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| SPONSOR'S REVIEW OF CONTRACT CHECKLIST |  |  |  |
| Key contractual Terms/obligations | Y/N | Comments | GCP Principle |
| Allocation of Sponsor's Responsibilities clear |  |  | 1, 2, 4, 6, 8, 9, 10, 12, 13,14 |
| Protocol Activities/Roles & Responsibilities clear |  |  | 2, 8, 9,11,13 |
| Study IMP (if applicable) or Device Non clinical and clinical information |  |  | 5 |
| Data Protection, Data Security & Data Management |  |  | 13 |
| Confidentiality |  |  | 9 |
| Insurance & Indemnity |  |  | 14 |
| Risk Assessment |  |  | 10 |
| Informed Consent |  |  | 4 |
| Regulatory Authority (REC/MHRA/ARSAC review) considered? |  |  | 3,12 |
| Qualified and appropriately trained Personnel |  |  | 2,11 |
| Standards are applicable e.g. for CTIMPs this would include Clinical Trial Regulations |  |  | 3, 5, 6, 7,8,9,12.14 |
| Pharmacy Technical Agreement required? (e.g. IMP packaging, manufacture, radiolabelling & importation which require QP certification, GMP Compliance) |  |  | 5 |
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| **Sponsor representative confirmation of completion of contract review checklist** |  |  |  |
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| Sponsor(s) representative |  |  |  |
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| Signature |  |  |  |
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