

Part E

Managing research

A summary of Part E

Why is Part E important?

In the NHS, all research and development must be managed. During this stage of the research cycle a number of procedures take place:

- The research will be subject to external and internal peer review
- The research will be registered, reviewed and approved - by the host organisation (often within the research and development department)
- The research will be assessed by a research ethics committee for ethical review and approval

Throughout the research cycle the research managers and project board will also support and guide the project through all of its stages and provide advice where needed. In Part E participants will learn about the details of this stage and analyse real examples. They will also consider the practical issues of user involvement in managing research to help them decide if they would like to do this work.

What will participants learn by doing Part E?

At the end of this part participants will be able to:

- Understand what managing research means - Activity 1
- Understand what happens in the managing research stage- Activity 1 and 2
- Discuss the practical issues of user involvement in the managing research stage- Activity 3

Skills participants will strengthen or develop

Skills that participants will strengthen or develop include:

- Level 2: Further practice with thinking about issues
- Level 2: Further practice with developing and presenting an argument
- Level 2: Further practice with speaking in large groups
- Level 2: Further practice with planning what to do next
- Level 3: Demonstrate ability to think about issues
- Level 3: Demonstrate ability to think about case examples

Background information

The background information provides trainers with additional information that prepares them for issues that may be discussed during the training.

Managing research

The Research Governance Framework for Health and Social Care states that the dignity, rights, safety and well-being of participants in research must be the primary consideration in any research study¹. The National Health and Social Services have a duty to ensure this occurs. Therefore, before any research can start a number of procedures of review and assessment must take place:

- project board review
- host organisation approval
- research ethics committee approval

The research project is then continually monitored and supported by these groups throughout the project's journey until it's completion and dissemination. Historically users, carers and the public have not been involved in this stage. This is

beginning to change and users are increasingly becoming involved in the review and management of research projects.

A group who brings together staff researchers with users, carers and the public to do research work together say that:

“Everyone should be involved as early as possible in the research process, so that the direction of the research is clear, everyone knows what they are doing and there is commitment to the project. This is especially important for professionals so that they will be committed to making any necessary changes at the end of the project. It is possible to be involved in ALL stages of the research process, as a researcher or by guiding research on a project steering group.” (p.10)²

Their comments focus on the need for early user involvement and to **manage** the project in partnership throughout its life.

In this part of Unit 5 participants will be given an introduction to the structures and processes in place at this stage of the cycle, the practicalities of being involved at this stage, and ideas about where they can potentially become involved as user consultants.

The structures and processes in place for managing research

Project Boards/Review and Reference Group

Project Boards, or Review and Reference Groups (RRG)³ as they are sometimes called, are a group of professionals with experience and knowledge of the research project topic and/or methodology. It is possible that they could also include lay members. The purpose of this group is to:

- continually monitor, support and give guidance to the project
- develop and comment on the design and methods used through regular dissemination and feedback
- ensure the timings and budget are adhered to
- develop a strategy to ensure the results are disseminated and findings put into practice

The group are usually set up prior to the design of the study and meet regularly throughout the research process until its completion.

Host Organisation (Research and Development) Review

Each research active Trust or organisation should have a Research and Development (R&D) department that is

responsible for overall management of all research undertaken in their organisation. Their role is to ensure the scientific quality of a research project, ensure the organisation has the resources and suitable expertise to undertake the research, and most importantly, ensure its patients are adequately protected.

Each research active organisation should have a policy document to give guidance to investigators on the registering, review and approval of projects. All projects need to be registered with the organisation's R&D Department. Once registered the review process will begin. The review process will include:

- scientific (peer review) of the project
- identification of costs involved in undertaking the study
- identification of the project funding
- ensuring that the project has been reviewed and approved by a research ethics committee

Peer review

An experienced researcher or someone who has experience of the research topic usually carries out peer review. Academic professionals have previously led this process; however, increasingly users are becoming involved (an example of this is

the Alzheimer's Society - see Case Example 1). The peer review focuses on the scientific aspects of the protocol⁴. In particular they assess the project for:

- skill and experience of the project team
- adequate timing and resources
- sufficient supporting evidence for the project
- if the aims and objectives are clear and appropriate
- appropriate research questions to fulfil the aims of the project
- appropriate numbers needed to fulfil the aims of the project
- appropriate method (e.g. questionnaire, interview) to fulfil the aims of the project

Once the proposal has been fully reviewed and they are satisfied that the project can be undertaken by the organisation, the R&D department will approve the project to go ahead.

