SOP TITLE: **Data Submission**

Relevant Forms: CRF Submission Schedule, CRF Submission Checklist (SC), Relevant Case Report Forms (CRFs)

1 Purpose

1.1 To describe the procedures for obtaining and submitting patient data.

2 Procedure

2.1 General Data Submission Procedures

2.1.1 The CRF Submission Schedule and CRF Submission Checklist (SC) provides a timeline for procedures and office visits, and the corresponding forms to be completed at each patient visit.

2.1.2 The forms are designed to be used as a checklist during the procedure or office visit to ensure each item is completed and to record pertinent data.

2.1.3 Completed CRFs and relevant source documents (i.e. lab reports, H&P, imaging reports, radiation therapy summary, etc.) should be submitted to Sponsor via secure fax or e-mail (listed on the bottom of each form) as soon as possible.

2.1.4 The relevant CRF, and when necessary a Data Cover Sheet (Form DC) should be used as a cover page when submitting data to Sponsor. Persons completing the submission package will record their name, date, and when required signature, certifying the records enclosed are accurate, complete, exact copies of the original documents associated with the listed patient, and represent all relevant information related to the patient visit.

2.1.4.1 When submitting a document consisting of more than one page the submission will be considered as one record.

2.1.4.2 The number of pages of the submission should be annotated on the Data Cover Sheet. If no DC is included, this may be annotated on the CRF, Source Document(s) included, or email where the packet is attached.

2.1.4.3 If submitting individual source records without a CRF, a separate Data Cover Sheet should be used for each record.

2.1.4.4 If no CRF or Data Cover Sheet are provided, site should sign and date the first page of the submission packet.

2.1.4.5 In addition, if data are de-identified, and no CRF or Data Cover Sheet are provided, site should annotate at a minimum the first page of each source record with the patient's unique Protocol Case Number (PCN).

2.1.5 Sponsor will review the documents for completeness and accuracy and reconcile any discrepancies through the generation of data queries.

2.1.6 If records are de-identified Sponsor will confirm records are associated to the listed patient through one or a combination of the below methods.

2.1.6.1 Confirmation the record is submitted in totality with a completed and signed CRF or when applicable Data Cover Sheet (Form DC), that includes the unique protocol case number (PCN).

2.1.6.2 Confirmation through site annotated PCN on each source record.

2.1.6.3 Confirmation through available information (e.g. Patient initials, visit date). Visit date should be maintained in deidentified records.