Short Title:
Da*te*:
Study Protocol Version:

PHOTON Pre-**HO**spital **T**rainee **O**perated research **N**etwork

PHOTON is a national pre-hospital care collaborative research network with the aim "*To undertake trainee-led high quality multi-regional collaborative pre-hospital research, audit and quality improvement projects, striving to inform and develop the pre-hospital care delivered to our patients".* PHOTON is supported by the Faculty of Pre-Hospital Care of the Royal Surgeons of Edinburgh and by PHEMTA and full membership is open to all non consultant grade doctors working in pre hospital care, we currently have trainees from across England, Scotland and Wales contributing to our projects.

PHOTON aims to deliver national audit, research and improvement projects whilst taking into account the different models of pre-hospital critical care delivery seen across the country due to geography, case mix and staffing. The results of any PHOTON study will be anonymous by Air Ambulance organisation and no organisation will be identified as an outlier. Data security and confidentiality are key principles of the work of PHOTON and all our data handling and storage methods have been carefully selected to achieve this. PHOTON aim to make publicly available the results of any study that is conducted, and therefore we will submit papers for publication in relevant journals. Further details of our policies can be found in our terms of reference.

Project summary

(Like the abstract of a research paper, the project summary should be no more than 300 words and at most a page long (font size 12, single spacing). Please outline the rationale for the study and objective (introduction), the methods (including setting, timeframes, data collection), expected results and your hypothesis of the conclusion.

Protocol title, number and date

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Study sponsor and funder (name, title, address and contact number/email)

Sponsor:
Funding:

Study investigator(s) (name, title and contact number/email)

Chief Investigator:

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Principal investigator(s):

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Study investigator(s):

- See study institution list for local investigator contacts

Study institutions and/or departments (name, address and contact number/email)

Pre-Hospital Trainee Operated Research Network (PHOTON) – email
The Pre-Hospital Emergency Medicine Trainees' Association (PHEMTA) - email
HEMS Services:

- Cornwall (CAAT) – HM01: email – site investigator
- Devon (DAAT) – HM70, HM71: email – site investigator
- Dorset & Somerset (DSAA) – HM10: email – site investigator
- East Anglian (EAAA) – HM85, HM88: email – site investigator
- Essex & Hertfordshire (EHAAT) – HM07, HM55: email – site investigator
- Great Northern (GNAA) – HM58, HM63: email – site investigator
- Great Western (GWAAC) – HM65: email – site investigator
- Hampshire & Isle of Wight (HIWAA) – HM56: email – site investigator
- Kent Surrey Sussex (KSS) – HM21, HM60: email – site investigator
- Lincs & Notts (LNAA) – HM29: email – site investigator
- London (LAA) – HM27, HM28: email – site investigator
- Mid-Anglia (MAGPAS) – HM33, HM66: email – site investigator
- North West (NWAA) – HM08, HM72, HM75: email – site investigator
- Northern Ireland (NIAA) – HM23: email – site investigator
- Scotland (EMRS) – HM02, HM05: email – site investigator
- Scotland (SCAA) – HM76: email – site investigator
- Thames Valley (TVAA) – HM24: email – site investigator
- The Air Ambulance (TAAS) – HM53, HM54: email – site investigator
- Wales (EMRTS) – HM57, HM59, HM61, HM67: email – site investigator
- West Midlands (MAA) – HM03, HM06, HM09: email – site investigator
- Wiltshire (WAA) – HM22: email – site investigator
- Yorkshire (YAA) – HM98: email – site investigator

Study Rationale & Background

The Rationale specifies the reasons for conducting the research in light of current knowledge. It should include a documented statement of the need/problem that is the basis of the project, and why this is an important topic to study. It is the equivalent to the introduction in a research paper and puts the proposal in context. A full literature review MUST be completed to identify what studies have already been published on the same topic. The search strategy must be included in your submission and a description of the key findings of each paper (one sentence for each).

References

1. *Vancouver style*
2.

Study goals and objectives

(Goals are broad statements of what the proposal hopes to accomplish. They create a setting for the proposal. Specific objectives are statements of the research question(s). Objectives should be simple (not complex), specific (not vague), and stated in advance (not after the research is done). After statement of the primary objective, secondary objectives may be mentioned.)

Study Design

(The scientific integrity of the study and the credibility of the study data depend substantially on the study design and methodology. The design of the study should include information on the type of study, the research population or the sampling frame, and who can take part (e.g. inclusion and exclusion criteria, withdrawal criteria etc.), and the expected duration of the study.

Type of study –

Setting –

Research population –

Studied intervention/comparator –

Expected duration of study –

Methodology

(The methodology section is the most important part of the protocol. It should include detailed information on the interventions to be made, procedures to be used, measurements to be taken, observations to be made, laboratory investigations to be done etc. If multiple sites are engaged in a specified protocol, methodology should be standardized and clearly defined. Definitions must be made clear for the outcome measures and exactly how these will be collected so that anyone could follow the methods perfectly. There must be no ambiguity to allow reproducibility.