Research Ethics Committee

A NHS Research Ethics Committee provides **independent** advice to participants, researchers, funders, sponsors, employers, care organisations and professionals on the extent to which research

proposals meet ethical standards.⁵ Their primary purpose in reviewing a research proposal is to protect the dignity, rights, safety and well-being of participants and the concerned communities.

Each committee consists of a number of professional and lay members - at least one third are lay members. The maximum number of members is 18 and should allow for a sufficiently broad range of ages, cultural diversity, experience and expertise (scientific, clinical, and methodological).

The ethics committee review focuses on the ethical aspects of the protocol (safety to participants, informed consent, process and feasibility). In particular they assess the project for:

- **Scientific design and conduct** - appropriate design in relation to the objectives and potential for reaching sound conclusions; justification and awareness of possible risks weighted against the anticipated benefits of the project; and adequacy of the research site and service provision
- **Recruitment of participants**- appropriate population included and clear decisions about who is included or excluded
- **Protection of participants** - the safety of any treatment, the suitability of the investigator, the informed consent process,

the physical, emotional and personal support mechanisms, and confidentiality procedures

- **Community considerations** - the impact and relevance on the concerned community, the steps taken to consult the community during the course of the design and the dissemination strategy

Any changes to the protocol during the conduct of the study will have to be reviewed and approved by the host organisation and the research ethics committee.

Opportunities for user involvement in managing research

There are potentially many areas where users, carers and the public can become involved with managing research, such as being a:

- member of a project board/RRG
- peer reviewer for new projects
- member of an ethics committee

In some cases, user involvement is new to these areas and systems to support users have not been put into place as yet in many Trusts.

Issues with user involvement in managing research

At present very little research has been done and written up about user involvement in managing research. One example of a review of user involvement in joint research, where user consultants were on the project board, found that their involvement:⁶

- changed the focus, design and content of a study
- raised new research questions
- ensured interventions and outcomes were kept 'user-friendly'
- encouraged the dissemination of the findings

The study also noted that user involvement:

- increased the time taken to carry out and write up the study
- increased financial costs for the user consultant's payments and dissemination

This highlights that user involvement can be very beneficial to a study, but time and financial implications must be considered when applying for funding.

Other examples of where users have become involved within the managing of research will be discussed within the case examples in this part. However, it is important to recognise that further research into user involvement and managing research is needed.

References

1. Department of Health (2003). Research Governance Framework. Available online at:
<http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance>
2. Thorne, L. Purtell, R. & Baxter, L. (2001). *Knowing how - A guide to getting involved in research*. Folk.us, Exeter University. Available online at:
http://www.invo.org.uk/pdf/knowning_how.pdf
3. Herron-Marx, S., Stacey, K., Dunn, L., Miles, B. & Williams, A. (2004). *Involving Users, Carers and the Public as Equal Partners: A Learning and Development Resource for Health and Social Care Staff - Project Report*. UK: Birmingham and Black Country Strategic Health Authority.

4. Birmingham Heartlands and Solihull NHS Trust (undated). *Example Peer Review Form*. UK: Research and Development Department, Birmingham Heartlands and Solihull NHS Trust.
5. Department of Health (2001). *Governance Arrangements for NHS Research Ethics Committees*. Found at: <http://www.dh.gov.uk/assetRoot/04/05/86/09/04058609.pdf>
6. Premila, T. & Wykes, T. (2002) From passive subjects to equal partners: Qualitative review of user involvement in research. *British Journal of Psychiatry*, 181, 468-472.

Activity 1

What does managing research mean?

