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I. **Goal**: National Taiwan University Hospital (hereafter referred to as "NTUH") has established this SOP to ensure that the rights and welfare of human research participants are protected and human research conducted by personnel of NTUH in compliance with the Department of Health and Human Services (DHHS) Code of Federal Regulations (CFR) Revised Common Rule (45 CFR 46).

II. **Scope**: This Standard Operating Procedure (SOP) is the NTUH REC policies and procedures regarding research at NTUH involving human subjects that is conducted or funded by the Department of Health and Human Services (DHHS) in comply with DHHS regulations. NTUH research not covered by DHHS should comply with Taiwan laws and regulations.
II.1.When a conflict of laws occurs between Taiwan laws/regulations and another legal system, such as the US DHHS and FDA regulations, the staff of Research Ethics Center and Human Research Protection Center will discuss and propose a solution, to be discussed and determined in the monthly meeting of Human Research Protection Center.The determination made by HRPC will afford protection thatare at least equivalent to those provided by the US DHHS and FDA regulations.

III. This SOP describes the variations in requirements and procedures that NTUH HRPP/REC, and investigators, will adhere to for research subject to the revised common rule (45 CFR 46).

IV. **Definition**: The following definitions will be applied when NTUH REC reviews research subject to the revised Common Rule, and for exempt determinations and evaluations regarding whether a proposed activity is human subjects research when the research (or activity) is conducted or supported by DHHS.

1. **Clinical trial**: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

2. **Human subject**: Means a living individual about whom an investigator (whether professional or student) is conducting research:
   (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
   (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

3. **Research**: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For purposes of this rule, the following activities are not considered research：
   (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

   (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
   (i) Such activities are **limited to** those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products).
   (ii) Such activities **include** those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

   (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or

criminal investigative purposes.

(4) Authorized operational activities (as determined by a federal agency) in support of intelligence, homeland security, defense, or other national security missions.

Note: Secondary research involving non-identifiable newborn screening specimens will not be considered research involving human participants.

References

1. Code of Federal Regulations, Title 45 – Public Welfare DHHS, Part 46 – Protection of Human Subjects 46.101, 46.102, 46.104, 46.111, 46.116, 46.117.
2. An addendum to the University of Virginia HRPP SOP.
3. University of Missouri-Columbia SOP: Research Subject to the Revised Common Rule.