Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
PPH kits study: photo-based survey

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Ionising Radiation for combined review of clinical trial of an investigational medicinal product

( ) Ionising Radiation and Devices form for combined review of combined trial of an investigational medicinal product and an investigational medical device

( ) Clinical investigation or other study of a medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

(●) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ( ) Yes (●) No

b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (●) No

c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

☑ England

- [x] Scotland
- [x] Wales
- [x] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (•) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which applications do you require?

- [x] IRAS Form
- [ ] Confidentiality Advisory Group (CAG)
- [ ] HM Prison and Probation Service (HMPPS)

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

( ) Yes (•) No

5. Will any research sites in this study be NHS organisations?

(•) Yes ( ) No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out the research e.g. NHS support costs) for this study provided by a NIHR Biomedical Research Centre (BRC), NIHR Applied Research Collaboration (ARC), NIHR Patient Safety Translational Research Centre (PSTRC), or an NIHR Medtech and In Vitro Diagnostic Co-operative (MIC) in all study sites?

Please see information button for further details.

( ) Yes (•) No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

(•) Yes ( ) No

The NIHR Clinical Research Network (CRN) provides researchers with the practical support they need to make clinical studies happen in the NHS in England e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, information from your IRAS submission will automatically be shared with the NIHR CRN. ***Submission of a Portfolio Application Form (PAF) is no longer required.***

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
PPH kits study: photo-based survey

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Mapping current designs and contents of PPH kits (Post-Box work package 2)

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Jan	van der Scheer
Post	Senior Research Associate		
Qualifications	PhD (Human Movement Sciences, Faculty of Medical Sciences) MSc, BSc (Faculty of Human Movement Sciences)		
ORCID ID	0000 0002 4368 0355		
Employer	University of Cambridge		
Work Address	Strangeways Research Laboratory Worts Causeway Cambridge		
Post Code	CB1 8RN		
Work E-mail	jan.vanderscheer@thisinstitute.cam.ac.uk		
* Personal E-mail			
Work Telephone	01223 331574		
* Personal Telephone/Mobile			
Fax	01223 331574		

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Ms	Carolyn	Read
Address	Research Governance Office		
	School of Clinical Medicine		
	University of Cambridge		
Post Code	CB2 0SP		
E-mail	researchgovernance@medschl.cam.ac.uk		
Telephone	01223 769291		
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	RG88620
Sponsor's/protocol number:	RG88620
Protocol Version:	v1
Protocol Date:	
Funder's reference number (enter the reference number or state not applicable):	RHZF/001 – RG88620
Project website:	https://www.thisinstitute.cam.ac.uk/research/projects/developing- post-pa

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

(●) Yes ( ) No

Please give brief details and reference numbers.
This study continues on from the study, "Post-Box Workpackage 1", IRAS ref: 274147.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

Post-partum haemorrhage (PPH) is a complication in labour where a woman experiences heavy bleeding after the birth of their baby. On maternity units, PPH kits bring together the equipment and drugs needed to manage PPH effectively and rapidly. They are an important safety feature of maternity care. Currently, the content, form (e.g. a box, bag, trolley) and packing of PPH kits varies across trusts. We have developed a programme of research that looks at how we can optimise the design of PPH kits that helps ensure the best can be offered to those experiencing a PPH. In the current study, participants will take photographs of the PPH kits and contents that they use on their own maternity unit. They will also answer survey questions about the content and layout of the kit. Data analysis will describe and compare the PPH kits of approximately 20 to 40 units to characterise and understand similarities and differences.

This research output will inform a co-design process with user-centred design methods (not part of this HRA application) to develop a recommended PPH kit design.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

The project team has developed a risk assessment (including potential risks and measures to mitigate risks relating to ethical considerations), which will be reviewed regularly to proactively assess if additional or alternative risk mitigation measures may be needed. One important consideration is the readiness of PPH kits in the maternity units.

