National Healthcare Group

Adding years of healthy life

NHG ROAM

Research Online Administration & Management

Guide to Reporting Multiple Non-Compliance (NC) Events/Study Deviations in a Single Non-Compliance/Study Deviation Report (NCR) Form

Version 2.0 dated 14 June 2018

1. If **multiple NC events/study deviations** had occurred/had been identified within the reportable timeframe for the same study, Principal Investigators and study team members can report them to the DSRB using **a single NCR form**.

2. It is not necessary to group the same events together as long as the required information is provided clearly in the NCR form. However, it is recommended **to keep to within 5 different events** in a single NCR form so that it doesn't become too difficult to read the information.

Important Things to Note

3. If multiple events are reported in the same NCR form, the date of occurrence in Question No. 1 of the NCR form should be the **earliest date** of all the NC events/study deviations.

4. All NC events/study deviations must be reported to DSRB as soon as possible but **no later than 14 calendar days** after first knowledge by the Investigator.

5. It is important for study teams to **list each NC event/study deviation (e.g. using numbers/alphabets)** and **state clearly the relevant information for each NC event/study deviation in order** in the respective sections of the NCR form. This would facilitate the efficient review of the NC events/study deviations. Please follow the examples below on how to report multiple NC events/study deviations using the same NCR form.

6. **Avoid cramming too many events** into the same NCR form. It is recommended to keep to a **word limit of 600 words** in each question of the NCR form. Use a separate NCR form if there are many events to be reported.

7. **Avoid using abbreviations** as this might require further clarifications/explanations and delay the review process.

1. Example 1 – Different NC events/study deviations for different subjects

Non Compliance/Study Deviation Report

*Denotes compulsory fields

Form Status:	Submission Draft
Form ID:	[DRAFT]
DSRB Reference Number:	2011/01684
Study Title:	ROAM's performance testing - Study Amendment
Principal Investigator:	PI-01 ROAM
Institution:	ROAM-INST
Department:	ROAM-DEPT

Principal Investigators and study team members can now report multiple NCR events/study deviations from the same study in the same NCR form, subjected to the word limit in the NCR form. Please refer to the guide here for more information.

1. Date of Non-Compliance/Study Deviation *

27-Nov-2017

2. Please describe in detail the nature of the Non-Compliance/Study Deviation including the date of occurrence.*

a) The study team did not use the correct version of the ICF to take consent (Date: 27th Nov 2017)
- The study team did not use the most updated approved version of the ICF for the consent process

b) Body weight, blood pressure were measured for subjects 123 and subject 456 (Date: 19th Dec 2017)
-Body weight and blood pressure measurements were not stated in the approved protocol

3. Explain/Describe*
(i) why or how the Non-Compliance/Study Deviation occurred,
(ii) the steps taken to rectify/correct the Non-Compliance/Study Deviation, and
(iii) the outcome of the Non-Compliance/Study Deviation.

(a) Oversight by the study team as they did not realized that there was an updated approved version of the ICF.

(b) The study team did not realize that body weight and blood pressure measurements are not stated in the approved protocol

The earliest date of all the NC events/study deviations should be stated under Question No. 1.

List the NC events/study deviations in order using numbers/alphabets and state the date for each NC event/study deviation.

If there are different reasons why the NC event/study deviation occurred, list the reasons accordingly for each NC event/study deviation.

Please also answer 3(i), (ii) and (iii) for each NC event.

5. In your judgement, did the Non-Compliance/Study Deviation increase the potential risk to the Research Participant and/or others?*

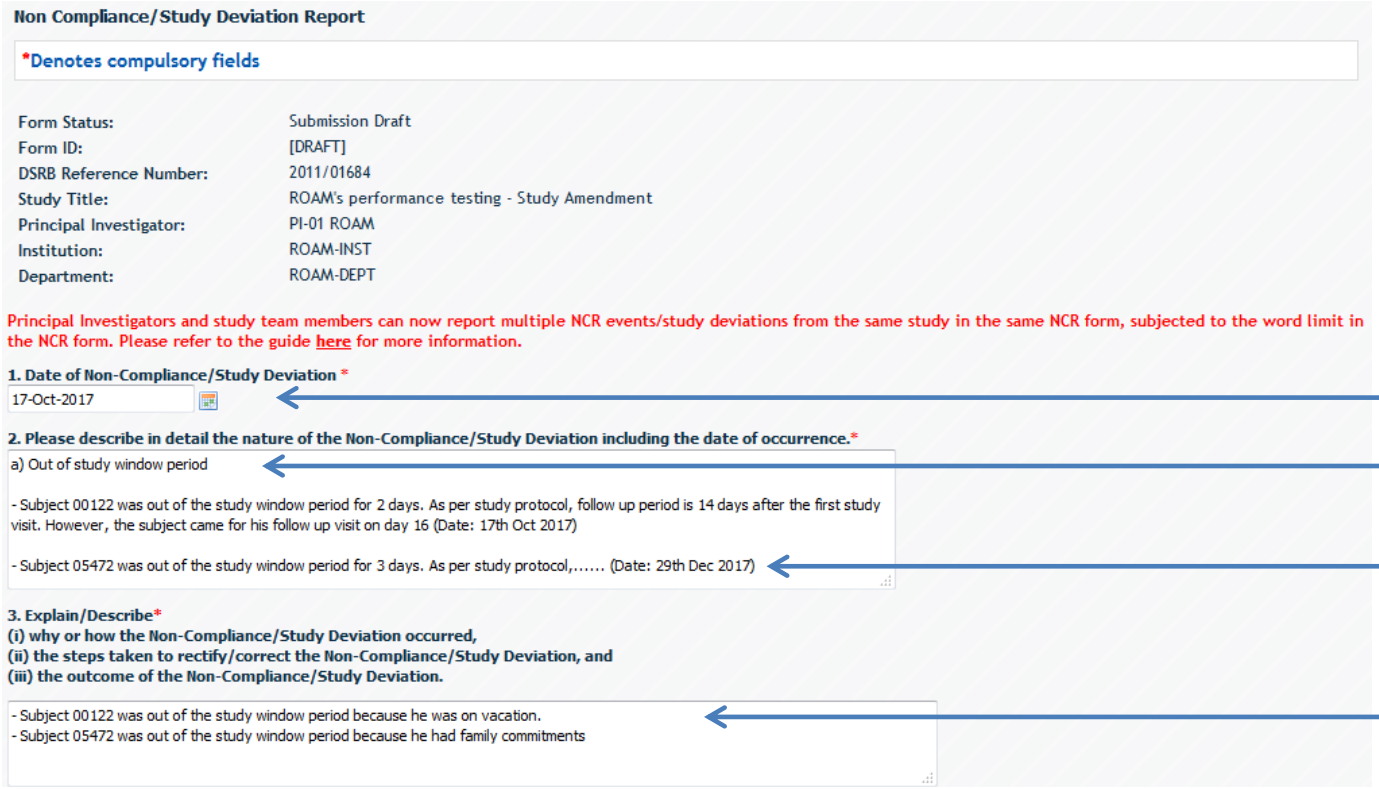
6. Describe any follow up action taken to prevent this Non-Compliance/Study Deviation from occurring in the future.*