Intervention –

Collection platform –

Measurements:

-

Inclusion:

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Exclusion:

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Safety Considerations

(The safety of research participants is foremost. Safety aspects of the research should always be kept in mind and information provided in the protocol on how the safety of research participants will be ensured. This can include procedures for recording and reporting adverse events and their follow-up, for example. It is useful to remember that even administering a research questionnaire can have adverse effects on individuals.)

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Follow-Up

(The research protocol must give a clear indication of what follow up will be provided to the research participants and for how long. This may include a follow up, especially for adverse events, even after data collection for the research study is completed.)

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Data Management and Statistical Analysis

(The protocol should provide information on how the data will be managed, including data handling and coding for computer analysis, monitoring and verification. The statistical methods proposed to be used for the analysis of data should be clearly outlined, including reasons for the sample size selected, power of the study, level of significance to be used, procedures for accounting for any missing or spurious data etc. For projects involving qualitative approaches, specify in sufficient detail how the data will be analysed.)

Quality Assurance

(The protocol should describe the quality control and quality assurance system for the conduct of the study, including GCP, follow up by clinical monitors, DSMB, data management etc.)

Expected Outcomes of the Study

(The protocol should indicate how the results of the study could change practice and how the results will be utilized eg impact on health care, health systems, or health policies.)

Dissemination of Results and Publication Policy

(The protocol should specify not only dissemination of results in the scientific media, but also to the community and/ or the participants, and consider dissemination to the policy makers where relevant. Publication policy should be clearly discussed- for example who will take the lead in publication and who will be acknowledged in publications, etc.)

Target journal:
Lead authors: ……. on behalf of PHOTON (Pre-Hospital Trainee Operated Research Network).

Authorship credit will be based on:

1) Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
2) Drafting the article or revising it critically for important intellectual content; and
3) Final approval of the version to be published.

Authors should meet conditions 1, 2, and 3 as per the National Library of Medicine guidelines. Those assisting with the work but not meeting conditions 1, 2, and 3 will be credited as collaborators on the paper and PHOTON website.

Duration of the Project

(The protocol should specify the time that each phase of the project is likely to take, along with a detailed month-by-month timeline for each activity to be undertaken.)

Problems Anticipated

(This section should discuss the difficulties that the investigators anticipate in successfully completing their projects within the time frame stipulated and the funding requested. It should also offer possible solutions to deal with these difficulties.)

Project Management

Chief investigator: Overview and co-ordination of study, REC submission (as required) and study protocol development

Principal investigator(s): Assistant to chief investigator and direct point of contact and support for study investigator(s)

Study investigator(s):

- Site lead – Data collection and point of contact for principal investigator
- Site investigator – Data collection

Ethics

(The protocol should have a description of ethical considerations relating to the study. This should not be limited to providing information on how or from whom the ethics approval will be taken, but this section should document the issues that are likely to raise ethical concerns. It should also describe how the investigator(s) plan to obtain informed consent from the research participants (the informed consent process).) Please use the HRA decision tool and record the outcome of this in this section – http://hra-decisiontools.org.uk/research/

Informed Consent Forms

(The approved version of the protocol must have copies of informed consent forms (ICF), both in English and the local language in which they are going to be administered. However translations may be carried out after the English language ICF(s) have been approved by the ERC. If the research involves more than one group of individuals, for example healthcare users and healthcare providers, a separate specifically tailored informed consent form must be included for each group. This ensures that each group of participants will get the information they need to make an informed decision. For the same reason, each new intervention also requires a separate informed consent form. For guidance on how to write an informed consent form.)

Budget

(The budget section should contain a detailed item-wise breakdown of the funds requested for, along with a justification for each item.)

Other support

(This section should provide information about the funding received or anticipated for this project from other funding organizations.)

Collaboration

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Links to other projects

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CV of investigators

(The CV of the Principal investigator and each co-investigators should be provided. In general each CV should not be more than one page, unless a complete CV is specifically requested for.)

Please see CV folder on PHOTON Dropbox admin section for this project

Other research activities of investigators

The Principal investigator should list all current research projects that he/she is involved in, the source of funding of those projects, the duration of those projects and the percentage of time spent on each.)

1. Chief Investigator:
   - Name of investigator, project, funding, commitment
2. Principal investigator(s):
   - Name of investigator, project, funding, commitment

Financing and insurance

(Financing and insurance if not addressed in a separate agreement, and where relevant should be described.)

Appendix 1. Case Report Form

Finalised data collection form addressing all the required information fields that the investigators need to complete when contributing to this study