The data collection process requires that the PPH kit is unpacked for a brief period, such that its contents can be photographed. There is a possibility that the kit is required during the time it is partially unpacked. To mitigate this risk, participants will be advised to photograph a spare/secondary kit if available. If the unit only has one kit, participants will be advised to be aware of the potential need for the kit (i.e. the end of second stage labour) and avoid conducting the photo-taking task in these periods. Additionally, the photo-taking task has been designed to be short (less than 30 minutes), for example by instructing for items to be recorded in group shots rather than as individual items. The risk assessment also considers data management relating to identifiable information.

Established data management procedures will be used to protect access to participant and research data. For data collection, participants are asked to register on the secure Thiscovery platform by providing their name and e-mail and accepting the Thiscovery terms and conditions. For each participant who consents to take part, all their activity in the project will be associated with a universally unique ID (UID) which, for the duration of the project only, will be linked to the participant's personal details (name and e-mail address) in the Thiscovery database hosted by Amazon Web Services (AWS). Personally identifiable data (PID) will be stored in one of the University of Cambridge safe havens, which are covered under the NHS England Data Protection Toolkit. Anonymised research data will be stored by The Healthcare Improvement Studies Institute in folders on secure servers within the University of Cambridge that can only be accessed by password protected computers.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☐ Qualitative research
- ☑ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

What differences and similarities exist in layout and content of post-partum haemorrhage kits in the UK?

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

What can we learn from differences and similarities in the kits so that we can improve their design as part of a future co-design process?

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

In the UK, the layouts and contents of PPH kits are currently agreed locally by individual maternity units. In consequence, they vary from one maternity unit to the next. The kit itself may take the form of a PPH box, a dedicated PPH trolley, specific drawers inside a general maternity emergencies trolley, and a variety of other forms. The contents of the kits are also variable — for instance, some include certain medicines while others do not.

The variation in layouts and contents of the kits incurs a learning overhead as professionals move between maternity units. Variability also introduces the possibility of error, confusion or lost time as staff attempt to find and use resources in an emergency situation. There is a risk that some emergency boxes are sub-optimal in design and/or contents, since local teams do not have access to design expertise. Additionally, boxes are typically produced and re-stocked by staff in the units themselves, potentially imposing supply chain costs, increasing waste, and missing opportunities for economies of scale. Defects in supply chains may also increase risks of delays in treatment if the kit has not been fully re-stocked and is lacking vital equipment or medication. Given these challenges, a recent World Health Organization-led systematic review of supply kits for antenatal and childbirth care recommended further research in this area.

One solution might be found in standardisation of PPH kits. However, a challenge with many present approaches to improvement (including standardisation) is that staff may feel “done to” rather than “with”, particularly when asked to implement a one-size-fits-all improvement solution.

This study addresses both the need for understanding variation of PPH kits across maternity units in the UK as well as engaging staff in efforts to improve PPH kits.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

SETTING

The setting is a sample of maternity units in the UK, where relevant staff will be invited to make photos of their PPH kits and upload these as part of a survey on Thiscovery, an online data collection and collaboration platform.
We aim to collect data on PPH kits from 20 to 40 units that are representative of the approximate 280 maternity units across England, Northern Ireland, Scotland, Wales. A purposive approach will be used to select a representative sample of units to invite to take part in the study, including representation of the various unit types (free-standing midwifery, alongside midwifery, obstetric unit), unit sizes (based on annual births), and countries (England, Scotland, Wales, North-Ireland) across the UK.

PARTICIPANTS

Eligible participants will be professionals from invited maternity units who are directly or indirectly involved in the use of PPH kits, including but not limited to Practice Development Midwives and Research Midwives. We aim to recruit 20 to 40 participants, one from each unit.

PROCEDURE

Following registration on Thiscovery, confirming their eligibility and completing the consent form, participants will be presented with online instructions which photos of the kits are rquired and how they should be made. The instructions will include a step-by-step guide about the photos that are required. Participants will then be asked to use a mobile phone or tablet to take around ten photos of a PPH kit on their unit, in accordance with the instructions.
Following this activity, participants are asked to log in again to the Thiscovery platform. They will be guided through a set of questions that will involve uploading the photos and answering associated questions. The questions concern the layout of the PPH kit (box, trolley or other type of kit), where it is kept, and what contents it has. Participants are also asked to complete a few short questions about the characteristics of the unit where the kit was photographed. We estimate that the participant will require up to 60 minutes in total to complete all steps outlined in Figure 1, which can

be conducted over separate, shorter time blocks.

