

Guidelines for the Establishment of the Institutional Review Board for Biomedical Science Research, Academia Sinica

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- 1 To ensure the appropriate handling of human subject research involving the collection and use of data and human specimens, to respect the dignity and protect the rights and interests of the participants, and to fulfill the spirit of the most recent version of the Helsinki Declaration as well as relevant laws and regulations, Academia Sinica (AS) hereby establishes the Institutional Review Board for Biomedical Science Research (IRB-BM) and these Guidelines in accordance with the Human Subject Research Act promulgated by the Office of the President of the Republic of China (Taiwan).
- 2 Responsibilities of the IRB-BM
 - (a) Establishing the scope and limitations of research involving human subjects and human tissue specimens conducted by AS staff.
 - (b) Determining the content and review guidelines for human subject research and human tissue specimen-related protocols.
 - (c) Reviewing and monitoring human subject and human tissue specimen-related research projects.
 - (d) Reviewing issues involving the rights and interests of participants as well as ethical and legal affairs.
 - (e) Other matters related to human subject-based biomedical research.
- 3 Organization of the IRB-BM
 - (a) The IRB-BM shall comprise seven to 21 members. These shall include one Chairperson, one or two vice-chairpersons, and one Chief Executive Officer (CEO) appointed by the President at the recommendation of the executive Vice President and reported to the central health authority for record-keeping. The term of IRB-BM members is two years and can be renewed upon reappointment. IRB-BM members shall serve without pay, but may receive review fees and other necessary expenses in accordance with regulations.
 - (b) In addition to medical professionals, one-third or more of IRB-BM members shall be legal experts, social workers, or other impartial members of society; at least two-

fifths shall be individuals from outside AS; neither gender shall be less than one-third.

- 4 The IRB-BM shall hold regular meetings and provisional meetings if necessary, and invite relevant entities, groups, experts or scholars if necessary. To achieve resolutions, the attendance of at least half of all members, and the agreement of more than half of the attending members are required.
- 5 The IRB-BM consists of an Executive Secretary to assist the Chairperson managing IRB-BM affairs. The Executive Secretary will be appointed by the IRB-BM Chairperson and then reported to the executive Vice President for approval. The Executive Secretary has a term of service for two years, which may be renewed upon reappointment.
- 6 The required staff members for IRB-BM affairs will be filled by the personnel of the Department of Academic Affairs and Instrument Service.