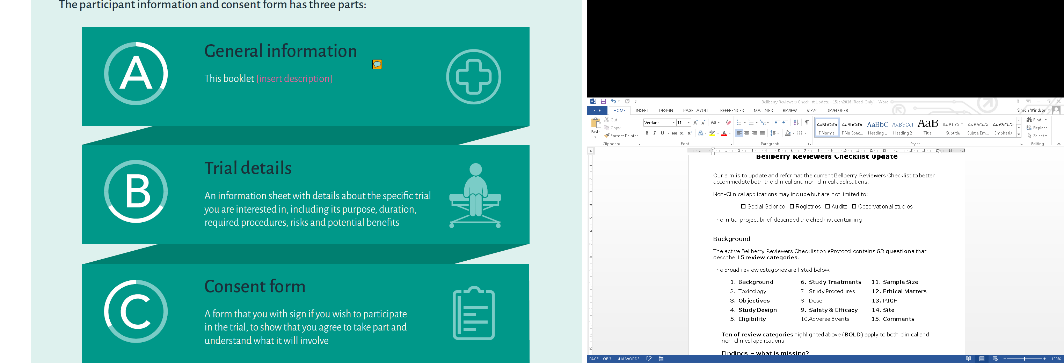
**Role of the Primary Reviewer (PR):** The HREC reviewer’s checklist - primary / secondary (LER F1.1.4) must be completed by the Primary Reviewer (PR). This is a record of the issues as considered by the PR. It can be used as a guide when presenting at committee meetings. The overview is expected to be a brief background to the research, particularly identifying key aspects of the study, methodology, study treatment (drug/device/procedure), and any issues that may be useful for the committee members’ understanding of the study. Please note the presentation should be kept brief, approximately 5 minutes.

**Role of the Secondary Reviewer (SR):** Secondary Reviewers (SR) may wish to use the HREC reviewer’s checklist - primary / secondary (LER F1.1.4) as a guide, however it is not compulsory. At the committee meeting the Secondary Reviewer(s) need not add anything further following study presentation by the Primary Reviewer if they are satisfied that the Primary Reviewer has captured all relevant matters.

**Role of the External Expert:** The Expert may wish to use the HREC reviewer’s checklist - primary / secondary (LER F1.1.4) as a guide. It is not compulsory for all items in sections A and B, or C are fully completed. Alternatively, a free form report may be provided.

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| The reviewer’s checklist is divided into three sections: | General Research Items | Clinical Research Items | Non-Clinical Research Items |

* Reviewers will only be required to complete two sections of the checklist.
  + When reviewing a clinical trial (drug/device/procedure) sections A and B are to be completed.
  + When reviewing a non-clinical trial (behavioural or social science study) sections A and C are to be completed.
* Reviewers are not required to complete all checklist questions but must confirm the review date and that all relevant checklist questions have been considered.
* Please email the completed Reviewers Checklist to [bellberry@bellberry.com.au](mailto:bellberry@bellberry.com.au) before the HREC meeting.

