

Ritsumeikan Asia Pacific University Guideline of Ethical Conduct in Research Involving Human Subjects

1. Aim

- (1) These guidelines supplement the ethical standards of behavior and approach expected of APU researchers conducting research involving human subjects, one of the types of research addressed by the Ritsumeikan Asia Pacific University Research Ethics Guidelines.

2. Fundamental research norms

- (1) Any researcher conducting research involving human subjects must have respect for the life, dignity and fundamental human rights of the individual, and engage in his/her research using methods and techniques that are both scientifically and socially legitimate.
- (2) Any researcher conducting research involving human subjects must use methods that are secure and safe, and endeavor to minimize any physical or psychological burden and/or discomfort experienced by the subject.

3. Definitions

For the purposes of these guidelines, the terms indicated in each of the following items shall be accorded the meaning specified in that item.

- (1) “Research involving human subjects” means any investigation or experiment in the course of a clinical study or a field study in the humanities or social sciences, including any activity that involves gathering information or extracting data pertaining to the behavior, physical or mental state, environmental circumstances or other characteristic of an individual or group subject.
- (2) “Personal information or data” means any information or data pertaining to the thoughts and beliefs, feelings, physical traits, behavior, environmental circumstances or other matter specific to either an individual or a group.
- (3) “Researcher” means any faculty member of this university, as well as any undergraduate student, graduate student or research associate engaged in research activity at this university.
- (4) “Research subject” means any person who becomes the subject of research by providing personal information or data for research purposes.

4. Researcher accountability

- (1) When gathering or collecting personal information or data, the researcher must explain to the research subject matters including the aims and plans of the research and the methods for presentation of research findings, using language that is comprehensible to the subject.
- (2) If gathering or collecting personal information or data is foreseen to involve any kind of physical or psychological burden and/or discomfort to the research subject, the researcher must explain to the subject that which is foreseen, using language that is comprehensible to the subject.

5. Informed consent

- (1) It is a basic rule that when gathering or collecting personal information or data, the researcher must obtain the consent of the research subject in advance.
- (2) “The consent of the research subject” must include matters pertaining to the handling of personal information or data and the methods for presentation of findings.
- (3) The researcher must inform the research subject that he/she has the right to withdraw consent and cease cooperating with the research and the right to demand disclosure of any personal information or data already obtained,

and that these rights can be exercised at any time during the period in which the research is undertaken and with no disadvantage to the subject.

- (4) If the research subject is judged unfit to provide consent, the researcher must obtain consent from a person acting on behalf of the subject.
- (5) The consent of the research subject must in principle be recorded in writing, and the researcher must store this record of consent for a minimum of five years counting from the date on which the record was created.
- (6) If the research subject withdraws his/her consent, the researcher must destroy all information and data relating to the subject.

6. Third party involvement

If the researcher engages a third party to gather or collect personal information or data on his/her behalf, the researcher and third party must enter into a contract in conformity with the aims of these guidelines.

7. Gathering and collecting in class situations

If a faculty member intends to gather or collect personal information or data for research purposes from a student in the course of a class, seminar, practical exercise, experiment, training or other educational activity, he/she must obtain the student's written consent in advance.

8. Remuneration

If the researcher intends to provide the research subject with remuneration in money or kind, he/she must determine a remuneration that ensure proper administration of its disbursement and receipt.