There are several activity options. Each one has a suggested time allocation. This is a rough guide and can be extended according to the programme you have set up. Combine different activity options depending upon your chosen programme and your participants' needs. Suggested combinations are:

- Large group discussion + mini-presentation
- Small group discussion + mini-presentation

Things to get ready

- Print the Unit 5 - Part E PowerPoint files 1A - 1J in 'note pages' for you and, where appropriate, 'handouts' (two slides/page) of the presentation material for participants
- Whiteboard and coloured whiteboard markers
- Flipchart paper and coloured markers

Activity Option 1

Large group discussion - Existing knowledge in managing research (10-15 minutes)

The purpose of the large group discussion is to practice skills in thinking about issues and speaking to large groups:

- Ask participants what they think managing research is
- Ask if any participants have ever been involved in managing research and development projects
- If no, move on to the mini-presentation
- If yes, ask these people to share their experience with the group if they are willing. Here are some prompt questions to help facilitate the story:
 - * How were you invited to be involved?
 - * What did you get to do?
 - * What did they do with your ideas?
 - * What feedback did you get about whether the project was funded/approved?
- Encourage other participants to ask questions about the process and discuss the issues being raised.
- If needed tell participants that managing research is when users, carers and the public are involved in the process of reviewing the project within the organisation, supporting

ethics approval and keeping a watch on the research process to make sure it goes smoothly

Activity Option 2

Small group discussion - Existing knowledge in managing research (15 - 20 minutes)

The purpose of the small group discussion is to practice skills in thinking about issues and speaking to large groups:

- Divide people into groups of 3-4 - give them a few minutes to think about and discuss this question
 - * What do you think happens if you are involved in managing research and development projects?
 - * What opportunities would you want to get to do this?
 - * What support would you like to get?
- Ask them to write key points about their answers for each question on flipchart paper and identify a person to present this to the wider group.
- Listen to the feedback from all groups - facilitate further discussion as needed.
- If needed tell participants that managing research is when users, carers and the public are involved in the process of reviewing the project within the organisation, supporting

ethics approval and keeping a watch on the research process to make sure it goes smoothly

Activity 3

OVERHEADS 1A - 1K

Mini-presentation - What does managing research mean? What happens in this stage? (15 minutes)

The purpose of the mini-presentation is to gain knowledge in this area. Cover these areas using the PowerPoint slides:

- What does managing research mean?
- Who is involved in managing research?
- Why is this stage of the research and development cycle important?
- During or after the mini-presentation facilitate further discussion as needed

Activity 2

Examples of user involvement in managing research

There are several activity options. Each one has a suggested time allocation. This is a rough guide and can be extended according to the programme you have set up. Combine different activity options depending upon your chosen programme and your participants' needs. Suggested combinations are:

- Mini-presentation and case example analysis + managing practice large group discussion
- Guest presentation and large group discussion + managing practice small group discussion

Things to get ready

- Print the Unit 5 - Part E PowerPoint files 2A - 2J in 'note pages' for you and, where appropriate, 'handouts' (two slides/page) of the presentation material for participants
- Flipchart paper and coloured markers
- If you choose Activity Option 1 then make sufficient copies of Unit 5: Part E - Appendix 1 for all participants - also create 'posters' on A4 paper by writing in clear large writing the following ratings: Poor, OK, Good, Excellent

- If you choose Activity Option 2 you will need to identify an appropriate presenter who can discuss current examples of managing research - meet with them to ensure they understand the task and prepare anything that they need.
- If you choose Activity Option 3 or 4 speak to the Research and Development Unit of your local NHS Trust or PCT - ask them for an example of a 3-page research proposal written as a 'lay summary' and peer review form (for confidentiality reasons, they will provide a project that has already been commissioned and can be publicly known)
- If you choose Activity Option 3 then you will need strips of scrap paper for people to use in the secret ballot

Activity Option 1

OVERHEADS 2A - 2J

Mini-presentation and case example analysis - Analysing case examples of managing research (40 minutes)

The purpose of the mini-presentation and case example analysis is to build on knowledge in this area and demonstrate the ability to think about case examples.

