NIHR Research Support Services Sponsoring Organisation Study Planning Tool

Toolkit Release: May 2011

Action required: This planning tool is intended to be done quickly before starting, or early in, the study sponsoring decision process. With experience using the tool should take less than an hour (depending on complexity of the study documentation and access to other staff facilitated through the R&D Operational Capability Statement).

It will help the organisation assess any operational concerns about the study which may delay the sponsoring decision or cause issues with study delivery. In certain circumstances it may indicate that the study should not be considered further and the investigator informed accordingly.

Your assessment is proportionate to the risks associated with undertaking this study. All questions should be answered based on your experience of the sponsoring process and this study. Select the most appropriate option for each question. As a planning aid, please add a short note on concerns and management actions (proportionate to the risks associated with undertaking the study) needed to address these concerns during the process and study delivery.

Where the response to any question is unclear (e.g. because it is not possible to discuss quickly with the relevant person) then this would indicate a risk that may need to be managed later in the process, and so this may indicate option 3 or 4 is appropriate.

Additional 'help' information is provided for each question when the cursor hovers over a 'cell'. This help text is also provided in the Help Text sheet.

Background: This planning tool will quickly highlight any concerns that the organisation may have when deciding whether to sponsor a particular study. The assessment is based on the organisation's capabilities to support a specific study at a specific time (i.e. organisation capabilities may vary over time for operational reasons). Generally it is completed by the sponsoring organisation's 'Research Manager'. Some areas may require early a short early discussion with the investigator(s) or other contacts in the organisation (e.g. finance managers) to share opinions on the study. Understanding any concerns quickly means that they can be addressed early with the funder / investigator or that appropriate plans can be put in place early in the process.

Notes: The planning tool can be used when there is a significant change to any of the areas described to support changes to management actions. This assessment should be undertaken for each study by the organisation (or on behalf of the organisation e.g. by a CLRN). This tool is not intended to duplicate activities within the decision-making process. It assesses the likelihood of the organisation successfully completing the process within an appropriate timescale and completing the study effectively and safely.

Assumptions: The sponsoring organisation has a R&D Operational Capability Statement that provides an overall understanding of its R&D capabilities supported by relevant policies. The organisation has been provided with sufficient and relevant information by the investigator so as to assess its readiness (and risks) appropriately.

Accountability: The organisation's board (delegated to designated 'responsible individual' for R&D management and governance e.g. Research Manager, CLRN).
The management of the sponsoring decision, set-up and delivery of this study will be undertaken as follows:

1. using existing/proven processes and arrangements in the organisation.
2. with only minor changes to processes and arrangements in the organisation.
3. using new/changed processes and arrangements in the organisation. 
4. May not be practical to achieve within a reasonable timetable.

Unknown. Insufficient information available.

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<thead>
<tr>
<th>Column A</th>
<th>Column B</th>
<th>Column C</th>
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<th>Column E</th>
<th>Column F</th>
<th>Column G</th>
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<th>Column I</th>
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<th>Column K</th>
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<tbody>
<tr>
<td>A Study Legal and Regulatory Needs</td>
<td>Is the study type clear (e.g. CTIMPS, devices, etc)? Is it likely that the organisation will be able to address legal and regulatory requirements relating to the study? (e.g. approvals including ethics opinion and regulatory, appropriate SOPs, indemnity cover, licences, etc)</td>
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<td>B Local Alignment</td>
<td>Is the organisation already aware of any constraining factors in the R&amp;D Operational Capability Statement that may impact on sponsoring or delivery of the study (and which may require escalation within the organisation to be resolved)?</td>
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<td>C Investigator Team</td>
<td>Is it likely that the organisation will be able to provide additional support (if required) to the senior investigator in delivering the study?</td>
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<td>D Research Team</td>
<td>Is it likely that the organisation will be able to provide appropriately experienced research staff that may be needed in delivering the study as planned by the CI?</td>
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<td>E Science Design</td>
<td>Is it likely that the organisation will be able to address aspects of study design relating to the science of the study (including peer review)?</td>
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<td>F Patient Safety Design</td>
<td>Is it likely that the organisation will be able to address aspects of study design relating to any additional patient safety requirements?</td>
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<td>G Patient Group Design</td>
<td>Is it likely that the organisation will have the appropriate experience / guidance needed for working with any vulnerable groups as part of the study?</td>
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<td>H Feasibility</td>
<td>Is it likely that the organisation will be able to support study feasibility with candidate participating organisations?</td>
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<td>I Management and Monitoring</td>
<td>Is it likely that the organisation will be able to manage and monitor the study? (taking into account single / multiple centres, study risk etc)</td>
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<td>J Sponsor Accountability</td>
<td>Is it clear how sponsor responsibilities for the study are likely to be allocated (if more than one organisation is involved)?</td>
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<td>K Finance</td>
<td>Is it likely that the organisation will have appropriate cost information and finance staff time to assess and manage financial risks relating to this study?</td>
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<td>L External Agreements</td>
<td>Is it likely that the organisation will be able to understand and manage contractual risks relating to this study? (including access to any additional and specialist contract knowledge)</td>
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Select the most appropriate option and add notes on any management actions required during sponsoring decision, study set-up and delivery.
This chart provides a high-level summary of the key management action areas anticipated during sponsor decision-making and delivery for this study.
Summary of management actions from planning sheet

