



***Addendum: Korea Law***  
***Governing Research Involving Human Participants***

## General Comments

Standards and Elements listed below address areas where policies and procedures must address specific requirements in Korean Good Clinical Practice Guidelines concerning drugs and devices (KGCP).

## Domain I: Organization

### Standard I-1: The Organization has a systematic and comprehensive Human Research Protection Program with appropriate leadership.

<b>Element I.1.B. The Organization delegates responsibility for the Human Research Protection Program to an official with sufficient standing, authority, and independence to ensure implementation and maintenance of the program.</b>	For organizations conducting research, the chief of the institution, or the director of the research institute must: <ul style="list-style-type: none"><li>• Organize an Institutional Review Board</li><li>• Appoint members of Institutional Review Board</li><li>• Provide policies and procedures specifying the composition of the IRB, the conduct of meetings, process of review, reporting requirements, and review of problems</li><li>• Provide appropriate clinical laboratories, facilities, personnel and measures to deal with emergency situations to facilitate clinical trials.</li></ul>
<b>Element I.1.C. The Organization has and follows written policies and procedures that allow the Institutional Review Board or Ethics Committee to function independently of other organizational entities in protecting research participants.</b>	The chief of the institution, or the director of the research institute must guarantee the Institutional Review Board (IRB) functions independently.

### Standard I-2: The Organization ensures that the Human Research Protection Program has resources sufficient to protect the rights and welfare of research participants for the research activities that the Organization conducts or oversees.

	The chief of the institution or director of the research institute must: <ul style="list-style-type: none"><li>• Provide labs, facilities and professional personnel which are necessary for a clinical trial, and</li><li>• Ensure measures are taken in an emergency situation as specified in the clinical investigation plan approved by the regulatory authority.</li></ul>
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### 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.

<b>Element I.7.B. The Organization has and follows written policies and procedures to ensure that the handling of investigational or unlicensed test articles conforms to legal and regulatory requirements.</b>	The chief of the institution or director of the research institute should assign one of their members as an investigational device manager, who is responsible for: <ul style="list-style-type: none"><li>• Maintaining medical records to verify that investigational devices were used in each subject in accordance with the clinical investigational plan and that the inventory matches the record.</li><li>• When delegating storage to a physician, documenting this in writing</li></ul>
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## Domain II: Institutional Review Board or Ethics Committee

### Standard II-5: The IRB or EC maintains documentation of its activities.

<b>Element II.5.A. The IRB or EC maintains a complete set of materials relevant to the review of the research protocol or plan for a</b>	The chief of the institution should entrust a person responsible for maintaining records and documents of the IRB or the principal investigator for a period of three years after the official discontinuation of
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<p><b>period of time sufficient to comply with legal and regulatory requirements, Sponsor requirements, and organizational policies and procedures.</b></p>	<p>the clinical trial except documents with specially designated storage period by law, and come up with measures to prevent accidental or premature destruction and loss of these documents. Upon request from the sponsor to extend the document retention period, the institutional chief can do so, if agrees. The sponsors should notify the chief of institution in writing when the trial related records are no longer needed.</p>
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