1. Check for accuracy and completeness of documents received from BI-IRB before signing the receipt for documents or within 1 working day of documents receipt by electronic file. Submit your objection and/or any query within the stated time for type to documents receipt. After that time frame, BI-IRB documents sent will be considered accepted by the recipient as accurate and complete.
2. Conduct research project as documented in the most recent BI-IRB approved research protocol and related document. The approved documents must have BI-IRB approval stamp which is signed by the person designated by BI-IRB chairperson on every page. Investigator must strictly follow BI-IRB conditions for approval as stated in the certificate of approval for the research project. Conduct research project according to an applicable laws and regulations.
3. Use the most recent BI-IRB approved and stamped participant information sheet and informed consent form, recruitment materials, brochure, and other material to be provided to research participants.
4. Investigator must submit the following documents to BI-RB for approval or acknowledgement using BI-IRB forms and accompanying required documents.

4.1 Protocol or Document or Project Amendment (AF03-IRB1.03)

Approval from BI-IRB is required prior to implementation of the following (unless the change is necessary to eliminate immediate hazard to research participant which must be reported as protocol deviation within 10 days after the event).

4.1.1 Research project according to research protocol that have been changed from the most recent BI-IRB approved research protocol.

4.1.2 Planned deviation from the most recent BI-IRB approved research protocol.

4.1.3 For changes necessary to eliminate immediate hazard to research participant

If investigator wants to conduct research project according to the changes, an amendment of the research protocol, using Research Project Correction / Amendment Form (AF03-IRB1.03) must be submitted for BI-IRB approval prior to performing the changes on research participant.

4.2 Progress report (AF01-IRB1.06)

Investigator must submit progress report for the research project as per frequency stated in BI-IRB certificate of approval. In case where research project is still ongoing and is not expected to end prior to expiry of BI-IRB approval for renewal of approval, investigator must submit Progress Report Form (AF01-IRB1.06) along with the required documents at least 1 month prior to the date of expiry to avoid lapse in approval.

4.3 Project Closure and Final report (AF02-IRB1.06)

When the research project is completed, investigator must submit Final Report Form (AF02-IRB1.06) accompanied by summary of the result of research project to BI-IRB for acknowledgement. After BI-IRB acknowledgement of research project closure, further intervention in research participant cannot be performed. As soon as the project’s publication and abstract (in Thai or in English) are available, investigator must submit a copy to BI-IRB for acknowledgement.

4.4 Protocol Deviation or Violation and/ or violation of regulations, law, good research practice, good clinical research
 practice (GCP) or ethical principal of research (AF03-IRB1.06)

When there is deviation or violation in conduct of research project from the most recent BI-IRB approved research protocol, and/ or violation of regulations, law, good research practice, good clinical research practice (GCP) or ethical principal of research, investigator must submit a Report of Protocol Deviation / Violation (AF03-IRB1.06) within 10 days after the deviation or violation is known to the investigator.

4.5 Adverse Event Report

When Serious adverse event (SAE) and Suspected Unexpected Serious Adverse Reaction (SUSAR), Adverse Event (AE), occur in research participant in BI-IRB approved research project, investigator must submit either SAE, SUSAR or AE report (AF04-IRB1.06 or CIOMs form) within the time frame as specified in ICH GCP. This report must specify whether the event has resulted in change in benefit/risk ratio to research participant.

4.5.1 Adverse Event on site (occurring in this institution or the institution principal investigator conducts research project).

4.5.1.1 Serious Adverse Event (SAE) on site

SAE results in death or is life threatening, submit SAE report within 24 hours. Other SAE report within 7 days. Use BI-IRB SAE Form and attach sponsor’s SAE report (if available).

4. 5.1.2 SUSAR on site

In case of death or life-threatening, investigator or sponsor report within 7 days, followed by full report within 15 days

Other SUSAR, investigator or sponsor report within 15 days, followed by full report as soon as possible. Use BI-IRB SUSAR report or CIOMs form.

4.5.1.3 Other changes that may increase risk or impact safety of research participant. Investigator or sponsor must report within 15 days.

4.5.1.4 Other unanticipated event or event that may affect research participant, report annually at time of annual progress report.

4.5.2 Adverse event occurring off-site

4.5.2.1 SUSAR off site report in summary at least every 6 months. Use BI-IRB Form or sponsor form that correspond to BI-IRB form.

4.5.2.2 Other unanticipated event that maybe harmful to research participant, report within 15 days.

4.5.2.3 Other events, investigator or sponsor report annually at time of annual progress report.

4.5.3 Other adverse event occurring on site or off site.

Investigator or sponsor report annually at time of annual progress report. Use BI-IRB form separately from SAE, SUSAR report occurring on site and off site, along with summarization of pertinent issues.

1. Inquiry, objection, complaint can be submitted to BI-IRB office as stated below.

Bumrungrad International-Institutional Review Board (BI-IRB)

14th Floor Building C (BI Tower),

33, Soi 3 (Nana Nua), Sukhumvit Road,

Khlong Toei Nua Subdistrict, Vadhana District, Bangkok 10110

Tel. 02-011-4156, 02-011-4157 Email: BIInstitutional@bumrungrad.com