- Using the PowerPoint slides provide a description of the case example
- Once you have presented the case example, give out Unit 5: Part E - Appendix 1 which has a written version of the PowerPoint slides and the steps needed to do the case example analysis
- Ask participants to divide into four groups
- Each group will follow the steps for analysing the case example listed at the end of Unit 5: Part E - Appendix 1
- They need one person to record the answers of the group for each question and another to be a representative to share their decisions with the large group
- Allow time for the small groups to do this analysis and be available to answer questions as needed

- When all groups have got through the questions ask the representatives of each group to come to the front
- Go through each of the questions listed at the end of Unit 5: Part E - Appendix 1 - ask the representatives to stand next to the poster that matches their group's answer
- For each question check the spread in answers between the groups and then invite people from the groups to explain why they chose that answer. For example, if two chose 'OK' and two chose 'Good' - then ask the groups who chose OK to give their reasons, and then the groups who chose 'Good' to explain why they gave a higher rating
- Continue until all questions have been discussed

Activity Option 2

OVERHEADS provided by guest presenter

Guest presentation and large group discussion - Analysing case examples of managing research (40 minutes)

The purpose of the guest presentation and large group discussion is to build on knowledge in this area and demonstrate the ability to think about case examples. The presenter will cover these areas:

- Case examples of managing research

- Roles of user consultants, support provided and level of involvement in decision making for user consultants
- What has been learned from doing this work - outcomes achieved, strategies for success and benefits gained
- What is happening to improve or expand this work - problems that occurred and how they were or could be addressed
- During and after the guest presentation encourage questions from participants to facilitate a discussion about the examples and issues raised

Activity Option 3

Managing research practice large group discussion - (20-30 minutes)

The purpose of the managing research practice large group discussion is to practice thinking about issues, and developing and presenting an argument:

- Give out copies of the research proposal 'lay summary' and peer review form to all participants
- Read through the proposal with the group
- Using the steps outlined in the peer review form review the proposal together - provide support as needed to the group

- Point out that if you were doing this in reality, then you would spend more time reviewing a proposal than you will today
- When you reach the final step hand out the strips of paper to all members of the audience and ask them to do a silent ballot
- They must write the score and description on the strip of paper to indicate whether or not they support the proposal
- Add up the ballot outcomes and announce the results
- Facilitate further discussion as needed

Activity Option 4

Managing research practice small group discussion - (20-30 minutes)

The purpose of the managing research practice small group discussion is to practice skills in thinking about issues, and developing and presenting an argument:

- Give out copies of the research proposal 'lay summary' and peer review form to all participants
- Ask the group to divided into 3 smaller groups and read out the proposal in that group
- Using the steps outlined in the peer review form they will review the proposal - provide support as needed to groups

- When they get to the last point see if they can reach a consensus as a group as to how they will score the proposal - they need to note down their reasons for this score
- Ask people to return to the large group and listen to each group's score and reasons
- Facilitate further discussion as needed, particularly on why there were differences or similarities between the groups' decisions

Activity 3

What could user involvement in managing research mean for you?

There are several activity options. Each one has a suggested time allocation. This is a rough guide and can be extended according to the programme you have set up. Combine different activity options depending upon your chosen programme and your participants' needs. Suggested combinations are:

- Mini-presentation + small group discussion
- Mini-presentation + values walk

Things to get ready

- Print the Unit 5 - Part E PowerPoint files 3A - 3B in 'note pages' for you and, where appropriate, 'handouts' (two slides/page) of the presentation material for participants
- Whiteboard and coloured whiteboard markers
- Flipchart paper and markers

Activity Option 1

OVERHEADS 3A - 3B

Mini-presentation - Review practical issues in user involvement work (5-10 minutes)

The purpose of the mini-presentation is to build on knowledge and support skills in thinking about issues. Cover these areas using the PowerPoint slides:

- Review the practical issues that are important to think and ask about before taking on user involvement work

TOP TIP

If this group has done Core 2 - Unit 2: Part C then they have covered this material. Remind them that they have already discussed these issues. If the group has not done this part of the training, it may be useful to go back and do Activity 1 & 2 with them first.

