Initial Protocol Review and Data Collection Procedures

(For protocols with a radiation treatment component)

I. Initial Protocol Review:

Initial Protocol Review occurs on an ongoing basis, please allow 3 weeks from date of submission for completion of the review.

Submit the Initial Protocol Review Form to: DROIPR@urmc.rochester.edu

Include the following items with the submission:

- Initial Protocol Review Form (See Appendix)
- Facilities at which subjects will be treated
- Protocol
- Radiation Treatment Case Report Forms
- Facility or Regulatory forms that are Radiation Specific

The Protocol will be reviewed by:

1. Radiation Oncology MD
2. Physicist
3. Dosimetrist
4. Radiation Therapist
5. Research Coordinator

After Review and approval an email will be sent for your department records.

This email will include:

- A signed and dated approval form.
- Credentialing approval letter or credentialing status (if required)
- A copy of the subject enrollment form and department contact list

II. Credentialing Process:

The protocol may require that a radiation treatment site be credentialed in order to enroll subjects on the protocol.

- The credentialing status will be assessed as part of the Initial Protocol Review.
- The credentialing status is treatment facility specific.

  Therefore you must indicate on the Initial Protocol Review form the facility(ies) at which you intend to enroll and treat subjects.
- For NCI Cooperative Group Studies the Credentialing Status Inquiry Form is submitted to IROC Houston.

IROC Houston will then issue a response via email that states whether or not a treatment facility meets the credentialing requirements.

- A copy of the credentialing approval letter will be sent with the Initial Protocol review approval.
- For Other Studies, Credentialing documentation will be provided as required per protocol.

  Please submit study specific forms with the Initial Protocol Review request.
- Please follow the steps in the protocol for the submission of the credentialing approvals.

III. Protocol Amendments:

If a protocol amendment includes changes to the Radiation Treatment Section, please submit a copy of the protocol to the Radiation Oncology Treatment Team for review.

IV. Budgets:

Budgeting needs will be discussed as necessary.

V. Subject Enrollment and Data Collection:

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 (See appendix).

- Subject Enrollment Notification Form (see appendix)
- 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.)
- 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.

Appendix: 1. Initial Protocol Review Form

Initial Protocol Review

Please submit the following to: DROIPR@urmc.rochester.edu

- This form
- The Protocol
- Radiation Specific Manuals
- Study Specific Forms to be submitted by DRO personnel

Date of Submission: _____ Department: _____

Protocol Title

_____

Protocol Version Date _____

Study Type:

☐ Investigator Initiated ☐ Other _____

☐ Cooperative Group ☐ Pharmaceutical Sponsor

Protocol Treatment will be given at the following Radiation Treatment Facilities:

☐ SMH ☐ Highland ☐ Parkridge ☐ Sands ☐ Pluta

Contact Information

Local Investigator: _____

Study Coordinator: _____

Other Personnel: _____

Initial Protocol Review Approval

Protocol Title: **Protocol Version Date:**

Department:

Local Investigator:

Study Coordinator:

☐ **APPROVED** at the following radiation treatment facilities.

☐ SMH ☐ Highland ☐ Pluta ☐ Sands ☐ Parkridge

☐ **APPROVED Pending** Completion of the following:

☐ **NOT approved** at the following radiation treatment facilities.

☐ SMH ☐ Highland ☐ Pluta ☐ Sands ☐ Parkridge

Reason not approved:

Reviewed by:

Attending: Dosimetrist: Physicist

Radiation Technologist Research Coordinator

DRO IPR SIGNATURE

Appendix: 2. Subject Enrollment Notification Form

Radiation Oncology Radiation Therapy Quality Assurance Subject Enrollment Notification Form

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 Name: Subject First Name

Subject DOB: Subject MRN:

Study Sponsor: Study #:

Subject #: Stratification Arm:

Date of Registration:

Approximate RT start date, as required by protocol: (Note: even a rough idea will help us to plan, e.g., end of May)

Is rapid review by required prior to the subject starting their RT? ☐ Yes ☐ No

Time Frame of First data submission(*e.g.,*3 days after RT start):

Time Frame of additional Data submission

Where is data to be submitted?

☐ QARC ☐ TRIAD ☐ Coordinator ☐ Other:

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 send an email reminder 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.