MDP Publication Policy

1.1 Publication and Presentation Policy

The following guidelines are intended to cover the entirety of work conducted under the NIH IPCP U19 "Microbicide Development Program" (AI 060614). The goals of this publication policy are to ensure that manuscripts resulting from research conducted within Microbicide Development Program (MDP):

- reflect accurate reporting of the design, conduct, and analysis of studies;
- are developed in a collaborative fashion with the active participation of all investigators participating in the design and conduct of the study;
- are published expeditiously and are widely disseminated (abstracts reporting the preliminary or highlighted results of a research study does not substitute for a full manuscript); and,
- protect confidentiality of medical, personal and product information in accordance with the Privacy Act, the requirements for the protection of human subjects and any applicable clinical trials agreements.

All publications will be reviewed by (i) the relevant Project Leader and (ii) the MDP Program Director, Peter Anton, MD and the NIH U19/IPCP Project Officer prior to submission. Prompt review will take place to ensure that investigators are able to meet publication deadlines. All abstracts should be reviewed prior to submission; review will be within 2-3 working days. Additional guidelines *within* Projects remain within the purview of respective Project Leaders and should have copies submitted to the Administrative Core.

1.1.1 Definitions

1.1.1.1 Primary Publications

Primary publications include journal articles as well as meeting abstracts that report the findings of study objectives (including secondary and tertiary) as described in an MDP study protocol and/or are derived from the original application. The requirement for informed consent should be included in the journal's instructions for authors. When informed consent has been obtained it should be indicated in the published article.

1.1.1.2 Secondary Publications

Secondary publications include journal articles and meeting abstracts that address scientific questions not identified as study objectives in an MDP study protocol, but rely on data collected or analyses performed by MDP investigators. These items must fill out a Concept Sheet in advance requesting access to the data and planned investigations and submit for review/approval to the Project Leader (See attached Appendix). If appeal is sought, the submitted request will

be forwarded to the MDP PI. The requirement for informed consent should be included in the journal's instructions for authors. When informed consent has been obtained it should be indicated in the published article.

1.1.2 Authorship

Authorship is the primary mechanism for determining the allocation of credit for scientific advances and thus the primary basis for assessing a scientist's contributions to developing new knowledge. As such, it potentially conveys great benefit, as well as responsibility.

An "author" is generally considered to be someone who has made substantive intellectual contributions to a published study. ***The guiding principles will be those established above and those of the International Committee of Medical Journal Editors (ICJME)***. "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" **N Engl J Med** 1997; **336**:309-315. The complete document appears at www.icmje.org.The primary criteria for authorship are intellectual contributions to protocol design, including those detailed designs and concepts developed for the Project/NIH grant, conduct of the protocol, interpretation and analysis of protocol data, including relating the results to other information in the literature, and drafting substantial portions of the manuscript. In many cases, protocol development and data analyses will rely heavily on specific Core members.

From the ICJME recommendations: "Authorship credit should be based on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.

From ICJME: "The order of authorship on the byline should be a joint decision of the co-authors. Authors should be prepared to explain the order in which authors are listed". In most cases, the first author will be the investigator who takes the lead in preparing the first draft of the manuscript. The Project Leader and/or those drafting the paper will decide decisions on first/last author position.

Additional authors must have participated sufficiently in protocol development or implementation, in the analytic design or interpretation of the findings, or in the preparation of the manuscript to assume public responsibility for the content of the manuscript. If authorship disputes occur, the MDP Principal Investigator will mediate.

Although the PI and collaborative investigators will retain custody and primary rights to the data consistent with current DHHS, PHS, and NIH policies, DAIDS will have access to all data generated by the MDP and may periodically review it.

1.1.3 Acknowledgments

For each publication that results from NIH grant-supported MDP U19, grantees must include an acknowledgment of NIH grant support and a disclaimer stating the following: "This publication was made possible by Grant Number AI060614 from NIH DIAIDS IPCP. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the NIH". All publications and presentations will include this statement and list the applicable cooperative agreement numbers. Other sources of support (financial or otherwise) should be made clear in this section.

1.1.4 Tracking Publications

One copy of each publication resulting from work performed under the MDP NIH grant-supported project must be submitted to the MDP Administrative Core to accompany the annual or final progress report submitted to the NIH awarding office.

1.1.5 Conflict of Interest and Financial Disclosure

When authors submit a manuscript, whether an article or a letter, or present findings at a meeting, they are responsible for disclosing all financial and personal relationships that might bias their work.

1.1.6 Publicity

All press releases and scientific press briefings by MDP investigators that present study data or results of NIAID-supported MDP studies must be approved by the NIAID Program Officer and the MDP PI and then coordinated with the journal in which the study results are expected to be published.

