



Association for the Accreditation
of Human Research Protection Programs, Inc.®

ADDENDUM

Republic of Korea

General Comments

The Republic of Korea Addendum to the *Evaluation Instrument for Accreditation* (“*Evaluation Instrument*”) is intended for use by organizations in the Republic of Korea seeking accreditation, by AAHRPP peer reviewers evaluating organizations in the Republic of Korea, and by accredited organizations in the US that conduct or oversee research in the Republic of Korea.

This Addendum includes Standards and Elements where the Republic of Korea (henceforth South Korea) law, regulations, and guidelines require significant additional protections beyond those defined in the *Evaluation Instrument* or are significantly different from requirements in the *Evaluation Instrument*, and is intended to be used in conjunction with the *Evaluation Instrument*. The Addendum focuses on the laws most relevant to human research protection programs, including research ethics committees. However, it is not an exhaustive account of all requirements covering research involving human participants in the Republic of Korea.

AAHRPP evaluates organizations in the Republic of Korea under the Republic of Korea law. If an organization in Korea does not have to follow US regulations, AAHRPP will not request that organizations in the Republic of Korea add to policies any definitions or other requirements found in US regulations.

Organizations that follow ICH-GCP (E6) will be evaluated under that Guideline.

The Addendum is based on a review of South Korea regulations and guidance including but not limited to:

- Bioethics and Safety Act (BSA), Act No. 7150 (2004)
 - Enforcement Decree of the Bioethics and Safety Act (2019): Implements BSA (IRB operations, consent, record keeping, etc.)
 - Enforcement Decree of Bioethics and Safety Act (2025)
- Pharmaceutical Affairs Act (PAA), Act. No. 1491 (1963)
 - Enforcement Decree of the Pharmaceutical Affairs Act (2019): Makes KGCP legally operative
- Medical Device Act, No. 14330 (2016)
 - Enforcement Rule of the Medical Devices Act (2020) (attached GCP table): Clinical Trial Device GCP and Sponsor Duties

- Korean Good Clinical Practice (KGCP), also known as the Pharmaceutical Clinical Trial Management Standards Act, Annex 4 to the Ministry of Food and Drug Safety (MFDS) Rule
 - Amendment Ordinance No. 1544 (2019)
 - Amendment Ordinance No. 1835 (2022)
- Personal Information Protection Act (PIPA), Act No. 10465 (2011)
- National Research & Development Innovation Act, Act No. 17343 (2020)

While the Bioethics and Safety Act references “Institutional Bioethics Committees,” the term Institutional Review Boards (IRBs) is used for consistency with global terminology.

This Addendum represents AAHRPP’s current understanding of additional requirements covering organizations conducting or reviewing research under the laws of the Republic of Korea.

We appreciate questions, concerns, and suggestions to improve this document. Please email accreditation@aahrpp.org.

Domain I: Organization

Standard I-1: The organization has a systematic and comprehensive Human Research Protection Program that affords protections for all research participants. Individuals within the organization are knowledgeable about and follow the policies and procedures of the Human Research Protection Program.

Element I.1.A. The organization has written policies and procedures for determining when activities are overseen by the Human Research Protection Program.

An organization should describe in written materials a definition of “human subjects research.” (BSA, 2004)

- “Human subjects research” is defined as research performed through interactions including physical intervention, communication, and interpersonal contact or as a study using personally identifiable information.
- “Personally identifiable information” is defined as information from which an individual can be identified, such as the name and resident registration number of a human subject of research or the donor of an embryo, egg, sperm, or human material.
- “Human materials research” is defined as a study to investigate and analyze human materials directly.

When following PIPA, written materials define “personal information” as information about an individual, such as personally identifiable information, genetic information, or information about health.

Regulatory and guidance references

- Bioethics and Safety Act, 2004. Article 2: Definitions
- Personal Information Protection Act (PIPA), 2011.

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

South Korea regulations include a provision for institutions to specify areas that are unique to their organization, which is represented by the language referring to any other matters concerning the institution’s bioethics and safety oversight.

Written materials should describe how the IRB functions independently of other organizational entities and should be granted specific authorities to establish ethical guidelines that ensure: (BSA, 2004)

- The IRB maintains independence.
- The safety of donors (i.e., human biological specimens).
- Safety measures for protecting personal information of donors.
- Any other matters concerning the organization’s bioethics and safety oversight.
- Inspection and supervision of the progress of outcomes of research conducted by the relevant organization.
- Development of measures to protect donors who are in vulnerable situations.

Regulatory and guidance references

- Bioethics and Safety Act, 2004. Article 10: Establishment and Functions of Institutional Bioethics Committees, Article 11: Composition and Operation of Institutional Committees

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.

