Organizational and Operational Framework of the Institutional Review Board for Biomedical Science Research, Academia Sinica

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1. General Rules
   (a) The following framework has been put into place to enhance the functionality of the International Review Board for Biomedical Science Research (IRB-BM), to establish an independent review mechanism to improve the effectiveness of medical research project reviews and to protect the rights and interests of study participants.
   (b) To protect the rights and interests of study participants and to review medical research projects, Academia Sinica (AS) has established the IRB-BM in accordance with the regulations of the Human Subject Research Act.
   (c) In its reviews of medical research projects, the IRB-BM shall consider the principle of respect for autonomy to ensure that study participants have received sufficient information and voluntarily consented to research participation after rational consideration in the absence of any form of coercion or manipulation. The rights and interests of participants with diminished autonomy or without the capacity to consent shall be particularly protected.
   (d) The IRB-BM shall base its reviews of research projects on the principle of beneficence, to ensure that potential risks do not outweigh the possible benefits and to protect study participants from unnecessary harm and promote their well-being.

(e) In its reviews of medical research projects, the IRB-BM shall consider the principle of justice to ensure that research participants experience fair and equal treatment. Groups that will not share in the benefits resulting from the research shall not be selected as research subjects.

2. The Composition and Convention of the IRB-BM
   (a) The IRB-BM shall be established in accordance with Point 3 of the Guidelines.
   (b) The IRB-BM may set up several panels. Each panel shall be composed of five to nine members, one of whom shall be the convener, all of whom are members of the IRB-BM. Moreover, each panel shall include one or more members with non-biomedical backgrounds, at least one of whom is not affiliated with Academia Sinica.
   (c) IRB-BM Members will serve for a term of two years and may be reappointed to a second term. However, in principle, the number of reappointed members must not exceed more than half of the total number of members.
   (d) When the IRB-BM and its panels convene meetings, a quorum consisting of at least half of the members shall be present. This quorum shall include at least one member from a scientific field (defined as an individual with training in the natural or social/behavioral sciences) and at least one member from a non-scientific field (defined as an individual without such scientific training, but from disciplines such as religion, philosophy, theology, or ethics), and at least one member from outside of Academia Sinica with a non-biomedical background (for example, a legal expert or a professional engaged in social justice) to represent the perspective of the subjects. Meetings shall not proceed if only members of one gender are present. Additionally, a minimum of five members of the Board or panel must attend to constitute quorum. If the required quorum cannot be achieved due to vacancies, substitute members shall be immediately appointed to fulfill the necessary roles, serving until the expiration of the term of the original members they replace.
   (e) The chair of the meetings shall be either the chairperson of the IRB-BM or a member designated by the chairperson. No votes shall be cast, nor decisions made, if all members with the most relevant expertise, including the experts and scholars in the specialized field, are absent, or if all non-scientific or unaffiliated members are absent.
   (f) An Executive Secretary shall be appointed to assist the chairperson in

coordinating IRB-BM affairs.

(g) The IRB-BM shall perform its duties independently of the AS administrative system. AS shall supply sufficient full-time or part-time personnel to handle IRB-related affairs in accordance with the following provisions:
  (1) The duties, obligations, and responsibilities of the personnel shall be clearly defined.
  (2) Personnel shall sign a confidentiality agreement.
  (3) A location shall be provided for personnel to work and for document storage.
  (4) Personnel shall receive extra training when necessary.

(h) The IRB-BM members shall receive training courses.

(i) A member may be dismissed in any of the following circumstances:
  (1) The member is absent from three or more review meetings during the term of office without a justifiable reason, or is absent from one-third or more of the meetings that they should attend during their term of service.
  (2) During a member's term of office, review meetings are postponed three or more times for reasons attributable to the member.
  (3) A serious violation of the principles to avoid conflicts of interest.

(j) The Central Competent Health Authority may make public the names and occupations of board members, and their relationships to AS.

(k) The proceedings of IRB-BM meetings may be made public.

(l) During meetings, members shall observe the following principles to avoid conflicts of interest:
  (1) In any of the following circumstances, the reviewers shall recuse themselves and shall not attend the review meeting:
    (A) The reviewer is the primary investigator (PI), sub-PI, or sponsor of the research project under review, or of its sub-projects.
    (B) The reviewer is currently or was previously the spouse, or within the fourth degree of consanguinity or the third degree of affinity to the PI of the research project under review.
    (C) The reviewer has an employment relationship with the sponsor.
    (D) There is sufficient factual evidence to indicate that the reviewer may be subject to potential bias.
    (E) Anything else deemed a conflict of interest by a resolution of the

IRB-BM.

(2) Under the following circumstances, reviewers may attend the review meeting, but shall not participate in voting:
   (A) The reviewer has served as an advisor to the PI or sub-PI of the research project under review for their master's thesis, doctoral dissertation, or post-doctoral research at any time within the last five years.
   (B) The PI, sub-PI, or sponsor of the research project under review served as an advisor to the reviewer for the reviewer's master's thesis, doctoral dissertation, or post-doctoral research.
   (C) The PI, sub-PI, or sponsor of the research project under review has been a colleague of the reviewer in the same division, department, or institute. At AS, the Institute of Biomedical Sciences bases its standard for conflict of interest on research groups; the Genomics Research Center, on divisions or centers according to their fields of specialty; and other institutes, preparatory offices, and research centers on the institute, preparatory office, or research center.
   (D) Any other conditions under which reviewers are deemed ineligible to vote by resolution of the IRB-BM.

