Working in partnership with people outside of the university system –Guidance for UCL researchers and staff considering ethics and research ethics.

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Where has this guidance come from?

In many fields, researchers are increasingly, and rightfully, expected to work with people outside of the university system.

Public engagement, Patient and Public Involvement and Engagement, and co-production of research are a continuum which aims to collaborate with patients and members of the public who are often "outside" of the formal research system. The work is done with, or led by, the people whose lives will be affected by the topic of the research. Further definitions of these ways of working are included below.

But what does this mean for research ethics? There can be a lack of confidence among researchers about the ethical and safeguarding dimensions of this work – as well as a perceived tension between protecting people from harm and their rights to open participation. We wanted to create some guidance to improve knowledge and confidence about the ethical and safeguarding dimensions of collaborating with those "outside" the formal research system. Creating this guidance on the subject was a joint project between UCL Engagement and the Co-Production Collective. The project team was made up of public contributors, UCL researchers and UCL staff members involved in public engagement and co-production.

In the end, we have very few absolutes. However, we hope that this work gathers scattered guidance together in one useful place. The UCL Research Ethics service (weblink) has provided comments on the guideline elements, and we have also had feedback from Co-Production Collective (weblink), and UCLPartners (weblink). If you have doubts about any elements, including whether you need to apply for ethics approval, please speak to the relevant team about your work (contact details can be found at the end of this document).

As this work has developed, we have also broadened our horizons beyond UCL, and hope to spur more conversations on this topic that will be useful for everyone who is considering how to engage with public groups

ethically, and when to apply for formal research ethics. Therefore, we hope this guidance will be helpful to those outside of UCL as well, and we have a full project write-up that is less UCL focused which is available as a weblink in PDF and Word document.

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Defining key terms - PE, PPI, Co-production and more

Here, we've set out the most common definitions of the three areas we have most experience in. We feel differing interpretations of these has caused uncertainty regarding research ethics, for example, the widespread conflation of involvement and participation in research. We also include a non-exhaustive list of other ways of working and research methods that involve working with those outside of the university system – it is important to be ethical in this work too. ,

Public engagement (PE)

- Refers to the many ways research can be shared with the public. Engagement is a two-way process, involving interaction and listening, with the goal of generating mutual benefit. For more information see the National Coordinating Centre for Public Engagement (weblink.)
    - In health research especially, this may also be used to describe dissemination and sharing activities like public events.
- Three principles underpin the UCL approach to PE:
    - Equip UCL to listen and respond to community need, locally and globally.
    - Open conversations that inform UCL research and teaching
    - Encourage a spirit of experimentation, learning and sharing.
- While there are ethical considerations to be made, public engagement is not considered a research method and therefore rarely requires a research ethics application.

Patient and public involvement (PPI)

- Involves collaborating with patients and members of the public to plan, manage, and carry out research. Patient and public

involvement in research is often defined as doing research 'with' or 'by' people who use services rather than 'to', 'about' or 'for' them. Definition from National Institute of Health Research Glossary. (weblink.)

- PPI is distinct from participation, which involves recruiting patients to take part in clinical trials or to be participants in a research project. You can find out more at the National Institute of Heath Research (weblink.)
- Some forms of PPI may not require a research ethics application, as they don't constitute research, e.g., working with a group of public contributors to identify a research question, or consulting with a PPI group to design a research project.
    - While these examples may not constitute research, there are still important ethical considerations to be made together as a team which involves public contributors. (e.g., how will all group members, including the person who initiated the research, be protected from physical/psychological harm?)
- But lines can be blurred – sometimes PPI turns into research (with PPI contributors becoming research participants, as well as consultants/advisors). Details of some of these blurred lines are shared in this paper: Lost in Co-production (weblink.)

Co-production

- Co-production refers to a type of research that involves community members as equal co-researchers.
- Research is produced together and there is co-ownership of the knowledge generated.
- Power is a key consideration – successful co-production means all researchers work together without considering one type of knowledge as more important than another.
- This approach differs from PPI in that power is more evenly distributed. For more information visit the Co-Production Collective (weblink.)
- Co-production often forms a part of research ethics applications, when discussed as a research method that will be used.

