

Involving Service Users and Carers as Co-Applicants, Project Team Members and Co-researchers in Research

Guidelines for Sponsors, Research Managers and Governance Leads

These guidelines outline the management, governance and ethical implications of involving service users and carers as co-applicants, project team members and co-researchers in health and care research. They have been produced by the **NHS Research and Development Forum Service User and Carer Working Group**, following extensive consultation across the NHS R&D Forum, and in conjunction with National Institute of Health Research (NIHR) Involve, which has produced accompanying guidelines for researchers and service users and carers '[NIHR Involve guidance on Public Co-applicants in Research – Guidance on Roles & Responsibilities](#)'.

Background

Personal experience of service users and carers highlighted several challenges and issues for those fulfilling the roles of co-applicant, project team member and co-researcher in research studies. The challenges included:

1. How to ensure service users and carers as co-applicants, project team members, or co-researchers engaging in funding applications, are fully aware of their responsibilities in these roles and what the implications might be.
2. How sponsors, grant holding organisations, funders and other members of the research community can communicate with and support service users and carers in their role.
3. Understanding and clarifying the contractual and legal governance issues and responsibilities that are particular to service user and carer co-applicants, project team members, and co-researchers, from both an organisational and individual service user and carer perspective.

Service users and carers as co-applicants, team members, co-researchers in research studies

The following definitions are used throughout the document.

Co-applicants:

“Co-applicants are individuals with responsibility for the day-to-day management and delivery of the project. Collaborators normally provide specific expertise on aspects of the project. Co-applicants are considered part of the project team and are expected to share responsibility for its successful delivery”.¹

¹ NIHR: http://www.nets.nihr.ac.uk/_data/assets/pdf_file/0005/79664/FullGuidanceNotesSAF-V1_26.pdf)

Project team members:

These are service users and carers who take part in a study as part of the core project management team, as members of a steering group, a review group or panel, or on an advisory panel or similar. They may also be referred to as public contributors or researchers, but their role is quantified as a non-professional team member in this context.

Co-researchers:

Service user and carer co-researchers may undertake specific roles within the research project e.g. conducting interviews or focus groups, supporting data analysis. This can be independent from or in collaboration with contracted research team members.

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(Click on the links in the diagram to access further information)

Roles and responsibilities

In all cases, service user and carer involvement should be properly costed to enable the level of involvement necessary for the type of study (see: <http://www.invo.org.uk/resource-centre/payment-and-recognition-for-public-involvement/involvement-cost-calculator/>). Where the level of involvement is determined by the availability of funding for the conduct of the project, sponsors, staff and research leads should make this clear from the outset and not set unrealistic expectations

Responsibilities

A service user and carer co-applicant will have the same responsibility as any other co-applicant and systems should be in place to ensure they fully understand their legal and ethical responsibilities when conducting research in a health and care setting. Study-specific tasks can vary between projects, and all should be clearly documented from the outset. Research teams should elicit and facilitate what type of support the service user or carer co-applicant requires.

Contracts & written agreements

Service users and carers may have different roles and relationships with the organisation that is applying for grant funding or sponsoring a research study. This can vary from being registered as or considered a volunteer to being registered as an employee. Some organisations issue service users or carers with an honorary contract (conferring no employment rights). Other service users prefer to act as independent consultants. However, contracts of some kind are usually required for those who are involved in project teams or as co-researchers. It is important that this should not create a barrier to involvement which should be as inclusive as possible. Involvement should be based on the skills and experience of the service user or carer who will normally provide supporting information.

Preferred practice varies widely across organisations and the preferences of service users and carers must also be considered as the choice of agreement may be dependent on their employment status and personal circumstances, for instance being in receipt of benefits. Research leads should consult with their HR department to clarify the nature of the contract and agreement in place for each study.

A research sponsor should always make clear which duties and responsibilities they are delegating to others. This is usually done in the form of a written agreement. Involve guidance on payments is an important resource (see: <http://www.invo.org.uk>).

Wellbeing of service users and carers

Sponsors and research teams have a responsibility to ensure the physical and mental wellbeing of all service users and carers engaged in research teams or as co-

researchers. Some service users and carers are potentially vulnerable through the nature of their health issue or disability. It could also be the nature of their role where they may be exposed to difficult and challenging aspects of care where data collection is taking place, or when conflicts of interest may arise. Research team members and organisational representatives should enable all service users and carers engaged in research teams to deliver their role. Therefore, service user and carer research team members should be included in all activities, opportunities and communications relevant to their role to prevent exclusion, which may result in an inability to discharge their duties.

Effective involvement

Service users and carers actively involved in research may have little knowledge of research funding applications, managing a research study, or of undertaking research. Whereas sponsors are required to ensure their researchers are competent by education, training or experience, enabling service users to become members of project management teams or co-researchers may require a different approach whereby training and support in the roles involved in research study management or methodology are provided during the project itself. Training and support need to be proportionate to risk and activity. Peer support could also be utilised to ameliorate risk in these circumstances.

Service user and carers should be clear who to go to if they have a problem or feel unable to discharge their responsibilities.

