The UK Obstetric Surveillance System (UKOSS)

Guidance for Submitting an Application for Inclusion of a Study

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Approved by	**UKOSS Steering Committee**

1. Submitting applications to UKOSS

Applications for including a study in the UKOSS programme are considered in two stages.

Preliminary applications are considered by the UKOSS Steering Committee who meet every four months. Applicants whose projects fulfil the criteria for inclusion of studies in the UKOSS programme (see section 5) will be invited to submit a full application. UKOSS staff will provide advice and support for preliminary applicants to complete a full project proposal (please note that detailed feedback/input regarding the data collection form will be provided once full funding has been obtained).

Full applications are considered by the UKOSS Steering Committee and the study applicants will be invited to discuss the application with the Steering Committee (in person or via zoom).

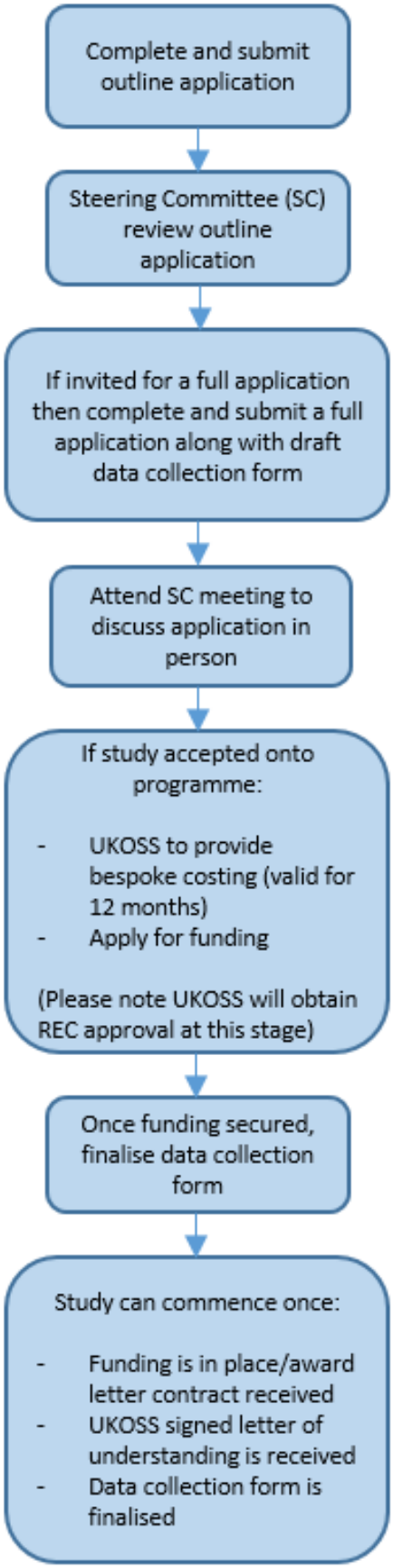
Applicants whose studies are accepted into the UKOSS programme will then be expected to obtain funding before the study can be included in the monthly report requests.

The University of Oxford has obtained Research Ethics Committee (REC) approval for UKOSS (10/H0717/20) and a substantial amendment will be made to this to include any new study.

The UKOSS study application process is illustrated in Figure 1.

Note: Application to the UKOSS programme is not a guarantee that the study will be accepted.

Figure 1. UKOSS Study Application Process



2. External Investigators' responsibilities

Investigators whose studies are included in the monthly report requests are expected to fulfil certain undertakings. This reporting system is dependent entirely on the time and effort of reporting clinicians.

2.1.1 Dissemination strategy

It is extremely important that information obtained from UKOSS studies is fed back to clinical staff in a timely manner in order that it may be used to make practical improvements in prevention and treatment of these uncommon conditions and allow for more effective service planning. Each study must therefore nominate a researcher to act as study guarantor who will undertake to make certain that the study results are submitted for publication within two years of completion of data collection. Outside of this time limit, UKOSS reserves the right to analyse and publish the data itself.