- Note: the term co-production is also used to describe the process of working with community members to create other outputs (not just research) – for example, an engagement project might talk about co-producing a resource or display, and in these cases co-produced research is not taking place.

Other ways of working

These are included for completion with links to further detail.

- Citizen Science (weblink.)
- Participatory Research, including Community-Engaged Research, Team Science, Health Impact Assessment, Participatory Action research and more - for more information and a list of Frameworks, Orientations, and Approaches see Participatory Research Methods – Choice Points in the Research Process (weblink.)
- Knowledge Exchange - a process that connects you with communities beyond the university to exchange ideas, evidence and expertise. (UCL Knowledge Exchange weblink.)

Who is this Guidance For?

This document is primarily for internal UCL researchers and staff, with the purpose of:

- Supporting you to consider ethics before and throughout the process of engaging with people outside of the University.
- Helping you to work with public groups in a way that is ethical, appropriate and mutually beneficial.

Providing guidance and clarity on when it is appropriate to seek ethics approval for your work with public contributors. We have done our best to be as clear as we can, but the situation is complex across UCL. Bear in mind that many UCL Departments and Institutes have their own Local Research Ethics Committees (LRECs) (weblink) and while they have devolved authority from the UCL Research Ethics Strategy Board and should therefore be very closely aligned with broader UCL processes, they may be slightly different from the central UCL Research Ethics Committee (UCL REC.) This guidance is not intended to replace consulting with your own internal review procedures and guidance.

An Introduction to Ethics

Ethics are a set of moral principles that are concerned with what is considered acceptable and/or unacceptable and guide people's behaviour. Common ethical considerations cover key dilemmas such as good vs bad, right vs wrong, and rights and responsibilities. They provide a framework that should embodied and evidenced in decision-making and actions.

What are research ethics?

Research ethics are a group of ethical considerations/principles concerned with conducting good, fair and safe research. Research ethics traditionally includes principles such as: the assessment of potential benefits and harms of the research; the rights of the participants to information, privacy and anonymity; and the responsibility of the researchers and academic institution to act with integrity. These principles are laid out in The Declaration of Helsinki (weblink), which has been codified in UK legislation and regulations. While it focuses on medical research involving human participants, it is a hugely influential declaration that drives much thinking worldwide on research ethics generally and is one of UCL's commonly agreed upon standards of good practice.

What is research ethics review for?

Research ethics review is designed to ensure research is conducted according to high standards of practice. Research ethics review processes at UCL are designed to support researchers to identify potential risks and consider effective mitigation/ management strategies, rather than reduce or remove risk all together. The service at UCL is a specialist team that can offer support and guidance on the appropriate ethical review route and guide applications through the approval process to ensure high quality ethical research.

We're keen for this guidance to spark considerations of potential risks to your own and your partners' safety and wellbeing, including those taking part as participants, consultants and/or researchers – within UCL and outside of UCL – as well as the more common principles listed above.

To gain ethical approval, you should demonstrate that appropriate steps are taken to inform participants of the nature and scope of a project, that they are aware of who the key contacts are if they have any issues and ensure that participants are aware of any risks. Accepted Ethical Standards across the UK include informed consent, benefit not harm, and confidentiality. Read more at UCL Ethical Approval (weblink.)

Both formal ethical review and considering the practical application of ethics within research play an essential part in helping to ensure both the integrity of research and that you are working appropriately with partners. You might also be interested in UCL's code of conduct for research (weblink.)

What is research ethics review not for?

As a rule of thumb, while you should always be thinking ethically, you should only apply for formal ethics review for the parts of a project that are, themselves, research – and not public engagement or patient and public involvement. For example, you may want to speak with a patient involvement group about your research plans and developing materials before you begin a research project– this work does not usually require ethical approval.

Existing research ethics processes and policies focus on the relationship between researcher and participant and are not concerned with the consideration of ethical issues in public engagement and Patient and Public Involvement and Engagement. (Although the same broader ethical considerations apply.)

