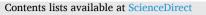
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# Local authorities need tailored research ethics processes to support research capacity building

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#### ABSTRACT

*Background:* Local authorities (LAs) are increasingly aiming to become more research active. Research ethics review is an important prerequisite of high-quality research. It is not clear what a LA ethics review process can (or should) look like, or whether it is needed in addition to external review processes. We aim to describe the scope and purpose of research ethics processes in LAs across England, and factors that are salient to their design. *Study design:* Qualitative interview study.

*Methods*: Staff from 15 LAs in England were recruited to describe their research ethics process using purposeful and snowball sampling. One-hour interviews were conducted using a topic guide with five scenarios, drawn from LA projects. Interview transcripts were thematically analysed using a consensus building process among the research team.

*Results*: Factors salient to the design of research ethics processes in LAs included: definitions of research, research ownership, and the distinct relationship LAs have with research participants. A typology with four models is used to describe existing processes. These models are: *No Process; The Assurance Model* (where LAs assure an external ethics committee has reviewed projects); *The Advice Model* (where there is no formal review, but ethical considerations are made through formal and informal advice); and *The Review Model* (where LAs establish their own formal internal ethics committees). These typologies emerged from divergent understandings of the role of research in LAs and can reflect varied views of research as an activity "done to a local authority", "done with a local authority".

*Discussion:* Research ethics processes in LAs need to reflect various LA approaches to what constitutes research, who owns the research process, and how a LAs relationship with research participants may vary from other settings. As LAs continue articulating what research means in their setting, they need support and guidance to establish research ethics processes that enable research activity, while simultaneously being sensitive to the level of research readiness and distinct LA need.

# 1. Introduction

English local authorities (LAs) are well-positioned to generate research on the wider determinants of health. They have responsibilities for both public health provision and other public services such as housing, education, transport, and social care, allowing them to collect and link data across services while maintaining long term relationships with service users. Recognising this potential, national policy has sought to enable LAs to become more research active. This includes substantial funding from the National Institute of Health and Care Research for Health Determinants Research Collaborations (HDRCs) – LA research capacity building initiatives focused on wider health determinants [1]. However, LAs face challenges to implementing research practices [2]. To increase health determinants research capacity, several LAs have identified a need to strengthen their research ethics processes [3,4].

Kolstoe and Pugh [5] define research ethics as the judgement about the ethical acceptability and permissibility of a research project, commonly made though a formal review process that involves

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submitting an opinion by an ethics committee. This can be distinguished from research governance, which focuses on the legality and institutional management of research projects, including guidelines that guarantee quality, safety, and integrity [6]. While research ethics and governance can overlap, most notably by the fact that many research governance processes will require an ethics opinion submitted by an ethics committee, they are distinct processes.

In clinical and academic settings, research ethics [7,8] is based on widely accepted principles [9] and well-established frameworks [10], and is supported by extensive infrastructure. In the UK, research in social care (a service commissioned and provided by LAs) has research ethics processes nested within clinical ethics infrastructure (the NHS Human Research Authority). However, LA research on wider health determinants has no established framework for a research ethics process. Establishing research ethics pathways could help LAs to maximise benefits and minimise harms of wider determinants research, and support capacity building in this area.

There is, however, little understanding of how LAs that engage in wider determinants research (including those receiving HDRC funding) approach research ethics, or how they interact with established review committees.

We aim to describe perspectives on the scope, purpose, and operation of research ethics practices within LAs in England. We do so by answering the following research questions.

- How do LAs understand the purpose of research ethics in their context?
- What factors are salient to establishing a LA research ethics process?
- What research ethics processes exist in LAs to encompass research on wider health determinants?

# 2. Methods

# 2.1. Study design

We undertook a qualitative interview study.

#### 2.2. Recruitment

Purposeful and snowball sampling was used to identify LA staff with prior involvement in work on LA research ethics. Initial contacts were made via an existing formal network. Snowballing was used to expand beyond contacts known to the researchers. Twelve staff members were initially invited for an interview. One declined, citing being ill-resourced to participate in research capacity building. Additional participants were recruited via a standardised email circulated through LA research networks, some of which were tied to, and some of which were independent of, HDRC funding. Interviewees gave written consent for interview and recording.

#### 2.3. Data collection

Hour-long interviews were conducted on MS Teams using a topic guide piloted in three LAs, covering the purpose, structure, and application of research ethics in LAs. Five practitioner-derived scenarios, based on real LA projects researching wider health determinants were used to prompt discussion about research ethics in practice. These included an evidence review, service evaluation, resident co-production, data linkage, and academic collaboration. Scenarios were designed to capture both conscious knowledge and implicit understandings of the applicability of research ethics to various types of LA work. Participants were asked to share documents related to their research ethics process (e.g. policies, guidance). Council websites were searched for publicly available content.

