

Document 4	Articles of Association of TMU-JIRB	Version 1.3 2013.10.23
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Articles of Association of Taipei Medical University Joint Institutional Review Board

Approved by University Council Meeting on 20th May 2009
Amendment approved by University Council Meeting on 26th May 2010
Amendment approved by University Council Meeting on 20th Oct 2010
Amendment approved by University Council Meeting on 23th Oct 2013

- Article 1 The Taipei Medical University (TMU) established the TMU-JIRB in accordance with ICH-GCP E6, the Medical Care Act, the Human Research Act as well as Regulations Governing the Organization and Operational Management of the Institutional Review Board for Human Subject Research to protect human trial/study participants' right and welfare and to encourage research and development in TMU.
- Article 2 The Articles of Association of TMU-JIRB is applicable to TMU system, include TMU and affiliated hospitals, establish in independent IRBs for operation according to Article 5, Taiwan Human Research Act.
- Article 3 The responsibilities of TMU-JIRB are as below to protect the rights and welfare of human trial/study participants :
1. To set up the TMU Ethical Policy for Human Trial/Study and review system.
 2. To set up the definition, content, range of review of human trial/study.
- The responsibilities of independent IRBs are as below :
1. To review and give recommendations for human trials/studies.
 2. To evaluate the safety, feasibility of human trials/studies and monitor trials/studies periodically.
 3. Responsible for human participants' protection in trials/studies.
 4. Other evaluations or special concerns in human trials/studies.
- Article 4 The member of TMU-JIRB are members of every independent IRBs. The Principal of TMU will appoint the General Convener, Chairs and the Vice Chairs depends on independent IRBs, the General Convener will recruit/appoint the Executive Secretary of independent IRBs.
- Article 5 The members of TMU-JIRB are engaged by the Principal of TMU with a variety of backgrounds include but not limited in Biomedical fields, Paramedical fields, Legal experts, Social Work, Ethics and Impartial citizens. At least 40% of members should be non-affiliated to TMU and people of either gender shall constitute no less than one third of the board according to Taiwan Laws/Regulations. The constitution of each

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independent IRB should be agreed by the MOHW by official process and document (the same process when adjust or re-appointment). Each independent IRB should consist of at least 15 members and members can be repeated but up to 50% of the independent IRB to maintain variety.

- Article 6 The term of office of members is 2 years and can be reappointed. Every constitutional change should not exceed half of the members and the expiry of terms of office of those employing replacement are as the original.
- Article 7 The independent IRBs' meeting can only start when meet the quorum that at least half of the members attending the meeting and resolved when more than half of the attendees move to the same motion. The Chair of the meeting can invite trial/study related personnel attend the meeting for further clarification if necessary.
- Article 8 The members will be dismissal if any of the following :
1. Absence without reasons for 3 times or exceed one third of total meetings in the terms of office.
 2. Individual imputability delayed review and result the meeting postponed for more than 3 times.
 3. Violate the principle of conflict of interest.
 4. Refuse for attending review or trial/study related continuous training courses.
- Article 9 In principle, TMU-JIRB joint meeting will held every 6 months to increase review consensus and consistency.
Every independent IRB meeting held monthly in principle, assigned personnel by the Chair to chair the meeting if they are not available.
Additional joint meeting or IRB meeting is available if necessary.
- Article 10 SOPs for human trial/study application and review will establish and announced by TMU-JIRB.
- Article 11 This Article of Association implemented after approved by the University Council Meeting, the same approval process when amendment.