Minimal Risk Registration Form

Section A: Confirm that your study requires KCL ethical clearance

1 Is your study considered research as defined in the guidance icon information?
Please note studies deemed to be either a service evaluation or audit do not require ethical clearance.

- (•) Yes
- ( ) No

2 Does your study require external ethical review by either the Health Research Authority (which includes the NHS REC and Social Care REC) or the Ministry of Defence REC?
See guidance icon for further information on the HRA and MOD REC ethical review remit.

- ( ) Yes
- (•) No

3 Please indicate which of the following data collection methods your study involves (select all that apply):

- [ ] Interviews
- [ ] Focus Groups/Workshop
- [x] Questionnaires/Surveys/App based research tool
- [ ] Observations
- [ ] Physical procedures (e.g taking body temperature, wearing a virtual reality headset, taking pulse)

Please note: Analysis of pre-existing data is not eligible for the Minimal Risk Registration Process. Before continuing, if your study involves the analysis of pre-existing data, please visit our 'Analysis of pre-existing data' page for advice on whether or not you will need to complete a 'Full Application Form' for ethical approval

Section B: Confirm that your study does not require High Risk review

Project ID: 8494

6 Does your study present any of the following risks to participants?

- ☐ a) Vulnerability: Does the study involve participants who are vulnerable, unable to give informed consent, or in a dependent position (e.g. vulnerable children, over-researched groups, people with learning difficulties, people with mental health problems, young offenders, people in care facilities, including prisons)?
- ☐ b) Consent and deception: Will participants be asked to take part in the study without their informed consent or knowledge at the time or will deception of any sort be involved?
- ☐ c) Participants disclosures: Is there a risk that the highly sensitive nature of the research topic might lead to disclosures from the participant concerning their own involvement in illegal activities or other activities that represent a threat to themselves or others (e.g. sexual activity, drug use, or professional misconduct)?
- ☐ d) Stress and anxiety: Could the study induce psychological stress or anxiety, or produce humiliation or cause harm or negative consequences beyond the risks encountered in a participant's usual, everyday life?

You should only select the statement below if you have not selected any of the above. Your application will be invalid if you select the below statement in addition to any of the above.

- ☑ I have answered no to all questions in the risk checklist above and I do not believe that my research is high risk

Section C: Confirm that your study does not require Low Risk review

7 Will all participants be over the age of 16?

- ◉ Yes
- ○ No

8 Can you confirm that you will not be asking participants to disclose any information of a personally sensitive nature that you cannot assume they would be otherwise willing to discuss in public? (such as salary, medical history or details of a personal relationship)

- ◉ Yes, I confirm that I will not be asking participants to disclose any personally senstive information
- ○ No, I will be asking participants to disclose personally sensitive information

9 Can confirm that you do not have any current or prior relationships with potential participants?

- ◉ Yes, I confirm that I do not have any current or prior relationships with potential participants.
- ○ No, I have a current or prior relationship

10 Can you confirm that no gatekeeper will be used to access potential participants? i.e someone will facilitate/ grant access to or contact participants on your behalf

- ◉ Yes, I confirm that no gatekeeper will be used
- ○ No, I will be using a gatekeeper to access potential participants

11 Can you confirm that the participants will not be subjected to any undue incentives to participate? (Receipt of a project report or a reasonable reimbursement such as travel/lunch costs or a voucher would not be considered undue incentives.)

- ◉ Yes
- ○ No

12 If you have answered 'Yes' to all of the low risk checklist questions in Section C, your study is suitable for minimal risk registration.
Please note:This includes questions where your initial answer has been 'No', but your ultimate answer to the subsequent dependency question(s) is 'Yes'.

Before completing your minimal risk registration form you must confirm that you have read the Minimal Risk Guiding Principles at the link below and that you will adhere to these principles in the conduct of your research.

Minimal Ethical Risk Guiding Principles

☑ I confirm that I have read the Minimal Risk Guiding Principles and will adhere to the principles within.

Section D: General Information

13 Applicant Details

Title	First Name	Surname
Dr	Amit	Desai

Department: Adult Nursing

Email: amit.desai@kcl.ac.uk

14 Faculty/Institute/School

Please refer to the information icon if you are unsure of your Faculty/Institute/School.

Nursing and Midwifery

15 Applicant Status

Staff

17 Are there any other investigators/collaborators involved in the study?

- (•) Yes
- ( ) No

Co-Investigator/ Collaborator Details

Name/s

Prof Glenn Robert (PI), Dr Giulia Zoccatelli, Prof Graham Martin, Ms Sally Brearley

Institution/s

KCL (GR+GZ), University of Cambridge (GM)

Section F: Study Overview

18 Study Title

A working title for your study that accurately reflects its aims

Mapping the variability in local Healthwatch operations across England

19 Study Overview: Briefly describe your research project, as you would to a potential participant, highlighting the aims of your research, who your participants are (type of people rather than individual names), how you will recruit them and what will be asked of them (try to use no more than 50 words for each section).

a) What are the aims of your study?

You should explain what the principal research question is and the specific objectives of the study

The aim of the study is to map the variability in operation of local Healthwatch in England. We will achieve this aim by pursuing the following objective: to establish current local priorities, activities (e.g. advocacy, signposting, surveys, inspections) organisational arrangements (e.g. staffing, nature of contract) and jurisdictional contexts of the 152 local Healthwatch in England. We will invite senior managers of the 152 local Healthwatch to complete anonymously an online survey which asks questions in these four areas.