2.1.2 Reports to other relevant bodies:

If studies are included into research portfolios, the UKOSS office should be notified. Provision and uploading of accrual data, as required by the portfolio remain the External Investigator's responsibility.

3. UKOSS' responsibilities

In return for the study fee, UKOSS will undertake the following:

- Peer review of study proposal by UKOSS Steering Committee and assistance with developing a data collection instrument (Data collection form)
- Obtain REC approval for the study
- Data collection form formatting by NPEU webmaster/ designer
- Study publicity through UKOSS newsletter and mailings to individual reporters
- Collection of case notifications
- Mailing of case/control data collection forms
- Following up of missing forms
- Data gathering, validating and cleaning
- Checking back all data and double-entry into a customised database
- Querying of missing or invalid information
- Data coding, if required
- Provision of an interim dataset as per letter of agreement to enable testing of analysis procedures and abstract preparation
- Provision of a complete, clean dataset to investigators four months after completion of the study
- Provision of mentorship from Steering Committee members, if required
- Study results publicity through UKOSS newsletters and via the UKOSS website

*Note: UKOSS will function only as a data gathering and cleaning service and under usual circumstances **will not** undertake any data analysis*.

4. Fees

Each UKOSS study will have an initial bespoke costing. The cost of each study will be determined by individual study requirements (for example whether any data analysis is required by the UKOSS team) and will also depend on the study funder. UKOSS reserves the right to charge a higher amount for labour-intensive studies. Commercial organisations will be charged the full economic costs of study administration. UKOSS reserves the right to make additional charges for any study that is extended beyond the initial agreed study period.

Below is an example of a UKOSS standard model costing for a basic 12 month study.
Please note this was accurate as of March 2024, each study will have a new bespoke costing calculated once the full application has been approved.

Total charged when the original source of funds comes from a charitable organisation, this reflects 100% of our Direct costs with no overheads.
UKOSS Manager
UKOSS Admin Assistant
UKOSS Programmer/Database Manager
UKOSS Programmer/OpenClinica
Database/form/website Designer
Consumables/postage
Steering Committee costs (PPI allowance, travel, video conferencing etc.)
Total: **£28,518.11**

Total charged when the original source of funds come from a higher education institute/commercial organisation, this reflects 80% or our Direct costs and also overheads at 80%.
UKOSS Admin Assistant
UKOSS Programmer/Database Manager
UKOSS Programmer/OpenClinica
Database/form/website Designer
Consumables/postage
Steering Committee costs (PPI allowance, travel, video conferencing etc.)
Estates costs
Indirect costs
Total: **£43,901.19**

5. Criteria for inclusion of studies in the UKOSS programme

Studies are expected to fulfil three or more of the following criteria:

5.1 The condition is an important cause of maternal or perinatal morbidity and/or mortality.

5.2 The condition is an uncommon disorder of pregnancy, thus inclusion within the study programme of UKOSS will not impose too great a burden on reporting clinicians [usually no more than one case per 2000 births annually in the UK (approximately 300 cases per year in total)].

5.3 The research questions posed by the study can be suitably addressed using the UKOSS methodology (prospective descriptive, cohort or case-control studies).

5.4 Other sources of information exist to enhance and/ or assess completeness of data collection.

5.5 UKOSS will consider a UKOSS study component being included as part of larger multi-centre grant applications (such as NIHR grant applications) to run parallel with the main programme of work.

6. Study acceptance and rejection

Following final acceptance of the application and before commencement the investigator and study guarantor will be asked to sign a letter of understanding indicating agreed responsibilities in relation to the project (Appendix 1). **Please note** that final acceptance of the study by the committee does not necessarily mean that surveillance can commence immediately. The timing of study inclusion in the UKOSS programme will depend on relative disease burden and existing conditions under surveillance and commencement may be delayed because of programme balance considerations. The Head of UKOSS will be able to give an indication of a provisional commencement date at the time of acceptance.

