Article Content

Title：	Regulations on Human Trials CH
Amended Date：	2016-04-14
Category：	Ministry of Health and Welfare（衛生福利部）

Article 1 These regulations (hereinafter “Regulations”) are enacted pursuant to Article 79-1 of the Medical Care Act (hereinafter “this Act”).

Article 2 A human trial research (hereinafter “Human Trial” shall be conducted prior to the registration of a new drug or medical device or before a medical care institution lists a new medical technology as a regular medical disposition item.

Article 3 With regard to the Human Trial, a medical care institution shall draft a proposal and submit same to the central competent authority for approval.
The proposal referred to in the preceding paragraph shall indicate the following items:
1. The subject.
2. The purpose.
3. The method.
1) The conditions of the person accepting the Human Trial (hereinafter the “Trial Subject”), recruitment method, and number of Trial Subjects required.
2) Implementation methods.
3) Duration of the Human Trial and scheduled progress.
4) Evaluation of treatment results and statistical methods.
5) Track of Trial Subjects and necessary rehabilitation plans.
4. The contents of Trial Subject consent forms.
5. The academic and professional background and received training of the trial conductor(s) and assistant trial conductor(s).
6. Relevant domestic and international publications and reports.
7. Relevant documents of proof in the event that the Human Trial has been approved overseas.
8. Required medicament or equipment including the name and quantity of the medicament or equipment to be imported.
9. Anticipated effects.
10. Possible damages and responding remedies.

Article 3-1 For the treatment of specific patients with life-threatening diseases or serious disabilities for which no effective drugs, medical devices, or medical technologies are available in

Taiwan, a medical care institution may draft a subsidiary proposal for a human cell therapy trial that has been approved by the central competent authority and has accumulated a considerable amount of safety data, and may submit the same, together with a photocopy of the original human trial proposal approved, for review in accordance with Paragraph 3 of Article 78 of this Act. After approval by the Review Board, the institution may apply to the central competent authority for approval of using the drugs, medical devices, or medical technologies involved on patients who meet the indications but fail to meet the eligibility criteria for original human trial subjects.

A medical care institution may charge the specific patients set forth in the preceding paragraph fees, without being subject to the provisions of Article 11. However, the amount of fees charged shall be limited to an amount that is sufficient to cover the fees incurred by handling, manufacturing, obtaining, transporting, or storing the drugs, medical devices, or medical technologies required for performing human cell therapies on such specific patients.

A medical care institution must not perform regular medical treatments under the pretense of carrying out the subsidiary proposal, and must not charge fees from specific patients in violation of the fee rules stipulated in the approved subsidiary proposal.

The subsidiary proposal, as set forth in Paragraph 1, shall indicate the following:

1. Reasons and purposes;
2. Methods: including the conditions of the specific patient(s), recruitment method, number of persons enrolled, implementation method, duration and schedule, track and necessary rehabilitation plans;
3. Possible damages and responding remedies;
4. An analysis, list, and amount of the cost for the fees if fees will be charged, and the methods of providing subsidies or the amount of subsidies if subsidies are provided.

The number of specific patients enrolled, as set forth in Subparagraph 2 of the preceding paragraph, shall not exceed the number of original human trial subjects.

The subsidiary proposal conductor shall be the conductor of the original human trial proposal. The disclosure, review, avoidance, inspection, disposition or termination, retention, reporting, publication or promotion of the trial subject consent forms and proposals, as well as the destruction or reutilization of the data thereof, shall be subject to the applicable provisions of this Act and these Regulations.

Article 4

The trial conductor referred to in the preceding article shall possess the following qualifications:
1. being a licensed physician, dentist, or traditional Chinese medicine physician with five (5) or more years of experience in clinical treatment.
2. having received human trial related training of more than thirty (30) hours within the past six (6) years; being the trial conductor in Human Trials of somatic cells or gene therapy with additional five (5) or more hours of relevant training.
3. taking medical ethics related courses for more than nine (9) hours within the past six (6) years.
Those who have been subject to physician disciplinary or whose licenses have been suspended for more than one (1) month or abolished due to any violation of laws and regulations related to Human Trials shall not serve as a trial conductor.

