To: Presidents of Iranian Medical Universities/Faculties

In order to address ethical considerations in medical research, and pursuant to the decision of the Parliament of the Islamic Republic of Iran dated ٢٧ January ٢٠٠٩ on implementing ethical codes in medical research, please find the attached "Special Guidance for Medical Research on HIV/AIDS". Initially considered by the Secretariat of the Policy-Making Council of the Iranian Ministry of Health and Medical Education, and the Medical Ethics and History of Medicine Research Center of Tehran University of Medical Sciences, the Guidance was finally approved on ٦ March ٢٠١١ by the Medical Ethics High Council of the Ministry of Health and Medical Education. The Guidance stands as national research regulations, mandatory for all Iranian scientific and research institutes. It must be mentioned that the provisions of the attached guidance may be revised or updated by the mentioned High Council and at intervals stipulated thereby.

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Minister

Health and Medical Education

In the Name of God

Special Guidance for Medical Research on HIV/AIDS in the Islamic Republic of Iran

Introduction

Medical research is conducted with the aim of protecting and promoting human health and living quality, and expanding science and knowledge. The concern, however, always exists that the rights or liberty of participants – or other parties involved – be compromised during research, or measures be taken in contrast to people's reasonable beliefs or values. Therefore, preparing, approving and implementing research ethics guidelines have usually been considered and pursued by research management authorities at national, regional and international levels. The mentioned considerations, with a focus on cultural principles and Islamic ethical and religious instructions, have transformed the development of such guidelines into a necessity in Iran as well. Fortunately, favorable strides have been taken to satisfy this demand, and in addition to signing a number of related international declarations, such as the Helsinki Declaration, one general and seven special guidances on research ethics have been prepared and communicated to date. Each special guidance addresses a research field where the particular ethical considerations necessitate the stipulation of additional requirements to supplement the general guidance. Research on infection with the human immunodeficiency virus (HIV) and AIDS (hereinafter known as "HIV/AIDS") qualifies as a field with sensitive ethical concerns, such as potential discrimination and stigmatization, special importance of confidentiality, social patterns of spread and transfer, existence of special vulnerable groups, and the extent of studies on vaccination and treatment of this disease. Development of a special ethical guidance for such research thus seems crucial and desirable.

This guidance is presented as the "Special Guidance for Medical Research on HIV/AIDS", to be followed along all other related legislations and regulations, religious instructions, the "General Ethical Guidance for Medical Research", and special domestic guidances for research ethics in different disciplines.

Articles

١ General Ethical Considerations

١.١ The provisions of this guidance shall be observed in all domestic research projects related to HIV/AIDS, including basic sciences, epidemiology, clinical trials, community-based studies, and all other research.

١.٢ Researcher(s) shall follow the provisions of this guidance, the "General Ethical Guidance for Medical Research", other relevant special domestic guidances, and any other related regulations or requirements.

١.٣ This guidance shall be reviewed, amended and updated regularly by relevant authorities, in cooperation with researchers, beneficiaries or other parties involved in such research.

١.٤ Apart from following this guidance, researchers, beneficiaries or other parties involved in such research shall also be sensitive to its implementation by other individuals or legal entities, and take the actions required by the related legislations and regulations upon observing any violations of the provisions of this guidance. Such action may include warning the violators, terminating cooperation with them or reporting the issue to the relevant authorities.

١.٥ Research results shall not be published in a manner that would foster stigmatization of, or result in discrimination against a special group in the community.

Note: This paragraph shall not be interpreted in a manner to hinder publication of research results in globally established and acceptable ways.

١.٦ Researchers shall strive to provide valid and accurate information to the participants and community, and prevent social stigmatization related to this disease in all stages of the research project.

١.٧ Participants shall have full and unconditional access to their own information, gathered in the research at any time they wish. In double-blind trials, meeting such requests would terminate the participant's involvement in the research.

Each participant shall also be entitled to request the omission of their information from the research process at any stage. Such cases shall be reflected in the final report of the research while maintaining confidentiality, especially in regard to the particular participant's identity.

١.٨ Post-exposure preventions (PEP) shall be provided for any infected or suspicious contact of the people involved in a research (including the participants, researchers, and service providers) during or resulting from the research, in accordance with the latest related protocols approved by the Ministry of Health and Medical Education. The lead researcher shall be responsible for providing such services.

١.٩ The lead researcher shall brief the research team in regard to the ethical instructions provided in this Guidance, and other documents mentioned in paragraph ١.٢ above, and supervise their implementation.

١.١٠ Participants in the research project shall not be isolated on the sole ground of their infection with HIV/AIDS, but only for research purposes under sound scientific reasons.

٢ Ethical Considerations Regarding Research Design

٢.١ Research projects shall be designed in line with religious and ethical principles and norms of the society, and adopting methods in grave contradiction with the above provisions shall be seriously avoided.

٢.٢ The research proposal shall include detailed descriptions of the methods of guaranteeing confidentiality of the participants' identities and personal information.

٢.٣ Research projects shall be designed to guarantees fair distribution of the possible benefits and risks of the research among all strata of the society. For this purpose, sampling shall be conducted fairly among all sub-groups that might benefit the research findings.

٢.٤ In international research projects including human participants, it shall be taken into consideration that a part of the research may be conducted in Iran only if access to the possible future benefits of the research can be provided in this country.

