Friendly Project Review Tool

This resource includes details of how to undertake or participate in a Friendly Project Review, as well as a project questionnaire and report template.

Aim and scope of a 'friendly project review'

- Friendly Project Reviews are designed to assist clinical trial teams better prepare for external audits undertaken by trial sponsors or other bodies such as the Therapeutic Goods Administration (TGA), Food and Drug Authority (FDA) or National Clinical Trials Governance Framework (NCTGF).
- They are intended to provide an **independent "high level" review** of a study team's project, in preparation for a more comprehensive audit completed by other bodies.
- The reviews can be "internal" (i.e. reviewer is from a different trial unit within your organisation) or "external" (i.e. reviewer is from a different organisation).
- The reviews should be performed by a person with significant clinical trial operations experience (i.e. research manager, senior study coordinator, quality manager).
- The reviews are pitched at a project level, focusing on processes and operations (question/conversation based) and will not involve checking of documentation (i.e. GCP certificates, CVs, Protocol/PICF versions etc).

Which studies could be reviewed and at what stage of the project?

- Given that industry-sponsored trials are routinely monitored and reviewed by the trial sponsor, collaborative and investigator-led trials are considered most likely to benefit from this review process.
- Project teams can volunteer a project for a review, or a project can be identified by a department, quality team or organisation using a risk-based approach.
- The reviews can be conducted at any stage of the project, however earlier in the project when plans and templates are being developed, may be more beneficial.

How does the review process work?

- The reviewer organises a meeting with the project team (Principal Investigator (PI) and Study Coordinator (SC) would be most appropriate), ideally in-person.
- The reviewer is sent a copy of the study protocol prior to the meeting to prepare (allow 2 hours). No preparation by the study team is required.
- The reviewer will use the suggested questions in the template below to guide the review with the PI and SC (not all questions will be applicable to every study) and make notes.
- The meeting may take 1-3 hours depending on the complexity of the study.

What happens after the meeting?

- The reviewer will compile their notes into a summary report using the template provided (allow 2-3 hours).
- A Draft report will be sent to the study team along with recommendations for the study team to consider (e.g. implementation of checklists for site activation, maintaining a PICF version control tracker, etc).
- The study team is given the opportunity to comment on the recommendations, or clarify any questions the reviewer may have, before final sign off.
- The study team is responsible for implementing the suggested recommendations.
- If it is evident that a more detailed review is needed, the reviewer may be able to recommend other audit checklists or resources to assist.

If you have any questions regarding the review process, please contact the SHP Clinical Trials Project Manager (shp.reprogram@sydney.edu.au).

Have you completed a review?

We would value your anonymous feedback to help us improve the tool. The feedback survey below should only take 2-4 minutes to complete.

For reviewers: Use this **LINK** or scan the QR code below

For study team members: Use this **LINK** or scan the QR code below

Sydney Health Partners (SHP) and SPHERE sincerely thank the working group members who contributed to the development of the Friendly Project Review Form. The group comprised representatives from the following SHP member organisations: Sydney LHD (SLHD), Northern Sydney LHD (NSLHD), Western Sydney LHD (WSLHD), Nepean Blue Mountains LHD (NBMLHD), the Sydney Children's Hospitals Network at Westmead (SCHN), and The University of Sydney's NHMRC Clinical Trials Centre. The group also included SPHERE affiliated representatives from The George Institute for Global Health, the University of Technology Sydney, and St Vincent's Centre for Applied Medical Research.

SHP/SPHERE Friendly Project Review Questionnaire and Report

Organisation	
Department Name	
Project name/reference no.	
Project summary	
Date of review	
Mode of review (remote, on site, mixed)	
Reviewer Name and Organisation	
Meeting attendees/roles	

Review Items	**Considerations**	**Notes/recommendations**
Sponsor	*Who is the study sponsor?* *Is it industry, collaborative or investigator-led?* *How does the sponsor oversight the project?*	
Study organisation, roles and responsibilities	*Who are the key stakeholders?* *Is there a study organisation chart?* *Is there a RACI?*	
Protocol	*Who was responsible for coordinating and finalising?*	
Participant Information Sheet and Consent form	*Who was responsible for coordinating and finalising?*	
Committee Management	*What study committees are there and who is managing them? Who is chairing them? Are there committee charters in place?*	

