NUH Human Research Conduct and Protection (HRP) Policy

CONTENT:

1.0 Objective

1.1 This policy is NUH’s policy on Human Research Conduct and Protection. It commits NUH to protect the rights and welfare of all human research participants.

1.2 All of NUH’s human research activities will be guided by the ethical principles of respect for persons, beneficence and justice.

1.3 The Leader of this policy is the NUH CEO and Senior Management and the Office responsible for administering this policy is the CEO’s Office.

1.4 This document does not supersede any document.
1.5 This document is scheduled for review 3 years post implementation or upon enactment of new legislation on human research conduct and protection, whichever earlier.

1.6 This policy affirms NUH’s commitment to protecting the rights and welfare of all research participants in research within NUH by specifying the roles and responsibilities of NUH employees, agents and principals.

1.7 Ethical responsibilities for human research conduct and protection extend to all NUH employees, agents and principals involved in planning, reviewing, executing or administratively supporting human research.

2.0 Scope

2.1 This policy applies to employees, agents and principals of NUH, i.e. NUH staff, subcontractors and external sponsors (e.g. government and industry sponsors).

2.2 All research activities pertaining to the use of human materials or health related data or on human subjects are covered under this policy.

3.0 Definition

3.1 Institutional Review Board:

An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of human subjects involved in a research study by, among other things, reviewing, approving, and providing continuing review of research studies, of protocols and amendments, and of the methods and materials to be used in obtaining and documenting informed consent of the research subjects.

3.2 Researchers:

Researchers that conduct research using NUH’s premises, facilities or funding. Examples include employee or agent or principal of NUH (i.e. employee of NUH, or employee of NUH’s subcontractors, or employee of NUH’s external sponsors) (8).

3.3 Agents of NUH:

A person (human or legal entity) authorized to act for NUH by contractual arrangements, e.g. by service contract between NUH and a Contract Research Organization.

3.4 Unexpected Serious Adverse Event:

Serious adverse events that is unexpected as defined by local laws and regulations e.g. Singapore Good Clinical Practice.

4.0 References

4.1 This HRP Policy references the Helsinki Declaration, the Singapore Bioethics Advisory Committee’s reports, the International Conference on Harmonization (ICH), World Health Organization (WHO), Good Clinical Practice (GCP) standards and Singapore Ministry of Health Institutional Review Board Operational Guide.

5.0 Policy
5.1 Responsibilities

5.1.1 All persons covered by this policy are responsible for being familiar with Singapore human research legislations, regulations and guidelines and this policy as they relate to their official duties. (1,2,3)

5.1.2 Responsibility of the NUHS Board of Directors, NUH Chief Executive Officer (CEO) and NUH Senior Management

The NUHS Board of Directors and NUH CEO or his designate and NUH Senior Management has the authority and responsibility for the following:

a) Ensure NUH-wide compliance with all applicable laws, regulations, policies, and standards regarding protecting the rights and welfare of human participants of research conducted or supported by NUH;

b) Set the tone for the institution by promoting an institutional culture of respect and conscience, so that the ethical conduct of human research is supported at the highest levels of the organization; (4)

c) Ensure that the human research protection program functions effectively and that NUH provides the resources and support necessary to comply with all requirements applicable to human research;

d) Monitor and measure the effectiveness of NUH’s human research protection program, plan improvements based on those measures, implement planned improvements, and monitor and measure the effectiveness of those improvements;

e) Designate IRBs that will review human research conducted by NUH;

f) Provide sufficient resources to support the IRBs’ review and record-keeping duties;

g) Respect, support, and defend the autonomy of NUH’s IRBs and other IRBs of record to act within their purview;

h) Ensure that the human research protocols submitted for IRB approval are scientifically sound and supported by scientific merit by putting in place mechanisms for supervisors or reporting officers of Researchers to counter sign on Researchers’ IRB applications; (1,4)

i) Ensure that there is in place a funding mechanism and committee to deliberate on research funding and resource allocation to ensure effective operation of human research activities;

j) Ensure all Researchers are educated on and honor research ethics;

k) Define scope of research activities in NUH and ensures adequate resources are available for effective operation of all research activities (9);

l) Integrate the Human Research Protection Program into the quality and patient safety programs of NUH

m) Evaluate Researchers on their professional performance on human research; and
n) Obligate, by means of contractual agreements, or other means, external government or, industrial sponsors to adhere to this policy.