#### 2.4. Analysis

Interviews were recorded and transcribed. Transcripts were coded and analysed using an inductive thematic approach [11] in NVivo 12 [12] and manually. Themes were finalised through consensus-building across the research team and aligned to research questions. Similarities and differences between LA processes were compared based on identified salient factors to LA research ethics and used to generate a typology of approaches to LA research ethics processes.

# 2.5. Profile of participating LAs

In total, 16 participants were interviewed from 15 LAs, diverse in terms of urban and rural characteristics, geographic spread, and availability of HDRC funding. [Table 1].

# 3. Results

We present our findings organised by each of our three research questions: the purpose of research ethics, factors salient to a LA research ethics process, and existing LA research ethics processes that encompass research on wider health determinants. To describe existing processes, we have derived a typology of four LA research ethics models. These models do not reflect LAs' exact step-by-step processes but provide broader archetypes that describe how research ethics is envisioned.

# 3.1. Purpose of LA research ethics processes

Interviewees mentioned various purposes of having LA research ethics review processes, including doing more good than harm, preserving equity and inclusive participation, and safeguarding staff and participants. Other reported purposes showed some confusion around the difference between research ethics, and research governance, such as reputational protection or legal compliance. However, there was general consensus that research ethics processes play an important role

# Table 1

Breakdown of	participating	g LA c	haracteristics.
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Region of England [13]	Number of Local Authorities in Sample				
North West	1				
North East	3				
East Midlands	2				
South West	3				
South East	2				
Yorkshire	2				
London	2				
Population Density [14]					
Urban with Conurbation	5				
Urban with City and Town	7				
Rural	3				
Local Authority Type					
Unitary	7				
Two-Tier	6				
London	2				
Recipient of HDRC funding at the time of interview [1]					
Funded	8				
Not funded	7				
Index of Multiple Deprivation Quintiles	[15]				
Quintile 1 (most deprived)	4				
Quintile 2	5				
Quintile 3	1				
Quintile 4	4				
Quintile 5 (least deprived)	1				

To organise the Local Authorities (LAs) into quintiles based on their 'IMD -Rank of average rank' we divided the total 151 ranked into 5 equal groups (30.2 per group rounded down to the nearest significant figure) such that Quintile 1 includes LAs that were ranked  $\leq$ 30 and so were among the 20 % most deprived LAs. The parameters for Quintiles 2–5 were: Quintile 2, 31–60; Quintile 3, 61–90; Quintile 4, 91–120; Quintile 5, 121–151. With Quintile 5 showing LAs ranking in the 20 % least deprived areas.

in facilitating wider determinants research in LAs, and that establishing clear pathways to research ethics review is part of research capacity building.

# 3.2. Factors salient to LA ethics review

When faced with topic guide scenarios, interviewees were prompted to consider existing research infrastructure around project types, including whether the project necessitated research ethics review, and what pathway would be used. Three salient factors emerged when considering the need for LA projects to undergo research ethics review: definitions of research, ownership, and relationships with research participants.

1. Clear tensions emerged about **definitions of research**, who is involved in it, how it differs from other contexts, and when it warrants research ethics review. For example, many interviewees expressed uncertainty about whether evaluation should be considered research, and if that distinction changes if the evaluator is a LA professional or an academic. Others argued that all data collection (e. g., surveys, focus groups) constitute research activities and should be treated on a continuum and not a binary understanding of something being, or not being, research.

... people going out and talking to residents about something. Is that research? Is it evaluation? Is it consultation? [...] if you just changed that, "who" [from "academic"] to "youth worker" [...] and they go out on the streets, and they talk to some young people ... Would they put that via any ethics process? [...] They would just do it because that is what they do and that is ... That's consultation.

#### [LA#5; No Process]

... the two things [formal research and evaluation] are interconnected. I've not really distinguished greatly between them. I'm more on the: you're doing research and evaluation, what's your topic, who's your group? [...] Because it doesn't matter what they're calling it, it's what they're doing.

# [LA#3; Advice Model]

Tensions also existed around using generalisability as a guiding principle of research in line with the Health Research Authority's (HRA) definition [16]. While some LAs found generalisability a good principle to determine if something requires research ethics review, others questioned this in a LA context where research activities are primarily used as insight for local action and not aimed at cross-context applicability.