A lack of formal processes for ethical considerations in these circumstances mean some researchers do not know where to go to ask questions on these issues, especially when involving young people or groups perceived as "vulnerable." While researchers have sometimes used

the research ethics process for these considerations, and this option is open to them, it is not currently designed for them. [1]

As best practice, research ethics review should and will encourage researchers to think ethically about their research. It provides a structured process to make important ethical considerations and get input from peers about key points that may have been missed. But research ethics review is not a tick-box that proves everything is all right. Ethical approval should be the start of the journey, and researchers should continue to consider the evolving ethical implications of their work throughout the whole research process.

[1] Some committees, keen to mitigate against potential harm, have asked that all work with those outside the university also go through research ethics review – for example, the Institute of Education, UCL's Faculty of Education and Society. But this is uncommon.

Which activities require research ethics review?

As a rule of thumb, if your activity is not research on human participants, formal ethics review should not be necessary. This is the line taken by the Health Research Authority decision making tool (weblink), which you may find helpful to use if your project is health-related.

More broadly, you may wish to consider the following questions:

- Why are you engaging with community members? E.g., Is it to help design, conduct, interpret, disseminate your research, or is it to answer a research question?
- What role are community members playing in your work? E.g., Are they consultants, advisors, co-researchers, or participants? Will they potentially play different or multiple roles at various stages of your project?
- Will community members' input be used as outcome data? E.g., Will their contributions only be used internally to inform the research design, or will they potentially be published as research findings? Will you be publishing about the way you worked together – some journals may demand research ethics before they will share details like this.
- How are community members helping to answer the research question? E.g., Are they providing advice on how to conduct your research, helping to interpret the data, or taking part in the research itself?

We discuss these ideas as they apply to public engagement, Public and Patient Involvement and Engagement and co-production above. We have also included two case studies that show researchers considering these questions in real-world projects.

A note on low-risk ethics or proportionate review. This can be a good option for non-complex projects but bear in mind that UCL perception on what makes something low or high risk may vary from your or your partners experiences.

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What issues can arise from applying for research ethics review?

We consider this question more fully in the Ethics project report which is available as a is available as a weblink in PDF and Word document.

One issue is that of **time and expertise**. UCL research ethics applications are considered by the Research Ethics Committee (REC): a multi-disciplinary team working in different fields and disciplines and including lay members. They may not be experienced in your specific area of interest, which makes it important to provide context and to seek external input too. A significant amount of time and resource goes into reviewing UCL REC applications. As such, it is important to only apply to research ethics when they are needed - the Research Ethics Service, or your local research ethics committee, can advise you if you are unsure and will also screen applications.

Another is **exclusion**. Ethics applications often exclude public contributors, and the formal process can introduce complications in power dynamics and in requiring actions that can reinforce inequalities between partners. For example, long wait times that can imply lack of prioritisation, public contributors being asked to provide their qualifications or experience in a way their academic partners are not, or being classified as vulnerable or fragile when similar considerations are not given to the academic partners, can all reinforce unequal power distributions between public and academic partners. Meaningful involvement of public contributors at all stages of the research process (including ethical review) and clear communication about what to expect from the process can avoid some of these pitfalls.

A third is **thinking the process is enough on its own**. We're keen to spark conversations between researchers and public contributors about ethical considerations at all stages of their project, with or without a formal ethics review. That's why it's important to think beyond just "ticking the box" of your research ethics application – and why you still need to consider ethics even if your project is not research and doesn't require the committee's

formal approval. We link to some key ethical considerations in the “What next” section on page 17.

What issues can arise from not applying for research ethics review?

We consider this question more fully in the project report which is available as a weblink in PDF and Word document.

The first issue is **complacency**. Remember that projects that do not require research ethics review still require you to think and act ethically. UCL's general code of ethical principles (weblink) for students and staff applies to all your public engagement and patient and public involvement activities. Working ethically should something considered throughout the project, in collaboration with your partners.

