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| --- | --- | --- | --- | --- |
| Project Number: | | PICF type: | Site version:  Master version: | |
| Reviewed by: | | | | |
| **Items to Check** | | | **Compliance with**  **NS / CHA / APP / Other** | **Y or N/A** |
|  | Based on a HREC approved Master? (For single site studies, Cabrini’s PICF can functions as the Master) | |  |  |
|  | Tracked & clean formats? | |  |  |
|  | Footer - correct site-specific version control reference which corresponds to the latest approved Master, including across section breaks | |  |  |
|  | Footer - correct pagination (numbering), including across section breaks | |  |  |
|  | Cabrini Research logo – top of front, consent and withdrawal page | |  |  |
|  | Correct Cabrini PI and AI names | |  |  |
|  | Cabrini Address:  Malvern - Cabrini Hospital 183 Wattletree Road, Malvern VIC 3144  Brighton – Cabrini Hospital 243 New Street, Brighton VIC 3186 | |  |  |
|  | Trial registration on a publicly accessible register complying with international standards e.g. International Clinical Trials Registry Platform (ICTRP) trialsearch.who.int, ClinicalTrials.gov or ANZCTR.org.au – is Cabrini listed as a recruitment site? | | NS Chapter 3.1.17 |  |
|  | Reproductive Risks - CHA Pregnancy Statement <https://www.cha.org.au/wp-content/uploads/2021/06/Catholic-Pregnancy-Statement-Sept-13.pdf>  adherence, and other pregnancy avoidance references | | CHA Chapter 2 Code of Ethical Standards |  |
|  | Reproductive Risks - Cabrini Health disclaimer where ‘Prevention of Conception’ language must be included:  ***Because of the unknown risks of this trial agent, it is important that you do not become pregnant during this trial. For legal reasons, the pharmaceutical company requires us to provide you with the information outlined in [refer to section / page] about methods of avoiding pregnancy. Not all of this information is endorsed by Cabrini Health, nor reflects its ethical standards as a Catholic hospital. You should discuss with the study doctor and/or your own doctor and ethical advisor an effective way for you to avoid pregnancy that is in keeping with your beliefs and values.*** | | Approved wording by St Vincents Hospital Sydney and the Plunkett Centre for Ethics |  |
|  | Infertility  To be included in all PICFs where sperm and/or egg donation is to be avoided  ***You should talk to your doctor if you would like to be referred to an infertility specialist before commencing study treatment if reduced fertility or infertility is a concern for you. Infertility care is not part of this study. You should discuss this with the study doctor and/or your own doctor. Some methods of preserving fertility may not be endorsed by Cabrini Health.*** | |  |  |
|  | Radiation Safety – standard of care exposure statement (with PI letter to HREC and Cabrini MPRA – Medical Physics Risk Assessment) or above standard of care (SOC) exposure statement (as prescribed by independent Medical Physicist). Dose magnitude must be stated if above SOC.  <https://www.arpansa.gov.au/about-us/advisory-council-and-committees/radiation-health-committee/trials-statement>  <https://www.health.vic.gov.au/publications/standard-radiation-risk-statements-april-2015> | | ARPANSA Guide & Victoria Department of Health Standard Radiation Risk Statements |  |
|  | Distribution of Patient Samples / Research Data – must state ***where*** the samples / data are being stored / tested / transferred, and ideally include a statement advising that the sponsor will make every effort to ensure participant’s coded personal data is afforded the ***same level of protection*** when shared overseas as is legislated in Australia.  <https://www.nhmrc.gov.au/about-us/publications/guidelines-under-section-95-privacy-act-1988>  For NHMRC PICF templates, ensure countries of distribution are specified in Section 10 (What will happen to my biological samples?) and Section 16 (What will happen to information about me?)  Cabrini requires inclusion of the following statement addressing compliance with privacy legislation:  ***‘Participants should note that some data derived from your participation in this study will be sent overseas to countries such as [insert country names]. The regulatory regimes governing data access and use in other countries may not be the same as those that are in place in Australia. In the case of data that identifies you, or from which your identity may be ascertained, [an entity subject to Australian privacy laws that has collected your personal information/local Sponsor] must take reasonable steps to ensure that an overseas recipient handles the information in accordance with any relevant Australian privacy principles (unless an exemption applies).’***  For use where the list of countries to which data may be sent is extensive:  ***A full list of countries where your de-identified data may potentially be sent is available via the study coordinator should you wish to review it.***  In the case that data/samples are potentially sent to third parties, regardless of their location, the following statement **must** be included:  ***The sponsor of this trial is liable for any potential breaches to Australian privacy principles by its representatives in the handling of your data.*** | | Section 95 of Privacy Act 1988 – Section 2.4q states countries must be listed. APP8 (Australian Privacy Principles) – Cross-border disclosure of personal information – how will the data be treated once overseas?  Health Records Act 2001 - Transborder data flows  NS Chapter 3.1 Element 4: Collection, Use and Mgt of Data and Information  Wording approved by Cabrini legal Nov23  Wording approved by Cabrini legal Nov23 |  |