Applicants whose studies are rejected will be sent an initial letter detailing the Steering Committee's reasons for rejection. If they wish to appeal against the decision they are requested to write a letter to the Chair of the steering committee explaining the reasons why they disagree with the grounds for the rejection stated in the steering committee letter. If the Chair feels that these reasons are valid, the project may be brought before the Steering Committee for further review.

7. Information and contact details

Preliminary enquiries are welcomed. Please contact:

Professor Marian Knight (Head of UKOSS)
Tel: 01865 289727 Email: marian.knight@npeu.ox.ac.uk

or

Mrs Melanie O'Connor (Programme Manager)
Tel: 01865 617774 Email: melanie.oconnor@npeu.ox.ac.uk

or

UKOSS Administration Team
Tel: 01865 289714 Email: ukoss@npeu.ox.ac.uk

8. Completion of Preliminary Application Form

1. Title of research
   Give the full title and indicate in brackets a short title for the research of no more than 70 characters.

2. Condition to be studied
   Give the full name with any recognised abbreviation.

3. Investigators
   Please list all investigators and indicate the Principal Investigator, principal contact and Study Guarantor. Please provide a full postal address, telephone number and email address for the principal contact.

4. Research questions
   State the aims of the study and list clearly the questions which will be answered. For example:
   - What is the current incidence of disease X in pregnancy in the UK?
   - What are the risk factors for disease X?
   - How does it present?
   - How is disease X managed in pregnancy in the UK?
   - What are the outcomes for mother and infant?

5. Background information
   This should include a brief assessment of the state of current knowledge, including any estimates of incidence with any potential regional differences and indicate the need for the study including scientific and public health importance.

Submission of Preliminary Application Form
The application form should be completed using no smaller than 10 point type and covering no more than two sides of A4 paper and emailed to ukoss@npeu.ox.ac.uk.

UK Obstetric Surveillance System

OUTLINE APPLICATION FOR INCLUSION OF A STUDY

Title of research
Condition to be studied
Investigators (Indicate Principal Investigator and principal contact with name, address, telephone number and email address)
Research Questions (explain the aims of the study and the questions you think this study might answer)
Any other background information (e.g. state of current knowledge, public health and scientific importance. Please include an estimate of current incidence)

9. Completion of Full Application Form

1. Title of research
   Give the full title and indicate in brackets a short title for the research of no more than 70 characters.

2. Condition to be studied
   Give the full name with any recognised abbreviation.

3. Investigators
   Please list all investigators and indicate the Principal Investigator, principal contact and Study Guarantor. Please provide a full postal address, telephone number and email address for the principal contact.

4. Background information
   This should include an assessment of the state of current knowledge and indicate the need for the study including scientific and public health importance. This should be in language comprehensible to a lay person.

5. Research questions
   State the aims of the study and list clearly the questions which will be answered.
   For example:
   - What is the current incidence of disease X in pregnancy in the UK?
   - What are the risk factors for disease X?
   - How does it present?
   - How is disease X managed in pregnancy in the UK?
   - What are the outcomes for mother and infant?

6. Case definition
   Please give a clear case definition for the condition of interest, with reference if available, preferably one that is internationally recognised. This definition will be given to obstetricians, anaesthetists and midwives to enable them to identify the appropriate cases and should be clear and unambiguous with any unfamiliar terms explained fully.

7. Expected numbers
   Please give an estimate of the expected number of cases per year and describe the information on which this estimate was based. Any possible regional differences in incidence should be included.

8. Proposed duration of study
   The normal study duration is 12 months. Give justification if a longer study duration is proposed.

9. Planned methodology
   Indicate whether the planned study is of descriptive, case-control or cohort design. If data is to be collected on a control or comparison group of women, justify their inclusion and describe any risk factors or confounders to be studied. Provide a simple power calculation if possible.

