**Protocol Review Application**

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| **\* Receipt confirmation** (This is a field for Committee receivers, please researchers keep it blank.) | | | |
| **Receipt No.** |  | **Date of receipt** |  |

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| **1. Basic Information** | | | | | | | | | |
| **Project Name** | | (Korean) | | | | | | | |
| (English) | | | | | | | |
| **Type Research** | | □ Human subjects research → method : □ qualitative research □ quantitative research  □ Human materials research □ Embryo research □ Other( ) | | | | | | | |
| **Purpose Research** | | □ For general academic □ For thesis writing  □ Other( ) | | | | | | | |
| **Principal**  **Investigator** | | **Name** | | (Korean) | | | (English) | | |
| **Position** | | □ Professor □ student (□ Master’s course □ Doctors course)  □ Other : Post-Doc, ect. | | | | | |
| **Affiliation** | |  | | | | | |
| **Tel.** | |  | **e-mail** | | |  | |
| **Co- Investigator(s)**  (\*if there are two or more, write all) | | □ None | | | | | | | |
| **Name** | |  | **Position** | | |  | |
| **Affiliation** | |  | | | | | |
| **Academic advisor**  (\*If you are a student, must write ) | | □ None | | | | | | | |
| **Name** | |  | **Position** | | |  | |
| **Affiliation** | |  | | | | | |
| **Sponsor** | | □ None | | | | | | | |
| **Institution name** | |  | **Person in charge** | | |  | |
| **Tel.** | |  | **e-mail** | | |  | |
| **Budget** | | □ None | | | | | | | |
| □ Cash : won □ Spot goods ( ) | | | | | | | |
| **Type** | | □ None (Researchers pay for themselves)  □ UNIST □ Government agency( Program : )  □ Enterprise □ learned society □ Other | | | | | |
| **Institution name** | |  | | | | | |
| **Research Center** | | □ Single center  □ Multi-center (Number of participating centers : ) | | | | | | | |
| **Expected Period** | | ※This is the total research period to be approved. It is sufficient even it if it not consistent with the project period.  Date of approval ~ DD/MM/20YY  (or DD/MM/20YY ~ DD/MM/20YY) | | | | | | | |
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| **2. Research Information** | | | | | | | | | |
| **Human**  **Subject**  **Research** | □ None | | | | | | | | |
| **Intervention** | | □ Drug/Medical devices □ Cosmetics  □ Exercise □ body measurement □ Health foods  □ Environmental manipulation(light, sounds, degree, etc.) or providing sensory stimuli  □ Other( ) | | | | | | |
| □ Invasive □ Non-invasive | | | | | | |
| **Interaction** | | □ Survey □ Interview □ Behavioral observation  □ Video or voice recording for interaction process  □ Using test method about cognitive capability, linguistic ability, etc.↘ Test method type  □ Existing test method □ under development test method  □ Other : | | | | | | |
| **other** | | □ Single group research □ Case-control group research  ↘ Randomization process : □ Use □ Not use | | | | | | |
| □ Use blindness method □ take the education program  □ Use deception method □ Associated with clinical trial | | | | | | |
| **Human Materials Research** | □ None | | | | | | | | |
| **Classification,** | | □ Tissue □ Cell □ Blood □ Body Fluid □ Other( )  □ Serum, blood plasma, chromosome and DNA separate from human materials | | | | | | |
| **Method of Collection** | | □ Direct collection  □ Materials stored in bio-banks (Provided by : )  □ Materials received from external institute (Provided by : )  □ Other : | | | | | | |
| **Anonymity** | | □ Anonymous materials  □ Not anonymity  □ Requires anonymity  ↘ Method of maintaining anonymity  □ Permanently delete □ Replaced by unique identification number(cording) | | | | | | |
| **management method** | | □ Discarded after the end of research  □ Keeping after the end of research (storage period : )  □ Providing to other researcher or institution | | | | | | |
| **Collection of Genetic Information** | | □ Yes  □ No | | | **Storage of Genetic Information** | | | □ Yes  □ No |
| **Embryo Research** | □ None | | | | | | | | |
| **Purpose** | | □ Development research of subfertility treatment methods and contraception technology  □ Stem cell research for the development of rare diseases and incurable diseases treatment methods.  □ Other ( ) | | | | | | |
| **Information of embryo** | | □ a number of residual embryos : ( )개  □ residual embryos providing organization : | | | | | | |
| **Personal information collecting, recording, and using of subject or human material donor** | **Collection**  **subject** | | □ Do not collect and record personal information such as name, social security number, etc, of subject or human materials donor.  □ Use anonymous genetic, clinical or epidemiological information.  □ Collect and record personal information such as name, social security number, etc, of subject or human materials donor.  ↘□ No Anonymity  ↘□ Anonymity  ↘ Method of maintaining anonymity  □ Permanently delete □ Replaced by unique identification number(cording)  □ Collect and record sensitive information such as information revealing an individual’s ideology, membership in workers’ union or political parties, political views, health, sex life, genetic information, and criminal records, etc, of subject or human materials donor. | | | | | | |
| **management method** | | □ Discarded after the end of research  □ Keeping after the end of research (storage period : )  □ Providing to other researcher or institution | | | | | | |
| **Risk level of research** | □ level 1 : Minimal risk (measurement of height, weight, blood pressure, etc.)  □ level 2 : Low risk (occurrence of mild headache or muscle aches, stress-induced, etc.)  □ level 3 : Normal risk (May lead to serious aftereffects)  □ level 4 : High risk (May result in death or deformity) | | | | | | | | |
| **Specific description** | |  | | | | | | |
| **Benefit of research** | **Specific**  **description** | | \* Economic rewards for participation in the research are not benefit. | | | | | | |
| **Data Safety Monitoring** | □ Safety inspector (be involved in the research ) (Name: )  □ Academic advisor(Name: )  □ Independent inspector(Name : )  □ Other : | | | | | | | | |