|  | Additional Costs  Commercial-Sponsored Studies  ***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 will be provided as per your insurance arrangements or through Medicare. If you do not have private insurance, you may incur additional costs if you choose to receive medical care at a private hospital where the medical care is unrelated to the research project.***  Non-Commercially Sponsored Studies  ***You will not receive payment for participating in this study. All routine standard examinations will be handled as if you were receiving standard treatment and not participating in a clinical study. You will be responsible for the cost of the tests or treatments that are considered standard care in the usual way (health insurance, Medicare and your personal contribution depending on your circumstances). You should ask the study doctor to explain any payments for which you may be responsible.*** | | Wording approved by Cabrini legal May 2023 |  |
|  | Compensation for Clinical Trial-Related Injury  Commercially-Sponsored Studies  ***If you are injured as a result of your participation in this trial, you may be entitled to compensation. There are two avenues that may be available to you to seek compensation.***  ***1) Sponsors of clinical trials in Australia have agreed that the guidelines developed by their industry body, Medicines Australia [Medical Technology Association of Australia (MTAA)], will govern the way in which compensation claims from injured participants are managed by sponsors. However, as guidelines, they do NOT in any way dictate the pathway you should follow to seek compensation. The sponsor is obliged to follow these guidelines. These guidelines are available for your inspection on the Medicines Australia Website***  ***(www.medicinesaustralia.com.au) under Policy – Clinical Trials – Indemnity and Compensation Guidelines [MTAA website (***[***https://www.mtaa.org.au/clinical-investigation-research-agreements***](https://www.mtaa.org.au/clinical-investigation-research-agreements)***) under Policy-Clinical Investigations]. Alternatively, your study doctor can provide you with a hard copy of the guidelines.***  ***2) You may be able to seek compensation through the courts.***  ***It is the recommendation of the independent ethics committee responsible for the review of this trial that you seek independent legal advice before taking any steps towards compensation for injury.***  Non-Commercially Sponsored Studies  ***If, as a result of your participation in this study, you become ill or are injured, immediately seek medical advice and treatment, and advise your study doctor of your condition. Your study doctor will evaluate your condition and discuss treatment with both you and your regular treating doctor.***  ***Since you are participating in a non-sponsored study/investigation, any question about compensation for injury caused by participation in the study/investigation must initially be directed to your study doctor who should advise their insurer of the matter. It is the recommendation of the independent ethics committee responsible for the review of this study/investigation that you seek independent legal advice.*** | | Medicines Australia / Medical Technology Association of Australia Compensation Guidelines – Bellberry wording  Substitute MTAA for device trials  Original Bellberry wording – revised by Cabrini legal 30Jul24 |  |
|  | Counselling  ***If you become upset or distressed, your treating/study doctor can arrange referral to a counsellor or other appropriate support.***  This is a Sponsor cost. | |  |  |
|  | Cabrini Governance Approval  (For studies above low risk receiving external HREC-approval)  ***Cabrini Research Governance Office has approved the conduct of this study at Cabrini*.**  (For low/negligible risk studies receiving ethical review by Cabrini)  ***The ethical aspects of this study have been reviewed by the Cabrini Research Governance Office and the study complies with the NHMRC’s National Statement on Ethical Conduct in Human Research 2023.*** | | NS Chapter 5.1 Research Governance |  |
|  | Contact Details in a Medical Emergency  ***In the event of a medical problem (for example, any side effects), please contact your study doctor. Should you have a medical emergency you may contact Cabrini Emergency Department on (03) 9508 1500 or 000.***  ***If you have any questions about the study, you can contact the study doctor, [PI Name], or the study coordinator on (03) 9508 [XXXX]. During the call, please ask to be connected to the [XXXX] Research Department.*** | |  |  |
|  | Complaints Contact Person  ***Contact: Cabrini Customer Relations Manager***  ***Telephone: (03) 9508 1661***  ***Email:*** [***crm@cabrini.com.au***](mailto:crm@cabrini.com.au)  ***Project ID:*** | | NS Chapter 5.6 Handling Complaints |  |
|  | Open Disclosure  ***In the unlikely event that your clinical trial does not go according to plan, Cabrini’s clinical trial staff will communicate openly with you about what happened in a way that is known as ‘Open Disclosure’. Scan the QR code to view a consumer-friendly guide to Open Disclosure.*** | | National Clinical Trials Governance Framework Action 1.12 |  |
|  | Australian Charter of Healthcare Rights  ***The Australian Charter of Healthcare Rights describes the rights that consumers, or someone they care for, can expect when receiving healthcare. These rights apply to all people in all places where healthcare is provided in Australia. Scan the QR code to view the Australian Charter of Healthcare Rights and its translations.*’** | | National Clinical Trials Governance Framework Action 1.12 |  |
|  | Consent Form  Yes / No tick boxes for optional tissue collection, genetic results sharing, optional testing or use of data for future research (specific, extended, unspecified); survey participation, special access (e.g. remote access by sponsor’s delegate) to medical records, | | Health Records Act 2001 |  |
|  | Withdrawal Form  Yes / No tick boxes to confirm if participants want their collected samples (and data in some instances) retained, analysed or destroyed. | |  |  |
|  | Local References  i.e. references to domestic (not international) government bodies e.g. TGA, not FDA or EMA. This includes removing references to GDPR. | |  |  |
|  | General Editing  Repetition, grammatical and punctuation errors, spelling inconsistencies (no wordsmithing) | |  |  |