(3) Board members are required to disclose any of the following relationships between the member and AS or the sponsor of the research project under review.
   (A) Employment relationship; however, AS staff do not need to disclose such relationships.
   (B) Paid consultancies.
   (C) Financial transactions.
   (D) The reviewer, spouse of the reviewer, or anyone who is or has been within the fourth degree of consanguinity or the third degree of affinity has investments with AS or the sponsor of the research project.

(4) If, due to a need for the expert professional knowledge and experience of a reviewer, the avoidance of a conflict of interest will make it difficult to make an appropriate decision, the requirements for avoiding conflicts of interest stated in point 2, section 13, paragraphs 1 and 2 may be waived subject to the approval of the IRB-BM. However, such exceptions shall

be recorded in the meeting minutes.

(5) If the sponsor mentioned in point 2, section 13, paragraphs 1 to 3 is a juridical person or group, the relationship between the reviewer and the sponsor can be decided based on their relationship with the responsible person.

3. Project Application and Review

(a) The PI shall attach the following documents and submit them to the IRB-BM for review:

(1) Application form (online application)

(2) Research project: Please use the template provided by the IRB-BM

(3) Subject Information and informed consent forms (ICFs):

(A) Those who choose not to use the Participant Information and ICF template provided by the IRB-BM are required to attach a Participant Information and ICF checklist.

(B) For those studies that do not require any Subject Information & ICFs, please describe the reasons and attach supporting documents.

(4) Other documents: Questionnaires, any communication documents with the participants, letters of invitation inviting institutes or personnel to assist in the project, forms for withdrawal from the project, gifts for participants, etc.

(5) The educational backgrounds and work experience of the PI or sub-PI, and documents certifying research ethics training courses taken by them.

(6) Documents certifying research ethics training courses taken by other personnel involved in the project.

(7) Checklist for exempt review or expedited review (optional): If applying for exempt review or expedited review, please use the checklist to evaluate whether the research is completely qualified for exempt or expedited review. The final decision shall be made by the IRB-BM.

(b) The IRB-BM or its panels shall conduct reviews in accordance with the following procedures:

(1) Meetings to review cases shall be convened in a timely manner.

(2) Before a meeting begins, the chairperson shall ask members to disclose matters stated in Point 3 (1) of this framework.

(3) Board members must be given sufficient time to review the materials

before the meeting.

(4) The PI, co-PI or sub-investigator, or sponsor may attend the meeting to explain the research project, or explain a particular topic.

(5) During the review, the IRB-BM may invite experts in ethics, law, specific medical fields, or other fields, or representatives of patient groups to attend the meeting as independent consultants, or to present their opinions in writing. The above invited individuals shall be required to sign a confidentiality agreement.

(6) Members may enter into direct discussion with invited individuals who make statements in person.

(c) The focus of the review shall include the following items:

(1) The research design and implementation:

(A) The adequacy of the research site, including medical staff, facilities, and capacity to respond to emergencies.

(B) The appropriateness of the qualifications and experience of the principal investigator.

(C) A reasonable correlation between the research design and objectives, the rationale underlying the statistical methods (including the calculation of the sample size), and the possibility of reaching appropriate conclusions with the minimum number of participants.

(D) The reasonableness of the anticipated risk/benefit ratio.

(E) The rationale for selecting the control group.

(F) The criteria for early withdrawal from the study on the part of participants.

(G) The criteria for the suspension or discontinuation of the study.

(H) Whether the requirements for monitoring and auditing the study are sufficient, and whether a data security monitoring committee (DSMB) has been set up.

(I) Plans for the reporting or publishing of research results.

(2) Recruitment of potential participants:

(A) The characteristics of the pool of potential participants (including gender, age, educational level, culture, economic status, race/ethnicity, and whether the pool includes participants who are not suitable for exempt review pursuant to Central Competent

Health Authority regulations).

(B) The approach used for initial contact and recruitment.

(C) The manner in which information is communicated to potential participants.

(D) Inclusion criteria.

(E) Exclusion criteria.

(3) Care for participants:

(A) Psychological and social support for participants.

(B) Rationale for cancelling or suspending standard treatment for research purposes.

(C) Provision of medical care to participants during and after the study.

(D) Steps to be taken if a participant voluntarily withdraws during the course of the study.

(E) Criteria for the extended use, emergency use, and compassionate use of the investigational product.

(F) The procedures for notifying participant family physicians with the consent of the participants.

(G) Plans for continuing to provide investigational products to the participant after the completion of the research.

(H) Potential impact on the financial status of the participants.

(I) Reimbursement and compensation of the participants.

(J) Compensation and treatment for injury, disability, or death of a participant arising from their participation in the research.

