

# Self-Check Table for Review Exemption

Basic Information						
Name of Research Project		Lead Researcher	Name	Organization	Title	Major

**Possibility of review exemption is checked as follows. (Duplicate marking allowed)**

1. Is research conducted with human or human derived materials?  
 Yes (→ Go to question No. 2)  
 No (→ The research is not subject to review for research on human research subject or research on human derived materials.)

2. If corresponding to the following, the research is not subject to this law. If the research does not correspond to the following, go to question No. 3

- ① Research conducted by the nation or local government directly or through consignment in order to examine or evaluate public welfare or service program
- ② Research relating to usual educational practices conducted by schools according to Article 2 of 「Elementary and Secondary Education Act」 and Article 2 of 「Higher Education Act」 and educational institutes decided and announced by the minister of Health and Welfare

3. Are risks affecting human research subject or human derived material donor and the public insignificant?  
 Yes (→ Go to question No. 4) ※ In this case, judgement on the insignificant risks needs to be agreed between researcher and institutional committee, and if not agreed, review cannot be exempted.  
 No (→ Review cannot be exempted.)

4. Is personally identifiable information of human research subject or human derived material donor collected or recorded?  
 Yes (→ Review cannot be exempted.)  
 No (→ Go to question No. 5)

5. Is the research using only materials or documents produced already without collecting new information from human research subject and the like?  
 Yes (→ Review can be exempted.)  
 No (→ Go to question No. 6)

6. Is test subject under vulnerable environment included in human research subject or human derived material donor?

※ Test subject under vulnerable environment refers to human research subject whose voluntary decision of participation may be affected by expectation for benefits regarding participation in the research or concerns for disadvantage that he/she may receive from a superior in organization hierarchy when he/she refuses to participate (student, employee of laboratory of medical institutions, employee of company, soldier, etc.), terminal patient, inmate of group institution, unemployed person, poor person, patient under emergency, ethnic minority, vagrant, homeless person, refugee, minor and person who is not able to agree on his/her free will.

Yes (→ Review cannot be exempted.)

No (→ Go to question No. 7-1)

7-1. Do you conduct research directly having any operation or encouraging an environment for the operation with humans for the research?

Yes (→ Go to question No. 8-1)

No (→ Go to question No. 7-2)

7-2. Do you conduct research using materials obtained through interview, survey or behavioral observation with humans?

Yes (→ Go to question No. 8-2)

No (→ Go to question No. 7-3)

7-3. Do you conduct research using materials capable of identifying human research subject (human)?

Yes (→ Go to question No. 8-3)

No (→ Go to question No. 7-4)

7-4. Do you conduct research directly investigating and analyzing human derived materials obtained from human body although the research does not directly target human?

Yes (→ Go to question No. 8-4)

No (→ Ask Institutional Committee)

8-1. Review can be exempted if the research corresponds to any one of the following.

Research that does not involve invasive action such as drug administration or blood collection

Research using simple touch measuring device or observation device that does not cause physical changes

Research evaluating taste or quality of food permitted for sales according to Article 3 of the enforcement regulation of the Food Sanitation Act

Research investigating texture, satisfaction or the like using cosmetics suited for safety criteria according to Paragraphs 1 and 2 or Article 8 of the Cosmetics Act

8-2. Review can be exempted if the research corresponds to the following.

Human research subject is unspecific, and information collected by the research does not include sensitive information according to Article 23 of Privacy Protection Act

8-3. Review can be exempted if the research corresponds to the following.

Research using information open to general public

8-4. Review can be exempted if the research corresponds to any one of the following. However, for research conducted by the nation or local government directly or through consignment under circumstances requiring urgent action in terms of public health, the progress needs to be notified to the official committee before completing the research.

As research receiving and using human derived materials collected and stored in human derived material bank and genetic information obtained therefrom (hereinafter, "human derived materials, etc."), research that cannot identify personal information unless going through human derived material bank that provides human derived materials, etc.

Research conducting test lab quality management and test method evaluation such as accuracy test using human derived materials, etc. remaining after being used for the purpose of treatment and diagnosis in medical institution

As a case that does not directly collect human derived materials, research using research materials separated and processed from human derived materials (including pathogen, cell line, etc.) so that general public may use

Researcher cannot find out personally identifiable information of human derived material donor, and result obtained from the research is not related to a genetic trait of the donor him/herself (however, research using embryonic stem cell line is not included)