Ethical Review and Research Governance Procedure for all Early Phase Clinical Trials at Barwon Health

As a complement to current standard ethical review and research governance processes, and to adopt current best practice in Victoria for all Early Phase Clinical Trials (Phase 1), particularly for First Time in Human (patient) Clinical Trials (Phase 1a), the following steps are required for each Phase 1 Clinical Trial (a Phase 1 Clinical Trial includes, Phase 1a, Phase 1b, First Time in Human (patients) and excludes First Time in Humans (healthy volunteers).

Site Selection and Feasibility Assessment	Required For
Clinical Trials Manager or potential Principal Investigator (PI) to contact the Research Governance Officer (RGO) following first approach from Pharmaceutical Sponsor and provide contact details and description of study	Phase 1a & 1b
Chief Medical Officer (or delegate) to make contact with Pharmaceutical Sponsor to request a Confidential Disclosure Agreement (CDA), where the entities are defined as the Sponsor and Barwon Health and Barwon Health signatory is Chief Medical Officer (or delegate)	Phase 1a & 1b
General Counsel to review CDA prior to sign off by Chief Medical Officer (or delegate)	Phase 1a & 1b
Chief Medical Officer (or delegate) to request the preclinical and safety data, the ethics application and approval (if available) from Pharmaceutical Sponsor	Phase 1a Only
RGO to meet with relevant clinical trials team and/or Clinical Trials Manager to discuss and confirm process for feasibility assessment. Consultation and input from Pharmacy, BMI, Pathology, Nurse Unit Manager and ICU, where relevant, to be included in feasibility assessment process. Determination of applicability of Office of the Gene Technology Regulator (OGTR) notification, biosafety and patient restrictions	Phase 1a Only
Feasibility Assessment outcomes, protocol, pre-clinical, safety data, clinical teams qualifications and early phase clinical trial experience (current Good Clinical Practice training as a minimum standard) to be provided to Teaching, Training and Research Governance Committee sub group (TTRGC-SG) (including ex officio members) for review. Where deemed necessary an independent external expert reviewer can be appointed to assist the Committee in their review of technical data. Review Assessment to include preclinical data pharmacology, toxicology, immunology, formulation, safety evaluation, safety issues relevant to clinical use and other clinically relevant issues. Victorian Managed Insurance Agency First Time In Humans (VMIA FTIH) protocol templates to be used until there is an update of documentation	Phase 1a Only
TTRGC-SG (including ex officio members) to convene with relevant documents (e.g. feasibility assessment, expert review, study budget) and review to provide organisational decision of outcome of feasibility and advice provided to the pharmaceutical sponsor and clinical trials team	Phase 1a Only

Ethical Review and Site Specific Assessment (SSA)	Required For
Streamlined Ethics Review Process (SERP) reviewing HREC to follow VMIA FTIH protocol (as is current practice in Victoria) or an Early Phase Clinical Trials ethical review process that has been agreed for Victorian sites/units or the relevant jurisdiction of the reviewing HREC	Phase 1a Only
External mentor (with extensive Phase 1a experience in the therapeutic area and method of administration) to be nominated by the clinical trials team and appointed for each new trial, to provide support to the clinical trials team in considering and mitigating risks relevant to patient safety, staff credentials and training, as well as any ethical considerations	Phase 1a Only
General Counsel to review the clinical trial contracts, agreements and study budget as part of SSA process and provide advice to the RGO and Clinical Study Manager. Emergency Response Agreement and 24/7 medical cover and response to be included with SSA	Phase 1a Only
The relevant Executive or Chief Operating Officer to sign SSA	Phase 1a Only

Monitoring	Required For
TTRGC-SG to be immediately notified by the PI of any Significant Safety Issues (SSIs), Serious Adverse Events (SAEs) OR Suspected Unexpected serious adverse reactions (SUSARs) (via Chair) pertaining to Early Phase Clinical Trials open to accrual	Phase 1a Only
A copy of the annual and final ethics reports for each ongoing and completed Early Phase Clinical Trial to be provided by the Research, Ethics, Governance and Integrity Unit (REGI) to the TTRGC-SG for noting	Phase 1a Only
The TTRGC-SG to provide a 6 monthly update on early phase clinical trial activity to the TTRGC via the Chair	Phase 1a Only

Delegates

Chief Medical Officer Delegate: Director of Research

RGO Delegate: REGI Manager