When following KGCP requirements, written materials should describe that the head of the organization is required to ensure the following support is available for a clinical trial:

- Labs, facilities and professional personnel which are necessary for a clinical trial.
- A designated managing pharmacist.

- A designated person responsible for archiving research related documents.

Written materials should describe how clinical trial principal investigators shall be selected from among those with expertise, ethical discipline, and considerable experience in conducting clinical trials of the relevant medical devices. (Enforcement Rule of the Medical Devices Act, 2020).

Regulatory and guidance references

- KGCP, 2019. Article 6: Operation of the Review Committee
- Enforcement Rule of the Medical Devices Act, 2020. Article 24: Standards for Conducting Clinical Trials

Standard I-4: The organization responds to the concerns of research participants.

Element I.4.A. The organization has and follows written policies and procedures that establish a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol or plan.

Written materials should describe the process followed by the organization when participants request to disclose information about themselves and their participation in a study, including: (BSA, 2004)

- Who reviews requests for disclosures.
- Timeframe for review.
- Communication with the participant, or their legally authorized representative, requesting the disclosure the reason for a non-disclosure, when applicable.

When following KGCP requirements, written materials should describe if a participant discontinues participation before the completion of the clinical trial, there is no obligation for them to provide a reason, but the principal investigator must make efforts to confirm the reason while fully considering the participants' rights.

Regulatory and guidance references

- Bioethics and Safety Act, 2004. Article 19: Records Storage and Disclosure of Information
- KGCP, 2022. Article 7: Protection of subjects by investigators

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. 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.

Written materials should describe: (Medical Device Act, 2016)

- If the study is subject to Approval of the Minister of Food and Drug Safety, the protocol shall be also submitted to the Minister of Food and Drug Safety in addition to the IRB.
- The process for obtaining approval from the Minister of Food and Drug Safety for the clinical trial.

Written materials should describe: (PAA, 1963)

- How investigational drugs are maintained through accountability logs (receipt, dispensation, return, destruction).
- Logs are retained with the regulatory file.

Regulatory and guidance references

- Medical Device Act, 2016. Article 10: Clinical Trials Plan Approval
- Pharmaceutical Affairs Act, 1963. Article 34: Approval of Clinical Trial Protocols

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.

Written materials should describe how the head of the institution or director of the research institute should assign one of their members as an investigational device manager, who is responsible for: (Medical Device Act, 2016)

- 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.
- Documenting in writing when delegating storage to a physician.

Regulatory and guidance references

- Medical Device Act, 2016: Article 10: Clinical Trials Plan Approval

Standard I-8. The organization works with public, industry, and private sponsors to apply the requirements of the Human Research Protection Program to all participants.

Element I.8.A. The organization has a written agreement with the sponsor that addresses medical care for research participants with a research-related injury, when appropriate.

When following PAA, written materials should describe that contracts with study sites for interventional research specify the medical care, compensation, and indemnification that will be provided to research participants for research-related injury.

Regulatory and guidance references

- Pharmaceutical Affairs Act, 1963. Article 34. Approval of Clinical Trial Protocols

Element I.8.C. When the sponsor has the responsibility to conduct data and safety monitoring, the organization has a written agreement with the sponsor that addresses provisions for monitoring the data to ensure the safety of participants and for providing data and safety monitoring reports to the organization

Written agreements with sponsors should describe how: (Enforcement Rule of the Medical Devices Act, 2020)

- Sponsors report monitoring findings impacting safety to the IRB within set timelines.
- Data Safety Monitoring reports are shared with the organization.

Regulatory and guidance references

- Enforcement Rule of the Medical Devices Act, 2020. Article 24(1)11: Standards for Conducting Clinical Trials

Standard I-9. The organization has written policies and procedures to ensure that, when sharing oversight of research with another organization, the rights and welfare of research participants are protected.

South Korea does not specify the requirement of a single IRB to review multi-site research. Relying on another IRB or creating a joint IRB is permissible.

Written materials should describe that if an organization relies upon another organization for IRB review of research involving human participants or human materials conducted by its researchers, it must enter into a written agreement with that IRB that is consistent with the requirements of the Bioethics and Safety Act. The agreement should specify which organization takes responsibility for the following activities for bioethics and biosafety: (BSA, 2004)

- Education of researchers and employees of the relevant institution.
- Formulation of measures for protecting human subjects of research or donors (i.e., human biological specimens) in a vulnerable situation.
- Establishment of ethical guidelines for researchers.

Regulatory and guidance references

- **Bioethics and Safety Act, 2004.** Article 10: Establishment and Functions of Institutional Bioethics Committee. Article 12: Designation of Public Institutional Bioethics Committees and Joint Operation of Institutional Committees

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 research that involves vulnerable participants, one or more members who are knowledgeable about or experienced in working with such participants.

