Healthcare research study: Trust-sponsored

<table>
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<tr>
<th>FEASIBILITY</th>
<th>WORK-UP</th>
<th>GOVERNANCE</th>
<th>RECRUITMENT</th>
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<tbody>
<tr>
<td>Develop proposal</td>
<td>Coordinate work-up</td>
<td>Run governance checks</td>
<td>Initiate site and recruitment</td>
</tr>
<tr>
<td>Assess feasibility</td>
<td>Submit to IRAS</td>
<td>Issue Trust permission</td>
<td>FPFV</td>
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<tr>
<td>Apply for funding</td>
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<td>Close site</td>
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**CPI (study team)**
- Develop protocol
- Assess feasibility
- Assess costing
- Apply for funding

**ICH Divisions**
- Divisional review
- Confirm portfolio eligibility

**Ex. orgs**
- Advise costs / feasibility

**Support services**
- Process service request

**JRO (funding)**
- Prepare grant / contract
- Work-up award

**JRCO (sponsor)**
- Confirm sponsorship
- Arrange peer review

**DAY 0: IRAS Submission**
**DAY 30: R&D approval**
**DAY 60: First patient**

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Feasibility

<table>
<thead>
<tr>
<th>CnP (SID) study team</th>
<th>ICN Divisions</th>
<th>Ext. orgs</th>
<th>Support services</th>
<th>JRO (funding)</th>
<th>JRCA (funding)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding awarded</td>
<td>Feasibility</td>
<td>Control</td>
<td>Set-up</td>
<td>Process</td>
<td>Review (if reqd)</td>
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<tr>
<td></td>
<td>process</td>
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Work-up

<table>
<thead>
<tr>
<th>Plan patient recruitment / logistics</th>
<th>Prepare study documents</th>
<th>Complete study work-up</th>
<th>STUDY-WIDE CI submits REC / R&amp;D (IRAS)</th>
<th>LOCAL PI submits SSI (IRAS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coordinate study work-up</td>
<td>Reaffirm feasibility</td>
<td>Approve submission</td>
<td>Process approvals, eg REC / MHRA / ARSAC</td>
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Governance

<table>
<thead>
<tr>
<th>Log receipt (valid submission)</th>
<th>Governance process</th>
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Click buttons above for further information online
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**Work-up**
- CI/PI (study team)
  - Work-up process <<<
- JRO (funding)
- Support services
- JRO (funding)
- Ext. agencies
  - Issue approvals, eg REC / MHRA / ARSAC
  - Confirm contract / finance
  - Confirm service approvals

**Governance**
- Log receipt (valid submission)
- Initiate governance review
- Check policy / procedure / legal reqs
- Complete governance review
- Resolve study queries
- Reaffirm feasibility
- Issue Trust approval

**Recruitment**
- Brief trial team
- Recruitment process >>>

**Timeline**
- Day 0
- Day 30
- 20 days
- 30 calendar days

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Governance Thursday, 02 July 2015

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