Activity Option 2

Large group discussion - Plans for dealing with practical issues (30 minutes)

The purpose of the large group discussion is to demonstrate skills in thinking about issues and practice planning what to do next:

- As a large group go through the 15 points in the mini-presentation **one at a time** using the following steps

- On the whiteboard draw a picture of a hot air balloon with a basket at the bottom
- Ask participants to name any practical issues that would concern people if they were involved in managing research - write them in the basket - these are the things that weigh the balloon down and stop it from flying
- Then ask participants to suggest ways of dealing with these issues - write them in the hot air balloon - these are the things that make the balloon rise and lead to a good experience of user involvement in managing research
- Assist participants with suggestions as needed for either concerns or ways of dealing with issues
- Make sure that there is a positive response to all of the concerns raised
- If you run out of room draw another hot air balloon on a piece of flipchart paper and continue

Activity Option 3

Small group discussion - Plans for dealing with practical issues (30 minutes)

The purpose of the small group discussion is to demonstrate skills in thinking about issues and planning what to do next:

- Ask participants to divide into 4 groups - each group will have 3-4 of the 15 points in the mini-presentation to discuss using the following steps
- On the whiteboard draw a picture of a hot air balloon with a basket at the bottom - ask each group to copy this drawing on a piece of flipchart paper
- For the points their group are given, they must name any practical issues that would concern people if they were involved in managing research - write them in the basket - these are the things that weigh the balloon down and stop it from flying
- Then for each of these same points they must suggest ways of dealing with these issues - write them in the hot air balloon - these are the things that make the balloon rise and lead to a good experience of user involvement in managing research

- Tell them to just deal with one point at a time - do the concerns and then the suggestions
- Circulate among the groups and assist participants with suggestions as needed for either concerns or ways of dealing with issues
- After 20 minutes bring the group back together and ask them to share their ideas - facilitate a discussion
- Make sure that there is a positive response to all of the concerns raised

Activity Option 4

Values walk - Plans for dealing with practical issues (30 minutes)

The purpose of the values walk is to demonstrate skills in analysing issues and practice planning what to do next:

- As a large group go through the 15 points in the mini-presentation **one at a time** doing a values walk for each one based on a 'situation statement' that you create and read out.
- For example, for 'debriefing opportunities or support' the statement could be: "You are on the Ethics Committee at your NHS trust and keep on having a problem with one of the staff who treat any concern you raise as minor. No-one in the

group supports or speaks up for you. You talk to the R&D Manager and they make a time to discuss it with you in detail and work out how to deal with it. She also offers to meet with you and the other person to support you."

- Ask participants to decide how concerned they would be about this situation, where 1 = not at all concerned and 10 = extremely concerned - make the line for this go from one side of the room to the other
- After participants stand on the line check what range of numbers there are - ask people from different areas of the line to explain why they are there and what should happen to deal with the concern
- Assist participants with suggestions as needed or ask other participants to offer ideas for ways of dealing with issues
- Make sure that there is a positive response to any concern raised
- Repeat this process for the other 14 points using a situation statement that you have created that is relevant to your group
- Facilitate further discussion as needed

Personal exercises

Here are two exercises to help participants think about the ideas in Part E.

Learning from examples

They will think about the example of user involvement for managing research in Activity 2 and answer these questions:

- What did they learn from the discussion that will help them in their future user involvement work?
- Is there anything else they want to learn about this stage? If yes, they will identify who can help them with this. This may be a Link Person in their organisation.

Practical issues in managing research

They will review the practical issues in managing research discussed in Activity 3 and answer these questions:

- Identify which issues are of most concern to them: Do they have enough ideas about how to deal with these concerns? If no, they will identify who can discuss these issues with them further and help them plan what to do next.

Case examples

1. The Alzheimer's Society

<http://www.alzheimers.org.uk>

Tel: 0191 223 2830

Alzheimer's Society

Gordon House, 10 Greencoat Place

London, SW1P 1PH

Ph: 020 7306 0606

The Alzheimer's Society is a user and carer non-government support organisation. It has created a consumer network to lead its research program called the Quality Research in Dementia Network - here is the direct link:

http://www.qrd.alzheimers.org.uk/qrd_advisory_network.htm

The Quality Research in Dementia Network identifies a range of possible research topics and then participates in processes that select the priorities. The Society uses this as the basis for commissioning research. In addition, The Society aims to involve its members in every other aspect of its research program, including commissioning, grant application reviewing, grant awards, project management, implementation and dissemination.

