, data and resource sharing. Furthermore, the EDRN PRG will oversee and approve information that is released to the public concerning EDRN supported studies. In addition, the EDRN PRG will adhere to all current and future guidelines established by the NIH. (regarding publications, media interactions, etc.)

This PRG will review and grant final approval of all materials regarding pre-publication press releases of EDRN-supported studies as described below in section entitled, "Media Policy."

The PRG would meet on an ad hoc basis and discharge most of their duties by E-Mail and conference calls. The turnaround time for review of manuscripts will be determined based on the type of materials and the urgency of the review.

B. Members:

The PRG members will consist of a subset of the current Collaborations and Publications Subcommittee members. The membership of the PRG will always include member of the DMCC and a representative of the NCI.

II. PUBLICATION POLICY FOR COLLABORATIVE STUDIES

A. Definition:

This publication policy applies to all communications that relate any information about the objectives and findings of an EDRN Collaborative or Validation Study. Collaborative or Validation Studies include all EDRN-funded studies that involve at least two participant sites of EDRN including BVLs, BDLs, CECs, DMCC, and Associate Members.

B. Authorship:

(1) *Primary results publication*

It is the responsibility of the investigator who conceptualizes the Collaborative/Validation Study to submit the primary results manuscript for publication within one year of study closure, unless the Data and Safety Monitoring Committee decide that publication is premature. This investigator will assume the responsibilities of the lead author. If this person does not want to be the lead author s/he may assign the duty to a colleague.

All authors must have had significant contributions towards at least two of the following: study design, study conduct, or writing. Order of authorship should be decided jointly amongst authors before writing the paper. Ideally, the order of authorship should be discussed at the beginning of the research study. In the event of irreconcilable differences, complaints regarding authorship order can be submitted to the Publications Review Committee (PRG), who will make the final decision regarding authorship order.

(2) *Secondary publications*

The lead author for publications that are secondary to the primary results paper will be the investigator who conceives the idea for the paper. At least one investigator from each participating site should be offered the opportunity to be a co-author. The lead author of the primary paper should be offered the position of senior author. As above, all authors must have had significant contributions towards at least two of the following: study design, study conduct, or writing. Authors should decide jointly the authorship order prior to manuscript completion. In the event of irreconcilable differences, complaints regarding authorship order can be submitted to the PRG, who will make the final decision regarding authorship order.

(3) Lead author responsibilities (include, but not limited to)

- Assumes a leadership role in identifying co-authors, writes the manuscript, responds to reviewers' comments, and corresponds with Journal editors
- Submits a data analysis request to the DMCC
- Determines the authorship order for the paper in consultation with the co-authors

- Schedules writing committee meetings and conference calls, as needed
- Forwards the final draft of the paper to the selected Journal and send copies of the cover letter and the final draft of the paper to all co-authors
- Makes Journal revisions
- Incorporates Journal edits to galley proofs and return to the Journal within the stated time period
- Notifies all co-authors, the NCI Project Officer, and the DMCC when a Journal accepts a paper
- Sends the Journal citation(s) to the DMCC so that the information can be posted to the secure website
- If the Journal does not accept the manuscript, contact the co-authors to review the Journal critique and discuss alternative Journal options

(4) *Co-authors' responsibilities*

- Assist with selection of first choice and backup Journal
- Participate in development of the paper outline and analysis request
- Perform tasks assigned by the lead author and write the material in a prescribed format and within the stated time period
- Review draft paper expeditiously and return comments to lead author
- Make revisions, as required
- Affirm and accept public responsibility for authorship as specified by target Journals

III. PUBLICATION POLICY FOR REPORTING NEGATIVE RESULTS

As stated in Section II. under *Authorship,* the Primary Investigator assumes the responsibilities as lead author in any publication that result from work that is supported by the Network with funds and resources that also include: core funds, EDRN Specimen Reference Sets, and projects with set-aside funds. If the Primary Investigator does not initiate the primary paper within one year of the study's closure, then any investigator who participated in the study may become the lead author. At least one person from each participating EDRN site will constitute the remainder of the authors for the primary results paper. All authors must have had significant contributions towards at least two of the following: study design, study conduct, or writing.

If the study culminates in negative results and the Primary Investigator is reluctant to put forth a primary publication on these negative data, the primary investigator will be required to issue a full report of the negative results of the study. This report must be made available on a public EDRN website. Negative results are important for minimizing the duplication of similar studies the scientific community.

A. Arbitration:

In the event of irreconcilable differences, complaints regarding authorship of publications involving EDRN-funded studies, the EDRN PRG will act as arbitrator and determine the final decision regarding authorship order. If deemed appropriate by the EDRN PRG, an external panel may also be constituted to review an issue.

IV. MEDIA POLICY

The media policy is developed to insure an accurate representation of the results to the media and avoid any misinterpretation. The media policy allows the Principal Investigator to convey the information about the scientific discovery and avoid any miscommunication that a discovery is approved by the NCI, NIH or federal government as a new standard.

