Subject Enrollment and Data Collection

V. <u>Subject Enrollment and Data Collection</u>

When a subject is registered to an approved study, the coordinator needs to submit the following documents to the Radiation Oncology Treatment Team at the credentialed treatment facility.

- 1. Subject Enrollment Notification Form
- 2. Data collection forms that are to be completed and submitted by the treatment team's dosimetrist. (refer to protocol)

(These forms must have the subject and clinical data sections completed before they are submitted to the Treatment Team.)

3. A copy of the Current IRB Approved Protocol and/or access to this document in electronic format per submitting Department's Guidelines.

Email subject line should indicate: New Subject Enrollment Information for "Study #"

In the rare event that you are unable to directly communicate with the Treatment Team, please contact the DRO Clinical Research Group at 585-275-7848.

Please fill out completely, review the radiation section of the protocol as necessary to answer the questions.

Subject to be treated at: (check one)														
	SMH	Highland	Parkridge	Sands	Pluta									
	Subject Last I	Name [.]		Subject First Name										
	Subject DOB:			Subject MRN:										
	Study Sponsor:			Study #:										
	Subject #:			Stratification Arm:										
Date of Registration:														
		oximate RT start date, as required by protocol: (Note: even a rough idea will help plan, e.g., end of May)												
	Is rapid review by required prior to the subject starting their RT? Yes No													
	Time Frame o	First data submission(<i>e.g.</i> ,3 days after RT start):												
	Time Frame of additional Data submission													
	Where is data QARC	to be submitte C TRIA		dinator	Other:									
ç	t of Data required to be submitted by the Dosimetrist Please attach required forms with													

List of Data required to be submitted by the Dosimetrist. Please attach required forms with the subject and clinical data section completed.

Additional Information:

1. Coordinator Name:

Phone # and Email

Email the following to the Radiation Oncology Treatment Team when subject is registered.

• Subject Enrollment Notification Form, Current IRB approved protocol, Other required forms

Email subject line should indicate: New Subject Enrollment Information for "Study #"

If the RT is not required at onset of protocol treatment, please <u>send an email reminder</u> to the treatment team. This reminder should be approximately 3 weeks in advance of the required start date to ensure the subject starts their RT on time.

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