BR Form Completion Instructions

These instructions are meant to clarify form completion and web entry only. Refer to the Investigators Brochure Appendix I and II for instructions on preparing and quality control of Cu-ATSM. Contact Data Management with any form related questions.

The original signed form must be kept at the site for a minimum of 7 years and be made available in the event of an audit (per ACRIN and FDA policy)

This form must be completed each time the Cu-ATSM is prepared and QC'd, even in the event of a failed prep/QC. All BR forms must be web entered in the corresponding case calendar.

In the event more than one kit was used for a case, a request must be sent to ACRIN DM to add an additional BR form(s) to the case calendar within 48 hours of kit use.

This form should be completed during kit preparation and quality control.

All elements of this form are required
(as indicated by '[#]')

All data recorded in 1 and 2 must be verified. The person verifying the data must record their initials in the last column as indicated. It is acceptable to do a self verification.

3. ^{64}Cu-ATSM QC Results If the QC passed radiochemical purity and bacterial endotoxin testing per Investigators Brochure, these results must be copied exactly onto the corresponding TA form. In the event of failed testing results/purity measurements, a new kit should be prepared and recorded on a new BR form.

Radiochemical Purity- Copy the percentage purity as calculated in Step 5 above (2. Radiochemical Purity Measurement)

Bacterial Endotoxin- Check the appropriate procedure and testing result

The signature of the person(s) preparing ^{64}Cu-ATSM, QC'ing ^{64}Cu-ATSM, and web entering the form must be recorded on the original paper copy. All persons who verified data/initiated on the form must sign the appropriate line. During web entry, confirmation of the signatures on the original form will be verified.