NHS
Research and
Development Forum

Additional legal, ethical and governance considerations when engaging in Community Based Participatory Research (CBPR)

Introduction

Community Based Participatory Research (CBPR) is a "collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change." (Arbor et al 2003).

Partnering, or co-producing, with a community organisation or group[1] to develop, deliver and manage a research project brings different ethical, legal and governance considerations to those relevant to individual PPIE representatives. Firstly, ethical codes for research tend to focus on the rights of the individual. CBPR presents an additional challenge of extending rights to the community. The interests of the community may differ from the interests of the individual and consideration may have to be given to how informed consent can represent the group or community interests as well as those of individual participants. Individual service users may not have a sense of the collective whereas community partners will have more sense of the needs of the community they represent. However, it is important to recognise that communities are made up of individuals who may come together on a specific issue.

Ethical and governance considerations for CBPR should enable the assignment of the same status to communities as individual PPIE representatives by recognising the importance of community desires and interests. Ensuring the wellbeing of community participants is just as important as for individual PPI representatives as they may also still have conditions or illnesses. Although partnership and the principles of co-production imply shared responsibilities, this does not take away the sponsor and professional responsibility for ensuring the wellbeing of those who are partners.

These guidelines advise on the ethical, legal and governance issues that research managers may need to consider in studies involving CBPR.

Legal issues

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[1] In this context community organisation or group refers to health and care charities or Charitable Incorporated Organisations (CIOs), not for profit organisations, health and care research charities, those providing advocacy, supporting community projects, or empowering and developing communities.

The legal issues for CBPR can be slightly more complex than for individual PPIE representatives as a charity or independent organisation may be involved in working in partnership with a university or NHS organisation. Where community participants engage in managing a health or social care project or taking on responsibilities, they may have liabilities. There is a need to be clear about what is a community responsibility and what is an individual responsibility and whether either may lead to personal risks. This might involve shared liability if any adverse or unexpected harm results from a research study. Appropriate insurance and indemnity arrangements need to set out how, or if, community participants are covered should any events arise from the research study. Ideally a partnership agreement should be written at the start of a project to outline the following:

- Insurance and indemnity arrangements and how community participants are covered.
- Roles and responsibilities - what is the community responsibility and what is an individual responsibility within the project.

It is advisable for community organisations to check their constitution or articles of association before developing partnership agreements, as there may be restrictions on who can enter into agreements. There may also be responsibilities delegated to Directors and Trustees of organisations, which cannot be subsequently delegated to community members. In those instances, equitable engagement of community members may not be possible.

Responsibilities

As with any health research project, sponsors (funder/organisation where the research is taking place or employer) have ultimate accountability for ensuring the research team is competent, trained, and that contracts and agreements are in place. Host organisations, which may be community partners, should ensure agreements are in place, the study has been peer reviewed, researchers have received relevant training and have the appropriate indemnity and insurance. Sponsors and PIs should ensure that community participants know and understand their roles and responsibilities. Community participants should endeavour to be clear about their roles making sure they have agreements in place and requesting training where needed.

Achieving clarity about roles i.e. whether the community member is a volunteer, consultant, temporary employee, has an honorary contract, is particularly important in the context of participatory research as they will already have a relationship with their community group and the relationship to the research project may be different and involve payments or rewards.

Data and confidentiality

There is an absence of policy on privacy and confidentiality relating to community participation in research. Most policy, including the General Data Protection Regulation, relates to the rights of individuals but does not deal with the rights of communities. Whilst individual participants anonymity may be preserved, a community partner group is often more easily identifiable, and this can have implications if the research indicates that a community may be more pre-disposed to particular conditions or circumstances.

In developing a study protocol academic and community partners need to consider carefully issues of data ownership and access and develop agreements about the use of data and accessibility. The following questions may be useful to consider:

- Who owns the data and products?
- Who controls the data and access during and after the research?
- Where is the data stored and who has access during and after the research?
- Do subjects of research know who is likely to have access and why.
- What are the communities' interests? Is there other useful information that the community may be able to mine from the data?

Review processes

NHS and Research Ethics Committee review processes do not reflect the presence of community partners as participants with equivalence in the approval process. CBPR presents a further dynamic in the review of research proposals and whether the community organisation opinion holds equal weight to statutory organisations. For many community organisations research will be a small part of their business and they are unlikely to have formal processes for review of study applications. There are also issues for consideration in terms of representation, weight of opinion and potential conflicts of interest. If the Community organisation and partners views conflict on whether to approve a project a final decision making process will be required. The process for review and approval and weight given to each opinion should be set out in a partnership agreement.

Partnership agreements

Some principles

1. There are clearly defined rights and responsibilities that are jointly negotiated.
2. Agreements are an opportunity to develop trust and mutual respect and to set out expectations.
3. Agreements should define what is meant by representation and participation.

Partnership Agreements between community organisations, health and academic partners should cover the following:

- Project management
- Rights and responsibilities
- Ethical issues
- Partner's expectations
- Roles and relationships
- Community training and participation
- Data ownership & IP
- Data storage and access
- Decision making processes
- Practical matters
- Reward and recognition
- Feedback and review at the end of the project

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