5.1.3 Responsibilities of CEO

5.1.3.1 NUH CEO or his designate shall nominate, an Institutional Review Board (IRB) for the initial and continuing review of all human research conducted in NUH and ensure that the IRB

(a) Has written procedures to appoint, disqualify or renew IRB members (10);

(b) Carry out its functions and duties to safeguard against unauthorized access to the documents reviewed by IRB (13);

(c) Ensure that the IRB members have relevant experience or expertise, and continuing education in research ethics (3,10);

(d) Indicate the application requirements for initial and continuing review of research (11);

(e) Is responsible for the content of the certificate of IRB approval or waiver, to be issued. The contents shall include, at minimum, title of project, identification number of protocol, date of IRB approval, previous date of IRB approval, if any (1,15);

(f) Indicate the criteria for allocating research to, and the conduct of, different level/category/types of ethics review (i.e. full, expedited and exempted) (14);

(g) Communicate with the Researcher and NUH, e.g. on the outcomes of review, or on the request by IRB for more information from the Researcher to carry out its functions or on renewal of IRB approvals (12,25);

(h) Has a mechanism for identification, elimination and managing of conflicts of interest within the IRB (22);

(i) Ensure guidelines are made available on Researcher’s prompt reporting to the IRB of proposed changes in a research activity, or any new findings within the research community that may increase the risk to research subjects participating in the approved research (20).

(j) Ensure guidelines are made available for Researchers to be aware that any changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the research subject (23,31).

(k) Ensure guidelines are made available for Researchers to be aware that Researchers are to report to IRB and NUH CEO or his designate, any unexpected serious adverse events that occur to research subjects arising from their participation in research (29,31,23);

5.1.3.2 NUH CEO or his designate shall identify the facilities within NUH that can be used for research activities (ie the NUH main building, Kent Ridge Wing and Investigational Medicine Unit in Block MD6) and such facilities be listed in appropriate website (24).

5.1.3.3 NUH CEO or his designate shall ensure that Researchers are suitably qualified in accordance with the HRP Policy to conduct human research in NUH (5,21,32).
5.1.3.4 NUH CEO or his designate shall ensure that there is adequate indemnity insurance to compensate research subjects for adverse events due to human research conducted by or for NUH (35).

5.1.3.5 NUH CEO or his designate shall ensure that there is an approval for every human research protocol by an IRB and Health Science Authority (HSA) or a waiver of such requirement before such research protocol can be conducted by NUH Researcher within NUH premises (1).

5.1.3.6 NUH CEO or his designate shall
(a) Have oversight of the conduct of human research;
(b) Investigate and remedy any areas of concern; and
(c) Ensure that the human research is conducted in accordance with this HRP Policy
(d) Ensure he or she is kept well abreast of the commission of any suspected contravention of this HRP Policy and the occurrence of any unexpected serious adverse event.

5.1.3.7 NUH CEO or his designate shall maintain an appropriate written, enforced Conflict of Interest (COI) Policy and inform Researchers of that COI Policy and their reporting responsibilities. The COI policy should be made easily available to all NUH staff (eg via intranet or website). If NUH carries out the research through subcontractors, or collaborators, NUH CEO or his designate must take reasonable steps to ensure that such entities comply with NUH’s COI Policy eg by contractual arrangement.

5.1.3.8 NUH CEO or his designate must make the HRP Policy, information on all human research conducted by and for NUH, IRB contact information easily available to research subjects, agents and partners of NUH (e.g. via internet) (32)

5.1.3.9 NUH CEO or his designate, through the IRB, shall ensure Researchers renew their IRB approvals or terminate the human research if IRB approvals are not renewed.

5.1.3.10 NUH CEO or his designate, shall integrate the Human Research Protection Program into the Office of Medical Affairs’ quality and patient safety programs.

5.1.4 Responsibility of Researchers

5.1.4.1 Researcher may conduct any human research if—
(a) He has the appropriate qualifications as permitted under Singapore laws and regulations to do so;
(b) He has obtained from
   (i) An Institutional Review Board (IRB) and Health Science Authority (HSA), when applicable, approval for the research to be conducted or continued, or
   (ii) A waiver of the requirement for that research to be approved by an IRB;
(c) He has ensured that
   (i) Appropriate consent has been obtained for the participation of the research subject in human research and the consent has not been revoked or withdrawn, or
   (ii) The IRB has waived the requirement for appropriate consent to be obtained;
(d) The human research that Researcher wishes to conduct

(i) Does not contravene Singapore laws, ie the Human Cloning and Other Prohibited Practices Acts, the Medicine Act, the Health Product Act and the relevant rules and regulations;

(ii) is in line with local guidelines, ie the Institutional Review Board Operational Guide as indicated by the Singapore Ministry of Health;

(iii) Conforms to acceptable scientific requirements and substantiated by scientific merit and

(iv) is scientifically sound and resource wise, is feasible to be conducted in NUH and

(e) The human research is to be conducted in NUH designated research facilities as stated in appropriate website. (1,2,3,8)

5.1.4.2 Every Researcher shall ensure Researchers’ and Sponsors’ research data and statistical results are reliable and valid, and thus ethically sound.

