National Cheng Kung University Hospital

Human Research Protection Plan

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Document Establishment/Revision History

Version	Date	Establishment/Revision Note	Maintenance Unit: HRPC	
			Maintained by	Approved by
V1	20180117	Establishment of the Human Research Protection Plan	Yu-Chen, Tsai	Chih-Sheng, Lin
V2	20180801	1.Add the criteria of conducting human trials only in teaching hospitals 2.Add range of evaluation	Su-Ruey Chen	Chih-Sheng, Lin

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PURPOSE

The Human Research Protection Plan (hereinafter referred to as the "HRPP") is established in accordance with the Code of Human Research Protection of National Cheng Kung University Hospital (hereinafter referred to as "NCKUH"). The Plan aims to ensure that the subjects' right and welfare are protected and researchers in NCKUH execute the research in accordance with the human research-related laws and ethical regulations.

I.Scope

(I) Any personnel involved in HRPP, such as Superintendent, officials, Human Research Protection Center, IRB, Clinical Trial Center, Clinical Medicine Research Center, Pharmacy Department, Department of Legal Affairs Office and research team, shall be obligated to comply with HRPP.

(II) Activities are subject to the oversight of HRPP when the research are executed in NCKUH or the principal investigators of the researches are the personnel of NCKUH.

II.Definitions

(I) Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

(II) Human Subject Research: It refers to research involving obtaining, investigating, analyzing, or using human specimens or an individual person's biological behavior, physiological, psychological, genetic or medical information.

(III) Human trial: Refers to an experimental research of new medical technology, new medicament, new medical implement, or the bioavailability and bioequivalence of generic drugs conducted by medical care institutions on humans based on medical theory.

(IV) Human specimens: Refers to human (including a fetus and corpse) organs, tissues, cells, body fluids, or any derivative biomaterial arising from experimentation therewith.

(V) Human participant: A living individual about whom a researcher conducting research obtains data through intervention or interaction with the individual, or identifiable private information.

III.Responsible Unit

The roles and functions of each unit related to Human Research Protection Program are stipulated below.

(I) Superintendent:

1. In charge of overall planning of Human Research Protection Program.
2. Authorizing the Director of Human Research Protection Center to maintain and supervise Human Research Protection Program.

(II) Human Research Protection Advisory Committee:

1. Providing consultation on the strategies and regulations related to Human Research Protection Program.
2. Supervising the implementation of human subject protection.
3. Enhancing the quality of human subject protection.

(III) Human Research Protection Center (HRPC):

1. Under the authorization of Superintendent, the Director of Human Research Protection Center should hold sufficient knowledge about Human Research Protection Program and should ensure that the human subject protection be executed independently.
2. Establishing the strategies and policies about the protection of human subjects.
3. Consolidating, coordinating, managing and overseeing the affairs related to protection of human subjects.
4. Periodically evaluate whether the resources related to the Human Research Protection Program are sufficient.
5. Handling accreditations related to human subject protection.
6. Operating Human Research Protection Advisory Committee.
7. Establishing a quality management plan that can audit and improve affairs related to Human Research Protection Program.
8. Holding training programs related to the human research protection.
9. Handling consultations, complaints, or suggestions from human subjects, researchers, and others with respect to the issues related to human subject protection.
10. Processing incidents interfering the review procedure of IRB or affecting IRB’s operation.
11. Operating Human Research Conflict of Interest Committee.

(IV) Institutional Review Board (IRB):

1. Determining whether a research refers to a human research.
2. Conducting ethical and scientific review of human researches.
3. Auditing the ethical issues of human researches.
4. Maintaining the confidentiality of human research plans.
5. Holding training programs for IRB chair, members and staffs.
6. Handling the consultations, complaints or suggestions related to human researches.

(V) Clinical Trial Center (CTC):

1. Determining whether a research refers to a human research.

2. Arranging and supervising the contract review between sponsors and NCKUH.
3. Auditing the quality of clinical trials.
4. Holding training programs for researchers, research staffs and human subjects.