A second is **sharing your work**. Some journals will not publish work that does not have research ethics approval, even if it is not being presented as research. You should confirm your target journal's stance on this. Note that if you plan to share, publish or collect anything about your work, you should always be open with your partners about when and how their data, stories and experiences will be shared. If you are co-producing any work, such as artwork or co-produced research, you should also agree who will have ownership of it. With or without research ethics involvement, you still have responsibilities to meet regulations such as the General Data Protection Legislation. UCL has some guidance on understanding data protection (weblink) and on consent for sharing images of people.(Weblink) Be aware too that it is usually not possible to apply for research ethics retrospectively if you want to publish a project as research at a later date.

Finally, you should **be careful when working at the boundaries of qualitative research and Public and Patient Engagement and Involvement and Engagement**. Badging a project as Public and Patient Involvement and Engagement (for example, a qualitative study) is not a way to do the same work you planned to do without having to go through the research ethics process.

What next if research ethics review isn't needed for your project?

There is still a need to engage with ethics thoughtfully and meaningfully, together with your partners. Some resources on ethical and effective working with those outside of the research system include:

- Community Based Participatory Research: A guide to ethical principles and practice - Durham University Centre for Social Justice and Community Action (weblink to pdf)
- Facilitation tools for meetings and workshops (weblink) and Guide to group Agreements (weblink) – Seeds for Change
- Co-production Resource Library – Co-Production Collective (weblink.)

Planning your engagement, involvement or co-production properly can help avoid ethical pitfalls – consider using a planning tool such as this Patient Engagement Quality guidance tool (weblink) or one of the Practical Guides to Patient Involvement (weblink) gathered by UCLH Biomedical Research Centre. Consider support and training for yourself and for your partners.

You can also use standards such as the Health Research Authority Four Principles for Public Involvement (weblink) or the UK Standards for Patient Involvement (weblink) as a more general guide.

Contact details

UCL Research Ethics team: ethics@ucl.ac.uk

Co-Production Collective: coproduction@ucl.ac.uk

UCL Engagement: publicengagement@ucl.ac.uk

UCL PPI team: ppihelpdesk@ucl.ac.uk

Do let us know if you have any comments on these resources at coproduction@ucl.ac.uk

Case Studies

These are included to show the complexities of the issues covered. Please use them as a prompt for your thinking on these topics, and do contact your local REC or Research Ethics service if in doubt about whether to apply for formal ethical approval.

Case study 1: An occasion where there was no need to apply for ethics approval because public engagement/public and patient involvement does not cross over into research.

What is the background and aims of the project?

The research team plans to conduct a mixed methods project comprising three workstreams:

1. Working with an advisory patient and public involvement (PPI) advisory group of UK children and young people to explore a sensitive issue and co-develop workstreams 2 and 3.
2. Secondary analysis of data to examine the impact of the issue on child outcomes.
3. Conducting qualitative research with relevant stakeholders.

Workstream 1 will involve PPI workshops with a group of children and young people with three objectives:

1. Initial exploration: A few workshops will involve exploration of potentially sensitive topics with children and young people.
2. Co-development of workstreams 2 and 3: A few workshops will seek input on selection of outcome measures for secondary analysis and the topic guide for interviews.
3. Interpretation of findings from workstreams 2 and 3: A few workshops will involve discussion of emerging findings as regards their meaning, and potential implications for policy and practice.

Written reports will be produced for each of the objectives.

What happened/is going to happen?

- The researchers sought advice from the UCL Research Ethics Service on whether ethics review was needed for Workstream 1, i.e., the PPI component of their project. The UCL Research Ethics Service[2] advised that they did not need to apply for ethics approval of their PPI work because:
    - They are only planning to use community members' input to inform the research design, methods, and the interpretation of their results – not as the results itself.
    - The materials created during the workshops and written reports will be used internally to guide the research but not as published research outputs.
- If their plans change and they intend to use community members' inputs as outcome data (i.e., if they intend to publish information collected through PPI activities as research *findings*, and not just describe PPI as part of their *methodology*), they will seek ethics approval.

What was learnt/can we learn from this situation?