It has won national awards for its commitment to user involvement.

2. Review and Reference Group - Involving Users, Carers and the Public as Equal Partners: A Learning and Development Resource

Dr Sandy Herron-Marx (Project Manager)

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52 Pritchatts Road

Birmingham, B15 2TT

Tel: 0121 414 3571

Email: s.herronmarx@bham.ac.uk

'Involving Users, Carers and the Public as Equal Partners: A Learning and Development Resource' was a pilot project to develop a training mechanism for health and social service staff in engaging service users and carers. The review and reference group consisted of a group of health and social service professionals and service users and carers from the pilot organisations (Birmingham Heartlands and Solihull NHS Trust and South Worcestershire PCT and Social Services). Their role was to continually monitor, support and give guidance to the project. They reviewed and commented on the development of

the training resource and ensured that it was fit for the purpose and that user perspective was embedded in it. They were also involved in overseeing the evaluation of the resource during its first trial, and made recommendations for change based on the outcomes of the evaluation.

3. Consumers for ethics in research (CERES)

PO Box 1365

London N16 0BW

E-mail: info@ceres.org.uk

<http://www.ceres.org.uk/>

CERES is an independent charity set up 1989 to promote informed debate about research. It helps users of health services to develop and publicise their views on health research and on new treatments. CERES believes that everyone asked to take part in research should be able to make an informed, free choice as to whether or not they agree to take part. CERES works to help the voices of patients and research subjects to be heard more clearly to improve how research occurs.

Useful information for participants

Useful websites

Central Office for Research Ethics Committees (COREC)

www.corec.co.uk

This useful website is the department of Health's website for Local and Multi-centre Ethic committees. All protocols and national guidelines are stored on this website and are easy to download.

Ease of reading: Average

INVOLVE (formerly Consumers in NHS Research)

<http://www.invo.org.uk>

INVOLVE believes that members of the public should be involved at all stages of the R&D process. This means users, carers and the public are active participants, not just 'subjects' of research. INVOLVE supports and advocates for this to happen through working with the NHS, and providing training materials and guidebooks for health and social services staff, and users, carers and the public. They also monitor and assess the effects of public involvement in NHS, public health and social care research.

Ease of reading: Average

Folk.us

<http://latis.ex.ac.uk/folk.us/findex.htm>

This is the website of a user/carer and health and social service staff collaborative project. It aims to promote a research culture that is meaningfully controlled and influenced by service users, disabled people and informal carers, so that research and implementation reflects the concerns of ordinary folk.

Ease of reading: Good

Health Technology Assessment (HTA) Programme

<http://www.nchta.org/> - Main home page

<http://www.nchta.org/consumers/index.htm> - Consumer home page

The HTA programme is a national research programme funded by the Department of Health. Its job is to ensure that high quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most effective way for those who use, manage and provide care in the NHS. There is a consumer home page for users, carers and the public to learn about how user involvement occurs in the HTA programme. The HTA identifies and prioritises

research topics, then commissions research, monitors its progress and evaluates it when finished.

Ease of reading: Average

Useful reading

Royle, J., Steele, R., Hanley, B. & Bradburn, J. (2001). *Getting involved in research: A guide for consumers*. Winchester:

Consumers in NHS Research Support Unit. Available online at:

<http://www.invo.org.uk/pub.htm>

This is an excellent document with valuable information for users, carers and members of the public who want to become more involved in research. It describes the different stages in the research process and how people can be involved. On the website there is also a document for health and social service staff called 'Involving the public in NHS, public health and social care: Briefing notes for researchers.'

Ease of reading: Good

Sources used for the material in this part

Birmingham Heartlands and Solihull NHS Trust (undated).

Example Peer Review Form. UK: Research and Development Department, Birmingham Heartlands and Solihull NHS Trust.

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Premila, T. Wykes, T. (2002) From passive subjects to equal partners: Qualitative review of user involvement in research. *British Journal of Psychiatry*, 181, 468-472.