The AAS Policy on Use of Humans in Research

In realising its mission of utilising science, technology and innovation to solve Africa's developmental challenges, the AAS recognises that improving human health ultimately requires the involvement of humans as subjects of research. The AAS believes that research involving human participants is central in understanding the factors that underpin health and diseases, and is also important in evaluating the safety and effectiveness of biomedical and social interventions. Accordingly, the AAS supports such research as a key part of it broad mission. In conducting research that involves human participants, the first priority for researchers should at all times be the protection of the rights, interests and safety of research participants.

The AAS Expectations regarding Use of Humans in Research

1. The AAS expects that research involving human participants should be undertaken in accordance with the appropriate standards and principles. Research involving human participants is governed by principles outlined in the Declaration of Helsinki, the Nuremberg Code, and the Council for International Organizations of Medical Sciences (CIOMS) http://www.cioms.ch/publications/guidelines/guidelines_nov_2002_blurb.htm, all of which set out requirements with regard to the rights and safety of research participants and standards for research design and conduct.

2. The AAS-funded researchers are required to be aware of issues, comply with relevant legislation, and follow best practice guidance surrounding the use of human subjects in research.

3. The AAS requires that AAS - funded research involving human participants should meet the following minimal criteria
   a) Be responsive to the healthcare priorities or needs within the research setting and be relevant to the short- or long-term needs or priorities of the region(s) or population(s) where the research is to be carried out;
   b) Have outcomes that are likely to lead to sustainable health benefits and have local applicability; or
   c) Be research that could have a 'global public benefit' and have potential relevance to the health of humans anywhere in the world.

Ethics

4 the AAS requires that for AAS-funded research involving human participants, researchers must seek and obtain the relevant regulatory and ethical approvals, and appropriate governance mechanisms before the research begins. However, applicants may apply for funding before seeking and obtaining the above requirements. In the event of an award being made, commencement of any research involving human participants will be subject to these approvals and governance mechanisms being in place - including, in the case of ethical review, from an appropriately constituted ethics review committee.

   The AAS reserves the right to see relevant approval documents at any point during the lifetime of the grant.

5 Where research is anticipated to run over a number of years, for example in cohort studies, researchers must ensure measures are in place to maintain continuing appropriate ethical oversight and to monitor and, where necessary, obtain advice on ethical, legal and social issues on an ongoing basis. An example of this would be use of an oversight committee with members who are independent of the research in question. These measures would be additional to ethics review and would provide an additional layer of ethical oversight throughout the lifetime of the research.

Research ethics guidelines and oversight mechanisms are intended to ensure that research involving human participants is conducted in a manner that demonstrates, protects and preserves respect for persons, concern for the welfare of individuals, families and communities, and justice. The following guidelines should be adhered to:

a) If and when conducted or supported by researchers and/or sponsors based in industrialized nations, research involving human participants in Low and Medium Income Countries (LMIC) must constitute a collaborative partnership between the researchers and/or sponsors in industrialized nations and researchers and/or policy makers and communities in LMIC;
b) Prospective research participants must provide *voluntary* and *informed* consent to participate;
c) The proposed research must be designed in a manner that demonstrates and preserves respect for potential and enrolled participants;
d) Prospective research participants must be selected fairly, and no individual or group should be disproportionately burdened by or excluded from participation without justification;
e) Individuals involved in the conduct and/or support of research are obligated to avoid, if possible, and disclose and appropriately address any financial or personal conflicts of interest germane to the research project (please see AAS Policy on Conflict of Interest);
f) The proposed research must be scientifically valid, have potential social or scientific value, and have a favourable ratio of potential benefits to risk of harm; and,
g) Research proposals must undergo independent review by an appropriately constituted research ethics committee.
    - Review should be performed by a committee in every relevant jurisdiction (i.e., at the site where the research is to be conducted and at the investigators' home institution(s) if different from the institution where the research will take place, and by any necessary enhanced-oversight committees);
    - A review committee can, at its own discretion, accept the review of another institution as sufficient grounds for approval or an expedited review process;

    If a committee is not available at the research site, review may be provided by an appropriately constituted external committee.

6 The AAS may bear the actual direct costs of the ethics review process in resource-poor settings, as part of a grant application. However, this must be done in a way

that does not compromise the independence of the ethical review process. Such decisions will be made by the AAS on a case-by-case basis, where an applicant may request a one-off fee for ethical review.

7 All AAS-funded researchers must have an understanding appropriate to their role of the ethics of research involving human participants. The AAS recommends that all AAS-funded researchers involved in such research undergo training in the ethics of research where there is a need to build capacity in this respect.

8 Where an application for the AAS funding raises ethical concerns for AAS committee members, referees or staff, the AAS may arrange for independent expert review of the research protocol in question before a funding decision is made.

Consent

9 The AAS requires that all competent adults have the right to give or withhold consent to participate in AAS funded research. Such consent must be given in writing. Prospective research participants must therefore be provided with accurate, relevant and sufficient information on the nature and purpose of the study, the procedures involved, and any foreseeable risks associated with participation in the research in order to make an informed decision on whether or not to give or withhold consent. They must also be given an appropriate length of time to consider the implications of the information they have been provided with.

