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| The purpose of this checklist is to provide support for IRB staff conducting Administrative Review. This checklist or equivalent is to be completed by the IRB staff, signed, dated, and retained. | |
| **IRB Number:** |  |
| **Investigator:** |  |
| **Reviewing IRB:** |  |
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| **Reliance Eligibility Pre-Review** | |
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| UM is a site for Investigator-Initiated study and compelling argument for using the external IRB is provided.  Engagement of UM is confirmed.  Considerations for ceding IRB review is completed through Worksheet: HRP-832 | |
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| **Initial Administrative Review** | |
| The submission includes the following items:   * Protocol * Subject facing materials approved by the external IRB * Investigator Brochures * Approval letter of the external, reviewing IRB * The reliance agreement (when necessary and/or master on file with HSRO Administration) | |
| If there is a local COI: (either one and two must be checked or 3 must be checked)  1. The management plan has been shared with the reviewing IRB;  2. The consent document is consistent with the requirements of the management plan.  3. N/A - No COI reported. | |
| The University of Miami Investigator is not included on restricted list and has completed required training.  The research team has completed required training. | |
| Ancillary reviews are completed:  PRMC  N/A  ESCRO  N/A  UHT  N/A  IBC  N/A  Radiation  N/A  DSAC  N/A  JHS  N/A | |
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| The study does not involve an exception from the requirement for informed consent under 21 CFR 50.24  If consent is altered or there is a request to waive, the requirements for an alternation or waiver of consent are consistent with UM SOPs | |
| The consent document includes the appropriate University of Miami “boilerplate” language. | |
| UM will provide HIPAA waiver determination per agreement with the external IRB. | |
| HIPAA form that is an addendum to the ICF will be used if PHI will be collected, created or otherwise accessed.  The research will use a standalone HIPAA Authorization (Form B), if PHI will be collected, created or otherwise accessed. | |
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| Comments: | |
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| Acknowledgement sent to Relying Investigator  OR  Deficiencies that preclude acknowledgment are conveyed to the PI for reconciliation | |
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