Data analysis will consist of four stages: 1) data cleaning and content review, 2) coding photo contents, 3) description of layout and contents, and 4) exploration of relationships between maternity unit characteristics (type, size and country) and PPH kit layouts and contents.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [ ] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Throughout the study we will consider the perspectives of those with lived experience of labour and their birth partners by drawing on the extensive work on the perspectives of women and their birth partners in studies of obstetric emergencies carried out by THIS Institute and its collaborators (https://www.thisinstitute.cam.ac.uk/themes/maternity/).

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer
- [ ] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [ ] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents

- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [ ] Neurological
- [ ] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit: 67	Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Eligible participants will be professionals from invited maternity units who are directly or indirectly involved in the use of PPH kits, including but not limited to Practice Development Midwives and Research Midwives.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Staff who are not directly or indirectly involved in the use or re-stocking of PPH kits.
Staff who do not work in an invited maternity unit in the UK.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Photograph PPH kit	1	na	<30m	Participant - maternity professional who meets eligibility criteria
Answer online survey questions	1	na	<30m	Participant - maternity professional who meets eligibility criteria

A21. How long do you expect each participant to be in the study in total?

Maximum of one hour.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Participants are asked for their time, but are otherwise not expected to experience any adverse effects or risks. We have designed the study such that the data collection process is as short as possible, for example by asking for photographs of groups of kit items instead of individual items.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

○ Yes ◉ No

A24. What is the potential for benefit to research participants?

The participants may experience the benefit of contributing to improving a clinical toolkit that they either use or are responsible for in their day-to-day practice.

A26. What are the potential risks for the researchers themselves? *(if any)*

The research presents minimal risk for the researchers themselves as they will be remote from any NHS premises. Researchers will be able to seek support from managers at THIS Institute should they be negatively affected by any aspect of the study.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of social care or GP records, or review of medical records. Indicate whether this will be done by the direct care team or by researchers acting under arrangements with the responsible care organisation(s).*

An audit of maternity units (National Maternity and Perinatal Audit) or similar source will be used to inform initial sampling of maternity units in England, Scotland and Wales, while other sources will be used to gauge characteristics of maternity units in Northern Ireland. The research team will take a purposive approach to select a representative sample of units to invite to take part in the study.

The CRN will be asked to send a study information package to the Research and Development (R&D) offices of NHS trusts that include the units selected to be invited to take part. The CRN will be asked to provide the R&D offices with the nominal opt-out period of three weeks , and provide the option to contact the research team to gain further information or have questions about the study answered. Following this three-week period, the research team will generate a list of purposively sampled units whose trusts have not opted out.

Relevant professionals from the list with representative maternity units will be invited to participate in the photo-based survey. Networks of the project team, including (but not limited to) the nation-wide PROMPT Maternity Foundation and the Practice Development Midwife networks, will be used to contact and invite potentially eligible participants from the maternity units selected to take part. Recruitment will primarily target (but is not limited to) practice development midwives and research midwives.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

The project team will contact and invite potentially eligible participants from the maternity units selected to take part and that have R&D offices that have agreed to take part. Networks of the project team, including (but not limited to) the nation-wide PROMPT Maternity Foundation and the Practice Development Midwife networks, will be used to source potential participants. One or more of the following roles will be contacted: practice development midwife, research midwife and matron. Upon, or following initial contact an email will provide details of the study, an invitation to participate and a link to the data collection platform (called Thiscovery).