(VI) Clinical Medicine Research Center (CRC):

1. Determining whether a research refers to a human research.
2. Conducting scientific reviews of human researches
3. Holding training programs for researchers.

(VII) Investigational Pharmacy:

Being a division of Department of Pharmacy, exclusively responsible for safety management of investigational products.

(VIII) Department of Legal Affairs:

Provide the consultation service about human research laws and ethical regulations.

(IX) Where the human researches needed to be reviewed by Radiation Protection Management Committee or Biosafety Committee or Department of Biomedical Engineering, said Committee or Department shall complete reviews and deliver the review results to IRB promptly.

IV.Operational Rules

(I) All employees of NCKUH, IRB members, Chair of IRB, research team and students shall comply with the laws, decrees, ethical regulations, and NCKUH internal rules adequately. The related laws, decrees and ethical regulations include but are not limited to the Human Subjects Research Act, Medical Care Act, GCP, Human Biobank Management Act , Personal Information Protection Act, Belmont Report, Declaration of Helsinki and ICH E6 Guidance for Industry.

(II) NCKUH's Human Subject Protection Mechanism

1.Independence of review by Institutional Review Board (IRB)

(1)NCKUH authorizes IRB to function independently to review human research. Any human research that has not yet been reviewed and approved by the IRB shall not be executed with any excuse.

(2)NCKUH employees are prohibited from forcing, threatening, exercising their delegated power or using other undue methods to interfere on the review process, to intend to change the determinations of IRB or to influence on how IRB members and staff fulfilling their duties. In the case of said circumstance, the IRB will notify the HRPC its investigation result. Relevant regulations should be established by IRB and HRPC.

2.Financial interests and non-financial relationships management mechanism

(1)The HRPC shall hold the Human Research Conflict of Interest Committee meeting

periodically, in order to review the financial and non-financial conflicts of interest potentially arising from the human research.

(2)The officials of NCKUH, HRPC staff, IRB members and staffs, Clinical Trial Center staffs, Clinical Medicine Research Center members, research team, and any other personnel involved in HRPP shall declare and disclose their financial and non-financial interests to HRPC periodically.

(3)The related regulations for holding Human Research the process of Conflict of Interest Committee meetings and declaring and processing the conflict of interest shall be established by the Human Research Conflict of Interest Committee.

3.Education Program

(1)Research team:

A.The Clinical Trial Center and Clinical Medicine Research Center shall be responsible for planning the research team's training. The related details thereof shall be established by the Clinical Trial Center and Clinical Medicine Research Center.

B.The content of the training programs should include the method of research, design of research, regulations related to the subjects' protection, conflicts of interest, and NCKUH internal human research requirements.

C.The required training hours of members in the research team should be regulated by the IRB. If the research team fails to complete the educational training hours, the IRB will not accept its human research.

(2)Institutional Review Board (IRB):

A.IRB shall be responsible for planning the training. The related details thereof shall be established by the IRB.

B.IRB members and administrative staff shall all complete the educational training. The training hours to be completed shall be based on the standard operating procedures established by the IRB.

C.The content of the training programs should include the regulations related human research, conflicts of interest, and information published by Ministry of Health and Welfare of Taiwan.

(3)Other personnel involved in HRPP:

A.The HRPC shall be responsible for the planning. The training course related details thereof shall be established by the HRPC.

B.The HRPC Director shall urge the unit members to complete the training.

C.The content of the training programs should include the regulations related human research, conflicts of interest, and information published by Ministry of Health and Welfare of Taiwan.

(4)Educational programs for the programs public (including subjects and potential subjects):

A.The Clinical Trial Center shall be responsible for the. The related details thereof shall be based on the Clinical Trial Center's educational plan.

B.The content of the programs should include the regulations related human subject protection, the public knowledge about the human research and other related topics.

(5)Each unit in charge of educational training planning shall periodically evaluate the results of the training programs.

