1. PURPOSE
The purpose of this policy is to overview the mission, structure and institutional authority for the Human Research Protection Unit to protect the rights, dignity, welfare, and privacy of human research subjects at the Faculty of Medicine Siriraj Hospital.

2. POLICY
2.1 Mission
It is the policy of the Faculty of Medicine Siriraj Hospital that human research activities conducted by faculty staff, students, or other trainees, and any others conducting research using the patients, medical records, or facilities of the faculty must receive prior approval of Siriraj institutional review board (IRB). The Human Research Protection Unit (HRPU) was settled up to support the activities of Siriraj IRB in promoting ethical conduct of human involving research, and ensure the faculty commitment to the compliance with all applicable regulations and accreditation standards.

2.2 Structure and Institutional Authority
The HRPU at the Faculty of Medicine Siriraj Hospital is responsible for the administrative, quality improvement, and educational activities. These functions administer independently in the form of two committee groups, the Steering Committee and Administrative Committee on ethics for research involving humans. The Steering Committee is a policy and decision making body that is responsible for overall development of HRPU. The Administrative Committee is in charge of the administration and management of all HRPU activities.

The HRPU office is also the central administrative workplace for Siriraj IRB, serving as the central repository of all information affecting the protection of human involving research. It is located at Room 210 of His Majesty the King's 80th Birthday Anniversary 5th December 2007 Building. The HRPU has full-time staff who are responsible for coordinating and supporting all research approval processes by IRB committee until final decision is made, the post-approval and continuing review processes, as well as the quality improvement and educational program. The HRPU staff, IRB members, research staff, and investigators are expected to understand, adhere and apply their obligation to protect the rights and welfare of participants guided by the ethical and legal principles governing human subject research.

The HRPU office is directly under the authority of the Faculty Dean as shown in the structure charts below. The faculty retains ultimate responsibility for the maintenance, supporting and improvement of the HRPU. The resources are granted separately including budget, equipment, personnel, venue and space to ensure sufficient capacity to operate at all levels.
Title: 2.1 Overview and Structure of Siriraj Human Research Protection Unit

Administrative Structure of Human Research Protection Unit

Faculty Dean
Faculty of Medicine
Siriraj Hospital

Steering Committee
Human Research Protection Unit

Administrative Committee
Quality Assessment and Improvement
Institutional Review Board
Education in Human Research Ethics

IRB Chair
4 IRB Committees

Human Research Protection Office

HRPU Staffs

Organizational and Functional Structure of Human Research Protection Unit
2.3 Independence of the IRB

Siriraj IRB is independent and retains the final authority for all decisions regarding the protection and welfare of humans participating as subjects in research activities. Institutional officials may not approve the research if it has not been approved by the IRB. Inappropriate efforts to influence the IRB process, individual IRB members, or HRPU staff will be reported to the Administrative Committee, Steering Committee and Faculty Dean respectively. The faculty will cease any efforts at inappropriate influence, and the Faculty Dean has the authority to limit or remove an investigator’s privilege to conduct research.

3. SPECIFIC POLICIES

3.1 Steering Committee

The Steering Committee on ethics for research involving humans consist of 8 to 10 representatives that are considered partners or stakeholders in the HRPU, including the Faculty Dean, Deputy Dean of Research, Head of Department, internal experts and at least one external expert, with IRB chair as the secretary. They are appointed by the Faculty Dean for four-year terms. The Steering Committee organizes the meeting at least once a year. Their authorities and responsibilities are as follows:

1. Evaluate the activities and achievements of HRPU.
2. Assess compliance with HRPU policies and procedures.
3. Determine potential conflict of interest of organization.
4. Review and approve the policy and continuous quality improvement plan of HRPU.

The Faculty Dean as the chair of Steering Committee:

1. Has the authority at the organization to implement the human research protection program,
2. Regulates all researches involving humans in accordance with applicable national and international regulations,
3. Be responsible to ensure the protection of the rights, safety and well-being of human research participants in the faculty, under the operation of IRB,
4. Chooses and appoints the IRB chair, appoints the IRB members and directly involves in allocation of resources to HRPU.

3.2 Administrative Committee

The Administrative committee on ethics for research involving humans are appointed by the Faculty Dean to a 4-year term, consisting of the chair, vice-chair, secretary, assistant secretary, and HRPU staff, with a total of 9 or more members. The IRB chair will be designated as the chair of Administrative Committee, and be responsible for nominating the committee members. The Administrative committee will organize an official meeting at least 4 times per year, and on an as needed basis. The IRB chair is responsible to bring the resolution from the meeting to inform all IRB members in the panel meeting, as appropriate. Their authorities and responsibilities are as follows:

1. Set up the policy of HRPU,
2. Operate and evaluate the HRPU activities, and make quality improvement plan at least once a year,
3. Report activities and achievements annually to the Steering Committee and Faculty Executives,
4. Administer the office operations, budget, staffs as well as the operating guideline for the officers,
5. Formulate the SOP, researcher handbook and revise them periodically as appropriate,
6. Organize the training on ethical research in humans and details of the IRB operating process for the IRB committee, investigators, faculty personnel, and the trainees,
7. Manage and monitor post approval process of the research project,
8. Determine and solve the HRPU problems in case of emergency,
9. Determine and manage conflict of interest of IRB members, researchers and organization/senior executives.