A reminder to refer to relevant sections of the *National Statement on Ethical Conduct in Human Research (2007, incorporating all updates*). References contained within the reviewer’s checklist are a guide and are not exhaustive.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Title of the study:** | | | | | |
| **Protocol reference** (including version number and date): | | | | | |
| **HREC application ID:** | | | | | |
| **IB** (including version number and date): | | | | | |
| **PICF** (including version number and date): | | | | | |
| **Other documents reviewed:** | | | | | |
| **Principal Investigator:** | | | | | |
| **Primary reviewer**   **Secondary reviewer**   **Expert Opinion** | | | **Name of reviewer**: | | |
| **Date of review (confirming that all relevant items have been considered):** | | | | | |
|  | **General Research Items** | | **Y, N, N/A** | **Comments** | |
|  | **Background** - Provide a brief summary as to the background and purpose of the drug/study. | | Select |  | |
|  | **Objectives** - Note the main objectives of the study. Is the purpose of the study appropriate and ethical? (Refer NS 1.1, 3.1.2, 3.1.4 and 5.2.2). | | Select |  | |
|  | **Objectives** - Are the primary, secondary, tertiary and exploratory objectives, which are stated in the protocol, clearly and accurately reflected in the Participant Information Sheet? (Refer NS 1.7 (b), 2.2 and 3.1.19-22). | | Select |  | |
|  | **Objectives** - Are the objectives and conduct of optional sub-studies adequately explained in a separate Participant Information and Consent Form (PICF) where relevant? (Refer NS 1.7(b), 2.2 and 3.1.26). | | Select |  | |
|  | **Study Design** (Refer to the title if appropriate.) Is the study likely to meet the stated objectives, and does the research use procedures consistent with sound research design? (Refer NS 1.1, 1.8, 1.10, 3.1.1, 3.1.2). | | Select |  | |
|  | **Study Design** - Is it appropriate for the phase or study type? (Refer NS 1.1, 1.6, 1.7, 1.8 and 1.10). | | Select |  | |
|  | **Study Design** - If there is a control, comparator, comparison arm, is this appropriate? If there is no control, comparator, comparison arm, should there be one? (Refer NS 1.1, 1.8, 1.10, 3.1.1 (d), 3.1.1 (e), 3.1.2 (b)). | | Select |  | |
|  | **Study Design** - If the study design includes blinding/masking, does the methodology ensure integrity of the blinding process? If de-identification of data is proposed, is the methodology appropriate and robust (i.e. unable to be inappropriately re-identified)? (Refer NS 1.1, 1.7, 1.8 and 1.10). | | Select |  | |
|  | **Risks –** Are risks to participants minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk? | | Select |  | |
|  | **Risks –** Arerisks to participants minimized, when appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes? | | Select |  | |
|  | **Study Design** - Are there any sub studies? If yes are they an integral part of the main protocol or are they optional? (Refer NS 1.1, 1.6, 1.7, 1.8 and 1.10). | | Select |  | |
|  | **Study Procedures/ Visits -** Very briefly discuss time frames. Are standard of care and study specific procedures clearly differentiated? Are trial specific procedures beyond standard of care (blood, tissue sampling, etc.) justified? | | Select |  | |
|  | **Discontinuation of study criteria -** Is there a stopping criterion in the protocol? (Refer 5.5.9, NS 5.3.3 (e) and 5.5.7). | | Select |  | |
|  | **Efficacy, Safety and other measurements -** Is sufficient detail in protocol? (Refer NS 3.1.12, 3.1, 3.1.14 and 3.1.4). | | Select |  | |
|  | **Eligibility - Inclusion and Exclusion Criteria -** Are criteria adequate and appropriate? (Refer NS 1.4, 3.1.12, 3.1.15, GCP 4.8.13). | | Select |  | |
|  | **Participant recruitment –** Is proposed methods acceptable, including how participants will be approached? (Refer NS 3.1.18, 4.3.9). | | Select |  | |
|  | **Advertisements -** Is the information contained in advertisements, suitable? Consider the mode of communication (Refer NS 3.1.20, 5.2.25). | | Select |  | |
|  | **Sample Size -** Report as per protocol (Refer NS 3.1.4, 3.1.13, 3.1.14, 3.1.12 and 3.1.2). | | Select |  | |
|  | **Sample Size –** Is there a clear description of the sampling strategy and rationale? Is it appropriate? (Refer NS 35.2.2, 3.1.13, 3.1.14, 3.1.12 and 3.1.2). | | Select |  | |
|  | **Statistical analyses -** Refer to protocol and comment on adequacy of statistical plan (Refer NS 3.1.2 (b)). | | Select |  | |
|  | **Statistical analyses –** Where appropriate to study design, should the study have a power calculation and if so, has one been done (Refer NS 3.1.2 (c))? | | Select |  | |