Sponsors role

All research in the NHS must have a sponsor to take ultimate accountability for that study.

Levels of training and oversight requirements are dependent on study type but a gap in training or oversight by the sponsor, might lead to service users and carers engaged in project team management or as co-researchers inadvertently being both 'a risk' and 'at risk' if they do not fully understand their duties. Examples of relevant training might include:

- Patient confidentiality
- Data protection and information governance
- Principles of Good Clinical Practice (if a Clinical Trial of Investigational Medicinal Product/CTIMP)
- Record keeping and data integrity
- Reporting of adverse events and incidents
- Understanding standard operating procedures
- Understanding roles and responsibilities
- Recruitment and/or Consent
- Equality and diversity.

Any training needs to be proportionate to the role of the service user and carer in the study. Training may also be needed for researchers in how to involve service users and carers effectively in research teams or as co-applicants. Sponsors should consider these areas in their risk assessments and monitoring plans as well those areas outlined in the 'developing best practice' section below.

Service users and carers as project leads

User led research and service user and carers as research leads are still relatively rare in NHS health and care. Research managers, sponsor representatives, and other research leads, may find that they have very little experience of contracting, working with, or advising service users and carers on the issues that arise when they become the chief investigator, a co-applicant, or a study collaborator on their team. Consideration should be given to enabling greater involvement of service users and carers as research leads and ensuring the governance framework reflects this involvement.

Developing best practice

Excellent communication is critical, and a written communication plan is a good idea. As with any project communication is key and sponsors, collaborating organisations, and service users and carers, should agree from the outset how to ensure this occurs. This includes how to ensure good communication between research team members². The following good practice is recommended to ensure the effective involvement of service users and carers in a research team:

- Ensuring contact details and methods of accepted communication are made clear and are available to service users and carers in research studies. The ability to report to the sponsor, if they do not feel able to discharge their roles and responsibilities, should be clear.
- Enabling service user and carers to meet with the other research team members at the start of the project.
- Ensuring early and ongoing advice, support and training for service users and carers in the fundamentals of research management and study leadership roles where required. These needs should be assessed before and during the study and reflected upon at the end. A clear role description with guidance could be agreed in support of the role
- Ensuring other training needs that would otherwise be provided to clinical research staff are identified for the service users and carers engaged in similar roles, and that they are enabled to access this training as necessary with similar support.

² A useful resource can be found at Centre for Research in Public Health and Community Care. 2018. Guidance for Researchers: Feedback.

- Ensuring service users and carers in research teams are involved in the agreed delegation of responsibilities. This might be between sponsor and chief investigator, between sponsor and co-applicants or collaborators (and the organisations responsible for them) and between chief investigators and study teams. These should be written and agreed in a way that is understood between all concerned, including the service user and carer, with a clear explanation of terms.
- Including involvement in sponsor monitoring plans to ensure that it is happening effectively. Monitoring the involvement of their service user and carer research team members and co-applicants should occur throughout the life of a study, to support involvement, and this should be explicit. Monitoring activity might include conversations or face to face meetings with service user and carer research team members to check they feel able to meet their responsibilities rather than just a question to the research teams to confirm that they have included them.
- Ensuring training for sponsor representatives and other researcher leads about enabling involvement and service users and carers in a co-applicant or research team role.

The following areas require further development UK-wide

Contracts and written agreements:

- Consideration should be given to the different sorts of agreement that exist for service user and carer project team members or co-researchers and the risks and benefits of each type should be assessed.
- Consideration should be given to whether agreements should be in the form of a personal honorary contract, alongside a separate matrix to make clear the specific roles and responsibilities, or whether should this be more of a collaboration agreement.

Liability:

- Consideration should be given to the liabilities and personal risks for an individual who takes on specific roles and responsibilities on a project, for a grant, with and without an agreement in place with the sponsor and/or grant holding body.
- Consideration should be given to the liabilities for a sponsor/grant holding body conducting a study without written agreement with individuals undertaking activities within the study.
- Sponsors need to be provided with clarity on legal and indemnity issues relating to service users and carers. The NIHR 'Research in the NHS HR Good

Practice Resource Pack'³ and NHS Resolution 'NHS Indemnity Arrangements for Clinical Negligence Claims in the NHS' provides some general guidance⁴.

Grant funding awards

- Grant funders should consider the role of service users and carers as potential grant holders and incorporate this into their award literature. This guidance should include whether they are willing to award funding to individuals who are not based within an institution.
- A template needs to be created for the form of an agreement between a host institution and a service user or carer member of a research team or co-applicant where the institution holds a grant award for or with a service user or carer lead but is not the sponsor.

Intellectual Property, publication rights,

- Clear guidance on service user and carer co-applicants, research team members, and co-researchers as co-owners of Intellectual Property and publication rights.

The NHS R&D Forum Resources Exchange has numerous useful templates and resources: <http://www.rdforum.nhs.uk/content/resource-exchange-home-page/>

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³ <https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm>

⁴ <https://resolution.nhs.uk/wp-content/uploads/2018/10/NHS-Indemnity.pdf>