

## Requirements:

Each individual site in a multicentre study following PICF pathway 2, must submit a site-specific clauses document with their application. As such, a site-specific PICF is not required to be submitted and the Principal Investigator acknowledges they will imbed the approved clauses in the most current approved Master PICF/s.

- All non-administrative place-holders in the Main Master PICF must be addressed in the site-specific clauses document. Any further additions or deletions of ethical content or wording to the Master PICF must be clearly stated in this template for HREC review. At a minimum, the site-specific clauses document must list the Master Main PICF approved for the study and if there are no ethical changes, this must be stated in the site-specific clauses document.
- Any non-administrative place-holders, additions or deletions of wording relating to supplementary Master PICFs (e.g., Pregnant partner, optional genetic) should also be included in this template. If a supplementary PICF is not listed on the site-specific clauses document, the HREC will assume there to be no site-specific changes.
- Placeholders that are administrative in nature do not need to be addressed in the site-specific clauses document, for example <site name>, <Principal Investigator details>
- Clauses in the site-specific clauses document should not re-word approved wording within the Master PICF to alter clarity, grammar, or style. This is referred to as wordsmithing. If wording is required to be updated within the Master PICF, then the lead site should submit an updated Master PICF which is applicable to all sites.
- After review and approval by the HREC, the site-specific clauses document is included on the approval letter.
- After approval, any changes to the site-specific clauses document must be submitted as an amendment, including the submission of a tracked and clean version of the site-specific clauses document.

## Instruction:

1. Please copy and paste the following template to a clean word document or your site letterhead.
2. Name the document as per Bellberry guidance document BA G12 Version Control & Document Naming Conventions.
3. Ensure that the site-specific clauses document appropriately identifies any site-specific clauses that will be added to, deleted from, or replaced within the Master PICF/s:
  - 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"*).
  - If the Master Main PICF contains an optional clause (e.g., the site chooses one of two options for pregnancy wording), the site is not required to declare the selected option unless any changes to the approved wording are proposed.

4. The types of clauses that sites may need to include are:
  - a. Number of participants at the local site: *This should match your eProtocol Application Information page 2.*
  - b. Radiation: *Insert standard of care clause(s) for ionising radiation (refer to BA F13.1.1 Ionising Radiation Standard Clauses for additional information) or, if above standard of care, insert wording provided by the Radiation Safety Officer*
  - c. Pregnancy: *Refer to BA F14.1.1 Pregnancy & Sexual Health Standard Clauses for additional information*
  - d. Compensation: *Refer to BA F5.1.6 Compensation for Injury Standard Clauses for additional information*
  - e. Reimbursement: *Refer to BA G10 Participant Payment & Reimbursement Guidance for additional information*
  - f. Data Storage and Retention: *Refer to BA F11.1.1 Confidentiality & Privacy Standard Clauses for additional information*
5. Upload with your application.

**Please copy from here:**

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

| PICF Section/Heading | Clause                                               | Master Document Type (if clause will be entered on more than one PICF, add details here) |
|----------------------|------------------------------------------------------|------------------------------------------------------------------------------------------|
|                      | <Insert site specific wording here or delete if NA>. | e.g., Master Main<br>Master Optional Genetic                                             |
|                      |                                                      |                                                                                          |
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**To here.**

*Example document:*

| PICF Section/Heading                                                                                                                                                     | Clause                                                                                                                                                                                                                                                                                                                        | Master Document Type (if clause will be entered on more than one PICF, add details here) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| Section 5: Other relevant information about the research project                                                                                                         | <b>Deleting:</b><br>"Approximately <x> participants will be enrolled at this site."<br><b>Replacing with:</b><br>"Approximately <20> participants will be enrolled at this site."                                                                                                                                             | Master Main PICF                                                                         |
| Section 15. Will you pay me to participate in this study?                                                                                                                | <b>Deleting:</b><br>"If accepted into the study, as payment for your time and inconvenience experienced, you will receive \$xx for completing the study."<br><b>Replacing with:</b><br>"If accepted into the study, as payment for your time and inconvenience experienced, you will receive \$700 for completing the study." | Master Main PICF                                                                         |
| Master Pregnancy/Pregnant Partner PICF: There will be no site-specific content changes.<br>Master Optional Genetic PICF: There will be no site-specific content changes. |                                                                                                                                                                                                                                                                                                                               |                                                                                          |

**References**

[BA F5.1.6 Compensation for Injury Standard Clauses](#)  
[BA G10 Participant Payment & Reimbursement Guidance](#)  
[F11.1.1 Confidentiality & Privacy Standard Clauses](#)  
[BA G12 Version Control & Document Naming Conventions](#)  
[BA F13.1.1 Ionising Radiation Standard Clauses](#)  
[BA F14.1.1 Pregnancy & Sexual Health Standard Clauses](#)