5.1.4.3 Every Researcher conducting human research shall adhere to the research protocol approved by HSA and Institutional Review Board, unless a deviation from the approved research is necessary to mitigate an immediate risk of harm to a research subject (32).

5.1.4.4 Every Researcher conducting human research who deviates from an approved research protocol shall inform the NUHS Research Office, HSA and Institutional Review Board of the deviation within 7 calendar days (25, 34).

5.1.4.5 Every Researcher shall declare Conflicts of interest, i.e. the nature and extent of all actual or potential conflicts of interest in relation to a human research (5).

5.1.4.6 Every Researcher conducting human research shall adhere to this Human Research Protection Policy.

5.1.4.7 Every Researcher who is an employee of NUH shall ensure other Researchers e.g. agents or principals (e.g. sub-contractors or sponsors) are contractually obligated to adhere to the NUH HRP Policy in the course of conducting human research for and with the NUH.

5.1.4.8 Every Researcher who is an employee of NUH, when conducting human research jointly with or sub-contracts out the conduct of part or whole of a human research to, a Researcher who is not an employee of NUH shall ensure the activities and responsibilities of the contracting parties are clearly and contractually determined (32).

5.1.4.9 Every Researcher shall attend all - educational seminars on conflict of interests organized by the institution

5.2 Appropriate written consent to be obtained from research subjects (16, 17, 18, 33)

5.2.1.1 The appropriate consent is required for the participation of a person as a research subject, including the use of his biological material or individually-identifiable health information, in any human biomedical research.
5.2.1.2 A person who has attained the age of 21 years and is of sound mind shall be presumed, until the contrary is proved, to have sufficient capacity of mind to give his own consent.

5.2.1.3 A person who has not attained the age of 21 years shall be presumed, until the contrary is proved by this person or his/ her parents, not to have sufficient capacity of mind to give his own consent.

5.2.2 The appropriate consent shall be obtained after the research subject or, where applicable, his legal representative has been informed of the following:

(a) The investigational nature of the research;

(b) The purpose of the research;

(c) The reasonably foreseeable risks, discomforts or inconveniences to research subjects arising from this research;

(d) The benefits which research subjects may reasonably expect from the research;

(e) Where applicable, whether there are any alternative procedures or treatments available to the research subject, and the potential benefits and risks of such alternatives;

(f) Any compensation and treatment available to the subject in the event of injury arising from participation in the research;

(g) Any anticipated expenses to the subject from participating in the research activity;

(h) The extent to which records identifying the subject will be kept confidential;

(i) Whether individually-identifiable information obtained from research subjects will be used for future research;

(j) Where applicable, whether biological material taken from research subjects will be destroyed, discarded or stored for future research;

(k) The person to contact to obtain further information on the research;

(l) The person to contact to provide feedback in relation to the research;

(m) That the research subject's participation in the research is voluntary and that he may refuse to participate in or may withdraw from the research at any time without penalty or loss of benefits which the subject would otherwise be entitled;

(n) Whether, and the circumstances under which, the research subject (or his legal representative) will be contacted for further consent; and

(o) Any other information which the IRB may require to be given or which may be prescribed.

5.2.3 An IRB may

(a) Waive the requirement for the appropriate consent to be obtained in writing if the IRB is satisfied that —
(i) the research involves no more than minimal risk to the research subjects and involves no procedures for which written consent is ordinarily required outside of a research context; or
(ii) The only record linking the research subject and the research would be the consent form, and the principal risk would be the potential harm resulting from a breach of confidentiality.

(b) Waive the requirement to obtain appropriate consent from a research subject or his legal representative, as the case may be, in such other circumstances as may be prescribed.

