KDI School IRB Review Guidelines

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1. Target of Review

(General Principles)

The IRB review process (exemption or review) shall be applied to human subject research projects only, not to all research projects.

* Human subject research: Refers to a research project physically involving a human being as a subject; a research project conducted through communication, physical contact or other means of interaction; or a research project conducted by using information with which individuals can be identified (Article 2 (Definitions) of the Operational Regulations of the KDI School of Public Policy and Management Institutional Review Board, hereinafter referred to as the "Operational Regulations").

(Specified Subjects)

○ KDI School's own research project conducted by a KDI School's faculty member as the principal investigator

* All external research projects shall be subject to IRB review at the project manager's affiliated institution.

○ Any research project involving KDI faculty members as collaborating investigators that has not yet undergone IRB review in Korea

○ All publications including theses, SRP, ELP, and capstone papers resulting from research projects conducted by graduate students at KDI School

2. Review Principles

< Basic Principles >

(Refer to Article 3 of Operation Regulations)

1. No activity regulated under this Act shall be conducted in any manner that violates the dignity and value of a human being, and priority shall be given to the human rights and welfare of each human research subject or donor.

2. The self-determination of each human research subject or donor shall be respected, and the voluntary consent of a human research subject or donor shall be supported by adequate information.

3. The privacy of each human research subject or donor shall be protected, and personal information that has the potential to cause an invasion of privacy shall be protected as confidential information, except where the relevant party consents to disclosure or an Act expressly permits disclosure.

4. Full consideration shall be given to the safety of each human research subject or donor, and risks shall be minimized.

5. An individual or group in vulnerable conditions shall receive special protection.

6. International cooperation shall be promoted as necessary to ensure bioethics and biosafety, and efforts taken to adopt universal international standards to this end.

[Exemption from Review]

(Target of Exemption)

If the content of a study that applies for IRB review conforms to the IRB Review Exemption Criteria Table (Attachment), the study may be exempted from review.

(Submission Documents)

Appendix 1: Request for Review (Exemption) from IRB Review, research proposal (free form), and completion certificate of bioethics education (within previous two years as of the application date), Consent Form of Legal representative* (in case of data collection and survey on children), Supervisor Confirmation (in case of a student research project / it is mandatory to submit a course completion certificate of the supervisor if there is even a slight possibility that the supervisor might participate in the student research project as a researcher)

* Children: defined by Article 3, Clause 1 of the Child Welfare Act (person under 18 years of age)
* ①Legal representative, ②In the absence of a legal representative, it goes in the order of spouse, direct ascendant, direct descendant. If there are multiple direct ascendants or descendants, a decision is made by consultation, and if a consultation is not possible, the eldest becomes the legal representative.

(Procedures)

Receipt of application* (assistant administrator) → Written review (two reviewers**) and comments → Final decision → Decision notice

* E-mail application: si_lim@kdischool.ac.kr

** Designated by the chairperson (in consideration of their review experience in research involving human subjects and area of expertise)

[Review]

(Basic Principles)

Expedited reviews (written) shall be considered first in the review process.

(Required Documents to Submit)

Appendix 1: Request for Review (Exemption) from IRB Review, research proposal (free form), and completion certificate of bioethics education (within the previous two years as of the application date), Consent Form of Legal representative** (in case of data collection and survey on children), Supervisor Confirmation (in case of a student research project / it is mandatory to submit a course completion certificate of the supervisor if there is even a slight possibility that the supervisor might participate in the student research project as a researcher)

* Mandatory to be specified: If the research is anticipated to cause any possible harm to research subjects, the following must be specified:

** Children: defined by Article 3, Clause 1 of the Child Welfare Act (person under 18 years of age)

** ①Legal representative, ②In the absence of a legal representative, it goes in the order of spouse, direct ascendant, direct descendant. If there are multiple direct ascendants or descendants, a decision is made by consultation, and if a consultation is not possible, the eldest becomes the legal representative.

(1) Types of relevant risks; (2) methods of obtaining informed consent from a human research subject; (3) measures to avoid or minimize relevant risks; and (4) measures in response to the occurrence of harm

(Content for Review)

Evaluation items specified in Appendix 2: IRB Decision Letter

(Procedures)

Receipt of application* (assistant administrator) → Expedited review (two reviewers**) and delivery of opinions (suggesting a full review, if necessary) → Final decision → Decision notice

* E-mail application: si_lim@kdischool.ac.kr

** Designated by the chairperson (in consideration of their review experience in research involving human subjects and area of expertise)

(Target of Full Review)

Research that poses greater than minimal risk*to a human research subject

* *the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than what is ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests*

(Method of Full Review)

The method of full review is decided by a majority of those present in a face-to-face meeting (or an online conference where a majority of the registered IRB members are present).

3. Infraction Proceedings

(Basic Principles)

Application of Article 39 of the Operational Regulations (Protocol Violation and Deviation), etc.

Article 39 (Protocol Violation and Deviation)

(1) In the event of any violation of or deviation from the research proposal, the principal investigator shall report the issue to the IRB as soon as possible.