1.1.7 Manuscript Review Process

Manuscripts of primary publications may not be submitted to journals until after MDP review. This process is intended to be advisory. The review is designed to expeditiously assure and accurately report its design, conduct, and analysis. The timetable will be monitored carefully and exceptions will be made for fast tracking primary publications.

Following completion of the near-final draft manuscript, the manuscript is submitted to the MDP Principal Investigator, who reviews it within 10 working days. The lead author will confirm that all authors and Project Leader have signed off on the manuscript prior to the MDP Principal Investigator review. All Project members should have the opportunity to read the manuscript. Within 10 working days of manuscript receipt, the MDP Principal Investigator will convene a conference call with the Project Leader to discuss the manuscript. Prior to submission of manuscripts for publication, a final copy will be provided to DAIDS and to the MDP Administrative Core for tracking purposes.

1.1.8 Post-Journal Submission

If a primary manuscript is not accepted for publication and reviewer feedback indicates a need to substantially reformulate the essential components, the team must submit proposed revisions to the MDP Principal Investigator for re-review.

If a primary manuscript is accepted provisionally with required or recommended changes/additions, if a journal invites a revised draft of the same article, or if an article is

being submitted to another journal with minimal changes, the lead author in consultation with the writing team may respond to the editor without the MDP Principal Investigator's review. It is the responsibility of the team to differentiate between alterations that reflect mere editorial changes and those which essentially modify the analyses and/or conclusion of the study previously endorsed by the MDP. Communication regarding the status will be sent to the MDP Administrative Core.

Appendix 1 Excerpt of NIH Grants Policy

The following sections relate to data 'ownership', publications, IP, unique research resources (like computer programs, questionnaires etc) and asserts the importance of timely public access. http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54.

Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. PIs and grantee organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large. (See also "Public Policy Requirements and Objectives-Availability of Information-Access to Research Data <NIHGPS_Part5.htm>" for policies related to providing access to certain research data at public request.) If the outcomes of the research result in inventions, the provisions of the Bayh-Dole Act of 1980, as implemented in 37 CFR Part 401, apply.

As long as grantees abide by the provisions of the Bayh-Dole Act, as amended by the Technology Transfer Commercialization Act of 2000 (P.L. 106-404), and 37 CFR Part 401, they have the right to retain title to any invention conceived or first actually reduced to practice using NIH grant funds. The principal objectives of these laws and the implementing regulation are to promote commercialization of federally funded inventions, while ensuring that inventions are used in a manner that promotes free competition and enterprise without unduly encumbering future research and discovery.

The regulation requires the grantee to use patent and licensing processes to transfer grant-supported technology to industry for development. Alternatively, unpatented research products or resources-"research tools"-may be made available through licensing to vendors or other investigators. Sharing of copyrightable outcomes of research may be in the form of journal articles or other publications.

The importance of each of these outcomes of funded research is reflected in the specific policies pertaining to rights in data, sharing of research data and unique research resources, and inventions and patents described in the following subsections.

Rights in Data (Publication and Copyrighting)

In general, grantees own the rights in data resulting from a grant-supported project. Special terms and conditions of the award may indicate alternative rights, e.g., under a cooperative agreement or based on specific programmatic considerations as stated in the applicable RFA. Except as otherwise provided in the terms and conditions of the award, any publications, data,[12] <NIHGPS_Part17.htm> or other copyrightable works developed under an NIH grant may be copyrighted without NIH approval. Rights in data also extend to students, fellows, or trainees under awards whose primary purpose is educational, with the authors free to copyright works without NIH approval. In all cases, NIH must be given a royalty-free, nonexclusive, and irrevocable license for the Federal government to reproduce, publish, or otherwise use the material and to authorize others to do so for Federal purposes. Data developed by a consortium participant also is subject to this policy.

As a means of sharing knowledge, NIH encourages grantees to arrange for publication of NIH-supported original research in primary scientific journals. Grantees also should assert copyright

in scientific and technical articles based on data produced under the grant where necessary to effect journal publication or inclusion in proceedings associated with professional activities.

Journal or other copyright practices are acceptable unless the copyright policy prevents the grantee from making copies for its own use (as provided in 45 CFR 74.36 and 92.34). The disposition of royalties and other income earned from a copyrighted work is addressed in "Administrative Requirements-Management Systems and Procedures-Program Income <NIHGPS_Part8.htm>."

For each publication that results from NIH grant-supported research, grantees must include an acknowledgment of NIH grant support and a disclaimer stating the following:

"This publication was made possible by Grant Number _____ from _____" or "The project described was supported by Grant Number _____ from _____" and "Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the [name of awarding office or NIH]."