|  | **Ethical Matters -** Have specified groups been appropriately considered? (Refer NS):  4.1: Women who are pregnant and the human foetus;  4.2: Children and young people;  4.3: People in dependent or unequal relationships;  4.4: People highly dependent on medical care who may be unable to give consent;  4.5: People with a cognitive impairment, an intellectual disability, or mental illness;  4.6: People who may be involved in illegal activities;  4.7: Aboriginal and Torres Strait Islander Peoples;  4.8: People in other countries. | | Select |  | |
|  | **Ethical Matters -** Has publication of results been appropriately explained? (Refer NS 2.2.6(k) and 5.2.11(b)). | | Select |  | |
|  | **Ethical Matters -** Is the Principal Investigator appropriately skilled, qualified and experienced to conduct and supervise the study? (Refer NS 1.1(e), 3.1.9(b) and 3.2.4(b). | | Select |  | |
|  | **Ethical Matters -** Is the risk/benefit analysis satisfactory? (The likely benefit of the research must justify any risks of harm or discomfort to the participants. The likely benefit may be to the participants, to the wider community or to both. (Refer NS 1.1, 1.6, 1.7, 1.8, 1.10, 2.1.3, 2.1.4, 2.1.5, 2.3.6, 3.1.5 and 3.2.4). | | Select |  | |
|  | **Consent -** Does the application give adequate information to assess the consent process? (Refer NS 3.1.18 and 3.1.23)(GCP Section 4.8 Informed consent of trial participants) | | Select |  | |
|  | **Consent -** Does the PICF contain any language that would appear to waive any of the participants rights? (GCP 4.8.4) | | Select |  | |
|  | **Waiver of Consent –** If a waiver of consent has been requested, does the protocol adequately address NS 2.3.6-12, 4.4.1, 4.4.6? | | Select |  | |
|  | **Limited disclosure / opt out approach –** Will a limited disclosure or opt-out approachto participant recruitment be applied, and is it appropriate? (Refer NS 2.3.1 - 2.3.8). | | Select |  | |
|  | **PICF -** Is the description of the scientific component of the study in the Participant Information Sheet in lay terms and free of jargon? (Refer NS 1.7 (b), 1.1.10 - 1.1.13, 2.2, 4.8.21, 2.2.5 and 3.1.26). | | Select |  | |
|  | **PICF -** Does the PICF contain information not defined in the protocol, or is there information in the protocol that should be in the PICF (e.g. safety information)? (Refer NS 1.7 (b), 1.1.-1.10.13, 2.2, 4.8.21, and 3.1.26)**.** | | Select |  | |
|  | **PICF -** Is there information in the PICF that is more eloquently set out in the protocol e.g. tables? (Refer NS 1.1.10 - 1.1.13, 2.2 and 3.1.26). | | Select |  | |
|  | **PICF -** Does the PICF indicate who is to fund study related assessments and/or treatment and is the arrangement appropriate in the context of the study? (Refer NS 2.2.6 (i)). | | Select |  | |
|  | **Ethical Matters –** Forresearch that involves adults unable to provide legally effective consent, does the PICF / Protocol describe the process to determine who is a “legally authorized representative”? (GCP 4.8.14a-e) | | Select |  | |
|  | **Ethical Matters** - For research that involves children as participants, does the PICF / Protocol describe the process to determine who is a “child” and when a person can provide their own consent? | | Select |  | |
|  | **Ethical Matters –** Forresearch that involves children who are wards as participants, does the PICF describe the process to determine who is a “guardian” or “legally authorized representative” who can provide permission for research? | | Select |  | |
|  | **Site/Location of the study -** Is the investigator's site adequately resourced to conduct the study? (Refer NS 1.1(f), 3.1 and 3.1.9(b)). | | Select |  | |
|  | **Sponsor/Funding -** Does the protocol clearly identify the source of funding? (Refer NS 3.1.9). | | Select |  | |
|  | **Data Collection -** Are questionnaires and other assessment tools validated where appropriate for the purpose required in the study? (Refer NS 3.1 Element 4). | | Select |  | |
|  | **Data Handling and Record Keeping -** Are there appropriate processes for the management and retention of data? (Refer NS 3.2, Section 3 and 3.1.48, 3.1.45, 3.1.48, 3.1.53, 3.1.59 3.1.74, 3.1.56, and 5.2.25-29). | | Select |  | |
|  | **Privacy and Confidentiality -** Are Privacy and confidentiality requirements met? (Refer NS 1.11 and 2.2.6(f)). Consider D.5 (a-k) NHMRC Guidelines approved under section 95A of the Privacy Act 1988 when weighing the public interest. | | Select |  | |
