Checklist for sponsors

Please note - the checklist below has been adapted from the Health Research Authority (HRA) 'Hints and Tips for Sponsors' document (version 1.0, 24 October 2016).

Pre-Application

Sponsors should ensure that:

- Activities outlined are fully and accurately costed and costs attributed
- Where award bodies do not provide peer review, adequate scientific review has been undertaken
- The Chief investigator (CI) and research team are competent and suitably trained for the roles outlined in the application
- Support is given to the CI and research team in creating an appropriate and valid document set to support the application in line with HRA criteria and standards
- Appropriate risk assessment has been undertaken
- Adequate insurance and indemnity arrangements are in place to cover activity
- There is a mechanism for involving patients and the public, to a relevant degree, in the design and acceptability of the research
- Support is provided to CIs to identify sites to deliver the project
- Where the study is on the NIHR CRN Portfolio, work collaboratively with the Clinical Research Network (CRN) Study Support Service (if appropriate)
- The roles and responsibilities of both organisation and individual are clearly defined and signed off including any arrangements for joint or co-sponsorship
- Appropriate review of feasibility has been conducted including involvement with all support services
- All relevant reviews and authorisations are in place e.g. information governance.

HRA application submission

Sponsors should ensure that:

- Applications are made in line with HRA guidance on the correct form
- Research is categorised accurately to reflect study type
- The Integrated Research Application System (IRAS) form is authorised by all necessary parties including an individual authorised by the sponsor to do so
- Documents supplied for review are the versions which were reviewed for sponsorship
- Support and relevant guidance is given to applicant in applying for other relevant regulatory approvals
- The HRAs non-commercial list of authorised sponsor contact is kept up to date.

Educational supervision

Supervisors should:

- Ensure that the project is overseen and has relevant educational and scientific input
- Have the suitable level of training in relevant research methods for design and implementation of research
- Attend research ethics committee (REC) meetings with students/sponsees

- Provide clear guidance to students on the appropriateness of their research with emphasis on:
    - Potential unintended impact on participants as a result of the research
    - Appropriate understanding of the legislation around consent and vulnerable groups
    - Handling disclosure of sensitive information in the research process
    - Lone working arrangements

- Ensure that the student is adequately trained to conduct their own research safely and without reputational damage to the organisation
- Provide access to appropriate methodological expertise and guidance to ensure consistency and sufficiently high quality of the research throughout the duration of the project.

Working with sites

Sponsors (or their delegate) should:

- Send relevant site level documentation to sites when HRA initial assessment/HRA approval letter stipulates
- Liaise with sites in order to assess, arrange and confirm capacity and capability
- Where necessary undertake contract negotiation in a timely manner
- Assist applicant with responses to REC and HRA assessment
- If modifications are requested, re-review documentation to ensure that the study is still deliverable and that insurance and indemnity is adequate.

HRA Approval

Sponsors (or their delegate) should ensure:

- That sites are aware of the issuing of HRA approval
- Timely agreement to capacity and capability with sites.

Post Approval

Sponsors should ensure that:

- Studies are registered on an accessible database
- The required infrastructure is in place to ensure the appropriate level of monitoring and audit for the life cycle of the study as described in the application
- All findings are disseminated in an appropriate manner in line with the application
- Amendments are discussed with CI and research team and an impact assessment is made to ensure the delivery of the amended study
- Sites are aware of amendments to the study
- Capacity and capability is confirmed at sites where necessary and agreements renegotiated in a timely fashion
- Adverse events and incidents are reported in a timely fashion in line with regulation and HRA guidance
- Annual progress reports are submitted in line with conditions of approval.