A> Study Legal and Regulatory Needs  
1  
Follow standard management process

B> Local Alignment  
1  
Follow standard management process

C> Investigator Team  
3  
Significant additional management required

D> Research Team  
1  
Follow standard management process

E> Science Design  
Insufficient information. Refer back to investigator

F> Patient Safety Design  
1  
Follow standard management process

G> Patient Group Design  
1  
Follow standard management process

H> Feasibility  
2  
Some additional management required

I> Management and Monitoring  
1  
Follow standard management process

J> Sponsor Accountability  
1  
Follow standard management process

K> Finance  
4  
High level of management required

L> External Agreements  
1  
Follow standard management process

KEY

1  
Follow standard management process

2  
Some additional management required

3  
Significant additional management required

4  
High level of management required

Insufficient information. Refer back to investigator
Sponsoring Planning Tool: Notes for A> LEGAL AND REGULATORY
Does the organisation expect to be able to assess and address the legal and regulatory requirements (including determining the appropriate regulatory framework e.g. CTIMPS, medical devices, etc) in a way appropriate to the complexity and size of the study within a reasonable timescale agreed with the senior investigator?

Sponsoring Planning Tool: Notes for B> LOCAL ALIGNMENT
Is it expected that the study is likely to be compatible with the organisation's R&D Operational Capability Statement (or similar policy statements) and associated R&D policies? (e.g. are there other reasons to delay or withhold a sponsoring decision appropriate to the complexity and size of the study?)
OR
Does the organisation expect that the study decision can be escalated for senior level acceptance within the organisation within a reasonable timescale agreed with the senior investigator?

Sponsoring Planning Tool: Notes for C> INVESTIGATOR TEAM
Does the organisation expect to be able to provide additional support (if required) to the senior investigator in delivering the study.

Sponsoring Planning Tool: Notes for D> RESEARCH TEAM
Does the organisation expect to be able to provide sufficient and appropriately experienced and trained research staff (internally or contracted in) that may be required for the duration of the study in a way proportionate to the complexity and size of the study within a reasonable timescale agreed with the senior investigator?

Sponsoring Planning Tool: Notes for E> SCIENCE DESIGN
Does the organisation expect to be able to (in a way proportionate to the complexity and size of the study) undertake an appropriate independent (peer) review of the scientific design, quality and value aspects of the study, and assess that it can manage appropriately any changes to the study, and assess that it can manage the processing and dissemination of the final study findings and conclusions all within a reasonable timescale agreed with the senior investigator?

Sponsoring Planning Tool: Notes for F> PATIENT SAFETY DESIGN
Does the organisation expect to be able to (in a way proportionate to the complexity and size of the study) assess and confirm the patient safety aspects of the study, and assess that it can manage appropriately any changes to the study all within a reasonable timescale agreed with the senior investigator?

Sponsoring Planning Tool: Notes for G> PATIENT GROUP DESIGN
Does the organisation expect to be able to (in a way proportionate to the complexity and size of the study) assess and confirm that the consent and other processes related to vulnerable groups (such children, prisoners, the mentally impaired and those with heightened emotional states), and assess that it can manage appropriately any changes to the study all within a reasonable timescale agreed with the senior investigator?

Sponsoring Planning Tool: Notes for H> FEASIBILITY
Does the organisation expect to be able to support study feasibility with candidate participating organisations and/or Networks using appropriate processes and staff in a way proportionate to the complexity and size of the study within a reasonable timescale agreed with the senior investigator?
I  Management and Monitoring
Is it likely that the organisation will be able to manage and monitor the study?
(taking into account single / multiple centres, study risk etc)

Sponsoring Planning Tool: Notes for I> MANAGEMENT AND MONITORING
Does the organisation expect to be able to support the management and monitoring of the study using appropriate processes and staff which are proportionate to the complexity and size of the study (e.g. single or multiple centres, study risks, delegated responsibilities, etc) within a reasonable timescale agreed with the senior investigator?

J  Sponsor Accountability
Is it clear how sponsor responsibilities for the study are likely to be allocated (if more than one organisation is involved)?

Sponsoring Planning Tool: Notes for J> SPONSOR ACCOUNTABILITY
Does the organisation expect to be able to confirm in a way proportionate to the complexity and size of the study, that all sponsor and, where appropriate, funder responsibilities are clearly defined across all relevant parties within a reasonable timescale agreed with the senior investigator?

K  Finance
Is it likely that the organisation will have appropriate cost information and finance staff time to assess and manage financial risks relating to this study?

Sponsoring Planning Tool: Notes for K> FINANCE
Does the organisation expect to be able to provide operationally relevant Study costs using a standard template or other appropriate study costing template which is proportionate to the complexity and size of the study AND
Does the organisation expect to confirm that appropriate funding is available for the study both within a reasonable timescale agreed with the senior investigator?

L  External Agreements
Is it likely that the organisation will be able to understand and manage contractual risks relating to this study? (including access to any additional and specialist contract knowledge)

Sponsoring Planning Tool: Notes for L> EXTERNAL AGREEMENTS
Does the organisation expect to be able to use a standard template or other appropriate study contract / agreement with participating organisations which is proportionate to the complexity and size of the study within a reasonable timescale agreed with the senior investigator?