... if it's going to be new knowledge that is generalisable and is going to be shared outside the organisation in some formal sense [...] we use the definitions of the HRA for what is and isn't research.

[LA#7; Assurance Model]

2. There were also variations in the extent to which LAs felt **ownership for research** carried out in their areas, and how this might impact the degree they felt responsible for taking a project through research ethics review. Some articulated differences between research 'done to' a LA by external researcher and that 'owned by' a LA. We used this distinction to support derived models of ethics processes letter in this paper.

[...] I would in very layman's terms say that research was typically done to the council rather than council doing the research [...]

[LA#11; Assurance Model]

3. Finally, some interviewees attempted to highlight the **distinct** relationship LAs have with residents – a relationship that extends beyond the traditional researcher-participant dynamic, and includes responsibilities for care, political accountability, and local relevance when research participants are at once residents, service users, tenants, and constituents. Interviewees considered that university-based ethics committees were not set up to recognise this distinct relationship and therefore their review may not capture ethical dimensions specific to the LA context.

... the very nature of local government is that we're effectively working for our residents, so we need to be seen to be transparent in doing the right thing around people ...

[LA#11; Assurance Model]

#### 3.3. Models of LA research ethics processes

Most LAs in our sample were reconsidering pathways to research ethics processes, including defining what types of research activities require review, formalising pathways to use of existing ethics committees, or creating their own ethics committee structures. Across the 15 interviewed local authorities there was no single way of organising research ethics processes. We describe below 4 distinct models of abstracted LA research ethics, noting that some LAs were moving between models [Table 2].

# 3.4. No process (n = 2)

Some of the interviewed LAs had **no guidance on research ethics**, conceptualising research as an activity routinely initiated outside of a LA and subject to ethics committee review through the initiating institution (typically a university). Consequently, these LAs felt little ownership over the work they considered to be research. LA staff would only be considered researchers if they had a formal link (e.g., through a doctoral fellowship) to an external institution. In-house data generation (evaluation or engagement) would not be expected to undergo any research ethics review, though it would be expected to adhere to any relevant standards of professional ethical conduct. No distinct relationship with residents as research participants was articulated.

#### 3.5. The Assurance Model – research done "to" a local authority (n = 3)

Three LAs had a **formalised process of assuring research projects by checking that they had been reviewed by an ethics committee external to the LA** (e.g., at a university). This Assurance Model presumes LAs have research governance structures in place (typically a panel consisting of council staff from across directorates, information governance teams, and research officers), but they do not have their own LA ethics committee as an independent function. Like the "no process" model, the definition of research is narrow, ownership is limited, and the distinct relationship between LAs and residents as research participants is not articulated. However these LAs see themselves as more active stakeholders in research generation.

... we encourage them [staff] to have an academic partner to create those relationships that give them access to ethics. [...] So yes, we just have it as a prerequisite that they have to have ethical approval, and we don't try and do that ourselves.

[LA#7; Assurance Model]

This approach, however, only captures research conducted by collaborators and staff with links to external research institutions, as these are needed to access an ethics committee. LAs in this model were more likely to experience research as something done "to" a LA by external actors.

#### Table 2

Overview of research ethics process models.

	No process	Assurance Model	Advice Model	Review Model
Level of LA involvement in research ethics	No LA involvement in research ethics.	Assuring external ethics committee has made formal opinion.	No formal involvement in research ethics, however strong role of professional advice in bringing to light ethical considerations.	Independent LA research ethics function through LA ethics committee sensitive to local context.
Definition of research that falls in scope of research ethics	Research follows health research criteria, including generalisability.	Research follows health research criteria, including generalisability.	No formal research ethics, however, research understood on a continuum from formal academic studies, through evaluation, to resident engagement.	Research on a continuum from formal academic studies, through evaluation, to resident engagement.
Creators of research in scope of research ethics	Only externally affiliated researchers.	Only externally affiliated researchers.	No formal research ethics, however, both externally affiliated researchers and internal LA staff seen as potential research creators.	Both internal and external researchers, with an emphasis on internal staff as users of LA ethics committee.
Formal ethics opinion	Issued by eternal ethics committees.	Issued by external ethics committees.	No formal opinion. Informal advice exchanged by a range of stakeholders, including service directors and project steering groups. External ethics committee opinions taken into account for some projects.	Issued by LA ethics committee with membership including a range of council staff, and potentially residents.
Level of Ownership	No ownership.	Research experienced as "done to" a LA by external researchers.	Emphasis on collaborative nature of research and professional conduct; research "done with" a LA.	Research and research ethics process independently "owned by" a LA.
Perceived relationship to residents as research participants	No distinct research relationship articulated.	No distinct research relationship articulated.	Many research activities fall under "business as usual" and research relationships are based in professional conduct.	Articulated relationship between LAs and residents as research participants as distinct from that seen in university-based research, due to residents also being service users, tenants, and constituents.
Process Result	No process.	Assurance that external ethics opinion has been made, giving LA oversight of project.	Range of advice exchanged, with various levels of formality.	LA research ethics opinion with formalised exchange of comments and suggestions.

