1. PURPOSE
This policy describes Site Visit and Compliance Monitoring of the research study stating in the protocol approved by the IRB.

2. POLICY
The HRPU has the authority and responsibility to conduct site visit to ensure protection of the human subjects involved in research and compliance with the applicable regulations and Faculty policies by providing oversight and if needed, education for the researchers. The goal of compliance monitoring is to confirm, by observation, accurate and consistent protocol performance in a collegial and unobtrusive manner. The HRPU will review human research projects randomly, and for cause, based on the compliance records of the researchers.

Full cooperation by the department, principal investigator (PI) and other members of the research team is expected. The information gathered during the site visit is used to monitor the implementation of research studies, process necessary corrections, identify areas that need improvement, target education, and to gather information for quality improvement of the HRPU.

3. SPECIFIC POLICIES
3.1 Criteria of Selection
Given the large number of active human subject’s research activities at the Faculty, it is not possible for the HRPU to conduct monitoring site visit in every protocol. The HRPU selects research studies for site visit review or investigation based on either “Directed (for cause)” or “Routine” criteria.

3.1.1 Directed (for-cause) Site Visit
The criteria for selecting research protocol for Directed Site Visit may include but are not limited to:
- Protocols with history of poor adherence to regulations and IRB policies;
- Protocols with reports of serious adverse event;
- Protocols with reports of violation, continuing deviation, or regulatory noncompliance;
- Protocols received an internal complaint or concern of potential unethical conduct.

The Site Visit Team may specify whether the review focuses on one aspect of the research (i.e., the consent process) or a broad review of the study conduct.
3.1.2 Routine Site Visit
The HRPU selects active protocols that are greater than minimal risk, have been active for less than 5 years, and are currently enrolling or actively following participants for Routine Site Visit. Additional criteria may include, but are not limited to:
- Protocols that involve a vulnerable subject population or have a potential for increased risk to participants (i.e., phase I trial, gene therapy, etc.);
- Protocol that involve large numbers of subjects;
- Protocols that do not have formal routine provision for on-site monitoring.
- Protocol with random visit as selected at the discretion of the IRB;

3.2 Site Visit Procedures
3.2.1 Notice of the Site Visit
Except in cases where the safety of subjects is a concern or where the IRB specifically requests an unannounced site visit, the HRPU will provide a written notification of site visit. The HRPU staff will contact the PI to schedule the visit at a mutually convenient date and time, with at least fourteen (14) day-notice by phone call.

3.2.2 Site Visit Preparation
Prior to the Site Visit: For a minimum of fourteen (14) days in advance, the HRPU will notify Investigator by a formal letter that the Investigator’s study has been selected for review. Before the site visit, Investigators will collect and make all relevant documentation in the IRB file available for the research conduct assessment.

Site Visit Team Review: IRB Chair will appoint the Site Visit Team of at least 4 persons, consisting of the members in that IRB panel and HRPU staff, to evaluate compliance of such protocol. Depending on the nature of the research study, the member of another IRB panel who has experience in the study topic may participate in the team. The Site Visit Team will be called for preparation of the site visit issues by reviewing the protocols, continuing reports to the IRB, and Checklist of Site Visit Issues. All items on the Checklist may not apply to all research studies and the site visit schedule, time and venue will be adjusted for the suitability of the protocol according to the following:

1) Research protocol
   - The first draft of protocol and the additional amendment protocol which obtained the committee’s approval
   - Obtain the certificate of approval from the SIRB committee

2) Document data
   - Data record form is correct and complete
   - Data recorded in the data record form is the same as in the source data

3) The significant documents, if applicable, such as
   - A list of investigators and assistant investigators and responsibilities
   - The latest version of investigator’s brochure
- Document of transportation of products and substances used in the research
- Document of quantity control of receiving and dispensing the products and substances used in the research
- Record the sample keeping of liquid or tissue
- A copy of progress report sent to the SIRB committee to review
- The site visit report of the Data Safety Monitoring Committee

4) Investigator, co-investigator and assistant
   - Having knowledge, understanding and conducting the research according to the SOP strictly stated in the research protocol
   - The quantity of research protocol is not too much comparing to the number of investigators and assistant investigators

5) Research site
   - The research site is suitable and facilitating to the research project

6) Research product
   - Utilize and control the products used in the research as indicated in the protocol which obtained the committee’s approval

7) The volunteers/participants who joined the project received the complete details before giving the consent
   - Randomize to inspect the consent forms which are informed that the volunteers have signed the documents with the committee’s approval
   - Notice the process of requesting the consent from the volunteers in some cases.
   - If there is any significant amendment of data in the research study, the volunteers will be informed and sign the names again.

