CTRS (formerly CRC) Protocol Checklist

✓ For study feasibility inquiry, send completed CTRS Services/Resources Request Form to the CTRS Administrator Zeporia Kettles: zkettles@med.miami.edu

✓ For new protocols, add the CTRS to the protocol in the eProst Form submission (additional study information, items 4a & 5), and upload the completed CTRS Services/Resources Request Form.

✓ For on-going protocols that are new to the CTRS, file a modification in eProst to add the CTRS as a site where study activities will take place.

✓ The CTRS staff will review the CTRS Services/Resources Request Form and eProst protocol.

✓ The CTRS staff will send PI and study coordinator CTRS services and respective rates.

✓ PI must acknowledge CTRS services and respective rates.

✓ The CTRS ancillary committee will post their determination in eProst. The protocol or modification will proceed to IRB review.

✓ CTRS staff will assist in drafting required forms, including CTRS Physician Treatment Order(s) and Nursing Flowsheet(s).

✓ Confirm IRB approval. The CTRS will be informed via eProst notification.

✓ Provide the CTRS with the study account # for CTRS invoicing.

✓ The CTRS will schedule a protocol in-service. This is a time for the CTRS staff, the PI, and the study staff to meet and learn more about the participants and the procedures that will take place at the CTRS. The PI introduces the study (overview of rationale and methods) and all review the study assessments and the CTRS reservation process. It is important that the CTRS staff and study team are informed of their roles and responsibilities, as well as have an opportunity to ask questions prior to the initiation of study visits.

✓ The PI provides final approval of the forms reviewed at the CTRS protocol in-service.