3.3 Relationship to Other Institutional Constituencies Activities

Activities
- Legal Counsel (risk management unit)
- Research pharmacy (linkage with the Pharmacy Department)
- Radiation safety

Activities
- IRB (scientific & ethics)
- Conflict of Interest Management
- Monitoring and Compliance oversight
- Quality Improvement
- Education/Training program
- Research related injury investigation

Activities
- Research Grants
- Clinical Trial Agreement (CTA)
- Material Transfer Agreement (MTA)
- Siriraj Biosafety Risk Management
- Scientific integrity of research protocol
Faculty of Medicine Siriraj Hospital
1. Legal counsel (risk management unit)
   1.1 Prevent the organization’s risk from the effects or consequences of the processes conducted by the faculty personnel, trainees, researchers and students
   1.2 Provide advice regarding to legal issues upon request to HRPU and IRB
   1.3 Assist in the resolution of conflicts among applicable laws

2. Research Pharmacy
   The Research Pharmacy is responsible for: (i) assuring appropriate storage and handling of all investigational drugs; (ii) assuring inventory accountability of all investigational drugs; (iii) serving as a central source of information for all investigational drugs used for humans; (iv) dispensing medications only for protocols that have approval of the IRB and only in a manner consistent with the requirements of those protocols; and (v) distributing appropriate information about investigational drugs and their use in particular study protocols to individuals with direct care responsibilities for patients enrolled in those studies.

3. Radiation Safety Subcommittee
   The subcommittee is settled up, by the Faculty to oversees the use of radioactive materials and radiation-producing devices at the Faculty, and promotes radiological safety in both research and service activities through safety training, professional guidance, and technical support.
   The Radiation Safety Subcommittee has the vested authority to act immediately in all matters pertaining to radiation safety for the purpose of assuring individual well-being and the integrity of Faculty property.

Human Research Protection Unit
1. Institutional Review Board (See chapter 3 Siriraj Institutional Review Board)
2. Conflict of Interest Management (See section 3.4 Conflict of Interest Disclosure and Confidentiality Agreement)
3. Quality Improvement (See chapter 10 Quality Assessment and Quality Improvement)
4. Monitoring and Compliance oversight (See section 10.3 Site Visit and Compliance Monitoring)
5. Education/Training in human research ethics (See chapter 9 Education/Training in Human Research Ethics)
6. Research pharmacy (linkage with the Pharmacy Department)
   According to the ICH GCP recommendation in research used pharmacy, the faculty assigned the HRPU to take responsibility in this regard to:
   6.1 Provide oversight and direction for use of investigational medications in the Clinical Research Units and throughout the clinic facilities
   6.2 Provide expert consultation to investigators on medication-related issues
7. Research related injury

For injury that may occur as a result of participation in research activities covered by the Human Research Protection Unit,

7.1 Studies in which a commercial sponsor holds the IND or IDE and also controls the protocol must provide indemnification coverage and defense of the Faculty for performing the study, including its trustees, officers, investigators, employees and students, for all claims arising from the institution’s conduct of the study that are not due to an negligence or willful misconduct.

7.2 Investigator-initiated investigational studies and Non-commercial entities sponsoring and/or providing investigational products do not require provision of medical costs from research related injury. The Faculty will be responsible for medical care costs stemming from research related injuries, as is indicated in the Informed Consent Document.

Research Division

1. Research Grants

1.1 Assure that agreement with external parties funding the research are consistent with the faculty and university requirement related to the ethical conduct of human research
1.2 Negotiate agreement with external parties funding the research are consistent with the faculty and university requirement related to the protection of research participants
1.3 Guarantee that research grant and contract funds are not expended for human research prior to approval
1.4 Ensure that clinical trial agreement terms do not conflict with the IRB approved protocols
1.5 Scientific and propose output assessment of research protocol prior to funding approval

2. Clinical Trial Agreement (CTA)

CTA will be negotiated between the Research Division (endorsed by the President of Mahidol University) and the sponsor or other funded agency. Contracts or other funding agreements in written form require the sponsor to:

2.1 Provide care and payment for research related injury.
2.2 Promptly (no longer than 30 days) report to organization any findings that could.
   - Affect the safety of participants or data
   - Influence the conduct of the study or alter IRB’s approval to continue the study
2.3 Send data and safety monitoring plans and reports to the organization.
2.4 Specify the timeframe for providing routine and urgent data and safety monitoring reports to organization as indicated in the data and safety monitoring plans approved by the IRB.
2.5 Regarding the publication of findings from sponsored research, the Division of Research representative makes the decision with the sponsor under case by case basis
2.6 Describe the steps followed to communicate findings from a closed research study to the researcher or organization when those findings directly affect participant safety.
2.7 Specify a time frame after closure of the study during which sponsor will communicate such findings. This should be based on the appropriate timeframe for each individual study.
3. Material Transfer Agreement (MTA)

One academic interchange and collaboration is the sharing by researchers in academia, industry and government of various biological materials (i.e. cell lines, antibodies, plasmids, DNA libraries, etc.). Faculty of Medicine Siriraj Hospital researchers who wish to obtain such materials from outside persons or entities or provide them to others should understand that issues of ownership and liability may arise from such transfers.