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| **3. Human subjects and Informed consent** | | | | | |
| **Number of Subjects** | □ None  □ Single center study : (Target enrollment: persons)  □ Multicenter study with UNIST  : (UNIST target enrollment : persons / All target enrollment: persons)  □ Pre-existing data or documents ( items) | | | | |
| **Subjects**  **Information** | **Number of Subjects**  \* Adjusting Table by age of age division in accordance with the research plan |  | **Under age 20** | **Between age 20 to 64** | **Over 65** |
| **Male** |  |  |  |
| **Female** |  |  |  |
| **Study Group** | □ Healthy subjects □ Patients □ Vulnerable subjects | | | |
| **Vulnerable Subjects** | □ Pregnant □Minor(under age 20) □ Young/Children  □ Disabled □ Terminally ill patients  □ Employee (research institute, PI, or client, etc.)  □ Prisoners □ Researchers and students of Principal Investigator  □ Patents in mental institutions  □ Subjects recruited by the military or military organization  □ Other incompetent person | | | |
| **Acquiring**  **Consent** | **Classification,** | □ Acquiring Informed consent in writing (\*Submit Informed Consent Form)  □ Acquiring Informed consent except for in writing (\*Submit Waiver or Alternation of Documentation of Informed Consent Explanatory Statement)  □ No need acquiring Informed consent (\*Submit Waiver of Informed Consent Explanatory Statement) | | | |
| **Consent**  **rightful**  **person** | □ Subjects  □ Subjects + Legal representative  (A relationship with subject : )  □ Other( ) | | | |
| **Acquiring person** | □ Principal Investigator □ Co-investigator(Name : )  □ Other( ) | | | |
| **Other** | □ fair observer participation  □ interpreter, etc, auxiliary personnel participation | | | |
| **Acquiring**  **time** | □ Immediately after the explanation about participation in research  □ After the explanation about participation in research  : within ( ) days | | | |
| **Location of research** | Building Name: Room number :  the person in charge : (contact : - - ) | | | |
| **Subject recruitment paper** | □ Use or □ Do not use Documents for recruitment through posters, newspaper ads, e-mail, the internet, etc. \* If you use documents for recruitment, you should submit recruitment documents | | | | |

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| **4. Submitted Documentation list** | |
| **4-1. Required documents : You should submit documents below.** | |
| ■ Research Proposal (version : )  ■ Conflict of Interest Disclosure Form(Included in Protocol Review Application)  ■ Bioethics (Included in Protocol Review Application)  ■ Certificate of completion of bioethics training (All researchers)  \*Limited to within 2 years from the date of application  ■ Principal Investigator CV | |
| **4-2. Optional documents : Please mark "■" to the following documents you are submitting.** | |
| **Consent relevant documents for submission**  \*If human subject research, please submit one of the right documents. | □ Informed Consent Form (version : )  \* In the case that directly collect and use the humanderived materials for research, you should attach the < humanderived materials research agreement> form from Appendix Article 33 of the Enforcement Rule of the Bioethics and Safety Act. |
| □ Waiver of Informed Consent Explanatory Statement  \* If it is determined that you do not need consent, submit this.  □ Waiver or Alternation of Documentation of Informed Consent Explanatory  Statement  \* If you would get consent by means other than written agreement, submit this. |
| **Additional documents for submission** \*Please mark if it is included in the research proposal as well as submitted separately with research proposal. | □ Written oath of Academic advisor \* If research director is graduate student, submit this.  □ CRF(Case Report Form)/experiment daily record/Laboratory research note, etc  □ IRB approval document(other institution)  □ Research funds detailed statement  □ Compensation rule for the damage  □ Subjects recruitment documents  □ Research Tools ((Interview) Questionnaire, etc.)  □ Information or materials provided to subjects except questionnaire  □ MTA(Material Transter Agreement) related to human materials |
| **Other**  **documents for submission** | □ Response to Review Opinion  \*If you received conditional approval or reviewed again after revisions after result from deliberations of new research plan, submit this  □ Change Comparison Table  \*If you received conditional approval or reviewed again after revisions after result from deliberations of new research plan, submit this  □ Other : |

* All information written in this form is consistent with the contents of the research that I want to perform. I submit protocol review application as above.