Review Items	Considerations	Notes/recommendations
Consumer and Community engagement	*Have any consumers/community members been involved in the design or operations of the project?* *Was the Aboriginal Liaison Officer involved?* *Were these consultations documented?*	
Project Plan including scope, milestones and timelines	*Is there a project plan? Who was responsible for creating this?*	
Funding and budget	*Sources of revenue, project budget, country budget, site budget* *How was the budget calculated (eg. NSW Health awards, internal budget tool)?* *Is the budget sufficient? If not, what plans are there to obtain more funding or amend the project?*	
Ethics and Regulatory	*Was a regulatory submission required?* *Who is responsible for the ethics submissions?* *Was a specialist Ethics review required?* *What is the process to ensure that each protocol, PICF and other materials receive appropriate approval before use?* *Are ethical and regulatory communications and documents filed in the ISF?* *Has the project's approval lapsed at any point?* *Is the project registered in CTMS (NSW Health sites only)?*	
Sites	*How many? Where are they located?* *How were they selected? Was a feasibility checklist used?* *How is feasibility, selection and initiation documented?* *How is site performance evaluated (PI oversight, site training, communications) and non-performance managed?*	
Recruitment	*Is there a Recruitment Plan?*	

Review Items	Considerations	Notes/recommendations
	How many participants will be recruited? How many have been recruited? How is recruitment tracked/managed? Are there any issues with recruitment? Are recruitment issues managed in the recruitment or risk management plan or other strategy? Are the recruitment methods per the protocol/ethics, or have they evolved?	
Consent	*Has consent been conducted according to the protocol? How are you documenting the consent process? How do you track re-consenting? How you ensure the most recent HREC approval PICF is used? Electronic or paper? Has electronic system been validated?*	
Retention and follow-up	*Have any participants been in long term follow-up? Is there a system to retain participants? Is there an option for reduced follow-up? Is the follow-up data complete and accurate? How is withdrawal handled and documented (including data/samples)?*	
Statistics	*Who is doing the statistical analysis? Is there a SAP in place? Were statisticians consulted adequately during development? Are statisticians consulted in relation to data integrity risks, limits?*	
Data Management	*What EDC is being used? Who has designed and built the EDC? How is access managed? Is there a data management plan (including participant withdrawal procedure)? Who was responsible for UAT?*	

Review Items	Considerations	Notes/recommendations
	Is the data being monitored according to agreed timelines? *Are queries responded to according to timelines?*	
Contracts / Vendor management	*Is there any oversight of contract development?* *How are vendors selected and managed?* *How are issues with vendors managed?*	
Monitoring & Data Quality	*Is there a Monitoring Plan?* *Are there any current issues with monitoring?* *Are monitoring activities well documented and complete?* *How is data quality being managed?* *Are open action items resolved within agreed timelines?*	
Intervention	*Responsibility and plans for sourcing and managing (if applicable)* *i.e. accountability records, pharmacy manual and training, shipment records, dispensation logs and scripts.*	
Other project supplies	*Responsibility and plans for sourcing and managing (if applicable)* *i.e. Equipment registers or maintenance logs*	
Insurance and indemnity	*What are the insurance and indemnity arrangements?*	
Safety Reporting	*Is there a safety reporting plan?* *Who is responsible for ensuring events are reported?* *Have events been reported accorded to timelines?*	
Medical monitoring	*Does the study have a medical monitor?* *What is their role?* *What is the communication process?*	
Quality and risk management	*Is there a quality management plan?* *Is there a risk management plan?* *Are deviations and risks tracked, categorised and reported?*	

Review Items	Considerations	Notes/recommendations
Document management and maintenance	*How do you document version control? Who checks this?* *Is there an ISF/TMF index used?* *How are essential documents managed throughout the project?* *Where and how will project documents be filed and archived?*	
Handover process	*What happens when there is a significant team member change (eg. PI, SC, data custodian, etc)?* *Is there a handover document that is updated regularly?*	
Privacy considerations	*If PII is being collected, how is this being managed with reference to collection, storage and destruction?* *Are there adequate provisions in the consent forms and protocol?* *Is there a process for reporting a privacy incident?*	
Conflict of Interest	*Are there any conflicts of interest?* *Have conflicts of interest been managed appropriately i.e. declared to ethics, in the protocol, PISCF?*	
SOPs	*Are any SOPs being followed for study processes?*	
Other relevant notes and recommendations	*Use this section to add any further notes*	

Sign-off and approval	
Form completed by:	
Name	
Role	
Signature	
Date	
Form reviewed by:	
Name	
Role	
Signature	
Date	
Form approved by:	
Name	
Role	
Signature	
Date	