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Participants will be given an overview of the project on the initial invitation email. Participants who wish to find out more will be able to follow a link to a webpage on Thiscovery to read detailed information (a participant information sheet). If they choose to proceed, they will register on the Thiscovery platform, complete and eligibility check and then consent to participate.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

Invited individuals are given up to six weeks to consider taking part, ask questions, and – if they decide to participate – complete the photo-based survey.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

We will provide a contact email on the information sheet for people to inquire about anything they don't understand. We are unable to provide study materials in languages other than English. We believe that most staff working in the NHS who are eligible for the study will have an adequate understanding of English to perform their job role and therefore we do not envisage this excluding many potentially eligible participants.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

As the number of participants from Wales are likely to be less than five, the added cost of translating the material to Welsh was judged to outweigh the benefit.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the

study? *Tick one option only.*

- ○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ○ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.
- ◉ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☑ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☐ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☑ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☐ Manual files (includes paper or film)
  - ☐ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers
  - ☑ University computers
  - ☐ Private company computers
  - ☐ Laptop computers

Further details:

A37. Please describe the physical security arrangements for storage of personal data during the study?

Personally identifiable data (PID) will be stored in one of the University of Cambridge safe havens, which are covered

under the NHS England Data Protection Toolkit.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

Participants are asked to register on the secure Thiscovery platform by providing their name and e-mail and accepting the Thiscovery terms and conditions. For each participant who consents to take part, all their activity in the project will be associated with a universally unique ID (UID) which, for the duration of the project only, will be linked to the participant's personal details (name and e-mail address) in the Thiscovery database hosted by Amazon Web Services (AWS).

The general policy is to separate research data from participant identifiable data through the use of the UID. The UIDs are held in AWS, separated from the other research data. Anonymisation link keys are held on AWS servers only. Access to the Thiscovery database will be limited to the Thiscovery technical development and support team.

Personally identifiable data (PID) will be stored in one of the University of Cambridge safe havens, which are covered under the NHS England Data Protection Toolkit. Anonymised research data will be stored by The Healthcare Improvement Studies Institute in folders on secure servers within the University of Cambridge that can only be accessed by password protected computers.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Access to the Thiscovery database, which contains the link from participant name and email to UID, will be limited to the Thiscovery technical development and support team.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

Questionnaire data, which will include participant job role and maternity unit name, will be treated as personally identifiable data (PID). This data will be stored in one of the University of Cambridge safe havens, which are covered under the NHS England Data Protection Toolkit.

Photographic data will initially be stored on AWS and linked to participant only by the UID. Once the research team have checked for (and if needed redacted) any identifying information (e.g. any information about the participant or the trust where the photos were taken), then the photographic data will be stored on a secure research drive at the University of Cambridge, which is accessed only through password-protected devices (e.g. laptops managed and owned by the University of Cambridge).

Analysis will be undertaken by the project team listed in the protocol. These individuals are employed by either THIS Institute, University of Cambridge or the PROMPT Maternity Foundation, Bristol.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Dr	Jan	van der Scheer
Post	Senior Research Associate		
Qualifications	PhD (Human Movement Sciences, Faculty of Medical Sciences) MSc, BSc (Faculty of Human Movement Sciences)		
Work Address	Strangeways Research Laboratory		
	Worts Causeway		
	Cambridge		
Post Code	CB1 8RN		
Work Email	jan.vanderscheer@thisinstitute.cam.ac.uk		

Work Telephone	01223 331574
Fax	01223 331574

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ○ 3 – 6 months
- ○ 6 – 12 months
- ◉ 12 months – 3 years
- ○ Over 3 years

If longer than 12 months, please justify:
The research institute uses a 2 year retention period as standard. This provides the possibility to review or resolve participation queries during the reporting and analysis process.

A44. For how long will you store research data generated by the study?

Years: 10
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended.*Say where data will be stored, who will have access and the arrangements to ensure security.*

Anonymised research data will be stored by The Healthcare Improvement Studies Institute in folders on secure servers within the University of Cambridge that can only be accessed by password protected computers. Data will be only be accessible by the core research team.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50-1. Will the research be registered on a public database?