8) Confidentiality of information
   - Keep the volunteer’s information confidentially and limit the persons who can reach the information

9) Adverse event report and protocol deviation, if any
   - Compare the adverse event report with the report sent to the committee
   - Compare the protocol deviation report with the report sent to the committee

10) Compensation, travelling expenses, remuneration for time wasting, and responsibility for adverse events
    - Inspect the documents of travelling expenses and remuneration for time wasting
    - Inspect the documents or inquire about the adverse events occurred in the research site with the solution

3.2.3 During Site Visit: Through observation, interviews, and record review, the Site Visit Team evaluates various aspects of the compliance to regulatory requirements as mentioned. The Site Visit will follow the process as follow:
1) The Site Visit Team meets with the Investigator to discuss the objective of the visit;
2) The Investigator briefly talks about the study, and offers the Site Visit Team with the study files for review;
3) The Site Visit Team interviews the Investigator who is familiar with the study, or any research personnel knowledgeable about specific aspects of the study;
4) Throughout the site visit, the Site Visit Team will provide recommendations and educational support to the Investigator and their research personnel based upon the site visit findings;
5) At the conclusion, Head of the Site Visit Team provides a brief summary of findings, and exchange with the Investigator for quality improvement on both sides.

3.2.4 Post Site Visit:

1) The HRPU office will collect all comments and checklist from the Site Visit Team, draft a Summary Report (signed by the IRB Chair) and submit to the Investigator for review. The Summary Report will provide a detailed summary of the review identifying areas of improvement and recommendations.
2) When the Summary Report contains findings of non-compliance, the Investigator will respond with a corrective action plan for each finding within thirty (30) days of the date of the Summary Report.
3) In most cases, serious violations that present the risk of injury to study participants should have been immediately reported to the IRB by the PI. However, if a serious violation involving risk of injury to participants has been detected during site visit without prior report, it must be done immediately to the IRB Chair.
4) The Summary Report, including the Investigator’s responses, will be reviewed at the next convened IRB meeting. The IRB may take the following actions with respect to the Summary Report:
   4.1 Acceptable referring to a site visit that result in a finding of no deficiencies or lesser deficiencies that do not appear to involve risk to potential subjects.
   4.2 Acceptable with conditions referring to a site visit that result in findings of multiple lesser deficiencies that presents a potential risk to potential subjects that needs further consideration.
   4.3 Unacceptable referring to a site visit that result in findings of one or more major deficiencies that impacts human subject’s safety and welfare.
5) The Investigator will be informed of further monitoring and educational plan with a decision as Acceptable with Conditions (4.2) or Unacceptable (4.3).

4. RESPONSIBILITY
Administrative Committee and IRB Chair are responsible for the establishment, implementation and oversight of the research study according to the policy.
5. APPLICABLE REGULATIONS AND GUIDELINES
45 CFR 46.109 (e)
21 CFR 56.109(f)

6. APPLICABLE DOCUMENTS
Site Visit Form Checklist  (Internal Document No.23)

7. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

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<th>No.</th>
<th>Responsibility</th>
<th>Activity</th>
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| 1   | IRB Chair and Secretary         | • Selection of project or venue for the Routine or Directed Site Visit.  
• Select at least 4 suitable IRB member and staff as a Site Visit Team. |
| 2   | HRPU Staff                      | • Contact the PI or key site personnel to schedule a site visit.  
• Arrange the preparation for the Site Visit Team |
| 3   | Site Visit Team members         | • Review the research protocol, relevant documents submitted and the Site Visit Form Checklist.  
• Visit the site and confirm that the study is being conducted in compliance with the regulations, in particular of the safeguards in place for the recruitment of vulnerable subjects, informed consent documents and processes without coercion or undue influence, and the facilities available in an emergency.  
• If appropriate, obtain information about any adverse events that may have been reported and may not have been reported.  
• Complete the Site Visit Checklist and Summary Report. |
| 4   | IRB Secretary and Staff         | • Deliver a Summary Report – signed by the IRB Chair, to the Investigator within 2 weeks.  
• Include the Site Visit Summary in the IRB meeting agenda |
| 5   | IRB Chair                       | • Develop and implement quality improvements as indicated by audits |