The media policy is developed not to restrict the Principal Investigator. Prior to any media contact, the Principal Investigator MUST notify the designated EDRN NCI Program Director for the study and it is also advisable to contact the Media Office of his/her institution. The EDRN Program Director MUST notify the supervisor of the Program Director and the NIH Office of Media and discuss the upcoming media event (interview, press release, etc.). With input from the NIH Media Office and the Principal Investigator's institutional media office, the Principal Investigator and the designated Program Director will develop a plan for interaction with the media which will be reviewed by the PRG.

A. Disclaimer:

Normally, the need for a disclaimer in relation to official materials, presentations, or publications is eliminated through the clearance process.

However, a disclaimer may still be needed even after official clearance to make clear that the presentation should not be construed as necessarily representing the NIH view. Investigators may also need to use disclaimers to distinguish the status of information, e.g., preliminary data or incomplete data. Where appropriate, potential error sources affecting the quality of the data should be identified and disclosed.

B. Pre-Publication Press Releases:

A press release is defined as a document given to radio, television, newspapers, online websites, scientific journals not indexed in the Index Medicus, and popular periodicals.

ALL information released to the press and public media announcements concerning collaboration alliances and support by EDRN with academic or non-academic entities MUST be PRE-APPROVED by the PRG and follow the current NIH Clearance Process Guidelines. Local press releases must limit their substantive content to information items that previously have been described in materials approved by the PRG. A copy of each prepared release must be sent to the NCI Program Officer to maintain current knowledge for responses to national queries and to the DMCC for storage in the EDRN central files.

When a paper is scheduled for presentation before organizations that issue press releases, the presenter may submit the text of the presentation for release to the press only AFTER it has been reviewed and approved by the designated EDRN NCI Program Director for the study and the supervisor of the NCI Program Director.

C. Interviews:

An interview is any discussion with a member of the press, a science writer, or a radio or television interviewer or commentator, which provides information for public dissemination.

Interviews are subject to the same rules as press releases. Local information concerning participation by local organizations can be provided to encourage

cooperation and acceptance of the study. The ethics and legalities of medical confidentiality apply to the names and risk status of individual study participants.

Before interacting with the media, the Primary Investigator MUST submit to the EDRN PRG, for approval, a 'fact sheet' for the results of a study. Before individuals interact with the media, they MUST contact the appropriate Media Office in their institution as well as contact the designated EDRN NCI Program Director for the study. The EDRN Program Director MUST contact the NIH Office of Media and discuss the upcoming media event (interview, press release, etc.). Individuals from within the EDRN who participated in the protocol (as well as Program staff) may then interact with media on the subject of the study and may discuss the outcomes of the study using, as a guide, the “fact sheet.” In the event that there are issues that are questioned which are not on the Fact Sheet, then the Primary Investigator is, of course, permitted to use good judgment to answer those questions (or not answer them) to the best of their ability.

D. Abstracts/Presentations for National and International Meetings:

Presentation of EDRN data at scientific meetings is encouraged as a means of increasing the visibility of EDRN and facilitating the preparation of EDRN publications. Any investigator participating in an EDRN Collaborative or Validation Study can present an abstract at a scientific meeting as long as it has been approved by at least one of the PIs of the study. The DMCC, however, will only provide data analysis support presentations that are by-products of EC approved for prevalidation or validation studies.

The NCI Project Officer and the DMCC must be notified of all public presentations. These include presentations given to scientific, professional, or public groups. If presentation materials are likely to be published or publicized, such as in proceedings of the meeting or workshop, a copy of each presentation must be sent to the NCI Program Officer to maintain current knowledge for responses to national queries and to the DMCC for filing in the central files.

After an abstract has been presented at a scientific meeting, the tables used are available to EDRN investigators and may be used by them at other scientific meetings with appropriate acknowledgment. However, such subsequent

presentations should not appear in published form unless the data in the original paper are already published and appropriately referenced. Unpublished data or data not yet presented at national scientific meetings will not be released to the press.

E. E-Publication Policy

The EDRN PRG will follow the current NIH guidelines for Public Access to scientific research, which can be found at **(**http://publicaccess.nih.gov/**).** The NIH Public Access Policy ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication. To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

As of April 7, 2008, final peer-reviewed manuscripts arising from NIH funds must be submitted to PubMed Central upon acceptance for publication.

As of May 25, 2008, NIH applications, proposals, and progress reports must include the PubMed Central reference number when citing a paper that falls under the policy and is authored or co-authored by the investigator, or arose from the investigator's NIH award. This policy includes applications submitted to the NIH for the May 25, 2008 due date and subsequent due dates.

# # #

V. Useful links to NIH Policies and Guidelines:

http://www.nih.gov/sdminutes/2000/00.02.02/Publication.htm
E-Publication Policy

http://www1.od.nih.gov/oir/sourcebook/oversight/pub-clear-form.htm
Publication and Abstract Clearance Form

http://www.ott.nih.gov/about_nih/
The NIH Office of Technology Transfer (OTT)

http://epi.grants.cancer.gov/documents/CFR/Policy_on_Publications_Mar07.pdf
Policy on C-CFR Publications (Amended from June 2005 Publications Guidelines, Feb 2007)

http://publicaccess.nih.gov/
NIH Public Access Policy