Article 5 With regard to the adult or minor but married Trial Subject recruited in accordance with the proviso of Article 79, Paragraph 1 of this Act, the trial conductor shall obtain the consent of his/her interested party in the following priority order:
1. Spouse
2. Parent
3. Cohabiting adult child
4. Cohabiting grandparent
5. Cohabiting brother or sister
6. Any relative who has cohabited with the Trial Subject within the past one(1) year
The consent of the interested party set forth in the preceding paragraph shall not be against the Trial Subject’s will.

Article 6 With regard to the joint review of the Human Trial proposal referred to in Article 78, Paragraph 3 of this Act, the name list of the joint review board members and meeting minutes of the review board (hereinafter the “Review Board”) shall be disclosed to the public.
Relevant rules regarding the review referred to in the preceding paragraph shall be stipulated and disclosed.

Article 7 The following matters shall be attended to when reviewing the Human Trial:
1. The design of the Human Trial shall be of the lowest risks and take into account the reasonable risks and benefits.
2. Execution and contents of the Human Trial in compliance with scientific principles.
3. Conditions of the Trial Subject and recruitment methods.
4. Medical care and compensation or other remedy provided to the Trial Subject.
5. Protection of the Trial Subject’s privacy.
6. Contents of Test Subject consent forms and notification procedure.

7. Protection of vulnerable groups.
8. Necessary management measures protecting the Trial Subject's safety.

Article 8 A review board member shall immediately recuse himself/herself in any of the following circumstances:
1. serving as the trial conductor, assistant trial conductor, or entrustor of the Human Trial.
2. being, currently or in the past, the spouse, blood relative of four degrees or closer, or relative by marriage of three degrees or closer of the trial conductor.
3. being in an employment relationship with the entrustor of the Human Trial.
4. being in other situations where the recusal of the review board member is deemed necessary by the Review Board.
The Review Board shall audit those Human Trials reviewed and approved by this Review Board at least once a year.

Article 9 The Review Board, if discovering any of the following matters in the audit referred to in the preceding paragraph, may order the Human Trial to be improved within a prescribed period of time or terminated:
1. where the contents of the Human Trial are altered without the approval of the Review Board or central competent authority as required by law.
2. where the rights, interest, or safety of the Trial Subject is obviously affected.
3. where the frequency or seriousness of the occurrence of adverse events is abnormal.
4. where the existence of an occurrence is sufficient to affect the evaluation of Human Trial results.
5. where specific facts exist before the completion of the Human Trial proving that the Human Trial has no actual benefits, higher risks than potential benefits, or actual benefits that are disadvantageous to the control group.
The central competent authority when learning of the adverse event(s) referred to in the preceding paragraph may order the Human Trial to be terminated.

Article 10 The Review Board shall preserve the relevant documentation, such as Human Trial proposal, meeting minutes, or audit records for at least three(3) years after the completion of Human Trial.

Article 11 The medical care institution shall not charge the Trial Subject for any fees related to the Human Trial.

Article 12 The medical care institution shall report to the central competent authority when the Trial Subject experiences any of the following occurrences during the Human Trial period or

anytime when any of the following occurrences are related to the Human Trial:
1. Death.
2. Life-threatening.
3. Permanent mental and physical disability.
4. where the fetus or newborn of the Trial Subject suffers congenital malformations.
5. Complications requiring hospitalization or prolonged hospitalization.
6. Other complications possibly causing permanent damages.
The medical care institution shall make such report referred to in the preceding paragraph within seven (7) days after learning of the occurrence(s) and submit detailed investigation information to the central competent authority within fifteen (15) days.

Article 13 The central competent authority may order the medical care institution that conducts the Human Trial to provide relevant information, such as a summary of Human Trial proposal, case numbers, sex ratio, age statistics, review results of Trial Subject consent forms, and possible risks; or conduct necessary audit which the medical care institution shall not impede, avoid, or refuse.
The audit referred to in the preceding paragraph may be done by relevant organizations as entrusted by the central competent authority.

Article 14 The Trial Subject’s biological samples, personal data, or derivatives shall be destroyed immediately upon completion of the Human Trial. The reutilization of aforesaid material(s) as subject to the Trial Subject’s consent shall be reviewed and approved by the Review Board. A new written consent shall be obtained from the Trial Subject with regard to any non-delinked material(s).

Article 15 The medical care institution shall not publish or promote its results during the Human Trial period.

Article 16 These Regulations shall become effective as of the day of promulgation.