# DIAMONDS- Serious Adverse Event (SAE) Reporting Guideline

**Please refer to the protocol for assessment of safety, definition of adverse events and a list of anticipated adverse events due to laser treatment**

## 1 SAE REPORTING

### 1.1 WHO

All Adverse Events (AEs) not related to the patients underlying medical conditions will be assessed for seriousness, expectedness, and relatedness by the PI or designee and, recorded in the CRF. All AEs will also be recorded in the participant's medical notes.

If the event is judged to be serious based on the definition in the protocol, this should be reported to the NICTU using the Serious Adverse Event (SAE) report form.

### 1.2 WHERE

Serious Adverse Events (SAEs) require expedited reporting. The SAE Form should be submitted to the NICTU as soon as your site becomes aware of the event and no later than 24 hours after becoming aware of the event by email to clinicaltrials@nictu.hscni.net

All SAE's should be recorded on the AE Form in addition to the SAE Form. To facilitate reconciliation of data relating to AEs and SAEs, please ensure the information recorded across the AE and SAE Forms are recorded consistently. All AEs should also be recorded in the participant's medical notes.

### 1.3 ONWARD REPORTING

NICTU will be responsible for onward reporting of related and unexpected SAEs to the CI, main Research Ethics Committee (REC) and Sponsor within the required timelines.

An SAE occurring to a research participant will be reported to the main REC where in the opinion of the CI the event was:

a) Related- that is, it resulted from administration of any of the research procedures, and
b) Unexpected- that is, the type of event is not listed in the protocol as an expected occurrence.

This will be sent to REC within 15 days of the CI becoming aware of the event.

## 2.0 URGENT SAFETY MEASURES

The PI or designee may take appropriate urgent safety measures in order to protect participants from any immediate hazards to their health or safety. Sites should advise NICTU by telephone using 028 9063 5794 and follow up an email clinicaltrials@nictu.hscni.net as soon as it is safe to do so detailing reasons for the urgent safety measures and what steps were taken.

NICTU will be responsible for onward reporting of any urgent safety measures taken to REC and Sponsor.

The main REC will be notified by telephone immediately and in writing within three working days (by the CI or sponsor). The written notification should set out the reasons for the urgent safety measures and the plan for further action.