5.2.4 Notwithstanding the above, an IRB may waive —

(a) The requirement to obtain appropriate consent; or

(b) The requirement to provide all or part of the elements of information before obtaining consent,

If the IRB is satisfied that —

(i) The research involves no more than minimal risk to the research subjects;

(ii) The waiver will not adversely affect the rights and welfare of the research subjects;

(iii) The research may not practicably be carried out unless there is such a waiver; and

(iv) Whenever appropriate, the research subjects will be provided with additional pertinent information after participation. (28)

5.2.5 Vulnerable research subjects are to be treated with more care. For example, in the process of obtaining informed consent, such persons should be accompanied by at least 1 other party of his choice to help his decision making (if he is a staff or student of NUH) or be represented by a legal representative (if these vulnerable research subjects do not have legal capacity). Such “vulnerable research subjects” include pregnant women, human fetuses and neonates, prisoners, children, cognitively impaired persons, students, employees, minorities, economically and/or educationally disadvantaged, AIDS/HIV+ subjects and the terminally ill subjects.(6)

5.3 Management of individually-identifiable research subject information and material (26,30)

5.3.1 Researchers conducting human research with access to individually- identifiable research subject information should ensure the following:

a) Research subject information or material are made non-identifiable, and

b) Research subject information and materials are protected against accidental or unlawful loss, modification or destruction, or unauthorised access, disclosure, copying or use by ensuring there is adequate security procedures and system in place, and

5.3.2 Researchers will ensure the key to the de-identification of research subject information is held by a Trusted Third Party (e.g. a computational algorithm or software). Such Trusted Third Party will be the only party who has the means to re-identify Research Subjects and only for linking purposes or analysis purposes.
5.4 **Conflict of Interests (22)**

5.4.1 Researchers shall comply with the NUH Conflict of Interest Policy (36) and declare Conflicts of Interest to every human research that he is conducting, ie the nature and extent of all conflicts of interest or potential conflicts of interest in relation to a human research, including those arising from —

(a) His familial or other relationship with a director, partner or employee of the NUH / agent / sponsor of the human research;

(b) His familial or other relationship with any of the researchers involved in the conduct of the human research to be conducted within NUH;

(c) His connection or association with any body or person funding the human research.

5.4.2 Researchers shall be informed and educated on Conflict of Interests to human research.

5.5 **Duties of Institutional Review Board**

5.5.1 IRBs are to conduct its duties according to the NUH IRB Policy. (37)

5.6 **Compliance to HRP Policy**

5.6.1 NUH CEO or his designate (e.g. IRB) shall inspect the relevant Researcher and the facilities used for the conduct of any human research

(a) To ensure no provision of this HRP Policy has been or is being contravened;

(b) To investigate any complaint made by Research Subjects or from whistle blowing parties within NUH or

(c) To audit the adherence to HRP Policy.

5.6.2 NUH CEO or his designate shall increase the frequency of inspection if non-compliance observation is deemed to be frequent.

5.7 **Reporting of Serious Adverse Event (29)**

5.7.1 Researcher shall ensure that all relevant information about any serious adverse event related to any approved research protocol which occurs in a research subject during the research that is fatal or life-threatening is —

(a) Recorded; and

(b) Reported to the IRB as soon as possible and in any event not later than 7 calendar days after the Researcher first becomes aware of the event unless the report involves the death of a local participant, in which case the report should be in no more than 24 hours.

5.7.2 Researcher shall ensure that, within 8 days of the report to the IRB, any additional relevant information about the event is sent to the IRB.
5.7.3 Researcher shall ensure that all relevant information about a serious adverse event related to any approved research protocol which occurs in a research subject during the research, other than one referred to in paragraph 5.7.1, is —

(a) Recorded; and

(b) Reported to the IRB as soon as possible and in any event not later than 7 calendar days after Researcher first becomes aware of the event.

5.7.4 Where there is an event or occurrence that relates to any approved research protocol that is not fatal or life-threatening, but a recurrence of which might lead to a serious adverse event that is fatal or life-threatening, the Researcher shall ensure that all relevant information about the defect is —

(a) Recorded; and

(b) Reported as soon as possible to the IRB and in any event not later than 7 calendar days after the Researcher first becomes aware of the event.

5.8 Suspension or termination of human research (19)

5.8.1 NUH CEO or his designate may require the suspension or termination of a human research if NUH CEO or his designate has reasonable grounds to believe that —

(a) Researcher has contravened or is contravening any provision of the HRP Policy;

(b) The grounds for conduct of the trial on the basis of scientific validity are no longer applicable or true; or

(d) The continuance of the trial will compromise the safety of a subject.

6.0 Annex

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