(Background: Healthwatch was set up in 2013 with the ostensible aim of being the 'consumer champion' in health and social care in England, centrally concerned with the quality of and access to healthcare. There are 152 local Healthwatch, which are funded through local authority budgets and which have statutory powers to advise local authorities and NHS commissioners about their communities' needs and concerns relating to the provision of health and social care. Each local Healthwatch organisation is independent and operates in different conditions. The extent and nature of this variability is, however, currently unknown)

b) Who are your potential research participants?

This should outline any specific criteria participants must meet in order to be eligible take part (e.g. age, ethnicity, gender, members of a specific group etc.)

Our research participants will be senior managers of the 152 local Healthwatch organisations in England.

c) How will participants be recruited?

This should address how participants will be approached in the first instance (i.e. in person, telephone, email, etc.)

We will contact these managers by email and ask them to complete the survey anonymously through the Survey Monkey platform. These contact details will be provided in three ways: offered voluntarily by individual managers in person to the researchers at the Healthwatch National Conference; by study researchers searching publicly available information (e.g. contact details listed on Healthwatch websites); by liaising with Healthwatch England which coordinates the Healthwatch network. We will also publicise the survey and build engagement with it through Healthwatch's Yammer online forum to which we will ask permission for access, though this will not be a method of direct recruitment.

d) What will participation involve?

This should include what participants will be asked to do and an example of the types of questions they may be asked.

Participants will be asked to complete a short, anonymous online survey. Questions will cover four areas which will provide information about the operation of the local Healthwatch body. We will ask questions about local priorities and how they are decided; the range of activities conducted (e.g. signposting, advice, advocacy, inspection etc); organisational structure (e.g. number of staff, volunteers, length of contract from local authority etc); jurisdictional context (whether operating in a unitary or county council, number of NHS provider organisations they work with etc). Participants will answer questions by selecting from a fixed set of responses and/or writing free text.

In relation to Q21 below, participants will not be asked for identifiable details of their organisation. However, it is possible that participants may mention names of places or organisations in their free text responses, which would make them identifiable. Participants will also have the option of consenting to be contacted about the follow-up study and thus identifying themselves by providing name, organisation and contact details. This is entirely voluntary and will be made clear in the survey instructions.

20 Confirm which of the following consent processes will be used (select all that apply for multiple data collection methods):

- ☐ Written Consent: A written description of the research will be provided to all potential participants and written consent will be recorded in either paper or electronic form in advance of participation.
- ☐ Verbal Consent: I am able to demonstrate that written information and consent is not practical, or not appropriate, so I confirm that I will follow College guidance on providing information and gaining consent from participants verbally.
- ☑ Anonymous submission of survey/questionnaire/app based research tool data: A written description of the research will be provided to all potential participants and it will be made clear that the submission of a completed survey/questionnaire/app data implies consent.
- ☐ Non-invasive observation where no identifying information will be recorded: Informed consent is either not practically possible or may change the behaviour which is the object of the research

Provisions for anonymous submissions: I confirm that I will provide appropriate researcher contact details for purposes of questions and/or complaints wherever practical. It will also be made clear that due the data being submitted anonymously, withdrawal from the study will not be possible past the point of submission.

21 Management of personal data i.e data from which a living individual can be identified
See guidance icon for the full General Data Protection Regulation definition of personal data.

Please indicate which of the following applies:

- ○ Personal data will be collected in this study to identify and contact potential participants. No further identifying information will be collected as part of the study.
- ◉ Personal data will be collected from participants as part of their participation in the study

21a Important Notice: General Data Protection Regulation requirement

Projects involving the collection and processing of personal data must be registered with the King's Data Protection Register before data collection commences in order to comply with the new General Data Protection Regulation. Please indicate which of the following applies –

- ◉ I confirm that I will submit a King's Data Protection Registration Form prior to commencing data collection
- ○ The project has already been registered with the King's Data Protection Register

If you have any queries in regard to the completion of a KDPR form, please email gdpr@kcl.ac.uk or call 02078483323 (ex 3323) for further advice

Please note: Once you have gained ethical clearance, the important step is that you submit the KDPR form prior to commencing data collection. Providing you have submitted a KDPR for registration, you do not have to await confirmation of registration before commencing data collection.

I confirm that I understand that it is the responsibility of the researcher to ensure that all research data is securely handled and stored during and after the project in compliance with the General Data Protection Regulation (GDPR) and College guidelines:
KCL Research Data Management Guidelines

KCL guidance on the General Data Protection Regulation

Section G: Declaration and Signatures

22 Researcher/ Applicant Signature

I undertake to abide by accepted ethical principles and appropriate code(s) of practice in carrying out this study. The information supplied above is to the best of my knowledge accurate. I have read the key principles document and clearly understand my obligations and the rights of participants, particularly as regards obtaining valid consent. I understand that I must not commence research with human participants until I have received confirmation of minimal risk registration.

Please note that in order to authorise your application you must sign off using your KCL email address i.e. joe.bloggs@kcl.ac.uk and your KCL email password.

Signed: This form was signed by Amit Desai (amit.desai@kcl.ac.uk) on 12/09/2018 14:22