**(Please, write in your handwriting)**

Date of application : DD/MM/YYYY

Principal Investigator : (Sign)

* As the academic advisor of this research director I reviewed adequacy of the research proposal for the research that the research director wants to perform.

**(Please, write in your handwriting)**

Date of confirmation : DD/MM/YYYY

Academic advisor : (Sign)

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| **Disclosure of Conflict of Interest** | | |
| □ Applied for more than one item of the items below ( **Research-related conflict of interest exists** ) | | |
| **Conflict of interest**  **statement** | □ | (Except to receive research funding) Receive economic benefits totally exceeds 5 million won from research funding agencies in the form of purpose without restriction funds such as research, or education, lectures, consulting, honorarium . |
| □ | Own shares more than 5 million won of the research funding agencies |
| □ | (its value has not been determined yet, or even that value is difficult to convert in the usual manner) Provided economic benefits in the form of share ownership or stock options of research funding agencies. |
| □ | Have rights of patents, patent applications, trademarks, proprietary rights, copyrights and other intellectual property rights in object of research. |
| □ | Receive patent royalty, royalties, etc., in accordance with the merchandising with regard to the sale of research. |
| □ | Receive financial compensation varies by the extent of research results from research funding agencies,. |
| □ | Have formal or informal title in research funding agencies (ex, president, consultant, advisers, directors, etc.) |
| □ | Socially associated excessively with research funding agencies and affecting mutual relationship. |
| □ | Have no other economic benefits or compensation but conflict of interest exists for the fulfillment of the duty of care for subjects, may affect inappropriate to announce results for the research analysis. |
| □ | Research related conflict of interest which corresponds to the above exists to the researcher's spouse (including de facto spouse), parents (including the spouse's parents), and children. |
| **Specific contents** | \* Please describe specific details if there exixt conflict of interest. | |
| □ Not applicable to any of the above items (research-related conflict of interest does not exist) | | |
| * All information fill in this form is consistent with the information on the existence of a conflict of interest related to the research about the researchers and the immediate family members of the researchers. I know that are attributed solely to myself and responsible for the problem caused due to conflicts of interest that are not disclosed to the Commission. * If there are changes in conflict of interest. I will submit conflict of interest disclosure form to the Commission within thirty days from the date of aware and disclose its contents.   **(Please, write in your handwriting)**  **20 . .**  **Director of Research : (Sign)** | | |

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| **Bio Ethics Compliance Pledge** |
| * I will lead the research team of (research title) as a research director with overall responsibility for conducting research, and will perform the role of the ultimate responsibility to perform research, use research funds, balance accounts, and the research reports * I as a research director will lead co-researchers who are responsible for the tasks associated with the research, or determine the necessary changes and research representatives who are responsible for research and practice related research to conduct ethical research under my delegation and supervision * I will put the highest respect for protection of research subjects and perform research ethically and I will comply with 「Bioethics and Safety Act」 and research relevant domestic laws, and respect for international regulations about Bioethics and research ethics. I will fulfill the responsibilities and obligations as researchers in accordance with Committee regulations and guidelines * I respect the decisions and recommendations of the Committee and will start the research after receiving the approval of the Committee for the research plan. * I confirmed that approved research period is one year maximum and I will accept the re-approval in advance through application for change and lasts deliberation for research period in the case of exceed 1 year and also report other changes in the research plan, the research progress, problems to the Committee for deliberation. I will cooperate investigation and supervision of the Committee for the research. * I protect the privacy of the subjects related to the research and ensure the privacy and confidentiality and I will faithfully accede complaint of subjects or request additional information In particular I will make every effort to ensure that the problem does not occur to subjects such as health and safety, confidentiality. If problems occur, I will do my best to solve these issues appropriately. * In the case that there is not enough time and resources required to carry out the research, or significant danger occurred or possible to occur to bioethics or safety due to the research, or significant danger occurred or possible to occur to safety of subjects due to the research, I will take necessary measures such as suspend to perform the research or to terminate research early without delay. |
| **(Please, write in your handwriting)**  **20 . .**  **Director of Research : (Sign)** |