10 The AAS further recognises that written consent may not always be the most appropriate form of recording consent; for example, some participants might be visually impaired or illiterate. In such cases, it is recommended that alternative forms of recording consent be used. These could include making a note of verbal consent in a participant's personalised record or making an audio or video tape, with an independent witness to observe the consent process, where appropriate.

11 The AAS further requires participants on AAS funded research to be provided with information about any proposed arrangements for post-research access, including options for secondary use of tissue samples and data, where applicable.

12 The consent-seeking process must be appropriate to the cultural context and to individual needs. When reviewing grant applications, independent referees and the AAS Funding Committees may request clarification or information from grant applicants about the proposed consent procedures. In some cases, this could include asking grant applicants to supply them with the proposed consent forms.

13 The AAS further recognises the right of participants to withdraw from ongoing participation in a research study and requires participants be made aware of this right. Researchers need to give careful consideration to the implications of individuals withdrawing their participation from the research. The feasibility and implications of withdrawing from research, and the extent to which that applies to the withdrawal of data and samples from a study, need to be clearly explained as part of the consent process.

Research Involving Vulnerable Individuals and Children

14 Subject to relevant ethics committee approval, the AAS will consider funding research involving individuals incapable of providing consent, including children and people with mental disabilities, as long as their participation is deemed necessary to answering the research question and all measures have been taken to safeguard and promote their interests. Researchers are expected to carry out all necessary awareness sessions with a parent or other legal guardian and/or an appropriate legal authority responsible for the care of the child or a mentally incapacitated person (where such a body exists) and to ensure that the research approval complies with relevant laws and best practice guidance.

Emergency Research

15 The AAS will consider funding emergency research (e.g. accident and emergency research) where the ability of an individual to give consent is compromised or impracticable, provided that the research protocol receives ethics review committee approval and complies with all relevant national legislation and any best practice guidance. Where appropriate, measures to inform the general public that these studies are planned or are in progress should be implemented.

Use of Tissue Samples and Data

16 Where research will involve the collection of human tissue and/or data, researchers must outline as part of their application how the tissue or data will be collected, stored and accessed by any third parties and ensure that appropriate ethical approvals are sought. The confidentiality of research participants must be safeguarded, unless appropriate consent has been obtained to disclose information to a third party.

17 The consent process must, wherever practicable, include seeking consent for approved secondary use of the tissue or data in subsequent research studies. The AAS recognises, however, that in some situations, this may not be possible. In such cases, the AAS considers that it is acceptable to use samples and/or medical data for secondary purposes without returning to the participant for specific consent, if the proposed research:

- has clear healthcare benefits in accordance with this policy and complies with relevant national laws
- complies with any binding codes of practice or ethical guidance (such as professional guidelines or licensing regulations)
- is not inconsistent with the consent as approved by an ethics committee for the original study
- uses samples or data that have been anonymised (either fully or, at a minimum, from the researcher's point of view)
- meets policy requirements regarding secondary use as required by the principal investigator's employing institution
- includes appropriate mechanisms to monitor consent for the original study and any cases where it is withdrawn, where practicable.

Feedback to Participants

18 The AAS requires researchers to consider the circumstances and mechanisms by which aggregated research findings might be made available to research participants, where this is deemed appropriate, and the manner in which such information is presented.

19 Researchers funded by the AAS should carefully consider the issues around Health Related Findings (HRFs) when establishing a study involving human participants or re-consenting participants for follow-on research to an existing study. In particular, researchers must:

- Have a policy that indicates whether or not HRFs will be fed back to individuals that can be clearly articulated, and be able to demonstrate the reasoning behind their policy to research participants, funders and the Research Ethics Committee;
- Include clear information on the study policy on the feedback of HRFs in the consent process; and
- In cases where the policy is to provide individual feedback on HRFs, develop a practical feedback pathway that is adequately resourced.

20 Feedback pathways, where applicable, must be adequately resourced. The allocation of research-associated costs and healthcare-associated costs will depend on the nature and setting of the research. The costs of healthcare following the feedback of an HRF are always healthcare-associated costs, but the allocation of other costs is likely to depend on the nature and setting of the research. For example, for a study conducted in a clinical setting in which the participant is also a patient, the validation and subsequent follow up may be considered as a healthcare-associated cost because it is part of their care. However, in a non-clinical setting, researchers may need to make arrangements to involve those with appropriate clinical expertise in the validation, which may be considered as research-associated costs.

21 All those seeking AAS funding should consider their approach to HRFs at the research proposal stage. We reserve the right to see the study policy on HRFs during the application process or lifetime of the grant. Where researchers expect to provide feedback for a particular study, the research-associated costs should be budgeted in the grant application. In line with existing practice, the AAS will cover reasonable research-associated costs related to the feedback of HRFs, but will not cover any healthcare-associated costs.

Compensation for Injury

22 It is the responsibility of the research institution that receives AAS funding to conduct research involving human participants to ensure that appropriate compensation arrangements (including insurance or indemnity cover where available) are in place to cover research participants and/or their dependants against injuries or damage caused as a result of their participation in research, in accordance with local law and best practice. The AAS will not fund the costs of such insurance or indemnity cover and would not be liable for any such compensation.