**Research Proposal (For Human Subjects)**

Version :

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

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| **1. Title of Research Project** |
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| **2. Research background** |
| - Describe related studies and justify the need for research  - Present an ethical stance and suggest ways to resolve possible ethical problems that may arise in research  - Describe the appropriateness of research facility in terms of safety and function, and provide supporting statistics for the region or country |
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| **3. Research purpose** |
| - Describe purpose of research |
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| **4. Research subject** |
| - Specify selection/exclusion criteria for direct recruitment of subjects  - Justify your scope of recruitment in terms of age, gender, and social/economic factors  - Specify methods of subject allocation for case-control studies  - Provide reasons for including vulnerable populations and/or subjects with limited ability to consent, and introduce measures to minimize risk for such subjects  **(※ Under the 'Bioethics and Safety Act, students or researchers of research director, and undergraduate students under the age of 18 (minors) are classified as vulnerable subjects. Inevitably if these subjects’ participation are necessary, the participation should be voluntary and please describe the reason together. )** |
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| **5. Target number of subject enrollment and basis of calculation** |
| - Provide details in case of direct recruitment  - Provide evidence for target number based on past research or statistics  - Target number should be the minimum number of subjects required to obtain meaningful results |
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| **6. Recruitment of subjects** |
| - Describe measures needed to protect personal information and maintain confidentiality during recruitment (if applicable) |
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| **7. Informed consent** |
| - Describe plans to obtain written consent from subjects and procedures of delivering information to subjects  - Submit reasons for exemption from obtaining written consent (if applicable) |
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| **8. Research method** |
| - Describe the details of any procedure, treatment, acts.(research subjects’ work for research and time required)  - Describe the people who can affect the research subjects’ willingness which last research plans, procedures, and research, who are responsible to deliver information that may arise from other studies with the same subject or from other research (For example, damage or profit) |
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| **9. Observation item** |
| - Specify information or data to be obtained from research |
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| **10. Outcome evaluation criteria and evaluation methods** |
| - Specify evaluation criteria and methods pertaining to research outcome |
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| **11. Safety evaluation criteria and evaluation methods** |
| - Specify evaluation criteria and methods pertaining to research safety |
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| **12. Data analysis and statistical methods** |
| - Specify methods of data analysis and statistical applications |
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| **13. Expected adverse effects and precautions** |
| - Describe adverse effects or serious adverse effects that may arise in research  - Define “serious adverse effects” and provide related procedures  - Provide regulations for excluding researchers/institutions, or terminating the research  - For research involving pregnant women, provide monitoring plans for long-term effects on the health of women and babies  - Provide safety monitoring plans and designate independent committees for medicinal products or procedures involved in research |
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| **14. Disqualification/withdrawal criteria** |
| - Describes cases in which subjects are withdrawn by researchers |
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| **15.Risks and benefits for research subjects** |
| - Describe risks or inconveniences that subjects may experience from participating in research  - Describe potential or unexpected risks of procedures involved in research  - Describe possible benefits for subjects from participating in research |
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| **16. Safety measures and personal information protection for research subjects** |
| - Describe safety measures adopted to protect research subjects, and compensation/treatment in case of damages incurred during research  - Describe plans for treatment of injuries caused by conducting research with higher than minimal physical risk, and insurance coverage in case of disabilities or death  - In case of collecting personal information of subjects, specify items to be collected and methods of storage/disposal |
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| **17. Reference** |
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