**Report on Interim of Research**

**(Annual Continuing Report)**

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

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. Basic Information** | | | | | | | | | | | |
| **IRB Approval No.** |  | | | | | | | | | | |
| **Approval period** | DD/MM/YYYY ~ DD/MM/YYYY | | | | | | | | | | |
| **Project Name** | (Korean) | | | | | | | | | | |
| (English) | | | | | | | | | | |
| **Type Research** | □ Human subjects 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** | | |  |
|  | | | | | | | | | | | |
| **2.**  **Research Progress** | | | | | | | | | | | |
| **Progress status** | | □ Research has not yet started  □ Recruitment of research subjects + prior to registration  □ Registration in progress + Research-related procedures in progress  □ Registration terminate + Study-related proceedings of enrolled research subjects  □ Complete the study-related procedures of all research subjects + Organize and analyze collected information  □ Complete the research results obtained  □ Research is paused state | | | | | | | | | |
| **Research subjects**  **number** | | The maximum number of research subjects approved by the Committee  : total ( ) persons | | | | | | | | | |
| screening ( ) persons = screening eliminated ( )persons + register ( )persons | | | | | | | | | |
| register ( ) persons = participation completed ( )persons + Dropouts ( )persons + participating ( )persons | | | | | | | | | |
| <Dropout reasons> | | | | | | | | | |
| **Research Plan** | | current research proposal (most recently approved by the IRB)  version: Approved Date DD/MM/YYYY | | | | | | | | | |
| **Research Plan Change** | | Did you have any change in your research plan?  □ No change deliberation history  □ Change deliberation history total ( ) times  \* Write all history of change deliberations.  First change- version : , Approved Date DD/MM/YYYY  Second change- version : , Approved Date DD/MM/YYYY  Final change - version : , Approved Date DD/MM/YYYY | | | | | | | | | |
| **Agreement / Comment** | | □ Not applicable | | | | | | | | | |
| current research plan (most recently approved by the Commission)  version: Approved Date DD/MM/YYYY | | | | | | | | | |
| **Agreement / Comment**  **Change** | | □ Not applicable | | | | | | | | | |
| Did you have any change in your agreement/comment?  □ No change deliberation history  □ Change deliberation history total ( ) times  \* Write all history of change deliberations.  First change- version : , Approved Date DD/MM/YYYY  Second change- version : , Approved Date DD/MM/YYYY  Final change - version : , Approved Date DD/MM/YYYY | | | | | | | | | |
| **Monitoring plan for Research Data Security**  **and Safety of Research Subjects** | | **Contact Name** | |  | | | **Implementation** | | | | □ Yes □ No |
| <implementation result or reason for nonfulfillment > | | | | | | | | | |
| **Risk / benefit** | | Did the risk level of the study or new information that may affect evaluation of the research benefits be published in the literature or have been identified through research or similar research  □ No □ Yes  ↘whether notify this information to research subjects or not : □ Yes □ No | | | | | | | | | |
| Is there any change of research risk level or research benefit?  □ No change □ Risk level increase □ Risk level decrease □ Research benefit increase □ Research benefit decrease | | | | | | | | | |
| **Conflict of interest** | | Is there any change of conflict of interest with research?  □ No change □ Conflict of interest occur □ Conflict of interest increase  □ Conflict of interest decrease | | | | | | | | | |
| **Problem**  **Occur** | | **Minor problems** | | | | case | | | Committee report • approval incomplete ( ) case | | |
| **Major problems** | | | | case | | | Committee report • approval incomplete ( )case | | |
| **Unexpected problems** | | | | case | | | Committee report • approval Incomplete ( )case | | |
| **Major and Unexpected problems** | | | | case | | | Committee report • approval Incomplete ( )case | | |
| < main content of the problem , description of the causal relationship with research , description of measures taken > | | | | | | | | | |
| **Etc.** | | **Non-compliance / violation** | | | case | | | | Committee report • approval Incomplete ( )case | | |
| < main content of the non-compliance/violation, description of the causal relationship with research , description of measures taken ,etc. > | | | | | | | | | |
| **Complaints of research subjects** | | | case | | | |  | | |
| < main content of complaints of research subjects, description of measures taken, etc. > | | | | | | | | | |
| **Research Interim Analysis** | | < information to know the progress of the research, results of research interim analysis, etc. > | | | | | | | | | |
| **Research Progress Plan**  **after deliberations completion of Interim Report** | | < Research overview of the research perform until completion > | | | | | | | | | |
| **Termination report date** | | DD/MM/YYYY | | | | | | | | | |

|  |  |
| --- | --- |
| **3. Submitted Documentation list** | |
| **3-1. Required documents: You should submit documents below.** | |
| ■ Currently using Research Proposal (version : )  \* It refers to the most recently Commission approved. | |
| **3-2. 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. | ■ Currently using Informed Explanatory Statement (version : )  \* It refers to the most recently Commission approved  \* If you approved Waiver of Informed Consent Explanatory Statement (not required to obtain consent) from Commission, submission is not required  \* If you approved Waiver of Alternation of Documentation of Informed Consent Explanatory Statement(Obtain verbal consent is possible without written consent), only statements submission is required. |
| **Additional documents for submission** \*Please mark if it is included in the research proposal as well as submitted separately with research proposal.. | □ 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 Transfer Agreement) related to human materials  □ Principal Investigator CV |
| **Other**  **documents for submission** | □ All copies of Informed Consent Explanatory Statement obtained from research subjects  \* If the Commission require, submit documents. Scan to file submission is possible.  \* If you approved Waiver of Informed Consent Explanatory Statement (not required to obtain consent) or Waiver of Alternation of Documentation of Informed Consent Explanatory Statement(Obtain verbal consent is possible without written consent), submission is not required  □ Copy of human derived materials(test object) management register  \* It refers to legal format “Bioethics and Safety Act". [Appended Form No. 35]  \* If the Commission require, submit documents. Scan to file submission is possible  □ Certificate of completion of bioethics training (All researchers)  \*Limited to within 2 years from the date of application  □ Response to review opinion  □ Change comparison table  □ Others : |

* All information written in this form is consistent with the contents of the research that I want to perform. I submit Interim Report 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 interim report for the research that the research director wants to perform.

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

Date of confirmation : DD/MM/YYYY

Academic advisor : (Sign)