Adrian Costa CLINICAL TRIALS CENTRE

Barwon Health

Self-Assessment / Audit Checklist

Investigator:

Other study staff including their role and qualifications:

Date of Assessment

Study Title and Project Number:

- Type of study
- Approval date
- Approved Researchers (are they employees or external – do they have appropriate approvals to conduct research at the institution?)

Study Files/Records:

Are all approvals and approved documents available and appropriately stored?

For all study documents have you obtained HREC and RGO approval?

Have conditions of approval been followed?

Have protocol amendments been submitted to HREC and RGO?
Table of amendments and approval dates

Are you using the most recently HREC approved and RGO Authorised versions of documents?

Can you ensure that only correct versions of approved documents are being used by study staff?

Are contracts and regulatory approvals available and appropriately stored?

Have annual reports been submitted?

Have any issues or complaints been reported to HREC/RGO?

Have insurance policies been maintained?

Are roles and responsibilities clearly documented? Do you have a delegation log?

Do you have a study training log? Have all study staff been trained in all versions of the protocol (and or IB)?

Is appropriate experience, qualifications and training of study team properly documented? Eg for Drs are medical registrations on file?

Is documentation available for study personnel such as CVs, training certificates and registrations, financial disclosures (if applicable), FDA1572 (if applicable)?

Are GCP certificates on file for trial staff?

Has the coordinating PI completed GCP training for sponsors (extended version)?

Have electronic records been securely stored (secure network, password protected, backed up)?

Have paper records been securely stored?

Are patient screening, enrolment and identification logs available?

Are logs of biological samples available?

Patient Rights, Safety and Well-Being:

Has correct consent process been followed and documented?

If the trial has an investigational medical product (IMP), has a medically qualified Dr performed consent?

Has eligibility for the trial been assessed by a medically qualified Dr if the trial is using an IMP?

Have patients signed correct version/s of consent form?

Are the PICF/s being stored securely?

Has signed PICF been sent to HIS for scanning into EMR?

Has an alert been added to EMR if SOP?

Has the privacy of patients been appropriately protected?
Is there notification of research participation in participant's medical record?

Have all adverse and serious adverse events been appropriately managed and reported? Reviewed by a medically qualified team member? In a timely manner?

Have any patients withdrawn from the study? If yes, has this been appropriately managed and documented?

Have you had any issues with recruitment to target?

Does the trial have a safety monitoring plan? If yes, has this been followed?

Have you considered or does the trial have a documented Risk Management Plan, and does this inform the document Trial Monitoring Plan?

Source Documents:

Patient files reviewed and study notes up to date?

Participant identifiers are correct?

Has data been correctly transcribed to CRF or equivalent?

Have correct GCP practices for study documentation been followed?

Are there any inconsistencies or patterns that may indicate potential fraud or misconduct?

Research stickers (if applicable) on study records?

Study Medication/Devices

Have patients been correctly assigned and administered study medication/devices?

Has study medication/device been correctly stored?

Has study medication/device been securely stored?

Has receipt, dispensing and destruction been appropriately handled and documented?

Study Processes, Procedures and Equipment

Are study processes and procedures adequate?

Has correct equipment been used according to protocol?

Is equipment maintained/calibrated appropriately?
Are calibration certificates on file?

Study Conduct

Has study protocol been followed?

Have study activities been appropriately delegated and has delegation been documented?

Have all study related activities been included on the delegation log?

Has the PI demonstrated adequate oversight and appropriate study conduct (e.g. demonstrated by written communication, team meetings, and other study documentation)?

Any other comments:

Self-Assessment / Audit Checklist