**Informed Consent Form**

Version :

\* When you change consent description, you should mark upgrade version

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| **Basic Information** | | | | | | |
| **Approval Number** |  | | | | | |
| **Title of Research** | (Korean) | | | | | |
| (English) | | | | | |
| **Principal Investigator** | **Name** | **Affiliation** | | **Position** | | **Major** |
|  |  | |  | |  |
| **Tel.** | | **Fax.** | | **E-mail** | |
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| ※ If you have any question or discomfort about risks involved in this Informed Consent, or any damage incurs relating to a research, please feel free to contact researchers stated above ※ Contact and consultation regarding the rights of subjects who participate in the research: UNIST IRB administrator (Tel. 052-217-5214) | | | | | | |

\* Delete examples of each item and researchers should fill the blank.

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| **1. Background and purpose of research** |
| (Example) This research is about (a brief explanation on the research). This clinical test is intended to evaluate the ○○○○ effect of ○○○. (To describe the purpose of research clearly and briefly) |
| **2.**  **The expected period of participation and the estimated total number of subjects** |
| (Example) The expected participation period of this clinical test will be from ○ year, ○ month ○  day to ○ month, ○ day. You will go through tests of ○○ for approximately ○○ months. The  number of subjects is ○○ in total, considering a ○○% dropout rate. |
| **3. Selection criteria and exclusion criteria** |
| (Example) Selection criteria and exclusion criteria of this study are as follows.  Selection Criteria  A.  B.  C.  D.  Exclusion criteria  A.  B.  C.  D. |
| **4. Test and procedure that you have to go through by participating in the research** |
| (Example) If you are selected as a subject suitable for this clinical test, you will visit ○ times per  ○ week(s) for a term of around ○○ months to take a part in the test. Until the end of the test,  you will undergo the following examination and procedure. |
| **5. What the subject must observe for this research** |
| (Example) During the clinical test, you should comply with the following. You need to abide by general health rules such as getting a good night’s sleep on the day before the test, refraining from excessive drinking, and maintaining full cooperation in following the fixed schedule and directions. |
| **6. Unproven experimental part of this clinical trial** |
| (Example) ○○ (a company) developed ○○ to be used in this test by utilizing ○○ and released  research results that it is possible to do ○○ through basic experiments. The experiment stemmed  from the use of the principle of ○○ and shows promise that this ○○ can effectively be used for  ○○. However public evaluations results thus far do not exist regarding how much ○○ of ○○ is  improved. |
| **7. Risk (side effect) or inconvenience that is expected to be imposed on the subject (or a fetus if the subject is a pregnant woman or an infant if the subject is a breast feeder) by participating in this research** |
| (Example) As ○○ to be used in this research does not include an invasive treatment, you are informed that no side effects are known or expected. However, ○○○○○○ may cause discomfort to subjects. Also, you may experience unexpected risks by participating in the clinical research. |
| **8.**  **Benefit that you expect to obtain by participating in the research (If there is no profit, clarify about that.)** |
| (Example) There is no guarantee that you will gain ○○ benefits by participating in this clinical research. However, the information derived from this research will be helpful to ○○ research. It is expected to help identify ○○ in the future. |
| **9. (In case that a test is related with the treatment of a disease) Alternative treatment option for this disease and potential risk and benefit involved in this treatment** |
| (Example) Currently, there are no other treatments available clinically except for the present method. If necessary, surgical treatment can be chosen, but its effect is not confirmed. Among the other types of medicine in the clinical testing stages, there are none whose effects are clearly confirmed. |
| **10. Whether or not there is monetary compensation as well as additional cost that may incur by participating in a research** |
| (Example) As monetary compensation for the participation in this clinical research, the subject will be given a small amount for transportation (KRW ○○○) in exchange for visiting to attending ○ meeting. Subjects will not incur not be paid any additional costs associated with the research. |
| **11. Limitation of research participation** |
| (Example) You participation may be limited without your informed consent if a researcher determines it is necessary to do so.  A. If you do not follow the instructions of researchers  B. in case of serious illness regardless of research participation  C.  D. |
| **12. Even if the subject refuses to participate in a test he or she will neither be biased nor discriminated. In addition, even if the subject agrees to participate in a test he or she may withdraw the decision anytime (except, if there is a compensation paid in advance for participating in a test you should clearly state whether or not it should be returned)** |
| (Example) The final decision regarding whether or not to participate in the clinical research is to be made by you. You can always decide not to participate in the tests and can withdraw your participation in the tests anytime. Even if you refuse to participate in this research, you will not be disadvantaged at all and your decision will not have any affect ○○○○ in the future. |
| **13. Personal Information Collection and protective measures(이용 ․ 관리 ․ 파기)** |
| (Example) In this research, we want to collect personal information including your name, gender, for OOO purposes. We will collect only the minimum amount of information needed to conduct research, we do not intend to collect personal information no needed for research. The personal information is used only from OO (period) to OO (period) for the OOO purpose, and is managed by OOO (method). Your personal information will be deleted or destroyed by OOO (method) after the research. You have the right to ask for the correction, deletion, and viewing your personal information at any time. |
| **14.**  **Strict confidentiality of personal information (by setting privilege to view, save, manage and delete data, concealment of the subject’s identity in publishing the result of a clinical trial** |
| (Example) Your private and personal information will be kept confidential and access to it by the general public will be restricted. However, as long as the relevant law or regulation allows, your personal information can be made available to the review board and to governmental institutions with the aim of verifying the reliability of the clinical test procedure and data. However, even in such a case, the information will be kept in the strictest confidence. When the result of this research is published, your identity will remain confidential. |
| **15. We will notify you or your agent of any new information, if available, that may affect your continuous willingness to participate in a research.** |
| **16. The name of the person to contact and relevant phone number in the event you require additional information or if you suffer any injury related to this research are given below.** |
| (Example) If you have any questions or with to express any discomfort related to this clinical research, please feel free to contact the researcher below.  <Name of researcher: ○○○, Contact number (☎) 042-350-0000 or 010-1234-5678> |

