**AjouIRB E-IRB Guidelines (for researcher) (v1.0\_20220428)**

**<Application Process for E-IRB Review>**

1. Completion of IRB Education(All IRB Users)

2. Registration of E-IRB(<http://eirb.ajou.ac.kr/login>) (All researchers, available after approval)

3. Click 연구이력(researcher history)/교육이수관리(IRB training completion) in the left colum in E-IRB system and Upload C.V. and IRB training certificate (deliberation after approval)

4. Deliberation fee(payment amount by review type: <http://irb.ajou.ac.kr/irb/index.jsp>)

5. Fill in E-IRB system left to right tab.

**<IRB Review Classification>**

**1. 인간대상연구(Human subject research project):** a research project specified by ordinance of the Minister of Health and Welfare, such as a research project physically involving a human being as a subject, a research project conducted through communication, physical contact or other means of interaction, a research project conducted by using information with which individuals can be identified**.**

**2. 인체유래물연구(Human materials research project):** research project on human

materials through direct examination and analysis**. Human material means** a component of the human body, such as a tissue, a cell, blood, or body fluid collected or extracted from the human body, or serum, plasma, chromosomes, DNA (Deoxyribonucleic Acid), RNA (Ribonucleic Acid), protein, etc. isolated from such component

**<IRB review Type>**

**1. 신규심의(Initial review):** First review about human research to get an approval

**2. 보완 후 재심의(Re-examination review):** Review of modified research plan which required by initial review

**3. 심의면제(Exemption):** Review about researches with minimal risk and without vulnerable subject. Exemption does not mean exemption from consent.

**4. 지속심의(Continuing Review):** Review to remind the initial review at least once a year(must be submitted within the approval validity period)

**5. 변경심의(Revision review):** Review to change method, tool, research members, duration or informed consent(must be contained in continuing review and termination report)

**6. 문제발생(Problem arising):** Reports that have problems during previous approved studies(must be contained in continuing review and termination report)

**1) 연구계획 미준수(Noncompliance):** Research conducted differently from the research plan(should be reported within 48 hours)

**2) 중대한 이상반응(Serious adverse event):** Event may cause serious harm to the subject such as suicide or death(should be reported within 10 days)

**3) 예상하지 못한 문제(Unexpected adverse reaction**): Unexpected problems such as loss of consent, fire, and flooding, etc. (should be reported promptly)

**4) 연구의 조기종료(Early termination):** Early terminated research before estimated.

**7. 종료보고(Termination report):** Report that experiments and interaction between the researcher and the human subject has been completed(should be submetted within 3months)

**8. 결과보고(Result Report):** Report on the intellectual output (such as journal, report, thesis(dessertation) and patent, etc.) produced through analysis after completion of the research (should be submitted within 1year, IRB approval number must be entered in the output). If there is no output, you write there is no output.

**<Functions of IRB review Committee>**

**1.** Examination of the following matters

가. Ethical and scientific validity of a research plan

나. Whether consent has been duly obtained from human subjects of research

다. Matters regarding the safety of human subjects of research

라. Measures for protecting personal information of human subjects of research

마. Other matters regarding bioethics and biosafety in the relevant institution

**2.** Inspection and supervision of the progress and outcomes of research projects executed by the relevant institution

**3.** The following activities for bioethics and biosafety

가. Education of researchers and employees of the relevant institution

나. Formulation of measures for protecting human subjects of research or donors in a vulnerable position

다. Establishment of ethical guidelines for researchers

4. Cancellation of approval and request for disciplinary action

**<Ajou Institutional Review Board>**

1. Location: 율곡관 building Yulgok #509 (office), 율곡관 building Yulgok #353-5 (meeting room)

2. Contact: [ajouirb@ajou.ac.kr](mailto:ajouirb@ajou.ac.kr) 031-219-3742~4

3. Dealine for application: The first Wndnesday of every month at 5pm

3. Homepage: <http://irb.ajou.ac.kr/irb/index.jsp> (for users before January 2016)

4. E-IRB system: <http://eirb.ajou.ac.kr/login> (for users after January 2016)

5. Inquiries regarding other relevant laws and policies: Korea National Institute for Bioethics Poicy, KoNIBP (<https://www.nibp.kr:5002/xe/> 02-737-8910), IRB Information Portal (<http://www.irb.or.kr/> 02-737-8957)