- Understanding the boundaries between public engagement, patient and public involvement, and research and identifying the stages at which a project may cross boundaries is key. Thinking about these issues earlier on when planning a project is better than later only when hitting those boundaries.
- Even if PPI work may not require ethical approval, UCL expects all staff to abide by appropriate ethical principles. In this case, the researchers understand that they need to uphold both children's right to participation as well as their right to protection. We can learn

[2] *Note that this was the central UCL REC, and such projects may require ethics approval at local RECs (e.g., the Institute of Education, Faculty of Education and Society).

from how they intend to engage ethically with their community members (regardless of ethics review):

- The researchers have engaged an experienced PPI consultant to be responsible for obtaining informed consent, co-facilitating the workshops, and safeguarding. Initial workshops will set ground rules and expectations, ensuring that PPI members have a clear understanding of their roles. The consultant will create an accessible environment that gives all members an equal opportunity to contribute and ensure that their support needs are met.
- After each workshop, the consultant will provide brief summaries to the PPI group with an opportunity to give feedback. Group members will receive timely updates on the researchers' findings and be involved in preparing a young people's report.
- PPI members will be given vouchers and certificates that recognise their contribution and skills gained. Researchers will provide feedback on the impact their involvement had on the project. All published research outputs will acknowledge the PPI group's contribution.

Case study 2: An occasion where a project needed to apply for ethics approval because public engagement/patient and public involvement crosses over into research.

What is the background and aims of the project?

The research team wants to scientifically evaluate a public engagement project they are planning to conduct. Their project has three main aims:

1. To explore how young people living with a condition and their parents understand and experience the condition;
2. To co-produce effective toolkits for young people living with the condition and their parents;
3. To align their research to the needs of the community through stronger engagement with them.

Their project has three main phases:

1. Creative workshops – facilitators will run explorative workshops for young people living with the condition, their parents, and the research team to exchange ideas on the condition.
2. Co-production of toolkits – based on the insights from phase 1, the research team will work together with lived experience experts to co-produce two toolkits over a series of online focus groups.
3. Toolkit Dissemination – the finalised toolkits will be made publicly available on a website, widely disseminated via charity partners, and accompanied by a social media campaign.

What happened/is going to happen?

The researchers decided to apply for ethics approval because:

- Community members' input will be recorded and analysed as outcome data, including information on their lived experience of the condition, observational evaluation of discussions during the workshops, creative outputs (e.g., photos/videos/writing) submitted as part of the workshops, feedback forms, and recordings of online sessions.
- The findings will then be reported and disseminated publicly, including via peer reviewed paper(s), websites and social media channels, at a launch event and other conferences.
- The population will primarily be young people who will be discussing their personal thoughts, feelings and experiences of their condition. This could evoke distress, anxiety, or other unpleasant emotions, and necessitates measures to mitigate risk of harm.
    - It is important to note, however, that this third reason in itself does not necessitate an ethics application. The researchers would have considered these ethical concerns and put in place similar measures even if they had not gone through the formal ethics application process, including providing a staffed virtual 'breathing' or 'break' safe space, regularly checking in

with community members and directing them to support if appropriate.

What was learnt/can we learn from this situation?

- Going through the ethics application process for public engagement/PPI/co-production projects can be a helpful experience as it helps researchers to consider ethical concerns more specifically and thoroughly.
- However, the nature of such projects means that they are subject to change and evolve with time, so it can be a challenge to precisely define all activities in advance. Researchers must learn to craft their ethics application in a way that is honest and accurate but also broad and flexible enough to allow for project evolution. Seeking ethics approval is a time-consuming process, so start as early as you can and be prepared to submit ethics amendments if you deviate from originally stated plans.
- Bring on board people from the population you are working with before/at this stage to shape the application. Even if you can't involve the community members that you will be recruiting because that is what you are seeking ethics approval for, try to find other ways to consult relevant stakeholders. For example, in this case, the researchers would not involve community members participating in the workshops before getting ethics approval, but they held initial discussions with other groups of community members as well as charity partners working directly with this population.