10. Alternative sources of information
    Describe any other sources of information (e.g. CMACE, hospital episode statistics) about the disease in question. If other groups of clinicians, e.g. radiologists, pathologists, cardiologists are likely to see cases, it is essential that plans are made to seek cases through them as this improves ascertainment and reduces bias.

11. Justification
    Describe why UKOSS is the best mechanism for conducting your research and justify why this disorder should be included in the programme.

12. Funding
    Outline the potential funding arrangements for the project, naming the body(ies) to which applications will be submitted and giving the date by which the outcome of such applications will be known.

13. Additional documents to be submitted
    Attach the CV of the Study Guarantor (maximum 2 pages), a detailed research protocol and draft data collection form(s) which will be used to further assess studies which have been successful in the preliminary application process. The protocol should include the following: aims, background, methods (research design, case definition, plans to monitor ascertainment, statistical analyses), costs and resources, ethics approval, project management, dissemination and publication. The following checklist should be used when preparing the data collection form(s) to ensure that the data collection burden for reporting clinicians is not onerous and meets UKOSS and ethical guidelines. Please include a copy of the checklist on the front of your draft data collection form(s).

14. Checklist for data collection forms
    The following points should be considered when submitting a data collection from to UKOSS:

	Yes/No
Is the case definition included on the front of the form?	
Is all information requested anonymous?	
Can all the information be obtained from the woman's current maternity notes?	
Can you justify all the included questions in terms of your plans for data analysis?	
Are standard UKOSS questions (see current forms) used where appropriate?	
Are closed (yes/no or simple numerical response) questions used as far as possible for new questions?	
Are required free text responses brief? (As a guide, no answer should require more than a three or four word answer, with the exception of section 7).	
Are dates rather than durations used as far as possible? (E.g. use date drug started and date drug stopped rather than duration of drug use).	
Are the questions comprehensible to all UKOSS reporting clinicians (obstetricians, midwives and obstetric anaesthetists)?	
Are any unusual or non-standard terms defined at the end of the form?	
Are the questions arranged in the standard UKOSS form sections (1-8)?	
Do the questions cover no more than three sides of A4 in word format (excluding sections 7 and 8)?	

Please note that detailed feedback/input regarding the data collection form will be provided once full funding has been obtained.

UK Obstetric Surveillance System

FULL APPLICATION FOR INCLUSION OF A STUDY

Title of research
Condition to be studied
Investigators (Indicate Principal Investigator, study guarantor* and principal contact with name, address, telephone number and email address)
Background (explain the need to study the condition and include state of current knowledge, public health and scientific importance)
Principal research questions
Case definition
Expected numbers (please supply an estimate of the expected number of cases per year)

Proposed duration of study
Planned methodology (descriptive, case-control or cohort; if data is to be collected on a control or comparison group of women, justify their inclusion and describe any risk factors or confounders to be studied. Provide a simple power calculation if possible)
Alternative sources of information (Identify any other sources from which information about this condition may be obtained and indicate any plans to use these sources)
Justification (Justify why you think this disorder is of importance and why it should be included in the UKOSS programme)
Funding (Outline possible funding arrangements and name the bodies to which a grant application will be submitted)

1. Additional documents to be submitted

Attach the CV of the Study Guarantor (maximum 2 pages) and a detailed research protocol and draft data collection form(s) which will be used to further assess studies which have been successful in the preliminary application process. The protocol should include the following: aims, background, methods (research design, case definition, plans to monitor ascertainment, statistical analyses), costs and resources, ethics approval, project management, dissemination and publication. The data collection form(s) should follow the attached checklist.

*The Study Guarantor undertakes to ensure that results of studies are submitted for publication within two years of completion of data collection.

10. APPENDIX 1: UKOSS Letter of Understanding

Dear Investigator,

UKOSS LETTER OF UNDERSTANDING

The UKOSS Steering Committee has approved the 'XXX' study and we are looking forward to placing it on the monthly report for 'XX' months. There are some particular points that need to be agreed between the investigator and UKOSS.

