1.0 Purpose:

To describe the Division of Microbiology and Infectious Diseases (DMID) policy on recruitment and retention of volunteers participating in DMID funded research.

2.0 Scope:

This policy applies to all DMID staff who have responsibilities for the review and/or oversight of human subjects research studies.

3.0 Policy:

All human subjects research should include a recruitment and retention plan appropriate for the scientific proposal. Recruitment plans must define the appropriate target population and include how the potential volunteers will be identified and contacted. Recruitment efforts should not be coercive or provide undue inducements. Retention plans could include frequent communication with volunteers throughout the course of the study to address concerns and assess continuing consent.

Verbal and written communications should be in language that is understandable to the volunteer. Explanations of the disease, the study, risks, benefits, and confidentiality should be used in advertisements, informational materials distributed to potential volunteers, in the consent process, and other communications during the study. Site staff and volunteer contacts/advocates should be readily available to volunteers throughout the course of the study.

4.0 Background:

The Belmont Report identifies Respect for Persons, Beneficence, and Justice as the basic ethical principles of research involving human subjects. The principle of Justice or distributive justice emphasizes the moral requirements for fair selection of research subjects. Recruiting and retaining study subjects requires developing trust and cooperation with the participants by respect and communication at the introduction of the study and throughout the duration of participation.

The DMID is mandated by law (NIH Revitalization Act of 1993, PL103-43) to ensure the inclusion of women and minority groups in clinical research. The goal is to ensure that individuals are included in clinical research in a manner that is appropriate to the scientific question under study. Studies with restricted access must include a compelling rationale and justification provided for why inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. For studies done outside of the United States, the requirement for women remains the same but the minority requirement may not apply directly and/or the definition of a minority group may differ.

Children must be included in all human subjects research conducted or supported by DMID unless there are scientific and/or ethical reasons not to include them. This requirement applies to all DMID-conducted or supported research involving human subjects, including research that is otherwise "exempt" with Sections101(b) and 401(b) of 45 CFR 46 - Federal Policy for the Protection of Human Subjects. The inclusion of children as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent laws and regulations.
Sex as a biological variable must be factored into the research design, analyses, reports and publications. The absence of sex as a biological variable or the inclusion of a single sex in the research must be strongly justified in the context of the research question.

A plan to recruit and retain a representative study population that can be expected to meet the goals of the study is an essential element of a human subjects research proposal. The plan should address access to the targeted group and whether there are potential barriers that may need to be considered. Such efforts should represent a thoughtful and culturally sensitive outreach, which may include interactions with representatives of the community or disease group.

**Definitions:**

**Human Subjects Research:** A systematic investigation designed to develop or contribute to generalizable knowledge that involves a living individual(s) about whom an investigator obtains data through intervention or interaction with the individual; or identifiable private information.

**Minority Group:** Any readily identifiable subset of the U.S. population that is distinguished by racial, ethnic, and/or cultural heritage.

**Volunteer:** A person who, by his/her own free will, undertakes or expresses a willingness to undertake a service without obligation. In human subject research, this individual presents for consideration and/or consents to participate in human subjects research.

**5.0 Responsibilities:**

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| DMID Staff    | • Review the recruitment plan with special focus on the targeted population, expected gender/minority estimates, and inclusion/exclusion criteria, as appropriate  
|               | • Review retention plans, as appropriate                                        |
| Investigators | • Provide understandable verbal and written communications between volunteers and investigative staff throughout the clinical research  
|               | • Develop recruitment and retention plans that address DMID/NIH requirements    |

**6.0 References:**

- Consideration of Sex as a Biological Variable in NIH-funded Research
- NIH Grants Glossary
- NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research
NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects

The Belmont Report

7.0 Inquiries:

Questions or comments regarding this policy may be directed to:

Associate Director of Clinical Research
Division of Microbiology and Infectious Diseases (DMID)
NIH / NIAID
5601 Fisher Lane, Rm. 7E60
Bethesda, MD  20892
DMIDPolicyQuery@niaid.nih.gov

8.0 Availability:

This policy is located electronically at:  .
http://www.niaid.nih.gov/labsandresources/resources/dmidclnrsrc/Pages/studyvolunteers.aspx

9.0 Change Summary:

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