|  | **Quality Control and Quality Assurance -** Are monitoring and management systems adequate to ensure participant safety and data quality? (Refer NS 5.2.2, 3.1.2, and 5.5). | | Select |  | |
|  | **Study Registration** – does the study plan accurately report the public register where the study will be listed? (e.g. clinicaltrials.gov, anzctr.org.au). (Refer NS 3.1.7). | | Select |  | |
|  | **Insurance and Indemnity** – is it clear who is responsible for insurance and indemnification? (Sponsor/site?) | | Select |  | |
|  | **Questions/Comments -** List all questions that you would like the Investigator to answer via the Reviewers Comments section. | | Select |  | |
|  | **Recommendations -** Make a recommendation regarding the study - approved dependent on suitable responses to questions or not approved pending response to a principle questions or not approved based on no science, risk /benefit ratio etc. | | Select |  | |

|  | **Clinical Research Items** | **Y, N, N/A** | **Comments** |
| --- | --- | --- | --- |
|  | **Non-clinical pharmacology -** Any relevant information related to efficacy (pharmacodynamics) from in vitro or animal testing. | Select |  |
|  | **Pharmacokinetics and Metabolism of Agent in Animals -** Comment on animal pharmacokinetics (absorption, distribution, metabolism, excretion) and note any deficits in the information provided. | Select |  |
|  | **Safety Pharmacology in Animals -** Have sufficient pre-clinical safety pharmacology (cardiovascular, respiratory, central nervous system) studies been undertaken and are data from such studies included in the protocol and/or investigators brochure? | Select |  |
|  | **Preclinical safety studies -** Are the side effects in the investigator brochure, protocol, and PICF an accurate and appropriate reflection of known side effects from the non-clinical and clinical data in the protocol and investigator brochure, and from what may be known in the general literature? | Select |  |
|  | **Pharmacokinetics in Humans -** Comment on human pharmacokinetic testing and note any deficits in the information. | Select |  |
|  | **Non-clinical toxicology -** Have appropriate (for the clinical trial phase) preclinical toxicology studies been undertaken according to regulatory guidelines and are data from such studies included in the protocol and/or investigators brochure? Comment on tolerance of the drug, major concerns, target organs. | Select |  |
|  | **Non-clinical toxicology -** Comment or raise relevant questions on carcinogenicity, genotoxicity, reproductive and developmental toxicity. | Select |  |
|  | **Effects in Humans -** Report briefly on any earlier phase studies undertaken. Are side effects or toxicity accurately reported in the IB, Protocol and PICF? | Select |  |
|  | **Study Design -** If there is a placebo arm, is inclusion of the placebo appropriate? (It is considered ethically unacceptable where: other available treatment has already been clearly shown to be effective / there is known risk of significant harm in the absence of treatment). If there is no placebo, should there be one? (Refer NS 1.1, 1.7, 1.8, 1.10 and 3.1.5). | Select |  |
|  | **Study Treatments -** Very briefly discuss randomisation procedures. | Select |  |
|  | **Device/Treatment registration -** Is the study treatment/device/investigation appropriately registered and approved for the purposes of the study? | Select |  |
|  | **Study Treatments -** Is the issue of rescue treatment adequately addressed? Are there clear and appropriate decision-making criteria to begin rescue medication? | Select |  |
|  | **Dose Levels -** Is the dose justified by prior human data? | Select |  |
|  | **Dose Escalation criteria –** Are there clear and appropriate decision-making criteria for proposed dose reductions, withdrawal criteria, discontinuation of dosing including stopping rules, and trial termination.  *Also refer to A13: Discontinuation of Study criteria.* | Select |  |
|  | **Dose Levels -** Are the prescribed dose levels, route and frequency appropriate and adequately justified based on suitable evidence?  For two-part studies, is the second part dependent on the results of the first part (complete or part thereof)? and does the Committee require an interim report? *(Committee to determine on a case-by-case basis).* | Select |  |
|  | **Ethical Matters -** e.g. consider availability of medication post trial, use of placebo etc. (Refer NS 3.1.38(c)). | Select |  |
|  | **PICF -** If side effects are described in the PICF, should they be described in terms of frequency and severity? (Refer NS 1.7(b), 1.1.10 - 1.1.13 and 2.2). | Select |  |