Written materials should describe that the organization's IRB roster includes the following:

- Each IRB has at least five members with varying backgrounds to promote complete and adequate review of research commonly conducted by the organization.
- Each IRB has one chairperson, elected from among the members.
- No IRB has members of a single gender.
- No IRB has members who represent a single profession.
- Each IRB has at least one member whose primary concerns are in scientific areas. At least one person who has sufficient experience and knowledge to evaluate social and ethical validity, with qualifications to review medical aspects of a clinical trial.
- Each IRB has at least one member whose primary concerns are in nonscientific areas, such as a lawyer or a religious person, and who has not majored in medicine, dentistry, oriental medicine, pharmacy or nursing.
- Each IRB has at least one member who is not otherwise affiliated with the organization and who is not part of the immediate family of a person who is affiliated with the organization.

- Each IRB has at least one member who represents the perspective of research participants.

Regulatory and guidance references

- Bioethics and Safety Act 2004. Article 11: Composition and Operation of Institutional Committees
- KGCP, 2022. Article 6: Composition, functions, and operation methods of the review committee

Standard II-2. The IRB or EC evaluates each research protocol or plan to ensure the protection of participants.

Element II.2.A. The IRB or EC has and follows written policies and procedures for determining when activities are exempt from applicable laws and regulations, when permitted by law or regulation and exercised by the IRB or EC. Such policies and procedures indicate that exemption determinations are not to be made by researchers or others who might have a conflict of interest regarding the studies.

Written materials should describe: (BSA, 2004)

- How research may be exempt from deliberation by the IRB, if a risk to human subjects of research and the general public is insignificant and the research meets the exempt standards per applicable regulation.
- That only the IRB (or designated reviewer) may provide an exemption determination and researchers may not self-exempt.

When making exemption determinations, written material should describe that the organization follows the criteria for exemption within the Enforcement Rule of the BSA (2025), including:

- Research that utilizes information disclosed to the general public or research that does not collect or record personally identifiable information.
- Among studies that directly manipulate research subjects or their environment, any of the following studies:
 - Research that does not involve invasive procedures such as drug administration or blood collection.
 - Research using only simple contact measuring or observation equipment that does not involve physical changes.
 - Research evaluating the taste and quality of foods or food additives whose sale is permitted under Article 3 of the Enforcement Decree of the Food Sanitation Act.
 - Research on the user experience and satisfaction using cosmetics that meet safety standards under Article 8 of the Cosmetics Act.
- Research that does not collect or record sensitive information under Article 23 of the PIPA, even if the research subjects are directly encountered, and the research subjects are not identified.

- Research using existing data or documents about research subjects.

Regulatory and guidance references

- Bioethics and Safety Act, 2004. Article 15: Deliberation on Human Subjects Research, Article 36, Deliberation on Human Materials Research
- Enforcement Decree of the Bioethics and Safety Act, 2025. Article 13: Research on human subjects exempt from review by institutional committee

Element II.2.F. The IRB or EC has and follows written policies and procedures to conduct reviews by an expedited procedure, if such procedure is used.

South Korea recognizes a formal expedited IRB review for minimal risk research and minor modifications, defined under the Bioethics & Safety Act and KGCP framework and implemented through IRB standard operating procedures.

When following Enforcement Decree of Bioethics & Safety Act and KGCP, written materials should describe the types of research that may be reviewed using an expedited review:

- Initial Review: If the research poses less than minimal risk to participants and the public, including:
 - Research or post-market surveillance (PMS) of a drug or medical device being prescribed/used in the clinic is for a marketed use only and does not require approval by MFDS.
 - Blood draw research that is specified by the organization.
 - Research in which human material is collected for prospective research purposes and the method of collection of human material is non-invasive or equivalent as specified by the organization.
 - Research that collects data using non-invasive tests that are commonly performed in the clinic, as specified by the organization (e.g., body sensors, magnetic resonance imaging (MRI), Electrocardiogram, physical exercise, etc.).
 - Research using human remains, data, documents, or records that is specified by the organization.
 - Research involving the collection and use of audio or video, digital, or image materials for the research purpose.
 - Research involving individual or group behavior research as specified by the organization (e.g., research for perception, cognition, identity, social behavior and the use of surveys, interviews, oral histories, and program evaluation)
 - Continuing review that has been reviewed and approved by convened IRB review and that falls under any of the following categories:

- No more participants are scheduled to be enrolled, all participants have completed the study-related interventions, and only long-term follow-up remains.
 - No participants have been enrolled or there has been no change in enrollment status since the last continuing review, only drop-outs, completed participants, and no additional risks have been identified.
 - Only data analysis remains.
- Research that is not a clinical trial requiring MFDS oversight and the research was determined to be less than minimal risk via a convened IRB review and no additional risk was found.

