Annex A – Northern Ireland

List of common research activities attributed to Research Costs, NHS Treatment Costs and NHS Support Costs

The costs of activities listed in **Part A** should be funded **in full by all grant funders**.

The costs of activities listed in **Part B** will also need to be funded in full by grant funders **except** where the funder is a medical research charity that is a member of the Association of Medical Research Charities (AMRC) or where a charity has signed a partnership agreement with HSC R&D Division of the Public Health Agency and the activity is undertaken by existing staff employed by the NHS or through HSC R&D Division funding.

Under these circumstances the cost of the activities in Part B will not normally be recovered from the charity. For clarity this means that if an individual needs to be additionally employed to carry out these activities then their cost should be met by the funder.

Part A

1. Any screening tests/assessments, to determine whether a patient is eligible to participate in a study, performed after the patient has been approached to ask if they wish to participate in the study, but before they are accepted onto the study.
2. Study specific central trial co-ordination and management.
3. Patient randomization.
4. Investigations, assessments and tests relating to if, how, why and when an intervention/procedure works - in other words, activity which is intended to answer the research question.
5. Investigations, assessments and tests where the results are anonymous and unlinked to a patient identifier, or where the individual results will not be reported back to study participants or their clinicians, since such information is collected primarily for the purpose of answering the research question. However, exceptional circumstances may arise where there is an overwhelming clinical need to convey results to the clinician providing care. The possibility of such exceptional circumstances does not change the primary purpose.
6. Patient follow-up where the follow-up is not a part of individual patient clinical management.
7. Cash reimbursements or payments to volunteers to participate in the study.
8. All costs associated with placebos including but not limited to producing, formulating, disguising, shipping, storing and dispensing placebos, including administering sham treatments, since these costs do not form part of the patient's care and would not continue to be incurred once the study is finished.
9. Registration of trials.
10. Data storage archiving of clinical research records.
11. Costs associated with making the results accessible.
12. Training where new skills are required to carry out the R&D activity, but not training in obtaining informed consent, or training to deliver the treatment under investigation.
13. Data analysis needed to answer the questions that the research study is addressing.

Part B

14. Local study trial co-ordination and management.
15. Data collection needed to answer the questions that the research study is addressing (including collecting data for and completing the report).
16. Regulatory preparation and compliance including obtaining ethical approval and complying with the Medicine for Human Use (Clinical Trials) Regulations 2004.
17. The time taken by Chief and Principal Investigators (CI and PI) to explain the study to professional colleagues, and to understand, the research elements of a study. For example the time taken to explain the criteria for patient eligibility or to explain the randomisation protocol.
18. Sponsorship fees such as MHRA fees, and CTA annual renewal fees.

Activities that are attributed to NHS Treatment Costs include:

1. Supplying and administering the medicine/device/therapy being studied.
2. Supplying and administering any active comparators - including medicines, devices or therapies, but not placebo or sham treatments.
3. Training of clinicians to deliver the treatment.
4. Investigations and tests which would continue to be incurred if the patient care service in question continued to be provided after the R&D study has stopped.
5. Patient follow-up where this is required as part of the clinical management of a patient. If the primary purpose of the follow up is to inform the long-term evaluation of an experimental treatment, the activity should be attributed as a Research Cost. If the primary purpose of the follow-up is to monitor patient safety rather than efficacy, the activity should be attributed as an NHS Support cost.

Activities that are attributed to NHS Support Costs include:

1. The processing of the patient record to identify NHS patients who may be suitable to approach to ask if they wish to participate in a research project.
2. Obtaining informed consent from patients where the study is a health research study taking place within the NHS.
3. Additional investigations, assessments and tests where the results are required by the patient’s care team to ensure patient safety and where arrangements are in place to feed the results back to the clinician.