Attachment 3-

Form – Mentor Information and Agreement

OMB #0925-xxxx
Expiration date mm/dd/yyyy

Public reporting burden for this collection of information is estimated to take 20 minutes per response, including the time for reviewing the information and signing agreement. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20902-7974, ATTN:PRA (0925-xxxx). Do not return the completed form to this address.

Applicant Last/Family Name:_____ Mentor Last/Family Name: _____

Part II of Application—Mentor Information and Agreement

1. **First/Given Name of Mentor:**
   _____
2. **Last/Family Name of Mentor:**
   _____
3. **Position Title:**
   _____
4. **Institution:**
   _____
5. **Department, Division, Service, Laboratory:**
   _____
6. **Office Mailing Address** (street address, city, state, postal code)**:**
   _____
7. **Country:**
   _____
8. **Office Phone** (country code, city code, number)**:**
   _____
9. **Office Fax Number** (country code, city code, number)**:**
   _____
10. **Office E-mail:**
    _____
11. **Alternative E-mail:**
    _____

Men tor's Education and Training History

1. **Education** (Begin with baccalaureate or other initial professional education, such as nursing, and include any postdoctoral training.)

   a) Name and Location of Institution: _____
   Degree: _____
   Year Conferred: _____
   Field of Study: _____

   b) Name and Location of Institution: _____
   Degree: _____

Year Conferred: _____
Field of Study: _____

c) Name and Location of Institution: _____
Degree: _____
Year Conferred: _____
Field of Study: _____

d) Name and Location of Institution: _____
Degree: _____
Year Conferred: _____
Field of Study: _____

2. **List your most significant publications, honors, awards, or other accomplishments.**

   _____

3. **List the total number of pre- and postdoctoral fellows have you trained? _____**

4. **For a representative five of the trained pre- and postdoctoral fellows, please list their names and fellowship training dates, current employer, and position titles.**

   _____

Mentor Certification and Acceptance

I certify that the statements herein are true, complete, and accurate to the best of my knowledge, and accept the obligation to comply with terms and conditions if a fellowship is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

⌋ I have read and understand the application requirements and the fellowship policies and procedures.

Mentor's Signature_____Date _____

Applicant Last/Family Name:_____Mentor Last/Family Name: _____

Mentor's Statement

Add an additional page if more space is needed.

Describe the mentorship plan for the applicant. Only plans written in English will be reviewed. Include information that will help reviewers evaluate the applicant and the research proposal.

1. Detail the research support that will be available to the applicant during the fellowship. Include the number of other pre-doctoral and post-doctoral Fellows/trainees that will be supervised during the fellowship period (maximum 150 words). Include a description of your qualifications as a mentor.

   _____

2. Provide information about seminars and other opportunities for interaction with other groups and scientists (maximum 150 words).

_____

3. Describe the administrative support (e.g. office space, laboratory, equipment, training, financial support to conduct the study, human resource support to conduct study) that will be available to the applicant during the fellowship (maximum 200 words).

_____

4. Assess the applicant's qualifications and potential to conduct the proposed research (maximum 200 words).

_____

5. Describe the skills and techniques that the applicant will learn during the fellowship (maximum 200 words).

_____

6. Relate the potential impact of the fellowship to the applicant's career goals and the capacity building in the applicant's home country (maximum 200 words).

_____

Ethical Research Declaration by Mentor

I, the mentor, confirm that the research presented in this application will be conducted in accordance with the protocol approved by the institutional or local committee on ethics in human and animal investigation. Where no such committee exists, I attest that the research will be conducted in accordance with the principles of the **Declaration of Helsinki of World Medical Association (WMA)** or **WMA Statement on Animal Use in Biomedical Research**. The Review Board may contact me to enquire further into ethical aspects when evaluating this proposal.

⌋ I have reviewed the WMA principles as listed.

Mentor's Name: _____

Email: _____

Office Telephone: _____

Signature_____**Date** _____

WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

http://www.wma.net/en/30publications/10policies/b3/

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the: 29th WMA General Assembly, Tokyo, Japan, October 1975, 35th WMA General Assembly, Venice, Italy, October 1983, 41st WMA General Assembly, Hong Kong, September 1989, 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996, 52nd WMA General Assembly, Edinburgh, Scotland, October 2000, 53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added), 55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added), 59th WMA General Assembly, Seoul, Republic of Korea, October 2008, 64th WMA General Assembly, Fortaleza, Brazil, October 2013

Preamble

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

General Principles

3. The Declaration of Geneva of the WMA binds the physician with the words, “The health of my patient will be my first consideration,” and the International Code of Medical Ethics declares that, “A physician shall act in the patient's best interest when providing medical care.”

