DIAMONDS Protocol and GCP Deviations / Serious Breach Reporting Guidelines

1. PROTOCOL & OR GCP DEVIATIONS

1.1 Definition

A deviation is defined as an incident which deviates from the trial protocol or GCP or expected conduct of the trial.

1.1.1 Minor deviations

The majority of these deviations do not impact on participants' safety or compromise the integrity of study data, and would be classified as minor. Examples of these include;

- Missing original signed consent form (only photocopy present).

1.1.2 Major deviations

Deviations which may impact on the participants' safety or affect the integrity of the study data would be major deviations, for example;

- Failure to obtain informed consent (i.e. no documentation in source data or an informed consent form)
- Enrolment of subjects that do not meet the inclusion/exclusion criteria
- Undertaking a trial procedure not approved by the REC (unless for immediate safety reasons)
- Failure to report a SAE (Serious Adverse Event)

1.2 Recording and reporting of protocol &/or GCP deviations

All deviations from the protocol should be fully documented on the protocol deviation form in the CRF which should be completed by a member of the research team.

If a deviation is deemed to be minor in nature, these should be documented on the protocol deviation form; further notification to the CTU or Sponsor is not required.

SERIOUS BREACH

2.1 Definition

A serious breach is defined as a deviation from the trial protocol or GCP which is likely to effect to a significant degree:
i) the safety or physical or mental integrity of the subjects of the trial; or
ii) the scientific value of the trial

2.2 Recording and reporting of potential serious breaches

It is the responsibility of the PI to identify and assess serious breaches occurring during the day to day running of the clinical trial. The PI or designee is responsible for ensuring that potential serious breaches are reported directly to the CTU and Sponsor within one working day of becoming aware of the breach.

If the deviation is suspected by the PI to be a 'serious breach' according to the definition above, the PI should contact the CTU immediately and provide all available information. A 'Notification of

serious breach of trial protocol or GCP' form can be found in Section 6.0 of your Investigator Site File (ISF). Please complete this form and email it to DIAMONDS@nictu.hscni.net (CTU) & Clinical.Trials@belfasttrust.hscni.net (Sponsor).

Once the CTU has been notified of a suspected serious breach, the Chief Investigator (CI) will be notified by a member of the trial management team. The Sponsor, along with the trial management team, will investigate reports of potential serious breaches and fully document any action taken. If evidence is obtained that a serious breach has occurred the Sponsor will report the serious breach to the competent authority in accordance with the applicable regulatory requirements.

2. MONITORING

Members of the trial management team including Monitors will periodically review the protocol deviations reported by sites and:

(a) decide whether deviations need to be investigated further
(b) ensure that the relevant information has been obtained and recorded
(c) ensure appropriate remedial action has been taken and documented
(d) ensure serious breaches have been reported and the Sponsor informed

3. QUERIES

If staff are unsure if an event should be recorded as a protocol deviation, violation or serious breach they should seek advice from the Northern Ireland Clinical Trials Unit (NICTU) either by emailing DIAMONDS@nictu.hscni.net or by telephone on (028) 9063 5794.