(2) The principal investigator shall include the following items in order to report the matters falling under paragraph (1):

1. Description of the violation or deviation;
2. Cause of the violation or deviation;
3. Measures taken to prevent the occurrence of similar cases.

(3) Pursuant to paragraph (2), the IRB may conduct an expedited review, determine the appropriate measure(s) from among the following, and impose said measure(s) on the research staff in order to prevent the reoccurrence of such cases.

1. Warning;
2. Completion of relevant education;
3. Other measures decided by the IRB.

(4) A regular meeting shall be convened, if subparagraph (3) of paragraph (3) is necessary due to the significance of the violation or deviation and the resulting level of risk to which research subjects were exposed.

(5) When a measure specified in subparagraph (3) of paragraph (3) is taken, the IRB may, if necessary, report the matter to the Dean of the KDI School or to relevant institutions or organizations, including research funding sponsor organizations.

*** As for other details, the Operational Regulations of the KDI School of Public Policy and Management Institutional Review Board shall apply.**

[Attachment 1]

IRB Review Exemption Criteria Table

No.	Content
Category 1. Cases that are exempt from IRB review	
Category 1-1	Research directly conducted or commissioned by the State or local governments to examine or evaluate public welfare or related service programs (Article 2 of the Enforcement Rule of the Bioethics and Safety Act)
Category 1-2	Research directly conducted or commissioned by the State or local governments in a situation where emergency measures are required in relation to public health (Article 33 of the Enforcement Rule of the Bioethics and Safety Act)
Category 1-3	Research conducted on general educational practices in schools or other educational institutions designated and publicly announced by the Minister of Health and Welfare (Article 2 of the Elementary and Secondary Education Act, Article 2 of the Higher Education Act)
Category 2. Research involving existing data and de-identified information	
Category 2-1	There is minimal risk to research subjects and the general public; and the research subjects' personally identifiable information such as name, phone number, and identification number is not collected.
Category 2-2	The research subjects are not public officials or candidates for public office; and the research subjects' personally identifiable information such as name, phone number, and identification number is not collected.
Category 3. Research involving surveys, educational assessments, interviews, or observations	
Category 3-1	Research involving the use of survey procedures, educational assessments, interview procedures, or behavioral observations that does not fall under any of the following: • The research subjects' personally identifiable information or sensitive information is collected (Article 23 of the Personal Information Protection Act) • The research subjects' responses place the subjects at risk of criminal or civil liability or damage the subjects' financial standing, employment, reputation, etc.
Category 4. Research involving some degree of experimental and operational interventions*	
Category 4-1	When conducting research (see explanation) involving adult subjects that includes information collection, operational interventions (including deception), environment manipulation, and behavioral experiments, it may be exempted from IRB review if informed consent is obtained from the subjects in advance, and if, at the same time, the relevant research activity does not fall under any of the following: • The research subjects' personally identifiable information or sensitive information is collected (Article 23 of the Personal Information Protection Act) • The research subjects' responses place the subjects at risk of criminal or civil liability or damage the subjects' financial standing, employment, reputation, etc.

* Research involving some degree of experimental and/or operational interventions

Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else."

[Attachment 2]

Supervisor Confirmation

Basic Information				
Research Project Name				
Research Period				
Research Principal Investigator (Student)	Name	Degree	Report Type*	Major
		☐ Master's ☐ Doctorate		
Major Supervisor	Name	Affiliation	Position	Field of Expertise
Second Supervisor	Name	Affiliation	Position	Field of Expertise

Confirmation Content	
1. Review of Ethical Validity of Research - I have fully understood the research content written by the student I am supervising and have completed the review on the research design.	☐ Yes ☐ No
2. Supervision for Research Execution - I will supervise so that the research adheres to life ethics and research ethics. - While supervising this research, I will ensure that all matters related to personal information and data that I come across as a supervisor are handled in strict compliance with life ethics and research ethics.	☐ Yes ☐ No
I confirm to diligently supervise the above matters related to life ethics and research ethics.	

Date of Completion : Year Month Day

Principal Investigator : _____(Signature)

Supervisor : _____(Signature)

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[Attachment 2]

Consent Form

Research Title:

1. I have read the description of this research and discussed it with the responsible researcher.
2. I have been informed about the risks and benefits and have received satisfactory answers to my questions.
3. I voluntarily consent to participate in this research.
4. I agree that the researcher can collect and process information about me obtained from this research within the scope allowed by the current law and the KDI Graduate School Human Subjects Research Ethics Committee regulations.
5. I agree that my personal information, which is kept confidential, can be directly viewed by the responsible researcher or a delegated representative in cases of conducting research, managing results, and when research institutions, research fund support institutions, and the Ministry of Health and Welfare are conducting an actual condition survey.
6. I understand that I can withdraw from participating in this research at any time and that such a decision will not cause me any harm.
7. My signature indicates that I have received a copy of this consent form, and I will keep the copy until the end of my participation in the research.

Research Subject	Name	Signature	Date of Signature
Legal Representative (If necessary)	Name Relationship with the Research Subject	Signature	Date of Signature
Consent Acquirer	Name	Signature	Date of Signature

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