



**Nova Southeastern University
Standard Operating Procedure for GCP**

Title: <u>ICH Guidelines for IRB</u>		Version # 1
SOP Number: OCR-IRB-003	Effective Date: August 2013	Page 1 of 4

POLICY: An IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid to trials that may include vulnerable subjects

PROCEDURE:

1. The IRB/IEC should obtain the following documents:
 - 1.1 trial protocol(s)/amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in the trial, subject recruitment procedures (e.g. advertisements), written information to be provided to subjects, Investigator's Brochure (IB), available safety information, information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications, and any other documents that the IRB/IEC may need to fulfil its responsibilities.
 - 1.1.1 The IRB/IEC should review a proposed clinical trial within a reasonable time and document its views in writing, clearly identifying the trial, the documents reviewed and the dates for the following:
 - 1.1.2 approval/favourable opinion;
 - 1.1.3 modifications required prior to its approval/favourable opinion;
 - 1.1.4 disapproval / negative opinion; and
 - 1.1.5 termination/suspension of any prior approval/favourable opinion.

2. The IRB/IEC should consider the qualifications of the investigator for the proposed trial, as documented by a current curriculum vitae and/or by any other relevant documentation the IRB/IEC requests.
3. The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year.
4. The IRB/IEC may request more information than is outlined in paragraph 4.8.10 be given to subjects when, in the judgement of the IRB/IEC, the additional information would add meaningfully to the protection of the rights, safety and/or well-being of the subjects.
5. When a non-therapeutic trial is to be carried out with the consent of the subject's legally acceptable representative (see 4.8.12, 4.8.14), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials.
6. Where the protocol indicates that prior consent of the trial subject or the subject's legally acceptable representative is not possible (see 4.8.15), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials (i.e. in emergency situations).
7. The IRB/IEC should review both the amount and method of payment to subjects to assure that neither presents problems of coercion or undue influence on the trial subjects. Payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject
8. The IRB/IEC should ensure that information regarding payment to subjects, including the methods, amounts, and schedule of payment to trial subjects, is set forth in the written informed consent form and any other written information to be provided to subjects. The way payment will be prorated should be specified.
9. Composition, Functions and Operations:
 - 9.1 The IRB/IEC should consist of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial. It is recommended that the IRB/IEC should include:
 - 9.1.1 (a) At least five members.
 - 9.1.2 (b) At least one member whose primary area of interest is in a nonscientific area.

- 9.1.3 (c) At least one member who is independent of the institution/trial site.
 - 9.1.3.1 Only those IRB/IEC members who are independent of the investigator and the sponsor of the trial should vote/provide opinion on a trial-related matter.
 - 9.1.3.2 A list of IRB/IEC members and their qualifications should be maintained.
- 10. The IRB/IEC should perform its functions according to written operating procedures, should maintain written records of its activities and minutes of its meetings, and should comply with GCP and with the applicable regulatory requirement(s).
- 11. An IRB/IEC should make its decisions at announced meetings at which at least a quorum, as stipulated in its written operating procedures, is present.
- 12. Only members who participate in the IRB/IEC review and discussion should vote/provide their opinion and/or advise.
- 13. The investigator may provide information on any aspect of the trial, but should not participate in the deliberations of the IRB/IEC or in the vote/opinion of the IRB/IEC.
- 14. An IRB/IEC may invite nonmembers with expertise in special areas for assistance.
- 15. Procedures
 - 15.1 The IRB/IEC should establish, document in writing, and follow its procedures, which should include:
 - 15.1.1 Determining its composition (names and qualifications of the members) and the authority under which it is established.
 - 15.1.2 Scheduling, notifying its members of, and conducting its meetings.
 - 15.1.3 Conducting initial and continuing review of trials.
 - 15.1.4 Determining the frequency of continuing review, as appropriate.
 - 15.1.5 Providing, according to the applicable regulatory requirements, expedited review and approval/favourable opinion of minor change(s) in ongoing trials that have the approval/favourable opinion of the IRB/IEC.
 - 15.1.6 Specifying that no subject should be admitted to a trial before the IRB/IEC issues its written approval/favourable opinion of the trial.

15.1.7 Specifying that no deviations from, or changes of, the protocol should be initiated without prior written IRB/IEC approval/favourable opinion of an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change of monitor(s), telephone number(s))

15.1.8 Specifying that the investigator should promptly report to the IRB/IEC:

15.1.9.1 Deviations from, or changes of, the protocol to eliminate immediate hazards to the trial subjects

15.1.9.2 Changes increasing the risk to subjects and/or affecting significantly the conduct of the trial

15.1.9.3 All adverse drug reactions (ADRs) that are both serious and unexpected.

15.1.9 New information that may affect adversely the safety of the subjects or the conduct of the trial.

15.1.10 Ensuring that the IRB/IEC promptly notify in writing the investigator/institution concerning:

15.1.10.1 Its trial-related decisions/opinions.

15.1.10.2 The reasons for its decisions/opinions.

15.1.10.3 Procedures for appeal of its decisions/opinions.

16 Records:

16.1 The IRB/IEC should retain all relevant records (e.g., written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence) for a period of at least 3 years after completion of the trial and make them available upon request from the regulatory authority(ies).

16.2 The IRB/IEC may be asked by investigators, sponsors or regulatory authorities to provide its written procedures and membership lists.