**\*\* Instruction: Please copy and paste the following template to a clean word document or your site letterhead. Please name the document as per the BA G12 guidelines. Upload with your application. Only one site-specific clauses template is required, encompassing all PICFs in use for the study \*\***

During the lead site HREC submission process, there is often the need to revise documents. The Principal Investigator acknowledges they will imbed the approved clauses in the most current approved Master. The form with the current site-based approved clauses will be listed on the approval letter.

**Prior to submission, please ensure the following has been completed:**

|  |  |
| --- | --- |
| 1. Minor administrative changes are the responsibility of the site and do not need to be submitted to Bellberry. These include adding the site name, Principal Investigator details, study contact personnel details, amending footers, formatting, and other typographical errors. Additions or deletions of ethical content must be submitted to the HREC via this template. 2. At a minimum, the site-specific clauses document must list the Master Main PICF approved for the study. Changes to supplementary PICFs (e.g., pregnant partner, optional genetic) should also be included in the last column of the table. 3. If a supplementary PICF is not listed on a site-specific clauses document, the HREC will assume there to be no site-specific changes. |  |
| 1. Ensure that the text included within the site-specific clauses document appropriately identifies any site-specific clauses that will be added to, deleted from, or replaced within the master:  * Added: include any additional clauses required for the site * Deleted: remove any clauses/wording not applicable to the site * Replaced: amend clauses or include wording at designated placeholders (e.g., *“You will receive $X for completing this study”*). * Please delete any rows that do not apply to your study (e.g., radiation) |  |
| 1. Individual sites should not re-word or change wording within the Master PICF to alter clarity, grammar, or style. If wording is required to be updated within the Master PICF, then the lead site should submit an updated Master applicable to all sites. 2. An amendment must be submitted if site-specific changes are required. A tracked and clean version of the site-specific clauses document must be provided with the amendment. |  |

***Please copy from here:***

|  |  |
| --- | --- |
| ***Insert your site/hospital logo*** *<if applicable>* | |
| **Study Title:** |  |
| **Principal Investigator:** |  |
| **Site name:** |  |
| **Site-specific clauses version and date:** | Version XXXX  Date XX-XXX-XX |

|  |  |  |
| --- | --- | --- |
| **PICF Heading** | **Clause** | **Master Document Type (if clause will be entered on more than one PICF, add details here)** |
| **Number of participants at local site** | *<Insert site specific recruitment details or participant numbers or delete if NA>.*  *This should match your eP application.* | *e.g., Master Main*  *Master Optional Genetic* |
| **Radiation** | *<Insert standard of care clause(s) for ionising radiation (refer to BA F13.1.1 for additional information) or, if above standard of care, insert wording provided by the Radiation Safety Officer, or delete if NA>.* |  |
| **Pregnancy** | *<Insert site specific pregnancy clause(s) (refer to BA F14.1.1 for additional information) or delete if NA>.* |  |
| **Compensation** | *<Insert site specific compensation clauses(s) (refer to BA F5.1.6 for additional information) or delete if NA>.* |  |
| **Reimbursement** | *<Insert site specific reimbursement amount(s) (refer to BA G10 for additional information) or delete if NA>.* |  |
| **Data storage and retention** | *<Insert site specific data storage information and retention period (refer to BA F11.1.1 for additional information) or delete if NA>.* |  |
| **Complaints** | *<Insert site specific complaints process clauses (refer to BA G5 for additional information) or delete if NA>. \*Please note that contact information is not required to be included.* |  |
| **Other** | *<Insert site specific wording here or delete if NA>.* |  |