1. PURPOSE
The purpose is to describe policies and procedures for maintaining and ensuring quality and standards for all human subject research protection procedures.

2. POLICY
Identifying the areas of strengths and opportunities for improvement of human research protection efforts is essential to maintain the effectiveness and quality of the HRPU. The goal of quality assurance (QA) and quality improvement (QI) program is to work collaboratively with IRB members and research community to ensure that the rights and welfare of research subjects are being properly protected in accordance with the applicable laws and regulations, ethical principles, and institutional policies.

The procedures in areas that are essential to the QA/QI plan are as follows:

- Conducting routine and ad-hoc reviews to monitor compliance with HRPU policies and procedures.
- Responding to and tracking questions, complaints and non-compliance to identify areas for improvement.
- Analyzing metrics of the IRB operations, as the input for decision management by the Administrative and Steering Committee.
- Providing education or assistance to IRB members, staffs, investigators in areas pertinent to human subjects’ protection.
- Providing basic knowledge for research participants/prospective participants regarding to human research.
- Periodic evaluation of the outreach activities.

3. SPECIFIC POLICIES
3.1 Institutional Review Board Effectiveness and Compliance
The operations of Siriraj IRB are subject to annual assessment for purposes of the protection of human research subjects and quality improvement. Such assessments will determine the extent to which the IRB complies with applicable regulations and SOP, and the adequacy of its processes and documentation.
3.1.1 Self Evaluation Checklist
Sriraj IRB evaluates procedures for the protection of human subjects of research by using the self-evaluation checklists developed by the Thai Food and Drug Administration (Thai FDA) and Mahidol University. The checklists cover a common core of topics in a systematic way to assess both the effectiveness (e.g. the amount of time from receipt of a submission through pre-review, assignment to the IRB, and final approval) and compliance with both the applicable regulatory requirements and the Faculty SOP. The policies and procedures are reviewed on an annual basis and updated as needed.

3.1.2 Evaluation of IRB Chair, Vice-Chair, Members and Staff
Evaluations of IRB Chair, Vice-chair, members, and staff are performed annually, and scheduled to occur at the time of re-appointment. The process includes both self-assessment and assessment by supervisors. The needed areas of improvement (both in function and knowledge) are defined as the topic for future training.

While IRB staffs are evaluated bi-annually according to the Faculty human resources policies and procedures, the HRPU also performs further evaluation pertaining specifically the unique requirements and knowledge necessary for IRB staff.

3.1.3 File Review
The QA/QI Team will evaluate the on-going activities of the IRB protocols, by reviewing not less than forty-eight proposal files per year. Items to be reviewed will include:

- Information considered during the initial review and approval,
- Use of the appropriate category for review,
- Designation of primary reviewer,
- Analysis of risks and benefits, including determination of minimal risk,
- Privacy and confidentiality protections,
- Use of a waiver or alteration of informed consent,
- Information considered while monitoring ongoing research (amendment, adverse events),
- Information considered at continuing review and approval, and
- Information considered at study closure

3.2 Investigator Compliance
The IRB Chair, Members and Staff will perform site visits to verify information in the study application, or in any interim or continuing review submissions. The criteria for selecting Investigators to be visited may include:

- Investigators who conduct studies that involve a potential high risk to subjects,
- Studies that involve vulnerable populations,
- Investigators who conduct studies that involve large numbers of subjects, and
- Investigators selected at the discretion of the IRB.

Due to the high variability in research projects, modifications will be made to tailor each audit to the specific project.

The IRB has the authority to observe the informed consent process, and to verify that the study is being conducted as approved and within the institutional policies and procedures. Investigators may be asked to submit copies of signed informed consent forms or other documents to ensure their compliance with IRB requirements. Sponsors may be asked to submit copies of monitoring reports. The purpose of the audit is to ensure protection of the human subjects in the research. The information is used to monitor the implementation of approved protocols, record keeping, identify areas that need improvement, correct of target education for continuous improvement of the audit tool and the audit process.

### 3.3 Evaluation of Outreach Activities

Evaluation of outreach activities are performed at least bi-annually using the feedback from IRB members, Chair and Staff regarding concurrent actions; Site Visit Review; and results from the annual Research Participant Survey. Suggestion for improvement plan will be issued to the IRB Administrative Committee. When local community issues are concerned, its representatives will be consulted in collaboration with the Faculty Research Administrative Team.

In addition, a specific “human research ethics” course which focus on human research protection and providing sufficient information for the participants and prospective participants prior to recruitment has been organized in a “New Staff Workshop” as a part of First-Year Faculty Development Program, as well as all 1st year medical trainee. Evaluation is conducted the end of the course and, later, during research activities.

### 3.4 Report of QA/QI Plan

The HRPU tracks internal metrics that are informative in considering IRB and Investigator efficiency and regulatory compliance. Findings/results from the metrics are reviewed at the IRB Administrative Committee Meetings, with emphasis on evaluation of the overall effectiveness and suggestions for corrective action plans for training, education, and outreach activities improvement. An aggregate summary of findings resulting from the noted review activities and the QA/QI plan will be reported to the IRB Steering Committee, at least once per year.
4. RESPONSIBILITY
The Steering Committee review and approve the QA/QI plan of the HRPU, set up by the Administrative Committee. The Administrative Committee act on supporting the QA/QI team in identification of deficiencies and implementing corrective action plans. The QA/QI team, with IRB Vice Chair as the Administrator, in collaboration with other members of the HRPU Staff, coordinates the QA/QI efforts.

5. APPLICABLE REGULATIONS AND GUIDELINES
21 CFR 11, 50, 54, 56, 160, 312, 812; 45 CFR 46.109;
International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) (1996)

6. APPLICABLE DOCUMENTS
Evaluation Form for Internal Survey (Internal Document No.24)

7. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

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<thead>
<tr>
<th>No.</th>
<th>Responsibility</th>
<th>Activity</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Administrative Committee</td>
<td>• Prepare the annual QA/QI plan and present to the Steering Committee for approval.</td>
</tr>
<tr>
<td>2</td>
<td>IRB Chair and IRB Secretary</td>
<td>• Assign and Support the QA/QI working team.</td>
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<td>• Implement the QA/QI plan and educational program as indicated.</td>
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<td>3</td>
<td>QA/QI working team</td>
<td>• Assess the self-evaluation checklists and IRB metrics.</td>
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<td></td>
<td></td>
<td>• Conduct periodic assessments of IRB proposal files.</td>
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<td></td>
<td>• Contact the Investigator to set up for site visit.</td>
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<tr>
<td>4</td>
<td>IRB Secretary and IRB Member</td>
<td>• Conduct a site visit to confirm that the study is being conducted in compliance with the protocol.</td>
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<td>• Complete the Site Visit Report.</td>
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