٢.٥ In all research projects including diagnosis tests, where participants may be diagnosed with HIV/AIDS, sufficient consultation services shall be available before and after such diagnosis cases.

Note: In case pre-diagnosis consultation is impossible for valid methodological reasons, proper measures shall be taken to connect the participants in question to the system providing the relevant services, such as consultation and treatment after diagnosis.

٢.٦ All proper measures to sterilize and destroy instruments infected with HIV, in accordance with national requirements, and other related standard precautions to prevent transmission of infection, shall be stipulated in the research proposal. The researcher(s) shall personally supervise proper implementation of this section of the proposal.

٣ Ethical Considerations Regarding Informed Consent

٣.١ In studies involving human participants, the informed consent document to be used for the research shall be attached to the research proposal for ethical consideration and approval. The mere announcement that an informed consent document would be prepared and signed by participants in the research shall not suffice for this purpose.

٣.٢ For participants under guardianship, the informed consent document shall be signed by both the guardian and participant, if possible. In case obtaining the participant's informed consent is not possible, the participant shall not be included in the research if s/he gravely refused to participate.

٣.٣ The informed consent document shall guarantee confidentiality of the participants' identity and personal information, and vividly describe the measures designed to maintain such confidentiality.

٣.٤ In cases requiring informed consent to be obtained in writing, the informed consent document shall be prepared in two copies, one copy for the researcher and the other for the participant or his/her legal representative. Similar to other documents of the research, the signed informed consent documents shall be kept in a place and manner only accessible to people with proper authority or permission under the related regulations.

٣.٥ In studies involving the possibility of infection from suspected participants (such as accidental contact with a needle or surgical blade contaminated with infected blood), the informed consent document could stipulate that such cases would not require obtaining another informed consent for conducting diagnosis tests on the participant's sample, while fully observing confidentiality requirements.

٣.٦ For repeated use of databases, or molecular, cellular or tissue samples during the research project, the participants' general informed consent shall be obtained if anonymous data or samples with irreversible elimination of identity information. Researchers shall obtain the participants' informed consent for every instance of access to data or samples traceable to the related

participants. Similar to other research types, such studies may commence only after the approval of the related research ethics committee.

٤ Ethical Considerations Regarding Vulnerable Groups

٤.١ In studies related to HIV/AIDS, the following groups shall be considered vulnerable, and require special attention:

- Prisoners and camp inhabitants;
- Addicts, prostitutes and other sub-groups confronting social rejection or seclusion;
- Children, adolescents and senior citizens;
- Mental patients;
- Pregnant women and infants; and
- Immigrants and nationals of other countries.

٤.٢ The research project shall not involve any stigmatizing or discriminating behavior, speech or records against vulnerable groups during its process nor afterwards. This requirement shall be properly reflected and provided for in the research proposal.

٤.٣ The researcher(s) shall pay special attention to guaranteeing voluntary and informed consent of the participants belonging to vulnerable groups.

٤.٤ Studies on vulnerable groups shall aim at benefitting such groups, and no risk or damage (whether physical, mental or social) shall be imposed on them by non-treatment studies.

٤.٥ Participation of prisoners shall be permissible only in studies specially designed for them, lacking any additional risks for them, and impossible to be conducted on other groups.

٤.٦ In cases where a portion of participants are selected from vulnerable groups, all participants shall be treated equally and fairly, and provided equal access to services or exposure to risks during the research project.

٥ Ethical Considerations Regarding Vaccination Studies

٥.١ Initial phases (٠, ١ or ٢) of HIV/AIDS vaccination studies shall be executed on sub-groups exposed to lower risks or damages.

٥.٢ Using placebos shall be permissible in HIV/AIDS vaccination studies, as long as an effective and approved vaccine suitable for the group or population being studied does not exist.

٥.٣ Researchers shall obtain informed consent for participation in HIV/AIDS vaccination studies.

٥.٤ During or before commencing HIV/AIDS vaccination studies, all participants shall be provided with sufficient and proper services, such as comprehensive consultation and preventive measures, to the extent feasible in the society. Any new prevention technique developed and approved during the research shall also be made available to the participants.

٥.٥ Any participant infected with HIV/AIDS as a result of participating in such vaccination studies shall be sufficiently compensated for, and provided with the best treatment measures available. The methods for guaranteeing continuous treatment services for such participants shall be defined by researchers before commencing the research project.

٥.٦ Considering the possibility of positive-serum results for participants during common diagnosis tests, without the person being actually infected with HIV/AIDS, a suitable document certifying participation in HIV/AIDS vaccination studies shall be provided to the participants.

٥.٧ Considering their special need for research on vaccine safety and efficacy, children may be selected to participate in HIV/AIDS vaccination studies, while observing the required ethical, legal or safety considerations for them, respecting their rights, and obtaining the informed consent of the participants and their guardians.

٥.٨ The results of HIV/AIDS vaccination studies shall be published for the society, especially the participants and other beneficiary groups, while observing proper confidentiality requirements.

٦ Ethical Considerations Regarding Community-Based Studies

٦.١ Community-based studies shall avoid and prevent any stigmatization and discrimination.

٦.٢ Long-term research in a community shall involve promotion of service provision in regard to preventing and treating diseases in that community.

٦.٣ Along with the research being conducted, the community shall be properly informed about prevention, treatment and destigmatization of diseases.

٦.٤ The cultural and belief sensitivities and values of the communities involved in the research shall be duly respected, and competent local advisors shall be consulted for that purpose.