

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:
 - Grants
 - HIPAA forms
 - Data abstraction tools / CRFs
 - Surveys, interview guides, focus group guides
 - Data and Safety Monitoring Plans and DSMB charters
 - Recruitment materials including ads, flyers, recruitment texts for emails, letters, etc.
 - Drug information for study drugs
 - Device brochures for device studies