○ Yes ◉ No

Please give details, or justify if not registering the research.
The research is not being registered because it is not a clinical trial; we will report and disseminate the results of the study via a project website that is publicly available and accessible to all.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

☑ Peer reviewed scientific journals
☑ Internal report
☑ Conference presentation
☑ Publication on website
☐ Other publication
☐ Submission to regulatory authorities
☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
☐ No plans to report or disseminate the results
☐ Other (please specify)

Alongside traditional dissemination channels (e.g. scientific articles), we will also produce a “digest” summary of the findings which will be very accessible and visual, and freely available. We will aim to make the findings transferable to other healthcare settings and also available outside the UK to meet the demand for effective quality improvement programmes across the world.

We are engaged with the PROMPT Maternity Foundation, the Royal College of Obstetricians and Gynaecologists, and the Royal College of Midwives, and will aim to liaise with them and other stakeholder organisations, including patient organisations, to communicate our findings.

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Identifiable personal data will not be available during analysis nor publication.

Submitted images of PPH will be published but any potential identifying information will be removed or redacted to ensure anonymity of the participants and maternity units that have participated.

A53. How and when will you inform participants of the study results?

If there will be no arrangements in place to inform participants please justify this.
All participating sites will be able to read summaries of the research via a publicly available website page. Additionally, participants may opt in via the Thiscovery platform to receive email updates about the results.

5. Scientific and Statistical Review

A54-1. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- [x] Independent external review
- [ ] Review within a company
- [x] Review within a multi−centre research group
- [ ] Review within the Chief Investigator's institution or host organisation
- [ ] Review within the research team
- [ ] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
A protocol for the whole PPH kits study, which contains five sub-studies, was reviewed by two external reviewers (a consultant in obstetrics and gynaecology and a quality improvement specialist in obstetrics). We amended the protocol based on these comments.

The research team and two other senior investigators from THIS Institute have contributed to the development and peer review of the study protocol that is specific to this phase of the study (PPH kits study: photo-based survey).

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- [ ] Review by independent statistician commissioned by funder or sponsor
- [ ] Other review by independent statistician
- [ ] Review by company statistician
- [ ] Review by a statistician within the Chief Investigator's institution
- [ ] Review by a statistician within the research team or multi−centre group
- [ ] Review by educational supervisor
- [ ] Other review by individual with relevant statistical expertise
- [x] No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

Title Forename/Initials Surname

Department
Institution
Work Address

Post Code

Telephone
Fax
Mobile
E-mail

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

The proportion of sites that use each PPH kit layout and each of the associated kit contents.

A58. What are the secondary outcome measures?*(if any)*

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 40
Total international sample size (including UK):
Total in European Economic Area:

Further details:
The sample will be comprised of units from three maternity unit types: obstetric units, alongside midwifery units and freestanding midwifery units.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

A purposive approach will be used to select a representative sample of units to invite to take part in the study. Representation will be sought across the following three unit characteristics: 1) unit types (free-standing midwifery, alongside midwifery, obstetric unit), 2) unit size (based on annual births), and 3) country (England, Scotland, Wales, Northern Ireland). Additionally we seek representation from different regions in England. To provide sufficient coverage of each of the combinations of these three characteristics we estimate 20-40 units will be required.

A61-1. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

The analysis of photos of PPH kits will consist of four stages: 1) data cleaning and content review, 2) coding photo contents, 3) description of layout and contents, and 4) exploration of relationships between maternity unit characteristics and PPH kit layouts and contents.

The research team will quantify various properties of the PPH kits, such as the type of kit (bag, box etc.), the number of kits that are ¬accompanied by a PPH algorithm, the type of layout used (if any), the proportion of kits in which a particular item is found, and the number of items in each kit. Data may also be described using narrative or diagrams in terms of what forms of grouping/organisation exist. Where items have been grouped, analysis will identify the relative co-occurrence of items in different stages/compartments/panels of the kit (e.g. co-occurrence of tape and cannulas).