#### 3.6. The Advice Model – research done "with" a local authority (n = 6)

LAs in this group did not have a defined research ethics process that required research projects to go through a formal ethics committee. Instead, a mix of **formal and informal advice on projects from a wide range of professionals was the basis of ensuring projects were ethically acceptable.** Such advice was sought from service di**rectors, project steering groups, or collaborators such as the Integrated Care Board** [17]. Depending on the LA, a research governance board may also be part of these conversations, and may review ethics opinions made by external committees, however this was not seen as a prerequisite for a project to move forward.

Every project [...] will [have] some kind of group discussing it, so we would always, if we had any concerns, take it through our steering groups or our stakeholder groups, but not in a formal "this is our ethical approval process", just in a "this is a project I'm trying to do, can anyone think of any problems, or is everyone happy with us doing this approach?"

#### [LA#12; Advice Model]

Unlike previous models, this approach captures a wider continuum of research from academic studies to internal evaluation and insight gathering (e.g., resident surveys). It also more uniformly applies to both researchers affiliated with universities, and to council staff conducting in-house projects, giving the LA greater ownership over research generation. Research activities were also more likely to be seen as "business as usual" with professional standards used to inform ethical practices instead of relying on a formal ethics opinion. Research relationships with residents were thus also seen as part of regular practice, falling under standards of professional conduct. Given the emphasis on collaborative advice sharing, we've conceptualised this model as doing research "with" a local authority.

Simultaneously, LAs often recognised this wasn't suited to their needs and were actively seeking to change their approach to ensure more formal uniformity in how ethical considerations are made and captured. It's relying on that good practice, somebody knowing the right people to ask or somebody thinking about it. I'd like to move away from that, so that it's much more considered and much more: "This is what we do and there is a process and there is guidance."

[LA#3; Advice Model]

# 3.7. The Review Model – research "owned" by a local authority (n = 4)

The Review Model describes LAs that have an **internally led ethics committee**, **independent of external committees** and tailored to specific LA needs. Only one participant described an established committee of this kind already in operation, but others were taking steps to create one, though the specific membership profile of the committees was often under debate and included a mix of research-focused staff, social workers, and even aspirations for resident-members. Under this model, LA ethics committees can be sensitive to specific LA ethical needs stemming from the distinct relationship to study participants as service users and constituents, including democratic transparency, local actionability, and financial accountability.

[Researchers often] say, "Most councils don't do this, they just let us get on with it because we've got ethics through the university," and we're like, "These are our residents, they are service users in the borough [...] so we're not just going to give you a green light [because a university says it's ok]"

#### [LA#9; Review Model]

The Review Model explicitly captures research conducted by internal staff, without necessitating university collaborations to gain access to an ethics committee. It covers a wide range of activities on a research continuum, including resident engagement and evaluations, though the specific scope of projects to be reviewed by the committees was often still under debate. We conceptualise this model as researched "owned" by a LA because it features an independent LA research ethics committee and the use of LA-specific expertise to provide a formal ethics opinion.

# 4. Discussion

# 4.1. Main findings

In this qualitative interview study of 16 participants in England, we identified three factors salient to establishing a LA research ethics process: definitions of research, ownership, and relationship with participants. LA ethics processes related to research on wider health determinants conformed to one of four models: *No process, Assurance Model, Advice Model,* and *Review Model.* LAs that saw research as initiated or led by external researchers had no research ethics process (*No process*), or used governance structures to assure an opinion from an external ethics committee (*Assurance Model*). Other LAs relied on professional conduct and informal advice to make ethical considerations, though interviewees from these LAs often acknowledged a more formalised research ethics process may be beneficial (*Advice Model*). Finally, some LAs aspired to having their own LA research ethics committee, sensitive to local contextual needs (*Review Model*).

# 4.2. Methodological considerations

**Strengths:** This study addresses an important evidence gap around current research ethics practices in LAs in England at a time where national policy and funding are focused on supporting LAs in building up this type of research infrastructure. Participation was high among those approached, suggesting this was a priority for these LAs. The use of specific LA based scenarios during interviews helped surface implicit variations between LA approaches to research ethics.