Written materials should describe:

- If an adverse drug reaction is from a new or greater than minimal risk study, it must be reviewed by the convened IRB and cannot be reviewed under expedited procedures.
- How expedited decisions are reported to the next convened meeting.
- No additional approval is required unless stipulated by the IRB's SOPs or MFDS guidance.
- Decisions made through the expedited process may later be changed by the convened IRB.
 - When an expedited review determination is subsequently reviewed by the convened IRB, the IRB may revise that determination. Any such change, along with the reason for such change, must be communicated to the relevant researcher immediately after the convened meeting.
 - If research has already proceeded based on the previously approved results, the researcher must inform the IRB and the IRB must consider the effect of the revised determination and take appropriate action.

Written materials should describe the organization's administrative priority pathway process, including:

- The organization's definition of "administrative priority pathway."
- How research that has received IRB approval and that is in progress may be eligible for an administrative priority pathway review if it involves any of the following:
 - Reports of serious and unexpected medical device or drug adverse events have been reviewed.
 - Handling the termination of research.
 - Processing of clinical trial completion reports.
 - Addressing modifications and corrective action plans to the protocol (including protocol amendment) that was approved by MFDS.
 - Minor changes to the protocol, such as changes in administrative procedures, monitors, research related personnel, emergency

- contact information, or additions and deletions of tests that do not affect the validity and safety of the research.
- Review of investigator's responses to the conditional approval.
- Anything that does not fall under the above list, but that does not increase the risk to participants or that is considered as less than minimal risk.

Regulatory and guidance references

- KGCP, 2022. Chapter 6: Institutional Review Board
- Enforcement Decree of Bioethics & Safety Act, 2025. Article 13: Human subjects research that is exempt from IRB review

Standard II-3: The IRB or EC approves each research protocol or plan according to criteria based on applicable laws, regulations, codes, and guidance.

Written materials should describe how the IRB may determine that written informed consent may be waived if the research satisfies all the following prerequisites: (BSA, 2004)

- The IRB determines that obtaining consent from a human research participant is impracticable;
- Is likely to seriously affect the validity of research;
- There is no ground to find that a human research participant will decline consent to participate in the research; or
- The risk to a human research participant is very low even if consent is waived.

Regulatory and guidance references

- **Bioethics and Safety Act, 2004.** Article 16: Consent to Human Subjects Research

Standard II-4: The IRB or EC provides additional protections for individuals who are vulnerable to coercion or undue influence and participate in research.

Element II.4.B. The IRB or EC has and follows written policies and procedures requiring appropriate protections for prospective participants who cannot give consent or whose decision-making capacity is in question.

Written materials should describe that, when a research project is to involve a person incapable of or incompetent for giving informed consent as a human subject of research, the IRB ensures: (BSA, 2004)

- The representative for that person's consent must not be contrary to the intention of the relevant human subject of research.
- If no legal representative is appointed, the spouse or a lineal ascendant or descendant shall act as an agent for such person in the abovementioned order.

- If there are two or more lineal ascendants or descendants, the representative for such person shall be appointed under agreement by and between such ascendants or descendants, or the oldest person among them shall act as the representative for such person if they fail to reach an agreement.

Regulatory and guidance references

- **Bioethics and Safety Act 2004.** Article 10: Vulnerable populations.
Article 16: Consent to Human Subjects Research

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

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 period of time sufficient to comply with legal and regulatory requirements, sponsor requirements, and organizational policies and procedures.

When following KGCP, written materials should describe how the head of the organization 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 the clinical trial except documents with specially designated storage period by law, and implement measures to prevent accidental or premature destruction and loss of these documents.

Regulatory and guidance references

- KGCP, 2022. Chapter 6: Institutional Review Board, Article 57: Duties of the Review Committee

Domain III: Researcher and Research Staff

Standard III-2: Researchers meet requirements for conducting research with participants and comply with all applicable laws, regulations, codes, and guidance; the organization's policies and procedures for protecting research participants; and the IRB's or EC's determinations.

Element III.2.A. Researchers and research staff follow reporting requirements during a research study in accordance with applicable laws, regulations, codes, and guidance; the organization's policies and procedures; and the IRB's or EC's requirements.

Written materials should describe that if a principal investigator discovers that a research process is likely to cause a serious harm to an individual or society, the principal investigator shall immediately report to the organizational official and take appropriate measures. (BSA, 2004)

- Once the organizational official is notified, the official must convene the IRB to review the matter, and the outcome must be reported as required under the applicable law.

Regulatory and guidance references

- Bioethics and Safety Act, 2004. Article 17: Measures for Safety of Human Subject Research, Article 54: Reporting and Inspection