*During the course of a study many variables can contribute to the need to make adjustments and changes to your research protocol. Using this checklist may help you and your staff to confirm that only IRB approved procedures and documents are being used. It may also help you to self-identify issues that may require additional attention, an IRB submission, or other follow-up.*

PLEASE NOTE: ANY CHANGES TO THE IRB APPROVED PROTOCOL AND STUDY DOCUMENTS MUST BE REVIEWED AND APPROVED BY THE IRB PRIOR TO IMPLEMENTATION.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. **IRB History** | **Yes** | **No** | **N/A** | **Comments/notes** |
| A1. Is Brown IRB approval current? |  |  |  |  |
| A2. Is the current approval Full Board status? |  |  |  |  |
| A3. Is the current approval Expedited status? |  |  |  |  |
| A4. Has the study received an Exempt determination? |  |  |  |  |
| A5. Does the study have multiple sites? |  |  |  |  |
| A6. Is there documentation of [sIRB procedures](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/single-irb-review-sirb)/[reliance agreements (IAAs](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/hrpp-irb-home-page)) and copies of other IRB approvals in the study file? |  |  |  |  |
| A7. Are all study site permissions/approvals/letters of support included in the study file? |  |  |  |  |
| A8. Is there a current version of the study protocol on file? |  |  |  |  |
| A9. Does the current study protocol include all approved changes tracking clear dates of approval/implementation noted? |  |  |  |  |
| A10. Have any/all changes to the protocol been submitted and approved by the IRB prior to implementation? |  |  |  |  |
| A11. Are copies of all amendment submissions and approvals organized and maintained for reference and review? |  |  |  |  |
| A12. Are copies of all progress reports and approvals on file? |  |  |  |  |
| A13. Are copies of all [Reportable Events](https://www.brown.edu/research/sites/research/files/18.%20Reportable%20Events%20Policy%20%28Final_12Nov18%29.pdf) on file? |  |  |  |  |
| A14. Does the study have a [Mental Health Safety](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-templates) Plan and is a copy available to all staff? |  |  |  |  |
| A15. Is there documentation of any/all protocol deviations (i.e. instances where the approved protocol was not followed, but increased risk to participants was not apparent as a result) |  |  |  |  |
| A16. Are ONLY the most recently approved versions of study forms and procedures available to study staff? |  |  |  |  |
| A17. Are all IRB-approved study advertisements and recruitment materials present? |  |  |  |  |
| A18. Is all correspondence with the IRB included in the study file? |  |  |  |  |
| A19. Is there a screening and enrollment log? |  |  |  |  |
| A20. Is there an eligibility checklist containing inclusion/exclusion criteria? |  |  |  |  |
| A21. Does the study have a [Data Safety and Monitoring Board (DSMB)?](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/hrppirb-home-page/data-and-safety-monitoring) |  |  |  |  |
| 1. **Study Staff** | **Yes** | **No** | **N/A** | **Comments/notes** |
| B1. Are all [required trainings and certifications](https://www.brown.edu/research/sites/research/files/Training%20Requirements%20Policy%2C%2001-31-19.pdf) (including GCP training for NIH funded studies) current for all appropriate research staff? |  |  |  |  |
| B2. Is there a delegation of authority log (DOA) that lists study staff, title and responsibilities? |  |  |  |  |
| B3. Is there a staff training manual? |  |  |  |  |
| B4. Are there current (within last 2 years) CVs for the PI and any/all other study Investigators on file? |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. **Regulatory Issues/Documentation** | **Yes** | **No** | **N/A** | **Comments/notes** |
| C1. Does this study involve a drug, device or tobacco product? (If No or N/A, skip to section D.) |  |  |  |  |
| C2. If the study involves [an Investigational New Drug (IND),](https://www.brown.edu/research/sites/research/files/8.%20Studies%20Involving%20Drugs-Devices%20v120318.pdf) are completed FDA Forms 1571 and 1572 in the study file? |  |  |  |  |
| C3. [Is there documentation of the descriptions of procedures for obtaining, dispensing and disposing of study drugs/medications in the file?](https://www.brown.edu/research/sites/research/files/Guidance%20for%20Investigators-The%20Management%20of%20Human%20Research%20Studies%20Invo.pdf) |  |  |  |  |
