INSPIR SUBMISSION CHECKLIST

This is a final review checklist to use to ensure that the application is complete prior to submission (not all items are required for all submissions).

☐ All investigators are listed in Section 3 of INSPIR.
☐ All investigators are up to date with human subjects protection training certification (including HIPAA Privacy Module) and recertification requirements.
☐ All investigators have updated their personal profiles to include their titles, departments, roles, etc.
☐ All the necessary signators are listed in Section 3.5.
☐ All external investigators relying on BUMC IRB review are listed in Section 4.
☐ If investigators are listed in Section 4.1, then Question 10.4 is answered “Yes” and the subsequent questions have been answered.
☐ COI disclosures for all investigators have been submitted to the appropriate COI office.
☐ No COI disclosures are attached in INSPIR.
☐ Section 7.2 has been fully completed for all funding sources.
☐ Full grants have been attached, including face pages.
☐ Scope of work descriptions have been attached if funding is under a sub-award.
☐ Sponsor’s protocol has been attached for industry-sponsored research.
☐ A Detailed Protocol for the study has been provided.
☐ Section 10.6 is answered correctly, and the appropriate HIPAA forms have been attached.
☐ Appropriate consent forms have been attached.
☐ Consent forms have been “built” in INSPIR using consent template, final versions contain BUMC header, and “instructions” have been removed.
☐ Pediatric Assent forms have been “built” in INSPIR using assent templates, final version contains BUMC header, and “instructions” have been removed.
☐ All the necessary attachments have been attached to the protocol:
  o Grants
  o HIPAA forms
  o Data abstraction tools / CRFs
  o Surveys, interview guides, focus group guides
  o Data and Safety Monitoring Plans and DSMB charters
  o Recruitment materials including ads, flyers, recruitment texts for emails, letters, etc.
  o Drug information for study drugs
  o Device brochures for device studies

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