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**Appendix 1**

**HRA Expectations of Sponsors**

The Health Research Authority expects that an organisation which agrees to sponsor research of any level be confident in its ability to meet their responsibilities according to the standards as laid down in the Research Governance Framework (2005).

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| **Expectations regarding ALL types of studies sponsored by organisations** | |
| Peer review: | Proportionate peer review is in place for all sponsored research activity. This is appropriate according to the type of study and the perceived risk and ensures that the design of the study meets the appropriate standards. The review process and outcome are justified and clarified in the applications prepared in IRAS |
| Supporting information: | All appropriate, valid supporting documentation is supplied at the point of application |
| Defined roles and responsibilities: | Division of roles responsibilities of both organisations and individuals are clearly defined and signed off prior to the study commencing |
| Monitoring and audit: | The required infrastructure is in place to ensure the appropriate level of monitoring and audit is carried out which is proportionate to the type of study being undertaken and ensures the necessary level of oversight throughout the life cycle of the study. |
| Risk assessment processes/tools: | An agreed risk assessment process is in place to identify any potential risks to the organisation or the health, safety and well-being of researchers and research participants |
| PPI | Sponsors will ensure that patients and/or public have been involved in study design, or where this is not appropriate, the reasons are clearly explained in the applications prepared in IRAS. |
| Training and Suitability: | Arrangements are in place for ensuring the CI has the relevant experience and appropriate training to fulfil their role.  This should include no unnecessary requirements in place regarding GCP training. Sponsors should only require GCP training for those individuals who are taking part in a clinical trial and should not be a requirement for researchers undertaking all other types of studies (HRA information on training for researchers is available for download at http://www.hra.nhs.uk/resources/before-you-apply/roles-and-responsibilties/researcher-suitability-and-training/) |
| Registration: | Studies are registered on an accessible database (This is a requirement for Clinical Trials, and is expected for all studies as appropriate) |
| Dissemination: | All findings (including negative findings) are disseminated/published in an appropriate manner and intentions are made clear at the time of application |

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| **Expectations specific to Clinical Trials of Medicinal Products** | |
| Responsibilities: | As these are governed extensively by regulators and statutes, sponsors will discharge their responsibilities in accordance with the appropriate legislation and regulations. |
| Training and Suitability | CIs are eligible “Authorised Health Professionals” – medical doctors, dentists, nurses or pharmacists. Sponsors should require all individuals involved in the conduct of the study to be appropriately trained in the requirements of the Medicines for Human Use (Clinical Trials) Regulations, as amended, and the principles of Good Clinical Practice described within them (see MHRA statement [<http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/Background/index.htm>]). |

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| **Expectations specific to HEI/Student Research** | |
| Project Oversight: | Each student research project is overseen by a named supervisor with current knowledge of research methods and governance/regulatory approvals |
| Training: | Supervisors of student research are trained in their responsibilities. Both supervisors and student researchers are adequately trained in the relevant research methodology required for both the design and implementation of their research. |
| REC review: | Supervisors attend ethics committee meetings with their student |
| Guidance from Supervisors: | Supervisors, as part of their sponsor responsibilities, provide clear guidance to the student on the appropriateness of their research with particular 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   + Vulnerable lone worker arrangements   The supervisor ensures that the student is adequately prepared and briefed to conduct their own research safely and without reputational damage to the organisation. |
| Quality Assurance: | Access to appropriate methodological expertise and guidance throughout the duration of the project so that the research is of sufficient quality |