**Informed consent**

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| **Title of Research :** |  |
| **IRB Approval No. :** |  |

Do you agree to use research data (sample) or specimen of your research on secondary with the purposes other than described in this agreement?

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|  | **Use data (samples) as the state including personally identifiable information without further consent.** |
|  | **Use data (samples) as the state possible to trace the subjects identified by coding the data of personally identifiable information without further consent.** |
|  | **Use data (samples) as the state to completely remove personally identifiable information without further consent.** |
|  | **If you use in other types of research, progress after adding the prior written consent.** |
|  | **I do not agree to use for other purposes.** |

**I have no particular relationship with researchers or UNIST that may affect my decision to participate in the research.**

**I have read and understood this Informed Consent and received the response to each and every question. I hereby confirm that I would like to voluntarily participate in the research by signing it. In addition, I confirm that.**

**(Write in your handwriting)**

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| **Subject** | (Name) | (Signature) | (Date) | |
| **Legal agent(if needed)** | (Name) | (Signature) | (Date) | |
|  | (Relationship with subject) | |  |  |
| **Observer(If needed)** | (Name) | (Signature) | (Date) | |
| **Principal Investigator** | (Name) | (Signature) | (Date) | |

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| **We use only approved consent form by UNIST IRB.** |

**Subject consent procedures**

Followings are the principles supposed to comply when the researchers obtain the consent from subjects. When writing consent form, please consider the information below to protect the rights and safety of subjects.

※ The purpose of this page is to guide researchers the process of consent from subjects. **Do not submit this page.**

※ Applicable regulation: Article 17 of the Food and Drug Administration regulations Notice No. 2009-211 "Good Clinical Practice"

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| 1. When researchers receiving consent documenting from the subjects or the legal representative, comply with relevant provisions and should follow the legitimate procedure on the basis of ethical principles based on the Helsinki Declaration.  2. Before obtaining consent, research director or people who received the delegation should provide sufficient time or opportunity to read the written information related to human subject research including the consent form to subjects or legal representatives.  3. Before obtaining consent, research director or people who received the delegation should answer the details of information related to human subject research when they are asked.  4. Researcher should minimize the possibility to affect unfairly forced subjects to participate or to continue to participate in human subjects research.  5. All terms used in the information related to human subjects research, whether oral or written, are easy to understand to subjects, the legal representatives or fair enrollees including consent form.  6. All expressions used in the information related to human subject research should not restrict or seem to imply the legal rights of subjects, or the legal representatives.  7. All expressions used in the information related to human subject research, whether oral or written, should not include exemption of researchers’ responsibilities or neglect of duties including consent form.  8. Before participating in human subject research, subjects (or legal representatives) and the research director (or authorized person responsible for research) should sign on consent Format and write the date.  9. Before participating in human subject research, subjects (or legal representatives) should provide the copy of consent format which has sign and date or copy of the documents provided to other subjects. |