Descriptive measures will be used to explore relationships between maternity unit characteristics and PPH kit layouts and contents.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Professor	Tim	Draycott
Post	Consultant Obstetrician		
Qualifications	BSc, MB, BS, MRCOG, MD		
Employer	Southmead Hospital Bristol		
Work Address	Department of Women's Health Southmead Hospital Bristol		
Post Code	BS10 5NB		
Telephone	01174146760		
Fax			
Mobile			
Work Email	tdraycott@RCOG.org.uk		

	Title	Forename/Initials	Surname
	Ms	Cathy	Winter
Post	Lead Midwife & PROMPT Training Coordinator for the PROMPT Maternity Foundation		
Qualifications	Registered Nurse – Nursing and Midwifery Council (formally UKCC) – 1981. PIN: 78J2327E Registered Midwife – Nursing and Midwifery Council (formally UKCC) – 1984. PIN: 78J2327E		
Employer	Southmead Maternity Unit, Bristol		
Work Address	PROMPT Maternity Foundation Dept of Women's Health Southmead Maternity Unit, Bristol		
Post Code	BS10 5NB		
Telephone	0117 4146760		
Fax			
Mobile			
Work Email	c.winter@promptmaternity.org		

	Title	Forename/Initials	Surname
	Dr	Alison	Powell
Post	Research Associate		
Qualifications	PhD, MA		
Employer	University of Cambridge		
Work Address	Strangeways Research Laboratory 2 Worts Causeway Cambridge		
Post Code	CB1 8RN		
Telephone	01223761841		
Fax			
Mobile			
Work Email	alison.powell@thisinstitute.cam.ac.uk		

	Title	Forename/Initials	Surname
	Mr	Matthew	Woodward
Post	Research Associate		
Qualifications	MSc, BSc(Hons)		
Employer	University of Cambridge		
Work Address	Strangeways Research Laboratory		
	2 Worts Causeway		
	Cambridge		
Post Code	CB1 8RN		
Telephone	01223761601		
Fax			
Mobile			
Work Email	maw215@cam.ac.uk		

	Title	Forename/Initials	Surname
	Dr	Katherine	Lattey
Post	Research Fellow and Obstetric Registrar		
Qualifications			
Employer	Southmead Maternity Unit, Bristol		
Work Address	PROMPT Maternity Foundation		
	Dept of Women's Health		
	Southmead Maternity Unit, Bristol		
Post Code	BS10 5NB		
Telephone	0117 4146760		
Fax			
Mobile			
Work Email	kat.lattey@promptmaternity.org.uk		

	Title	Forename/Initials	Surname
	Dr	Chloe	de Souza
Post	Research Fellow and Obstetric Registrar		
Qualifications			
Employer	Southmead Maternity Unit, Bristol		
Work Address	PROMPT Maternity Foundation		
	Dept of Women's Health		
	Southmead Maternity Unit, Bristol		
Post Code	BS10 5NB		
Telephone	0117 4146760		
Fax			
Mobile			
Work Email	chloe.desouza@promptmaternity.org.uk		

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	University of Cambridge
Given name	Carolyn
Family name	Read
Address	Research Governance Office
Town/city	School of Clinical Medicine
Post code	CB2 0SP
Country	United Kingdom
Telephone	01223 769291
Fax	
E-mail	Research_Governance@medschl.cam.ac.uk

Legal representative for clinical investigation of medical device (studies involving Northern Ireland only)
Clinical Investigations of Medical Devices that take place in Northern Ireland must have a legal representative of the sponsor that is based in Northern Ireland or the EU

Contact person

Name of organisation	
Given name	
Family name	
Address	
Town/city	
Post code	
Country	
Telephone	
Fax	
E-mail	

A65. Has external funding for the research been secured?

Please tick at least one check box.

- [x] Funding secured from one or more funders
- [ ] External funding application to one or more funders in progress
- [ ] No application for external funding will be made

What type of research project is this?

- ○ Standalone project
- ○ Project that is part of a programme grant
- ◉ Project that is part of a Centre grant
- ○ Project that is part of a fellowship/ personal award/ research training award
- ○ Other

Other – please state:

Please give details of funding applications.

