**SITE SPECIFIC PICF CHECKLIST (APPLICABLE FOR ALL STUDIES)**

|  | **Items to check** | **Completed**  **(Y or N/A)** |
| --- | --- | --- |
| 1 | Site specific updates to PICF (based on HREC approved document) are saved in **tracked and clean** formats? |  |
| 2 | When discussing patient out of pocket expenses the following guidance should be followed and the relevant site-specific wording included in the PICF for Epworth.  In addition to standard wording:  ***There are no additional costs associated with participating in this research project, nor will you be paid.***  The following wording should be used for clinical trials that involve an intervention (i.e. medication, tests, medical care) *and* all costs associated with the research are covered by the sponsor:  ***All medication, tests and medical care required as part of the research project will be provided to you free of charge. Medical care in circumstances unrelated to the research project will be provided as per your insurance arrangements.***  The following wording should be used for clinical trials that may include costs, such as medical care considered to be standard of care, and are not covered by the sponsor:  ***All medication, tests and medical care required as part of the research project will be provided to you free of charge. Regular medical care in circumstances unrelated to the research project or required for the project but not covered by the Sponsor will be provided as per your insurance arrangements.***  The following wording should be included for all projects involving Epworth patients that do not involve an intervention (i.e. observational studies):  ***Any medical care that you may require will be provided as per your insurance arrangements.***  This guidance has been reviewed by an accredited HREC and does not require approval by the reviewing HREC. If the suggested wording is not appropriate for your study, please contact the RGO. |  |
| 3 | Epworth complaints contact details added:  **Position**: Research Development and Governance Officer  **Telephone**: (03) 9936 8058  **Email**: research@epworth.org.au  **Epworth Project Reference**: <insert> |  |
| 4 | Epworth version and date included in the footer of each page? (in addition to the master version and date)? e.g. |  |
| 5 | Footer of all pages checked to ensure local version and date is updated on all pages (including across section breaks) |  |
| 6 | All pages of the PICF are accounted for and numbered in the following format: Page X of Y |  |
| 7. | Barcode added to first page of PICF in **top left hand corner** (vertical position as below) (for filing in the research folder of the patients medical records).  *Note – this is only applicable if the participant is also an Epworth patient at the time of participating in the research project. Please see SOP-TM-03 Informed Consent Appendix A for further information.* |  |

**Prepared by:**

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| Signature: |  |
| Print name: |  |
| Title: |  |
| Date: |  |

**Reviewed by:**

|  |  |
| --- | --- |
| Signature: |  |
| Print name: |  |
| Title: |  |
| Date: |  |

**CHECKLIST FOR DEVELOPING NEW PICFs**

|  | **Items to check against ICH Topic E6 Guideline for Good Clinical Practice** | **Included**  **(Y/N)** | **Comments/Corrective Actions (if any)** |
| --- | --- | --- | --- |
| 1 | A statement that the study involves research |  |  |
| 2 | An explanation of the purpose of the trial/study. |  |  |
| 3 | The trial/study/study treatment(s) and probability for random assignment to each treatment (if applicable) |  |  |
| 4 | A description of the trial/study/study procedures to be followed including all invasive procedures |  |  |
| 5 | The participant’s responsibilities |  |  |
| 6 | The aspects of the trial/study that are experimental |  |  |
| 7 | Information about who is organising and funding the research. |  |  |
| 8 | The reasonably foreseeable risks/inconveniences to subject/embryo/foetus/nursing infant (as applicable) |  |  |
| 9 | A description of any of the benefits to the subject or to others, which may reasonably be expected from the research. If none is expected, subject must be informed |  |  |
| 10 | A disclosure of the alternative procedure(s) or course(s) of treatment available, if any and their important potential benefits and risks |  |  |
| 11 | A statement describing the procedures adopted for ensuring data protection/confidentiality/privacy including duration of storage of personal data. |  |  |
| 12 | The compensation/treatment available in case of trial/study-related injury |  |  |
| 13 | The anticipated prorated payment if any, to the participants for participating in the study |  |  |
| 14 | The anticipated expenses, if any, to the participant for participating in the study |  |  |
| 15 | A statement that participant’s participation is voluntary and that the participant may refuse to participate or withdraw at any time without penalty or loss of benefits to which the participant is otherwise entitled |  |  |
| 16 | That monitors, auditors, the IECs/IRBs, the study team and regulatory authorities will be granted direct access to the subject’s medical records without violating the participant’s confidentiality, to the extent permitted by applicable laws & regulations and that by signing the consent the participant or the participant’s legally acceptable representative is authorising direct access to his/her medical records |  |  |
| 17 | That identifying records will be kept confidential and will not be made publicly available. If the results are published the participant’s identity will remain confidential. |  |  |
| 18 | That the subject or the legally acceptable representative will be informed in a timely manner if information becomes available that might influence the participant’s willingness to stay in the trial/study |  |  |
| 19 | The person(s) to contact for further information regarding the trial/study and the rights of trial/study participants, and whom to contact in the event of trial/study-related injury |  |  |
| 20 | The foreseeable circumstances/reasons under which the participant’s participation might be terminated |  |  |
| 21 | The expected duration of the participant’s participation in the trial/study |  |  |
| 22 | The approximate number of participants involved in the trial/study |  |  |
| 23 | Information about what will happen to the results of the research. |  |  |
| 24 | The text should not contain any language that causes the participant to waive or appear to waive any legal rights |  |  |
| 25 | The text should be written in understandable, non-technical language |  |  |
| 26 | ICH recommends that the participant’s primary care physician be informed of his/her participation in the trial/study, if the participant explicitly consents to this |  |  |

**Collated by:**

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| --- | --- |
| Signature: |  |
| Print name: |  |
| Title: |  |
| Date: |  |

**Reviewed by:**

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| Signature: |  |
| Print name: |  |
| Title: |  |
| Date: |  |