(K) Arrangements for compensation and insurance.

(4) The protection of participant privacy:

(A) A record of individuals who may access to the personal data of the participants (including medical records and specimens).

(B) Measures to ensure participant privacy and the security of personal information.

(5) Participant consent:

(A) Procedures to obtain participant consent.

(B) Provision of complete written or oral information to the participants or their legal representatives.

(C) Reasons for the inclusion of subjects who are unable to consent

to participate in the research.

(D) Ensuring that the participants will receive timely updates related to their rights, safety, and welfare during the study.

(E) A mechanism for receiving and responding to queries or complaints from participants or their representatives during the study.

(d) The IRB-BM may establish procedures for exempt review for studies that qualify for exempt review by the Central Competent Health Authority.

(e) Exempt reviews shall be executed by the Executive Officer. For studies that qualify for exempt reviews as stated in the preceding paragraph, the Executive Officer may approve the decision on behalf of the IRB-BM and submit a report of the decision to the Board. For any studies not approved for an exempt review by the Executive Officer, regular review is required.

(f) The IRB-BM may establish procedures for expedited review for studies that qualify for expedited review by the Central Competent Health Authority.

(g) Expedited reviews can be conducted by 1–2 members designated by the executive officer. For studies that qualify for expedited review as stated in the preceding paragraph, these members may approve the decision on behalf of the IRB-BM and submit a report of the decision to the Board. For any studies not approved by the members, full board review is required.

(h) The IRB-BM shall establish emergency review procedures in response to epidemics. AS may review relevant research projects if necessary for epidemic prevention.

4. The Formation of Meeting Resolutions

(a) Neither the IRB-BM nor its panels shall make decisions without proper discussion. Before making a decision, the chairperson should take the initiative to consult with members in non-medical professions.

(b) For IRB-BM reviews, decisions shall be made by majority rule. The number of affirmative, opposing, and abstained votes shall be recorded. Members who do not attend a meeting forfeit the right to vote in that meeting.

(c) The applicant will be notified of the review results in writing within 14 days after the decision has been made. The review results may be as follows:

(1) Approved

(2) Secondary review after amendment of the project

(3) Rejected
(4) Suspension or termination of the original approved research project

(d) Neither the IRB-BM, nor its panels, may issue any approvals for implementation of human subject research that is banned by the Central Competent Health Authority.

(e) Approval decisions shall be made as letters of consent that clearly state the following items:
(1) The complete project title, version (including amended versions), and dates of the research.
(2) The names, versions (including amended versions), and dates of other review documents.
(3) The name of the applicant.
(4) The name of the research institution.
(5) The date of the decision.
(6) The contents including the approval period of the decision.
(7) Other additional recommendations.
(8) The procedures and requirements for continuing review.
(9) The signature of the chairperson or the convener.

(f) For a decision of secondary review after amendment, the areas in need of amendment must be clearly indicated. The applicant shall be informed of the procedures for submitting the documents for the secondary review.

(g) When an application is rejected, the reasons for not granting approval must be clearly specified.

5. Oversight and Management

(a) The IRB-BM shall establish a monitoring mechanism for continuing review of approved studies. The same shall apply to studies approved by the Central Competent Health Authority. If necessary, the IRB-BM or its panels may decide on further follow-up and review after the completion of the research.

(b) The IRB-BM or its panels shall be responsible for oversight and shall clearly specify a plan for continuing communication with the applicant in the consent letter.

(c) For continuing review, the following shall be performed:
(1) Determination of the number of members and the review procedures for continuing review.

(2) Determination of the period of continuing review based on the type of research and the occurrence of adverse reactions. Review frequency shall not be less than once a year.

(d) In any of the following circumstances, a written report is required to be submitted or an onsite review conducted to investigate the situation:
   (1) Occurrences that affect the rights, interests, safety, or welfare of the participants.
   (2) The participants experience serious adverse events or reactions.
   (3) Major events or information that may affect the assessment of the risk/benefit ratio of the research occur or become known.

(e) Applicants shall be informed about decisions to carry out follow-up reviews and about amendments to, or suspension or termination of, the original decision, or confirmation that original decision is still valid.

(f) The applicant shall inform the IRB-BM or its panels of the reasons for suspending or terminating the study and the study results at the time of suspension or termination.

(g) Upon completion of the research, the applicant shall notify the IRB-BM or its panels in writing of the progress and results of the study. AS will forward the submission to the Central Competent Health Authority for reference purposes in accordance with regulations.

6. Records

(a) The IRB-BM shall stipulate procedures for documenting and archiving documents and communication records and determine eligibility criteria and procedures for accessing project documents, files, and databases.

(b) The IRB-BM shall retain all recorded procedures, lists of members, records of members' occupations and contact information, documents submitted for review, meeting minutes, letters, and other research data for three years after the completion of the study. The above files shall be made available to the Competent Health Authorities.

7. Appendices

If the IRB-BM is deemed unsuitable to review human subject research projects by the Central Competent Health Authority, the IRB-BM may entrust the review process to the Joint Institutional Review Board or the IRB of other medical institutes recognized by the Central Competent Health Authority.