Nova Southeastern University
Standard Operating Procedure for GCP

Title: Data Queries		Version # 1
SOP Number: OCR-ED-003	Effective Date: August 2013	Page 1 of 2

PURPOSE: Data Clarifications are used to explain problems usually associated with Case Report Forms. Data on the CRF's may be unclear because; the data might not be readable, the data may be missing, the data may be outside certain ranges, spelling may be incorrect, numerical values may be incorrect or outside expected parameters and certain blocks or fields in the data form itself cannot accept the information placed in the space. Other forms of errors or interpretations may occur and the site will be expected to verify the correctness of the CRF to the source documents using the DCF.

POLICIES:

1. Information collected on the CRF is sent from the site to a data manager who then takes the information contained on the form and inputs the data into a computer system. Certain clarifications and corrections will be required by the site who will receive the DCF back from the Data Manager. Some information will be incorrect and will need to be corrected by comparing to source documentation, other information is correct but needs to be further explained whereas other information may be simply omitted and needs to be filled in. Information one can usually expect on the DCF will include but not be limited to:
   - 1.1 Protocol number.
   - 1.2 Date of the DCF.
   - 1.3 Investigator.
   - 1.4 Unique DCF number.
   - 1.5 Subject unique number.
   - 1.6 Date the DCF was sent.
   - 1.7 Number of the particular Discrepancy.
   - 1.8 The number of times the DCF was issued.
   - 1.9 The level of priority.
   - 1.10 An explanation of what the discrepancy is.
   - 1.11 A request to review the discrepancy (the site) and explain the discrepancy on the DCF.

1.12 A description of the CRF data field.
1.13 A description of the CRF page.
1.14 A description of the CRF panel.
1.15 A description of the particular item.
1.16 A comment on the item.
1.17 The current value of the item.
1.18 The proposed new value that the site must fill in.
1.19 The reason why the change was made by the site or why the change wasn't made.
1.20 Any additional comments pertinent to the altered DCF.
1.21 The Data Manager who requested the site review the DCF.
1.22 The signature of the investigator.
1.23 The date the query and response was completed and verified that it was true, accurate, legible and complete.

2. Clarify the information requested on the DCF and return the DCF by the means requested by the Sponsor in a timely manner.
   2.1 No changes can be made to the CRF once the CRF has been separated and pulled by the monitor and transmitted to data management.

3. All DCFs will be reviewed and verified to the source documentation by the Monitor at the next monitoring visit.

4. Keep all completed DCFs with the original CRFs.
   4.1 It may be advisable to keep a separate copy of the completed DCFs in a separate binder for ease of accounting.
   4.2 All DCFs become part of the study related materials to be kept in long-term storage.