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

5. Medical progress is based on research that ultimately must include studies involving human subjects.

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

11. Medical research should be conducted in a manner that minimises possible harm to the environment.

12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.

14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

Risks, Burdens and Benefits

16. In medical practice and in medical research, most interventions involve risks and burdens. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation. Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed. When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

Vulnerable Groups and Individuals

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm. All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a nonvulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

Scientific Requirements and Research Protocols

21. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

Research Ethics Committees

23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

Privacy and Confidentiality

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

Informed Consent

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the nonwritten consent must be formally documented and witnessed. All medical research subjects should be given the option of being informed about the general outcome and results of the study.

27. When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.

28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.

30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving

informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorised representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.

31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.

32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.

Use of Placebo

33. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or

Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention. Extreme care must be taken to avoid abuse of this option.

Post-Trial Provisions

34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

Research Registration and Publication and Dissemination of Results

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly

available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

Unproven Interventions in Clinical Practice

37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.

World Medical Association (WMA) Statement on Animal Use in Biomedical Research

http://www.wma.net/en/30publications/10policies/a18/

Adopted by the 41st World Medical Assembly, Hong Kong, September 1989
and revised by the 57th WMA General Assembly, Pilanesberg, South Africa, October 2006

Preamble

1. Biomedical research is essential to the health and well-being of our society. Advances in biomedical research have dramatically improved the quality and prolonged the duration of life throughout the world. However, the ability of the scientific community to continue its efforts to improve personal and public health is being threatened by a movement to eliminate the use of animals in biomedical research. This movement is spearheaded by groups of radical animal rights activists whose views are considered to be far outside mainstream public attitudes and whose tactics range from sophisticated lobbying, fund-raising, propaganda and misinformation campaigns to violent attacks on biomedical research facilities and individual scientists. These violent attacks are carried out by a relatively small number of activists compared with those who use peaceful means of protest, but they have profound and wide-ranging effects.
2. The magnitude of violent animal rights activities is staggering, and these activities take place in many different parts of the world. Various animal rights groups have claimed responsibility for the bombing of cars, institutions, stores, and the private homes of researchers.
3. Animal rights violence has had a chilling effect on the scientific community internationally. Scientists, research organizations, and universities have been intimidated into altering or even terminating important research efforts that depend on the use of animals. Laboratories have been forced to divert thousands of research dollars for the purchase of sophisticated security equipment. Young people who might otherwise pursue a career in biomedical research are turning their sights to alternative professions.
4. Despite the efforts of many groups striving to protect biomedical research from radical animal activism, the response to the animal rights movement has been fragmented, under-funded, and primarily defensive. Many groups within the biomedical community are hesitant to take a public

stand about animal activism because of fear of reprisal. As a result, the research establishment has been backed into a defensive posture. Its motivations are questioned, and the need for using animals in research is repeatedly challenged.

5. While properly designed and executed research involving animals is necessary to enhance the medical care of all persons, we recognize also that humane treatment of research animals must be ensured. Appropriate training for all research personnel should be prescribed and adequate veterinary care should be available. Experiments must comply with any rules or regulations promulgated to govern humane handling, housing, care, treatment and transportation of animals.
6. International medical and scientific organizations must develop a stronger and more cohesive campaign to counter the growing threat to public health posed by animal activists. Leadership and coordination must be provided. In addition, there must be a clear understanding of the rights of animals who are part of medical research, and the obligations of those who undertake it.

The World Medical Association therefore affirms the following principles:

1. Animal use in biomedical research is essential for continued medical progress.
2. The WMA Declaration of Helsinki requires that biomedical research involving human subjects should be based, where appropriate, on animal experimentation, but also requires that the welfare of animals used for research be respected.
3. Humane treatment of animals used in biomedical research is essential and research facilities should be required to comply with all guiding principles for humane treatment. Education about these principles should be provided to all researchers in training.
4. Animals should only be used in biomedical research when it is clear that their use is required to achieve an important outcome, and where no other feasible method is available.
5. Duplication of animal experiments should not occur unless scientifically justified.
6. The use of animals for the futile testing of cosmetic products and their ingredients, alcohol and tobacco should not be supported.
7. Although rights to free speech should not be compromised, the anarchistic element among animal right activists should be condemned.
8. The use of threats, intimidation, violence, and personal harassment of scientists and their families should be condemned internationally.
9. A maximum coordinated effort from international law enforcement agencies should be sought to protect researchers and research facilities from activities of a terrorist nature.