| C4. Does the study involve [an Investigational Device Exemption (IDE)?](https://www.brown.edu/research/sites/research/files/8.%20Studies%20Involving%20Drugs-Devices%20v120318.pdf) |  |  |  |  |
| C5. Is there a device manual in the study file? |  |  |  |  |
| C6. Is the study a [clinical trial](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/clinical-trials)? |  |  |  |  |
| C7. Is the [study registered in clinicaltrials.gov](https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm)? |  |  |  |  |
| C8. [Does the study access, use, or disclose PHI](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/hrppirb-home-page/brown-univ-pol-proc)? |  |  |  |  |
| C9. Does the study include a [HIPAA authorization](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-templates)? |  |  |  |  |
| C10. Has the study obtained a waiver of [HIPAA authorization (appendix G)?](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-templates) |  |  |  |  |
| C11. Is there documentation of approval of the waiver of HIPAA authorization in the study file? |  |  |  |  |
| D. Consent Process | Yes | No | N/A | Comments/notes |
| D1. Does the study consent form include the [“key information” section?](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/revised-common-rule#keyinformation) |  |  |  |  |
| D2. Is the version of the consent form being used the most recent version approved by the IRB? |  |  |  |  |
| D3. Do the study records include all previous versions of IRB approved consent forms with clearly noted version #s/ dates? |  |  |  |  |
| D4. Is the consent process documented in the study file? |  |  |  |  |
| D5. Has the study obtained a [waiver of consent](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/revised-common-rule#keyinformation)? |  |  |  |  |
| D6. Has the study obtained a waiver of documentation of consent? |  |  |  |  |
| D7. Does the consent form include all applicable information as required by the [revised common rule](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-templates), [NIH, or FDA](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-templates)? |  |  |  |  |
| D8. Are there drug receipt, handling, dispensing, return, disposing logs? |  |  |  |  |
| D9. Are there temperature monitoring logs regarding the storage of study drugs? |  |  |  |  |
| D10. Are there device/measures calibration logs? |  |  |  |  |
| **E. Data Storage and Protection** | **Yes** | **No** | **N/A** | **Comments/Notes** |
| E1. Identifiable information of participants (e.g. names, \*addresses, etc.) is securely protected in compliance with by the IRB approved procedures |  |  |  |  |
| E2. If the study proposed to collect the data anonymously, has anonymity been maintained in the physical and/or electronic records?  E3. Electronic data storage is maintained in compliance with IRB approval and [Data Risk Classification.](https://it.brown.edu/computing-policies/risk-classifications) |  |  |  |  |
| **F. Study Communications** | **Yes** | **No** | **N/A** | **Comments/notes** |
| F1. Letters of Understanding/Confidentiality Agreements are included in the study file |  |  |  |  |
| F2. [Data use agreements (DUA)](https://www.brown.edu/research/content/data-use-agreements) are included in the study file |  |  |  |  |
| F3. [Material transfer agreements](https://www.brown.edu/research/conducting-research-brown/industry-engagement-and-commercial-venturing-iecv/faculty-inventors/material-transfer-agreements) are included in the study file |  |  |  |  |
| F4. Copies of reliance agreements ( [IAAs](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-templates), [Smart IRB](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/single-irb-review-sirb)…etc..) are included in the study file |  |  |  |  |
| F5. [Data Safety and Monitoring Board (DSMB)](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/hrppirb-home-page/data-and-safety-monitoring) correspondence are included in the file |  |  |  |  |
| F5. An FDA correspondence log is included in the study file |  |  |  |  |
| F6. Other study notes/information related to study conduct are included in the study file |  |  |  |  |

Please use the contact information below to contact ORI if you have questions regarding the checklist or any checklist responses.

Christiana Provencal, M.A.

QA/QI Administrator/Post Approval Monitoring Manager

Office of Research Integrity

Phone: 863-5729

Email: Christiana\_Provencal@Brown.edu