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| * **Not for submission. This list is imbedded in the continuing review application and is shown here for informational purposes only.** * **The following materials, if applicable to the protocol, must be submitted with the application.** |

| **Attached** | **N/A** | **Material Type** | | | | |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | - | Research Plan   * *Attach the most current approved version including applicable appendices.* | | | | |  |
|  |  | | Attached | | n/a |  |  |
|  |  | |  | |  | Appendix A – Drugs |  |
|  |  | |  | |  | Appendix B – Medical Devices |  |
|  |  | |  | |  | Appendix C – Ionizing Radiation |  |
|  |  | |  | |  | Appendix D - HIPAA |  |
|  |  | |  | |  | Appendix E – Genetic Materials |  |
|  | - | Current Personnel List (no new personnel may be added without an amendment) | | | | |  |
|  |  | Recruitment Materials   * *“N/A” only acceptable for studies that are closed to enrollment of new subjects* | | | | |  |
|  |  | Informed Consent/Assent/Debriefing Materials   * *Attach current versions of all consent, assent, parent/guardian permission, and debriefing forms.* * *“N/A” only acceptable for studies that: (1) have previously been granted a waiver of informed consent;* ***and/or*** *(2) the study status was reported as data analysis only for the last continuing review.* | | | | |  |
|  |  | External/Non-UO IRB Approval(s) – documentation of continued approval | | | | |  |
|  |  | Documentation of continued clearance or approval from Environmental Health and Safety (e.g., biosafety committee approval, radiation safety committee approval, etc ) | | | | |  |
|  |  | Abstracts, a list of citations, or relevant information (see Part IV above) | | | | |  |
|  |  | Appendix – (move above to under RP) DSMP - Data Safety Monitoring Plan | | | | |  |
|  |  | DSMB/DMC/Independent Monitoring – progress report and/or interim analysis | | | | |  |
|  |  | Investigator Brochure for FDA Regulated Research | | | | |  |
|  |  | FDA progress reports for Investigational Devices | | | | |  |
|  |  | List other: | |  | | |  |
|  |  | List other: | |  | | |  |
|  |  | List other: | |  | | |  |