4.Applicable laws

(1)Only teaching hospitals may conduct human trials, unless the Ministry of Health and Welfare has granted approval based on the specific expertise of the non-teaching hospital.

(2)All human research protocols executed in Taiwan shall comply with the laws and regulations of Taiwan.

(3)Where there is any question about laws or ethical regulations of human research, the department of Legal Affairs should provide legal consultation.

(4)In the case of multi-national human research led by the NCKUH, the research should be ensured that participants in other countries have the same protections as NCKUH participants do, and that research complies with local regulations and respects the sociocultural background of local participants.

5.Investigational product management

(1)Only researches involving investigational product approved by IRB upon review may be under control. Investigational product involved in researches conducted in NCKUH, should be managed by Investigational Pharmacy.

(2)Relevant management regulations over the investigational product shall be established by the Investigational Pharmacy of Department of Pharmacy.

6.Contract Execution

NCKUH may not sign the contract with the sponsor, unless the Clinical Trial Center ensures that the research team has obtained the approval of IRB.

7.Quality management of human subject protection

The HRPC shall have a quality management plan in place to review and evaluate the subject protection quality management by the units involved in HRPP and the research team.

8.Consultation or Complaint

(1)IRB handles the consultation, complaint or suggestion about NCKUH's human research made by human subjects, researchers and others. The related regulations

shall be established by the IRB.

(2)The HRPC handles the consultation, complaints or suggestions about NCKUH's subject protection affairs from human subjects, researchers and others. The related regulations shall be established by HRPC.

9.Evaluation of the resources

(1)NCKUH shall ensure that there are sufficient resources to execute HRPP, e.g. human resource, equipment, finances, information technology, systems, spaces, et al.

(2)HRPC shall evaluate resources needed for the HRPP, including but not limited to HRPP education program, legal counsel, conflict of interest, quality improvement plan, community outreach, and IRBs.

(3)The HRPC will send the annual resources evaluation forms to these units. CTC, CRC and investigational pharmacy shall insert their evaluation results into the annual resources evaluation forms and submit the same to HRPC.

(4)The HRPC Director shall be responsible for evaluating and allocating the resources according to the annual resources evaluation form to support effective operation of HRPP, and may adjust the resources, if necessary.

(5)The number of staff needed and office spaces/appliances shall be established base on the establishment policy of each unit to ensure the units operation of HRPP. Units shall conduct the evaluation based on the original resources evaluation method applied by their own departments and subject to the nature and workload of the subject protection affairs handled by the unit.

(6)The budget allocated to the related units involved in HRPP shall contain the personnel expenses and educational training expenses sufficient to maintain operation of HRPP. If extra budget is needed to maintain human research protection affairs, units shall report to NCKUH and sufficient resources shall be funded by NCKUH.

(7)Generally, IRB maintains its operation by the review income. If IRB suffers loss, the loss shall be reported to NCKUH and made up by NCKUH, in order to avoid overdue review and prevent the subjects' interest and right from being affected adversely. If the loss is serious that it is impossible to maintain the IRB's operation, NCKUH shall fund specific amount periodically to maintain the IRB's operation.

(III) Research Team's Human Subject Protection Mechanism

1.Before conducting the research, the research team shall draft the research protocol and submit the same to IRB for review, if necessary, to the NCKUH Biosafety Committee and Radiation Protection Management Committee, and Ministry of Health and Welfare in Taiwan. Changes of the human research, if any, shall be subject to IRB's prior approval.

2.It is necessary to ensure that the research should be supported by sufficient resources, e.g. competent human resources, equipment, time and space, et al.

3.The unanticipated events or other events to be reported pursuant to laws, shall be reported to the competent unit pursuant to laws, and also to IRB.

4.It is necessary to declare financial and non-financial interests and relations to the IRB based on the requirements of Human Research Conflict of Interest Committee.

5.The principal investigator shall maintain appropriate oversight of each research and appropriately delegate research responsibilities and functions.