|  | **PICF -** Is the frequency and type of medical imaging appropriately described? Is the radiation risk statement appropriate for the study? (Refer NS 1.7(b), 1.1.10-1.1.13 and 2.2). | Select |  |
|  | **PICF -** Is there adequate information in the Participant Information Statement and Consent Form/s (PICF) regarding disclosure of uncertainty and risks, and protection of participants’ personal data? | Select |  |
|  | **Radiation -** Is the medical imaging study specific or standard care? If above standard of care, Is there appropriate evaluation of radiation exposure including Medical Physicist safety assessment report? | Select |  |
|  | **Genetic Information –** Is there an ethically defensible plan for disclosing information to participants in genetics research, where research may discover or generate information about risks of potential importance to the future health of participants, or their blood relatives? Does the plan 1) enable participants to decide whether they wish to receive the information and who else may be given the information; 2) set out a process for finding out whether those other people want to receive information? | Select |  |
|  | **Adverse event recording and reporting -** Is safety monitoring and testing adequate and reasonable for the known, anticipated and potential adverse outcomes? (Refer NS 5.5). | Select |  |
|  | **Adverse event recording and reporting -** Is a Data Safety Monitoring Board in place? (Refer NS 5.5.3) Are there an adequate description of roles and responsibilities for decision making related to:   * Sponsors * Independent representative. | Select |  |
|  | **Adverse event recording and reporting -** Is there adequate provision for timely medical management and follow up of adverse outcomes and study related complications? (Refer NS 1.1 (e), (f) and 3.1.9(b), ICH GCP (E6)(R2)). | Select |  |
|  | **IP –** Have manufacturing, handling, and storage processes been established in accordance with applicable good manufacturing practice? | Select |  |

|  | **Non-Clinical Research Items** | **Y, N, N/A** | **Comments** |
| --- | --- | --- | --- |
|  | **Survey/Interview -** Are appropriate, unmodified validated scales being used? If not, provide detail of modifications or items to be included. | Select |  |
|  | **Survey/Interview –** Are appropriately qualified people delivering and interpreting the survey/interview? | Select |  |
|  | **Deception –** Are any levels of deception or limited disclosure utilised in the study? Is this appropriate? | Select |  |
|  | **Physical harm -** (Includes injury, illness, and pain.) Have these risks been appropriately considered? (Refer NS 2.1, 2.1.3, 2.1.4 and 2.1.5). | Select |  |
|  | **Psychological harm -** (Includes feelings of worthlessness, distress, guilt, anger or fear related, for example, to disclosure of sensitive or embarrassing information, or learning about a genetic possibility of developing an untreatable disease.) Have these risks been appropriately considered? (Refer NS 2.1, 2.1.3, 2.1.4 and 2.1.5). | Select |  |
|  | **Devaluation of personal worth -** (Includes being humiliated, manipulated or in other ways treated disrespectfully or unjustly.) Have these risks been appropriately considered? (Refer NS 2.1, 2.1.3, 2.1.4 and 2.1.5). | Select |  |
|  | **Social harm -** (Includes damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; and findings of previously unknown paternity status.) Have these risks been appropriately considered? (Refer NS 2.1, 2.1.3 and 2.1.4 and 2.1.5). | Select |  |
|  | **Economic harm -** (Includes the imposition of direct or indirect costs on participants.) Have these risks been appropriately considered? (Refer NS 2.1, 2.1.3, 2.1.4 and 2.1.5). | Select |  |
|  | **Legal harm –** (Includes discovery and prosecution of criminal conduct.) Have these risks been appropriately considered? (Refer NS 2.1, 2.1.3 and 2.1.4 and 2.1.5). | Select |  |
|  | **Adverse event or equivalent recording and reporting -** Is monitoring adequate and reasonable for the known, anticipated and potential adverse outcomes? (Refer NS 5.5). | Select |  |

|  | **Substantial Amendment** | **Y, N, N/A** | **Comments** |
| --- | --- | --- | --- |
| **SA 1.** | The aims and objectives of the study or the study design. | Select |  |
| **SA 2.** | Participants’ safety or physical or mental integrity. | Select |  |
| **SA 3.** | The scientific value of the study. | Select |  |
| **SA 4.** | The conduct or management of the study. | Select |  |
| **SA 5.** | The quality or safety of any investigational medicinal product used in the study. | Select |  |