



Addendum: China Law
Governing Research Involving Human Participants

General Comments

Standards and Elements listed below address areas where policies and procedures must address specific requirements in the law of China, including the Ministry of Health “Regulations on Ethical Reviews of Biomedical Research Involving Humans” and State Food and Drug Administration (SFDA) law, regulation and guidance:

- The Drug Administration Law of the People's Republic of China
- The Regulations for Implementation of the Drug Administration Law of the People's Republic of China
- Regulations on Administrative Protection for Pharmaceuticals
- Special Review and Approval Procedure for Drug Registration of the State Food and Drug Administration
- The Regulations for the Supervision and Administration of Medical Devices
- Provisions for Drug Advertisement Examination
- Guidance: Provisions for Drug Registration
- Guidance: Provisions for Clinical Trials of Medical Devices
- Guidance: Guidelines for Ethical Review Work of Drug Clinical Trials

Domain I: Organization

Standard I-7: The Organization has and follows written policies and procedures to ensure that the use of any investigational or unlicensed test article complies with all applicable legal and regulatory requirements.

Element I.7.A. When research involves investigational or unlicensed test articles, the Organization confirms that the test articles have appropriate regulatory approval or meet exemptions for such approval.	Any clinical trial to be conducted for research and development of a new drug, and any Class II or Class III medical device requires prior approval of the State Food and Drug Administration (SFDA). (Regulations for Implementation of the Drug Administration Law, Article 30; Regulations for the Supervision and Administration of Medical Devices, Article 8)
Element I.7.C. The Organization has and follows written policies and procedures for compliance with legal and regulatory requirements governing emergency use of an investigational or unlicensed test article.	Use of an unapproved drug during an emergency should be consistent with the “Special Review and Approval Procedure for Drug Registration” (SFDA Degree 21, Chapter 5).

Domain II: Institutional Review Board or Ethics Committee

Standard II-1: The structure and composition of the IRB or EC are appropriate to the amount and nature of the research reviewed and in accordance with requirements of applicable laws, regulations, codes, and guidance.

Element II.1.A. The IRB or EC membership permits appropriate representation at the meeting for the types of research under review, and this is reflected on the IRB or EC roster. The IRB or EC has one or more unaffiliated members; one or more members who represent the general perspective of participants; one or more members who do not have scientific expertise; one or more members who have scientific or scholarly expertise; and, when the IRB or EC regularly reviews	When research is conducted in areas where minority ethnic groups live, minority ethnic people should be considered to serve as ethics committee members. (Regulations on Ethical Reviews of Biomedical Research Involving Humans, Article 7) When describing the process for appointing members, ethics committee members should be appointed for five years, and that the organization that sets up the ethics committee should provide compensation to the members of the ethics committee based on the work they carry out. (Regulations on Ethical Reviews of Biomedical Research Involving Humans, Article 8)
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<p>research that involves vulnerable participants, one or more members who are knowledgeable about or experienced in working with such participants.</p>	
<p>Standard II-2: The IRB or EC systematically evaluates each research protocol or plan to ensure the protection of participants.</p>	
<p>Element II.2.C: The IRB or EC has and follows written policies and procedures for conducting meetings by the convened IRB or EC.</p>	<p>Ethics committee decisions must be agreed upon by two-thirds of the members constituting the quorum. (Regulations on Ethical Reviews of Biomedical Research Involving Humans, Article 21)</p>
<p>Domain III: Researcher and Research Staff</p>	
<p>Element III.1.C. Researchers employ sound study design in accordance with the standards of their discipline. Researchers design studies in a manner that minimizes risks to participants.</p>	<p>The investigator responsible for clinical trials must possess a technical title at the physician-in-charge level or above. (Provisions for Clinical Trials of Medical Devices, Article 24)</p>