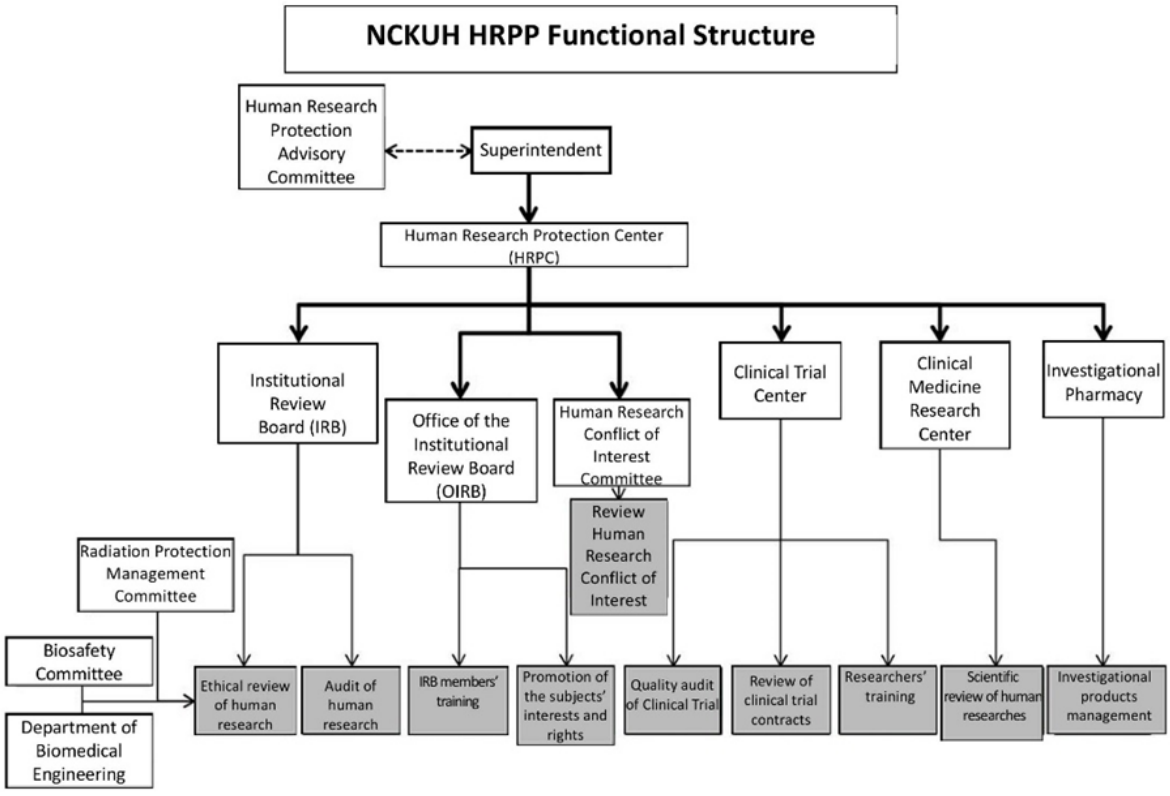
6.NCKUH encourages the involvement of community members, when appropriate in the design and implementation of research and the dissemination of results.

(IV) Supplementary provisions

1.HRPP shall be proposed, reviewed periodically and enforced by HRPC.

2.HRPP shall be kept updated on the HRPC's website after it is effective and enforced.

V.Structure



(I) The units identified in the white grids of the structural chart refer to the related units involved in the Plan, while the mission identified in the gray grids refer to the related missions involved in the Plan.

(II) Superintendent authorizes the HRPC Director to maintain and supervise the Plan.

(III)Human Research Protection Advisory Committee supervises and provides consultations related to the Plan.

(IV)HRPC is in charge of the Plan, and should supervise related units involved to complete the mission under the Plan. The units shall work with each other to ensure that the human subjects' interests and rights are protected.

(V) If necessary, the HRPC shall hold a meeting and invite the related units involved in the Plan to discuss the human subject protection affairs together. Each unit shall work with the HRPC actively.