Limitations: Most of the participant LAs were still developing their approach to research ethics, and barriers to embedding a process in practice are a future area to explore. Most recruited interviewees were already highly engaged in research capacity building. Our findings may thus overrepresent the perspectives of staff who are advocates for LA research ethics and underrepresent LAs less engaged (or less able to engage) in research capacity building. Interviewees also belonged almost exclusively to public health departments (likely due to public health HDRC funding playing a driving role in research capacity building). Because of this, we didn't capture the perspectives of non-public health staff on the purposes and requirements of research ethics processes for research activities they are engaged in. Finally, we did not retrieve (through website searches or from requests from interviewees) sufficient documentary sources to enable us to triangulate processes reported by interviewees with formal processes recorded by LAs. The lack of documentation available might also reflect that processes were in flux and not fully operational.

# 4.3. Implications

LAs are at varying stages of research readiness, including at different stages of articulating what constitutes research in a LA setting, who has ownership over that research, and what the various processes surrounding that research should be, including research ethics review. As they do so, external research ethics processes, such as those in universities or the NHS, can be experienced as inappropriate to LA research needs. This is because they often follow strict HRA research definitions, which fail to capture the range of research activities LAs are conducting. HRA definitions view these activities as binary: either they are research, or they are not [16]. LAs however are more likely to experience research activities on a continuum including evaluation and resident engagement as forms of research - a finding consistent with other work on research in LAs [18,19]. LAs thus need research ethics solutions sensitive to that continuum. If national ethics process frameworks are to emerge to support local authorities, they should identify what proportionate effort is needed for different levels of research activity.

Existing external research ethics committees may also insufficiently consider the ethical implications of the different relationship LAs have with their residents compared to participants of university research. LAs have to navigate the complexities of residents simultaneously being research participants, customers, service users, tenants, and constituents. This creates the need for any research ethics frameworks to be wellaligned with high standards for political accountability, financial transparency, and safeguarding protections. Research ethics suitable for LAs is thus made more robust by recognising this complexity.

These findings are in line with commentaries arguing that frameworks underpinning biomedical research in traditional research settings may be insufficient for LA research on wider health determinants. Wider determinants research complicates notions of agency with a focus on the whole population (in line with public health approaches) and away from individual health [20,21]. Our data also helps unpick why others have found that LAs' distinct cultural, political, and organisational characteristics mean that clinical or academic research ethics processes may not meet LA research needs [3].

To address this gap in research ethics infrastructure, participants described different ways to engage with (and establish) research processes, though they are still grappling with embedding research practices (for example differentiating between research ethics and governance or not mentioning need for sponsorship). Clarity in such processes is especially important for wider determinants research, which requires collaboration across departments where there can be unrecognised inter-disciplinary differences in standards of professional conduct and ethical considerations [22]. Having an established research ethics process can set common expectations of LA staff and research partners while enabling LAs to have meaningful ownership and oversight over the knowledge they generate.

# 4.4. Recommendations

As LAs continue articulating what research means in their setting, they need support and guidance to establish research ethics processes that enable research activity, while simultaneously being sensitive to the level of research readiness and distinct LA need. We recommend agreeing a set of joint principles between LAs nationally on research ethics in a LA context. These principles should be established both for and by local authorities, in ways that can be operationalised by each LA through research ethics processes tailored to current capacity levels.

# What this study adds

- There is currently little understanding about the structure and nature of research ethics processes in local authorities in England.
- We identify key themes that influence approaches to research ethics and governance in different LAs.
- We provide a typology with four models that captures common patterns and structures to local authority research ethics processes based on varying levels of research readiness.

# Implications for policy and practice

- Our findings show that LAs as research settings require distinct considerations when setting up research infrastructure, such as articulating their relationship with residents as study participants and defining their scope of research activities.
- We recommend establishing a set of joint principles on research ethics in a LA context that also allow for LAs to tailor processes to their current capacity levels.

# **Ethics** approval

UCL: 24349.001 Cornwall Council: Confirmation of approval received: April 11, 2023.

#### Author statements

E. Humphreys and J. Sheringham conceptualised the study and devised the research questions. A. Levitas, E. Taylor, and P. L. Navelle collected data and conducted the qualitative analysis, with all authors contributing to the interpretation of findings. A. Levitas drafted the manuscript. All authors commented on drafts of the manuscript and agreed the decision to submit for publication.

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# Declaration of competing interests

The authors declare no competing interests.

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#### Appendix A. Supplementary data

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