(a) Study team to obtain re-consent from subject. Study team will ensure that only the most updated ICF is to be used for the consent process.

(b) Study team will submit an amendment to include body weight and blood pressure measurements in the study protocol and DSRB application.

If there are different corrective actions for each NC event/study deviation, please state the respective corrective actions for each NC event/study deviation.

2. Example 2 – Same NC event/study deviation for different subjects (e.g. out of study visit window period):



Non Compliance/Study Deviation Report

*Denotes compulsory fields

Form Status:	Submission Draft
Form ID:	[DRAFT]
DSRB Reference Number:	2011/01684
Study Title:	ROAM's performance testing - Study Amendment
Principal Investigator:	PI-01 ROAM
Institution:	ROAM-INST
Department:	ROAM-DEPT

Principal Investigators and study team members can now report multiple NCR events/study deviations from the same study in the same NCR form, subjected to the word limit in the NCR form. Please refer to the guide here for more information.

1. Date of Non-Compliance/Study Deviation *

17-Oct-2017

2. Please describe in detail the nature of the Non-Compliance/Study Deviation including the date of occurrence.*

a) Out of study window period

- Subject 00122 was out of the study window period for 2 days. As per study protocol, follow up period is 14 days after the first study visit. However, the subject came for his follow up visit on day 16 (Date: 17th Oct 2017)

- Subject 05472 was out of the study window period for 3 days. As per study protocol,..... (Date: 29th Dec 2017)

3. Explain/Describe*
(i) why or how the Non-Compliance/Study Deviation occurred,
(ii) the steps taken to rectify/correct the Non-Compliance/Study Deviation, and
(iii) the outcome of the Non-Compliance/Study Deviation.

- Subject 00122 was out of the study window period because he was on vacation.
- Subject 05472 was out of the study window period because he had family commitments

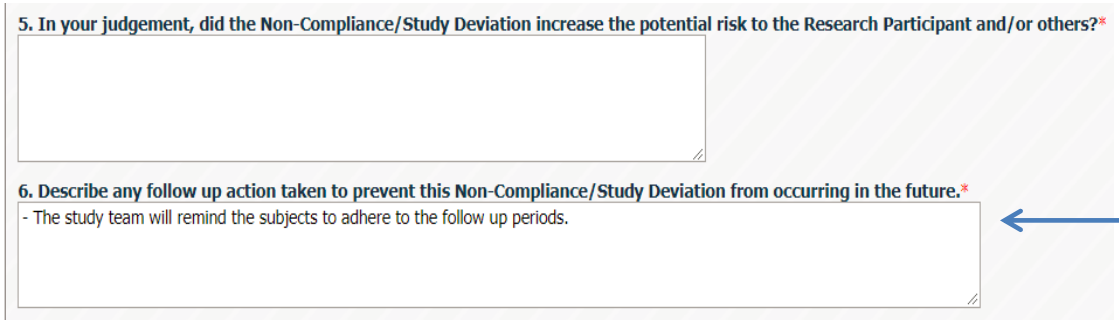
The earliest date of all the NC events/study deviations should be stated under Question No. 1.

State the NC event/study deviation.

List the relevant information in point form and state the date for each NC event/study deviation.

If there are different reasons why the NC event/study deviation occurred, list the reasons accordingly for each subject.

Please also answer 3(i), (ii) and (iii) for each NC event.



If there are different corrective actions for each NC event/study deviation, please state the respective corrective actions for each NC event/study deviation.

Contact us

For further enquiries, please contact us via email at OHRPP@nhg.com.sg or call the DSRB hotline at 6471 3266.