

Lead Site & Coordinating Principal Investigator Role in Multi-Centre Clinical Trials (Expectations and Challenges)

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**Government
of South Australia**

SA Health

Our site before National Mutual Acceptance (NMA)

- > Prior to the NMA, 380 studies initiated
- > Unit structure:
 - 1.0 FTE Manager
 - 1.0 FTE Administrative/Finance Coordinator
 - 4.0 FTE Senior Research Coordinators
 - 2.0 FTE Research Coordinators
- > Studies were submitted to local HREC by Manager or Research Coordinator

Our site after NMA

- > SA fully adopted the NMA in 2013
- > 100 studies initiated since NMA, we are the Lead Site for 20 of these
- > Unit structure:
 - 1.0 FTE Manager
 - 1.0 FTE Administrative/Finance Coordinator
 - 2.3 FTE Senior Research Coordinators
 - 0.8 FTE Investigator Initiated Research Coordinator
 - 2.0 Research Coordinators
 - 0.7 HREC Submission Specialist
- > All HREC submissions and communications are managed by the HREC Submission Specialist

How do we see our responsibility as the Lead Site?

- > Extra level of responsibility for CPI in addition to that of site PI
- > Responsibilities include:
 - Developing HREC application with consultation from PIs
 - Submission of documents requiring scientific and ethical review to HREC throughout project
 - Dissemination of HREC responses to Participating Sites and the Sponsor
 - Fostering strong partnerships between ourselves, Sponsor and Participating Sites
 - Working to NMA guidelines
- > Doesn't include:
 - Responsibility for the conduct of the study at individual Participating Sites

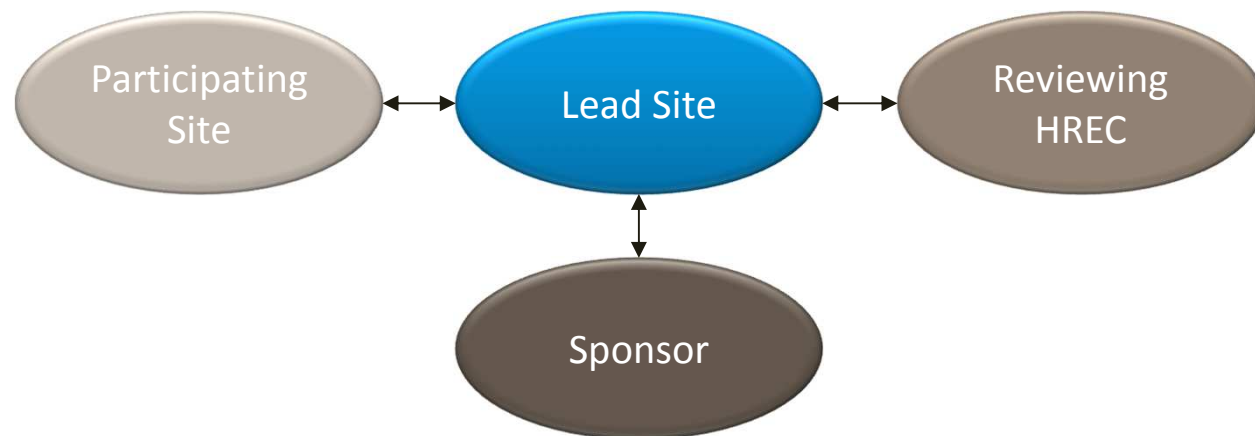
Communication

- > Agree on and establish communication plan upfront
- > One party, either Sponsor or Lead Site takes on responsibility for communication of HREC responses to Participating Sites, can be either, as long as clear and no overlap
- > NHMRC guidance regarding safety monitoring and reporting in clinical trials shifted responsibility for safety reporting to HREC from site to Sponsor.
 - Note – If an amendment to the PICF results from new safety information, Lead Site submits PICF to HREC.

Communication

When Lead Site we usually take responsibility for the ongoing communication with the HREC and pass information from the HREC to the sponsor and the PI at each site

- > HREC Submission Specialist responsible for all communications with Participating Sites and the HREC
- > Sponsor cc'ed into all communication between us and Participating Sites
- > Avoids duplication of workload, conflicting information and improves workflow



Start-up

- > Provide Participating Sites with:
 - Lead Site Team contact details
 - Reviewing HREC details and submission requirements
 - Time-lines for return of documents
- > Request from Participating Sites:
 - Site specific requirements for PICF(s) etc.
 - Notifications(s) to reviewing HREC regarding radiation
 - Email address for SSA
 - Review and comment regarding HREA, PI CV
- > Submissions proceed on time with available documents
- > Lead Site and Participating Site Governance :
 - Industry Studies-none
 - Collaborative Research Group Studies-none
 - Investigator Initiated Trial -depends on project set-up and Participating Site resources

During study conduct and at close-out

- > Request from Participating Sites:
 - Review and comment regarding amendments to protocol, PICF
 - Site specific requirements for amended PICF(s) etc.
 - Notification when study is initiated
 - Notification of changes in study status
 - Notifications(s) to reviewing HREC regarding radiation

- > Provide Participating Sites with:
 - Updates regarding submissions to HREC
 - HREC correspondence and approvals

Potential problems for Lead Sites

Possible problems	Possible solutions
Delayed response times from Participating Sites	Monitor situation. Offer assistance if possible. Submit to HREC with available documents to avoid delays to other Participating Sites
Delayed response times from sponsor	Contact Sponsor and discuss
Participating Sites communicating directly with reviewing HREC	Contact Participating Sites and discuss
Delays in reviewing HREC response times delaying Participating Sites	Contact the HREC and discuss. Keep Participating Sites and sponsors in loop with regards to the delay.
Trial doesn't recruit at Lead Site before closing.	Re-assess site feasibility information including recruitment timelines. Assess impact of protocol amendments.
Unanticipated shortage of Lead Site resources	Re-assign unit workload to ensure NMA Guidelines are met.

Extra work involved with being the Lead Site

- > Extra workload > created HREC Submission Specialist role
- > Estimated at 2.0 hours/month/Participating Site
- > Who pays the cost for this extra workload?
 - Industry Study – Sponsor payment
 - Collaborative research Group - Partially funded by, not usually
 - Investigator Initiated Trial – Project grant funding, departmental funding
- > Governance and administrative requirements increased in parallel so hard to measure savings in efficiency resulting from NMA

Minimizing the resource impact of being Lead Site for Investigator Initiated Trials

For studies initiated by our site, we are the Sponsor and the Lead Site. Important to factor the associated cost into grant applications.

- > Developed Investigator Initiated Trials Research Coordinator role
- > Benefits:
 - Specialised resource > efficiency gains
 - Able to quantify the resource cost required > important when applying for grants
 - Protected resource > increase in the quality of research conduct

Benefits of being Lead Site

- > Oversight of approval process. Always informed
- > Improves site profile. Sponsors selection of site as Lead indicator of site performance
- > Less time spent on Ethics overall. Need to maintain a balance of Lead Site and Participating Site studies however
- > If Lead Site submission resources are at capacity, can still participate in studies
- > Contributing to the success of the NMA.

Only as successful as we make it!

- > All sites need to build their Lead Site capabilities and become involved

The Future

- > Single Ethical Review has streamlined processes but some studies have more than one Lead Site. Is submission to HREC by the Sponsor a solution?

Questions





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