Organisation	The Health Foundation
Address	8 Salisbury Square London
Post Code	EC4Y 8AP
Telephone	02072578000
Fax	
Mobile	
Email	info@health.org.uk

Funding Application Status: ◉ Secured ○ In progress

Amount: £42.5 million

Duration
Years: 10
Months:

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

This project is part of THIS Institute's research programme on maternity safety. THIS Institute was funded by a grant from the Health Foundation, through a competitive, UK-wide bidding process for a defined program of work on improving the quality and safety of healthcare delivery in the UK.

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

○ Yes ◉ No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Ms	Lydia	Ufton
Organisation	Maidstone and Tunbridge Wells NHS Trust		
Address	Research and Innovation		
	Maidstone Hospital		
Post Code	ME16 9QQ		
Work Email	l.ufton@nhs.net		
Telephone	01622227265		
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A68-2. Select Local Clinical Research Network for NHS Organisation identified in A68-1:

Kent, Surrey and Sussex

For more information, please refer to the question specific guidance.

A69-1. How long do you expect the study to last in the UK?

Planned start date: 22/04/2024
Planned end date: 01/11/2024
Total duration:
Years: 0 Months: 6 Days: 10

A71-1. Is this study?

- ○ Single centre
- ◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☑ England
- ☑ Scotland
- ☑ Wales
- ☑ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study 20-40

Does this trial involve countries outside the EU?

(●) Yes ( ) No

[ ] USA

[x] Other international (please specify)

UK

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

[x] NHS organisations in England	26
[x] NHS organisations in Wales	5
[x] NHS organisations in Scotland	6
[x] HSC organisations in Northern Ireland	3
[ ] GP practices in England	
[ ] GP practices in Wales	
[ ] GP practices in Scotland	
[ ] GP practices in Northern Ireland	
[ ] Joint health and social care agencies (eg community mental health teams)	
[ ] Local authorities	
[ ] Phase 1 trial units	
[ ] Prison establishments	
[ ] Probation areas	
[ ] Independent (private or voluntary sector) organisations	
[ ] Educational establishments	
[ ] Independent research units	
[ ] Other (give details)	
Total UK sites in study:	40

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

(●) Yes ( ) No

A73-2. If yes, will any of these organisations be NHS organisations?

( ) Yes (●) No

If yes, details should be given in Part C.

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The study will be monitored via an internal review process within The Healthcare Improvement Studies (THIS) Institute, to ensure adherence to good research practice. Study progress will be reported regularly to the Research Study Manager, who will in turn report to the departmental senior management group. The study may also be subject to audit or monitoring by the sponsor or funding body.

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:* in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland**

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

The study will be insured by the University of Cambridge's Public Liability and Professional Indemnity insurance policies.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

The study will be insured by the University of Cambridge's Public Liability and Professional Indemnity insurance policies.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☐ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☑ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

The study will be insured by the University of Cambridge's Public Liability and Professional Indemnity insurance policies.

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

○ Yes ○ No ◉ Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site		Investigator Name	
IN1	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email Qualification (MD...) Country	Lydia Ufton l.ufton@nhs.net United Kingdom
	Organisation name	MAIDSTONE AND TUNBRIDGE WELLS NHS TRUST		
	Address	THE MAIDSTONE HOSPITAL HERMITAGE LANE MAIDSTONE		
	Post Code	ME16 9QQ		
	Country	ENGLAND		
IN2	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email Qualification (MD...) Country	Lona Tudor Jones BCU.research&development@wales.nhs.uk United Kingdom
	Organisation name	BETSI CADWALADR UNIVERSITY LHB		
	Address	EXECUTIVE OFFICES, YSBYTY GWYNEDD PENRHOSGARNEDD BANGOR GWYNEDD		
	Post Code	LL57 2PW		
	Country	WALES		
IN3	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email Qualification (MD...)	Gwen Baxter gwen.baxter@nhs.net
	Organisation name	DUMFRIES AND GALLOWAY		

Address	MOUNTAINHALL TREATMENT CENTRE BANKEND ROAD DUMFRIES	Country	United Kingdom
Post Code	DG1 4AP		
Country	SCOTLAND		