In most transfers of a “significant” biological material, the providing institution will require that the recipient institution sign an MTA. This is done to establish ownership of the material, give some legal protection to the institution and the providing scientist from potential liability resulting from the use of the material, and assure that the source of the material is identified and given appropriate credit in any resulting publications. Materials owned by a company or resulting from research sponsored by a company, either at another institution or at the faculty, may involve additional obligations to be assumed by the recipient. An MTA is a contract that spells out the conditions under which one organization agrees to transfer to another organization tangible research materials for use in the recipient’s research program, excluding clinical trials.

In both the receipt and provision of material, it is the responsibility of the Deputy Dean of Research Office to represent the researcher and Faculty of Medicine Siriraj Hospital. All MTAs involved must be reviewed by the Deputy Dean of Research Office staff.

4. Siriraj Biosafety Risk Management

The taskforce includes:

4.1 Preparation and provide the bio safety manual for laboratory work to laboratory personnel.

4.2 Cooperation with researchers having research involving microorganism/genetic modification type 1-3 or others, including assisting in proposal preparation for the protocol related to biosafety issues.

4.3 Approval of the laboratory research proposal involving microorganism/genetic modification type 1-2 according to the regulation of Mahidol University (www.mahidol.ac.th/green/Researcherf/Biosafety.Researcherf) and notify the result to the Institutional Biosafety Committee, Mahidol University.

4.4 Research involving genetic modification type 3, after consideration, the protocol will be sent to the Institutional Bio safety Committee, Mahidol University.

4.5 Training and/or coordination for training about bio safety for laboratory personnel

4.6 Control the quality for documents related to bio-safety laboratory.

4.7 Regularly tracking and monitoring the implementation of research laboratory bio-safety, according to rules and regulations previously described.

4.8 Regularly monitor and supervise the laboratory for its maintenance and safety.

4.9 Report the operating results of the risk management in microorganism and gene modification researches to the Risk management Committee and Research Development Committee, Faculty of Medicine at least once per year.

4.10 Perform other works related to the safety in research as assigned by the Faculty of Medicine, Siriraj Hospital.
5. Scientific Integrity of Research Protocol
   Department of Research and Development is responsible for
   5.1 Providing regular training course in research methodology, statistics and good clinical practice
   5.2 Providing consultation in statistical analysis of research project.

4. RESPONSIBILITY
The Steering Committee is responsible for making management-level decisions for the policy and operations of the HRPU, which includes the IRB.

The Administrative Committee is responsible for overseeing and making management-level decisions for day-to-day operations of the HRPU, which includes the IRB.

The IRB Chair has the responsibility of managing and supervising the IRB work.

The HRPU Staff has the responsibility of the cooperation and daily secretarial work of the HRPU and the IRB.

5. APPLICABLE REGULATIONS AND GUIDELINES
21 CFR 56.108, 56.109, 56.113;
45 CFR 46.108, 45 CFR 160 &164;
Belmont Report;
Mahidol University Biosafety Guideline; 2011.

6. APPLICABLE DOCUMENTS
   6.1 Material Transfer Agreement form (can be download from the website www.si.mahidol.ac.th/th/research-academics/research/Downloads_form.asp)
   6.2 Clinical Trial Agreement form (can be download from the website www.si.mahidol.ac.th/th/research-academics/research/Downloads_form.asp)
### 7. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

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<th>No.</th>
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| 1   | Steering Committee | • Ensure adherence to the ethical standards and compliance with international/national and institutional policy and regulations, to guarantee the protection of human subjects participating in research.  
     |                | • Investigate and acts on reports of any inappropriate efforts to influence the IRB process. |
| 2   | Administrative Committee | • Establish and support IRB operations in complied with the highest ethical standards and applicable policy and regulations.  
     |                | • Develop and implement initial and continuing training and education of those involved in Human Research Protection: investigators, research staff, HRPU and IRB administrators, and IRB members.  
     |                | • Evaluate the HRPP through a Quality Assurance and Quality Improvement component.  
     |                | • Communicate with the internal and external constituencies. |
| 3   | IRB Chair, IRB Members, HRPU Staffs | • Perform and evaluate on a day-to-day and on-going basis for the review and approval of all research involving human subjects.  
     |                | • Report to the Administrative and Steering Committee any inappropriate efforts to influence the IRB process. |