

Nagoya Institute of Technology Regulations on Bioethics Review Committee

Established on May 13, 2005

(Purpose)

Article 1 The purpose of these Regulations is to ensure that research undertaken at Nagoya Institute of Technology (hereinafter, “Institute”) that directly involves human subjects (hereinafter, “research”) is properly conducted with respect for human dignity and human rights and the understanding and cooperation of society, in line with the Declaration of Helsinki, the Ethical Guidelines for Human Genome/Gene Analysis Research (Notification No. 1 of the Ministry of Education, Culture, Sports, Science and Technology [MEXT], the Ministry of Health, Labor and Welfare [MHLW] and the Ministry of Economy, Trade and Industry [METI], 2001), the Ethical Guidelines for Epidemiological Research (Notification No. 2 of the MEXT and MHLW, 2002) and the Ethical Guidelines for Clinical Research (Notification No. 459 of MHLW, 2004).

(Establishment)

Article 2 To achieve the purpose stated in the preceding article, the Institute shall establish the Nagoya Institute of Technology Bioethics Review Committee (hereinafter, “Committee”).

(Organization)

Article 3 The Committee shall consist of the committee members listed in the following items.

- (1) An Executive Director appointed by the President
 - (2) A Vice-President appointed by the President
 - (3) A professor and an associate professor selected from each college (one professor or one associate professor)
 - (4) An academic in the humanities and social sciences, including ethics and law, who is not a staff member of the Institute (one person)
 - (5) An academic in natural science who is not a staff member of the Institute (one person)
 - (6) A Manager of the Research Support Division
 - (7) Some other persons if deemed necessary by the President (a few persons)
2. The committee membership in the preceding items includes both males and females.
 3. At the time of discussion and vote, at least one committee member specified in (4) or (6) of Paragraph 1 must be present at the meeting.
 4. A person who is involved in the clinical research for which the review is being conducted should not participate in the discussion or decision on the relevant clinical research. However, such person may attend meetings and express opinions, upon the request of the Committee.

(Duties)

Article 4 The Committee shall examine the content of the research plan submitted by an applicant and the publication of research findings.

(Review)

Article 5 The Committee shall conduct a review, taking into consideration the matters listed in the following items.

- (1) Ethical consideration for the protection of human rights of research subjects
 - (2) How to obtain understanding and consent from research subjects
 - (3) Consideration of disadvantages and risks to subjects which may arise during research
2. The Committee may invite persons who are not committee members to attend the meeting and ask for their opinions, when it deems such action necessary.

(Term of Office)

Article 6 The term of office of the committee members provided for in (4), (5) and (7) of Article 3 shall be two years, but this does not preclude reappointment. However, the term of office for a successor who is appointed to replace a resigned or dismissed member before the expiration of his/her term shall be the remaining office term of the predecessor.

(Chair)

Article 7 The Committee shall have a Chair. The Chair shall be an Executive Director or the Vice-President appointed by the President.

2. The Chair shall preside over all Committee meetings.
3. A committee member appointed beforehand by the Chair shall act for the Chair in his or her absence or incapacity.

(Quorum and the Number of Votes Required to Pass a Resolution)

Article 8 The quorum for any Committee meeting shall be a majority of its members.

2. A resolution on an agenda item at a committee meeting shall be made by a majority of the attending members. When the number of votes for and against is the same, the Chair shall make the final decision.

(Application Procedure)

Article 9 The person responsible for the research shall apply for a review of the research plan, by submitting the prescribed application form to the President, along with consent forms from the research subjects (if necessary). The same shall apply to a case where an approved research plan is to be changed.

2. The President shall, upon receipt of an application as in the preceding paragraph, consult the Committee immediately.

(Decision of the Committee)

Article 10 The decision of the Committee shall be one of the following:

- (1) Approval
- (2) Conditional approval
- (3) Reward for changes to the research plan
- (4) Denial
- (5) Not applicable

2. If approval or conditional approval is granted, the research can be undertaken.

(Notification of Decision)

Article 11 Upon completion of the review, the Chair shall report the results to the President.

(Re-review)

Article 12 If the applicant has an objection to the Committee's decision, he/she may file a request for re-review.

2. A request for re-review must be made to the President by submitting the prescribed application form for re-review.
3. The request for re-review prescribed in the preceding paragraph shall be made within two weeks from the day following the date of receipt of notice of the Committee's decision.

(Certification of Review)

Article 13 When a certification for an ethical review is required to publish a research paper in a journal, etc., such certification shall be issued by the President following the approval of the Committee.

(Protection of Personal Information)

Article 14 With regard to the protection of personal information, the Nagoya Institute of Technology Regulations on the Protection of Personal Information (established on March 22, 2005) shall be applied.

(Administrative Matters)

Article 15 Administrative matters relating to the Committee shall be handled by the Research Support Division.

(Miscellaneous Provisions)

Article 16 In addition to what is stipulated in these Regulations, necessary matters concerning the Committee shall be determined separately by the President.

Supplementary Provisions

These regulations shall take effect on May 13, 2005.

Supplementary Provisions

These regulations shall take effect on April 1, 2007.

Supplementary Provisions

These regulations shall take effect on May 1, 2009.

Supplementary Provisions (Regulation No. 7 of July 26, 2012)

These regulations shall take effect on August 1, 2012.

Supplementary Provisions (Regulation No. 1 of April 1, 2014)

These regulations shall take effect on April 1, 2014.