If the grantee plans to issue a press release concerning the outcome of NIH grant-supported research, it should notify the NIH awarding office in advance to allow for coordination.

One copy of each publication resulting from work performed under an NIH grant-supported project must accompany the annual or final progress report submitted to the NIH awarding office (see "Administrative Requirements-Monitoring-Reporting-Non-Competing Grant Progress Reports <NIHGPS_Part8.htm>" and "Administrative Requirements-Closeout-Final Reports-Final Progress Report <NIHGPS_Part8.htm>").

Sharing of Research Data

NIH believes that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. NIH endorses the sharing of final research data to serve these and other important scientific goals and expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. "Timely release and sharing" is defined as no later than the acceptance for publication of the main findings from the final data set. Effective with the October 1, 2003 receipt date, investigators submitting an NIH application seeking $500,000 or more in direct costs in any single budget period are expected to include a plan for data sharing or state why data sharing is not possible.

NIH recognizes that data sharing may be complicated or limited, in some cases, by organizational policies, local IRB rules, and local, State and Federal laws and regulations, including the "Privacy Rule" (See "Public Policy Requirements and Objectives-Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services-Confidentiality-Standards for Privacy of Individually Identifiable Health Information <NIHGPS_Part5.htm>"). The rights and privacy of individuals who participate in NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

Sharing of Unique Research Resources

Investigators conducting biomedical research frequently develop unique research resources. Categories of these resources include synthetic compounds, organisms, cell lines, viruses, cell products, and cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data. Specific examples include specialized or genetically defined cells, including normal and diseased human cells; monoclonal antibodies; hybridoma cell lines;

microbial cells and products; viruses and viral products; recombinant nucleic acid molecules; DNA probes; nucleic acid and protein sequences; certain types of animals, such as transgenic mice; and intellectual property, such as computer programs.

NIH considers the sharing of such unique research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can impede the advancement of further research. Therefore, when these resources developed with NIH funds and the associated research findings have been published or after they have been provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community.

To provide further clarification of the NIH policy on disseminating unique research resources, NIH published *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* (64 FR 72090, December 23, 1999), which is available on the NIH website (<http://www.ott.nih.gov/policy/rt_guide_final.html>). This document will assist grantees in determining reasonable terms and conditions for disseminating and acquiring research tools.

The terms of those agreements also must reflect the objectives of the Bayh-Dole Act and the Technology Transfer Commercialization Act of 2000 to ensure that inventions made are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery.

In addition to sharing research resources with the research community, upon request of the NIH awarding office, the grantee also must provide a copy of documents or a sample of any material developed under an NIH grant award. The grantee may charge a nominal fee to cover shipping costs for providing this material. Income earned from these charges must be treated as program income (see "Administrative Requirements-Management Systems and Procedures-Program Income <NIHGPS_Part8.htm>").

To facilitate the availability of unique or novel biological materials and resources developed with NIH funds, investigators may distribute the materials through their own laboratory or organization or submit them, if appropriate, to entities such as the American Type Culture Collection or other repositories. Investigators are expected to submit unique biological information, such as DNA sequences or crystallographic coordinates, to the appropriate data banks so that they can be made available to the broad scientific community. When distributing unique resources, investigators are to include pertinent information on the nature, quality, or characterization of the materials.

Investigators must exercise great care to ensure that resources involving human cells or tissues do not identify original donors or subjects, directly or through identifiers such as codes linked to the donors or subjects.

Organizations that believe they will be unable to comply with these requirements should promptly contact the GMO to discuss the circumstances, obtain information that might enable compliance, and reach an understanding in advance of an award.

Appendix 2 MDP Publication Request Concept Sheet

STUDY INVESTIGATOR CONCEPT FORM

FOR U19 MDP Investigators and other Collaborators to Specific Project Leaders

Date:_____

Submitting Investigator:_____

Study related to which U19 Project(s): _____

Study Title:_____

Institution:_____

Telephone Number: _____

FAX Number: _____

E-mail Address:_____

Proposed Collaborators:

_____

_____

_____

Proposed Data Sources to be utilized:

_____

_____

STUDY DESIGN

A. HYPOTHESES AND RATIONALE

B. SUMMARY OF PRELIMINARY DATA TO BE USED

C. CONCISE DESCRIPTION OF PROPOSED INVESTIGATIONS

D. PROPOSED DATE OF PROJECT COMPLETION: _____

U19 Executive Committee INFORMATION

MDP Project Leader Received Date: _____

MDP Project Leader Review Date: _____

ACTION Taken: