SUPPORTING EARLY MINDS Research Network

DSPI UNIVERSITY OF OXFORD

Guidance for researchers and NHS clinicians undertaking research with early years staff

Purpose

This guidance sets out the key stages involved in developing research with early years staff, from defining the research question and consulting the NIHR Research Support Service (RSS) through to costing, completing the Integrated Research Application System (IRAS) application where required, and securing the necessary approvals.

It is intended for NHS clinicians, academic researchers and collaborators undertaking research in health visiting, family hubs, children's centres, early years settings, local authorities and infant mental health services. It focuses on the activities that need to happen before a study is ready to begin, with particular attention to feasibility, service and treatment costs, research governance and working across NHS and non-NHS organisations.

Overview of the process

1. **Develop the research question and establish the project —** Define the problem, objectives, population, settings and initial feasibility.
2. **Consult the NIHR Research Support Service —** Seek advice on design, methods, feasibility, public involvement and funding.
3. **Identify the sponsor, collaborators and participating sites —** Agree responsibilities and assess organisational capacity.
4. **Develop the protocol and supporting documents —** Specify methods, recruitment, data collection, consent and safeguarding.
5. **Calculate research, service and treatment costs —** Develop a realistic budget and clarify cost attribution and funding responsibilities.
6. **Establish the approvals pathway and complete IRAS where required —** Confirm classification, ethics and organisational approvals, and site readiness.

These stages are interrelated rather than strictly sequential. RSS consultation may change the design, which in turn affects the protocol, budget, participating sites and approvals required.

Stage 1. Develop the research question and establish the project

1.1 Define the research question

Researchers should be clear about:

- The problem: what gap in evidence, difficulty in practice or service development need is the research addressing?

- The population: which early years staff are involved, for example, health visitors, nursery nurses, family support workers, early years practitioners, infant mental health practitioners or multidisciplinary teams?
- The setting: NHS services, local authorities, family hubs, children's centres, nurseries, voluntary-sector organisations or several sectors?
- The focus: practitioners' experiences, professional knowledge, assessment practices, service delivery, an intervention or outcomes for infants and families?
- The intended contribution: how might findings inform clinical practice, workforce development, service organisation, policy or future research?

Distinguish between research with early years staff and research about early years staff. Practitioners may be participants, intervention deliverers, recruiters of families, members of the research team or collaborators in study design. Each role has different implications for recruitment, training, consent, workload and costs.

1.2 Establish the type and scale of study

Consider whether the project is:

- An exploratory qualitative study of practitioners' experiences.
- A survey of workforce knowledge, confidence or practice.
- A feasibility or pilot study of an intervention or assessment tool.
- An evaluation of an existing service or workforce model.
- A trial or comparative study of an intervention.
- A mixed-methods study combining practitioner perspectives with service or family outcomes.

The design should follow from the research question. Interviews may be appropriate for understanding how practitioners experience a new assessment process, whereas a comparative design may be needed to estimate whether an intervention improves outcomes. Where an intervention is new, consider testing acceptability, recruitment, delivery, retention and outcome measurement before a larger evaluation.

1.3 Establish initial feasibility and resource implications

Consider the likely number of participating organisations, staff, sites and participants; the recruitment period; availability of suitable outcome measures; and time required from practitioners and managers. Identify barriers such as staff shortages, limited protected time, competing priorities, data access constraints, or additional training and supervision needs. Consider whether the study is proportionate to the available funding and timescale.

Output from Stage 1
A concise project outline covering the research question, rationale, population and settings, broad design, potential collaborators, anticipated resources and initial uncertainties.

Stage 2. Consult the NIHR Research Support Service

Consult RSS while the study is being developed, ideally before the protocol and funding application are finalised. RSS provides support with research design, methods, statistics, qualitative research, health economics, public involvement and funding applications. The appropriate support route depends on the study and its setting.

2.1 Prepare for the initial consultation

Provide a short description of:

- The research problem and proposed questions.
- The intended participants and service settings.
- The proposed study design and methods, if known.

- The anticipated scale and duration.
- The organisations likely to be involved.
- The proposed funding route and submission deadline, if known.
- The main uncertainties requiring advice.

A fully developed protocol is not necessary; early consultation is most useful while there is still scope to change the design.

2.2 Areas to discuss with RSS

Research design and methods. Is the design appropriate? Would qualitative, quantitative or mixed methods be most useful? Is a pilot or feasibility study needed? Are outcome measures valid, acceptable and sensitive to change?

Recruitment and feasibility. How many services and practitioners may be needed? Is recruitment realistic? What assumptions underpin sample size? How will differences between organisations and workforce roles be addressed?

Funding and costing. Which funding programmes may be suitable? What information is needed for a credible budget? Are specialist health economics, statistical or methodological inputs required?

Public and practitioner involvement. How should early years staff and parents/carers contribute to the research question, design, participant materials, outcome selection and dissemination? How will their time be supported?

Governance and approvals. What approvals pathway is likely? Is HRA or REC review required? Will IRAS be used? What sponsor, site and information governance requirements should be anticipated?

2.3 Seek specialist support where necessary

Projects involving several local authorities, NHS organisations or early years providers may need expertise beyond the core research team. RSS can help identify methodological needs and appropriate support. Separate discussions with NHS R&D teams, finance departments, costing specialists and local authority research governance leads may also be necessary. Keep a record of key advice and decisions, especially where these affect design, sample size, budget or approvals.

Output from Stage 2
A refined study design, plan for further methodological support, initial funding strategy and list of issues requiring resolution.

Stage 3. Identify the sponsor, collaborators and participating sites

3.1 Identify the research sponsor

The sponsor accepts overall responsibility for ensuring that the research is properly initiated, managed and appropriately financed, or that arrangements for financing are in place. Depending on the project, the sponsor may be an NHS organisation, university or another eligible organisation. The funder and sponsor may differ.

Approach the prospective sponsor early to establish:

- Whether the organisation is willing and able to sponsor the study.
- What internal review and approval processes apply.
- What documentation is required before sponsorship can be confirmed.
- Whether insurance, indemnity or other risk arrangements need consideration.
- Who will oversee regulatory compliance, monitoring and study management.
- Whether the proposed study is within the organisation's capacity and expertise.

Sponsorship should not be assumed simply because a clinician or academic is employed by the organisation.

3.2 Identify and engage participating organisations

Potential sites include NHS trusts, integrated care boards, local authorities, family hubs, children's centres, nurseries and voluntary-sector providers. Early discussions should establish:

- Who has authority to agree to the organisation's participation.
- Whether the organisation has the relevant staff, population and capacity.
- How practitioners will be approached and recruited.
- Whether managers need to allocate staff time or arrange backfill.
- Whether research activities can be undertaken during normal working hours.
- Whether routine data can be accessed and who controls those data.
- Whether local ethics, governance, information governance or contractual requirements apply.

For multi-site research, arrangements may differ between organisations. An NHS trust and a local authority, for example, may have different processes for granting access to staff and records.

3.3 Agree responsibilities and resources

Clarify the responsibilities of the chief investigator, research team, sponsor, participating organisations and site leads. Agree who will manage recruitment, provide training, arrange interviews, extract data, maintain records, handle safeguarding disclosures and communicate with participants. Any substantial time expected from service managers or practitioners should be reflected in feasibility planning and costing.

3.4 Consider practitioner involvement

Practitioners should be able to comment on the proposed study before it is finalised. Their input may identify inappropriate terminology, unrealistic recruitment expectations, overlooked professional groups or unintended consequences for service delivery. If practitioners act as co-designers or collaborators rather than solely as participants, agree their roles, responsibilities, time commitments and recognition.

Output from Stage 3
An identified sponsor, prospective sites, named organisational contacts, an initial capacity and capability assessment, and a clear allocation of responsibilities.

Stage 4. Develop the protocol and supporting documents

The protocol translates the research question into a detailed plan for review by the sponsor, funder, participating organisations and relevant approval bodies. Develop it alongside the budget and approvals plan, as changes in methods or intervention delivery may affect both.

4.1 Specify the study design and methods

The protocol should explain:

- The rationale, aims, objectives and research questions.
- The study design and why it is appropriate.
- The setting, participant groups and eligibility criteria.
- The proposed sample size and its justification.
- Recruitment methods and consent procedures.
- Data collection methods, measures and time points.
- The analysis plan, including handling of missing data where relevant.
- Anticipated risks, benefits and participant burden.
- How confidentiality, data security and safeguarding will be addressed.
- How findings will be reported and disseminated.

Specify whether staff are research participants, delivering an intervention, identifying eligible families or contributing as collaborators. These roles involve different responsibilities and resource requirements.

4.2 Specify interventions and treatment arrangements

If the study includes training, supervision, a therapeutic intervention or a new assessment process, describe what is delivered, by whom, to whom, how often and for how long. Include required training and competencies, supervision arrangements, and measures of intervention fidelity or implementation.

Where care or treatment is involved, clarify usual care, additional activities introduced by the study, and whether participants may receive different care depending on study allocation. These details inform risk assessment, costing and the approvals pathway.

4.3 Prepare participant-facing documents

Depending on the design, documents may include:

- Participant information sheets and consent forms.
- Staff recruitment invitations and study summaries.
- Questionnaires, interview schedules and observation frameworks.
- Information for parents/carers where family participation or family data are involved.
- Data collection forms and case report forms.
- Training materials and intervention manuals.
- Data management and confidentiality documentation.

Use clear, accessible language and explain the purpose of the research, what participation involves, how information will be used, the limits of confidentiality and how participants can withdraw. Where staff are recruited through their employer, explain how voluntary participation will be protected and whether managers will know who has agreed to participate.

4.4 Address data protection and safeguarding

Identify what personal data will be collected, the lawful basis for processing, who will have access, how long data will be retained and whether information will be shared across organisations. Research involving case records, video recordings or identifiable information about infants and families may require additional safeguards. Plan data minimisation, secure transfer, access controls and deletion before data collection.

The protocol should explain how researchers will respond if a participant discloses a current safeguarding concern or information indicating that a child or adult may be at risk. Confidentiality limits and escalation procedures should be explicit.

Output from Stage 4
A complete protocol and supporting document set, with sufficiently detailed methods and intervention arrangements to allow accurate costing and assessment of approvals.

Stage 5. Calculate research, service and treatment costs

Costing should begin early and be refined as the protocol develops. A study can be scientifically sound but undeliverable if it underestimates staff time, service capacity, training, treatment or infrastructure. The budget should distinguish the costs of conducting the research from the costs of providing services and care.

5.1 Identify the main cost categories

In England, the AcoRD framework (Attributing the costs of health and social care Research and Development) provides the basis for distinguishing research costs, NHS support costs and NHS treatment costs in applicable studies.

Cost category	Description and examples
Research costs	Costs associated with answering the research question, generally met by the research funder. Examples include research staff, research-specific interviews, data collection and analysis, and research-only assessments.
NHS support costs	Additional patient-related activities that support research but are not themselves research or treatment. Eligible NHS support costs are met through relevant NHS research support arrangements. Examples may include identifying and recruiting eligible participants, depending on the protocol and attribution rules.
NHS treatment costs	Costs of providing care to participants under the applicable attribution rules. The protocol should identify the care involved and distinguish usual care from activities undertaken specifically for research.
Excess treatment costs (ETCs)	Where eligible NHS treatment costs arising from a study exceed the costs of standard care, the difference may be an ETC. Funding responsibility depends on the study, commissioning arrangements and applicable policy.

Determine categories from the activities specified in the protocol, not solely from the professional title of the person undertaking them. Not all studies involving NHS staff have treatment costs or ETCs.

5.2 Calculate the costs of service participation

Research involving early years services can create substantial indirect demands on organisations, even when the research itself appears low-cost. Consider time required for:

- Managers to review the study and agree local participation.
- Practitioners to attend interviews, complete questionnaires or provide observations.
- Staff to undertake research-related training or supervision.
- Service leads to identify potential participants or facilitate recruitment.
- Administrative staff to arrange appointments and manage communications.
- Data managers or analysts to extract and prepare routine service data.
- Staff to attend study meetings or support implementation.

For each activity, estimate the number of staff involved, time required, frequency and relevant staff cost. Establish whether time can be absorbed within existing capacity, requires backfill or needs direct funding. For example, a study across several family hubs may require little additional clinical treatment but substantial manager and practitioner time for recruitment and data collection.

5.3 Cost interventions and treatments separately

Where a study introduces or evaluates a treatment, therapeutic intervention or structured training programme, identify the full cost of delivery. Potential costs include:

- Initial training and ongoing supervision.
- Practitioner time delivering sessions.
- Assessment and formulation time.
- Materials, equipment and licensing fees.
- Travel and home visits.
- Administrative support and appointment coordination.
- Clinical oversight and fidelity monitoring.
- Additional care arising from the intervention or study procedures.

Distinguish the cost of establishing an intervention for research purposes from the likely cost of routine delivery after the study ends. If local authority or voluntary-sector staff deliver the intervention, agree costing and funding with the relevant organisations; NHS treatment-cost arrangements should not automatically be assumed to apply.

5.4 Use appropriate costing processes and tools

Consult the sponsor's finance team, relevant NHS R&D office and, where applicable, the NIHR Regional Research Delivery Network's AcoRD costing expertise.

- AcoRD guidance: https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research
- Schedule of Events Cost Attribution Tool (SoECAT): used in applicable studies to document attribution of activities and costs. Confirm whether it is required for the study and funding route.
- DHSC guidance on excess treatment costs: https://www.gov.uk/government/publications/excess-treatment-costs-etcs-in-non-commercial-research

The costing process should identify who is responsible for each cost and confirm funding arrangements before the study begins. Do not assume every study involving NHS staff requires a SoECAT.

5.5 Build a realistic project budget

Include research staff, statistical and methodological support, data management, travel, participant expenses where appropriate, public and practitioner involvement, training, equipment, dissemination and applicable indirect or infrastructure costs. Reflect the time needed to obtain approvals, recruit sites and participants, and manage a multi-site study. If a funding application requires a SoECAT or other costing documentation, allow time for completion and authorisation.

Output from Stage 5
A justified budget, documented allocation of relevant research and service activities, confirmation of applicable SoECAT requirements, and clarity about treatment costs and ETC funding where relevant.

Stage 6. Establish the approvals pathway and complete IRAS where required

Research governance and approvals should be considered from the outset. Confirm the formal pathway once the study design, population, setting and data requirements are sufficiently clear. IRAS is an application system, not an approval in itself, and is not required for every project involving early years staff.

6.1 Determine the classification and approvals required

Establish whether the project is research, service evaluation, clinical audit or quality improvement. Use the HRA decision tool and seek advice from the sponsor or relevant governance team if the classification is unclear.

The approvals pathway depends on factors such as:

- Whether the research takes place in the NHS, local authority services or other settings.
- Whether NHS patients, service users, staff or their records are involved.
- Whether the study involves an intervention, randomisation or changes to care.
- Whether identifiable personal data are collected or accessed.
- Whether NHS Research Ethics Committee (REC) review is required.
- Whether additional approvals or permissions are required from participating organisations.

Interviews with practitioners about their professional experiences may follow a different route from a study involving NHS patients, clinical records or a new therapeutic intervention. The fact that NHS staff participate does not by itself determine whether HRA approval or REC review is required.

6.2 Identify the sponsor's requirements

Confirm with the sponsor which documents and checks are needed. These may include:

- The final or near-final protocol.
- Participant information sheets and consent forms.
- Recruitment materials and data collection tools.
- Evidence of appropriate insurance or indemnity arrangements.
- Data protection and information governance documentation.
- Risk assessments and arrangements for monitoring the study.
- Site and organisational information.
- Costing documentation, where applicable.

The sponsor should confirm the approvals pathway and responsibilities of the chief investigator and research team. Avoid submitting an application before the sponsor has confirmed that the documentation is sufficiently developed.

6.3 Complete the relevant IRAS application

Where IRAS is required, use https://www.myresearchproject.org.uk/ and its project filter to establish the relevant application route. The process generally involves:

7. Creating or accessing the project record.
8. Completing the project filter and identifying required approvals.
9. Completing the relevant application questions.
10. Preparing supporting documents and checking consistency with the protocol.
11. Arranging sponsor review and sign-off.
12. Submitting through the appropriate process and responding to requests for clarification or revisions.

Ensure that the IRAS information matches the protocol, participant documents and proposed site arrangements. Inconsistencies in recruitment, consent or data handling can lead to queries and delays. Follow current IRAS and HRA instructions because submission arrangements depend on the approvals required.

6.4 Obtain site permissions and confirm readiness

Approval of a study does not necessarily mean that every organisation is ready to begin. For NHS sites in England, the relevant capacity and capability process must be completed. Local authorities, universities, family hubs and other providers may have their own governance and access requirements.

Before starting at each site, confirm that:

- Required approvals and local permissions are in place.
- The organisation has agreed to participate.
- Staff roles and responsibilities are clear.
- Recruitment and data access arrangements are agreed.
- Relevant training and safeguarding procedures are in place.
- Funding and service costs have been agreed.
- Any conditions attached to approvals have been met.

Researchers must follow applicable processes for reporting amendments if the protocol or study arrangements change after approval.

Output from Stage 6
A confirmed approvals pathway, completed IRAS application where required, appropriate ethics and organisational approvals, and documented confirmation that participating sites are authorised and ready to proceed.

Final checklist: key deliverables before the study begins

- **1. Research question:** Clear aims, target population, proposed settings and initial project outline.
- **2. RSS consultation:** Advice on design, feasibility, methods, involvement and funding.
- **3. Sponsor and sites:** Sponsor identified, participating organisations consulted and responsibilities agreed.
- **4. Protocol and documents:** Study design, recruitment, outcome measures, participant materials and data management plan.
- **5. Costing and finance:** Research and service costs estimated; treatment costs, ETCs and SoECAT requirements considered where applicable.
- **6. Governance and IRAS:** Classification confirmed, approvals pathway established, applications and site permissions completed as required.

Key resources

- **NIHR Research Support Service:** https://www.nihr.ac.uk/
- **HRA: What approvals do I need?:** https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/
- **IRAS:** https://www.myresearchproject.org.uk/
- **AcoRD guidance:** https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research
- **DHSC: Excess treatment costs:** https://www.gov.uk/government/publications/excess-treatment-costs-etcs-in-non-commercial-research

Overall recommendation: involve RSS early and develop the protocol, costing and approvals plan in parallel. For research involving early years staff, pay particular attention to the demands placed on participating services, the distinction between research and service delivery costs, and governance arrangements across NHS and non-NHS settings.