Investigator fee

The investigator will be required to pay the fee of £XX through quarterly invoices during the study. The cost of each study will be determined by individual study requirements and will also depend on the study funder. In the event of the extension of the study beyond its original agreed period, the fee will be reviewed by the UKOSS Steering Committee and a further charge may be made as appropriate.

Conduct of the Study

UKOSS is based at the NPEU, a department of the University of Oxford. The University of Oxford has obtained REC approval for the study (10/H0717/20). The University of Oxford shall act as Sponsor of the study and Professor Marian Knight of the University of Oxford shall act as Chief Investigator. The Investigator must provide the Sponsor and Chief Investigator with such assistance and information as is reasonably required for the Sponsor and/or Chief Investigator to be able to conduct the Sponsor/Chief Investigator's duties and responsibilities in respect of the study.

The draft data collection form, once approved by the UKOSS Steering Committee, will be reformatted to the UKOSS standard design, and should not exceed 4 sides of A4 at this stage.

Reporting Study Findings

The study has been approved by UKOSS because important clinical or public health issues are being addressed so publication of the findings is expected. All investigators are expected to provide a short summary of the outcomes of the project for the UKOSS newsletter in the year following completion of data collection. Where appropriate, and with agreement of the chapter authors, summary results will be included in the appropriate chapter of the UK Confidential Enquiry into Maternal Deaths report.

Pending submission of the final results for publication, investigators are expected to present the results at appropriate conferences, noting particularly the annual meetings of the British Maternal Fetal Medicine Society and the Obstetric Anaesthetists Association. In order to facilitate this, investigators will be provided with an interim dataset to include information on all cases reported before the mid-point of the study. These data will be provided four months after the mid-point of the study in order to allow sufficient time for completion of data collection forms. Where such abstracts are presented, the UKOSS Steering Committee should be supplied with a copy of the abstract upon acceptance.

Study investigators are expected to submit full results for publication in a peer-reviewed journal within two years of the completion of data collection. The UKOSS Steering Committee should be supplied with a draft copy of any report before submission for publication, and similarly a copy of the final version of the paper upon acceptance. Papers must not be submitted for publication without prior review by member of the Steering Committee. A description of the UKOSS methodology has been prepared and

should be used as the basis for the description of the UKOSS methodology in any publication based on the UKOSS system, available via the UKOSS office.

References to all completed studies will be listed both in the UKOSS newsletter and on the UKOSS website, and requests for reprints will be addressed to the study investigators where these are received by UKOSS. Investigators will be asked to supply copies of any completed papers for the Department of Health and the Scientific Advisory Committees of the RCOG, RCM and OAA.

Content and title of papers and presentations are entirely at the discretion of the researcher. UKOSS does not require its acknowledgement in the title of a paper or collectively in the list of authors. Researchers will be required to include a disclaimer in any publication stating that the views expressed do not necessarily represent those of the UKOSS Steering Committee. The Steering Committee retains a right of veto over any publications that it regards to be scientifically unsound. In order to minimise the risk of this happening, the Steering Committee will undertake to provide or locate appropriate mentorship for less experienced researchers on request.

When a member of the committee contributes to a project to such an extent that the study or resulting paper could not be completed without their contribution, and they meet the ICMJE criteria for authorship of scientific papers, they should be included as an author of any resulting papers.

UKOSS and the clinicians contributing to it should be acknowledged as follows in any relevant papers or presentations: "this work would not have been possible without the contribution of the clinicians reporting to UKOSS who have supplied information".

Professor Marian Knight acts as overall guarantor for UKOSS. However, each study must nominate a researcher to act as individual study guarantor who will undertake to make certain that the study results are submitted for publication within two years of completion of data collection. Outside of this time limit, Professor Marian Knight will take on this role and UKOSS reserves the right to analyse and publish the data itself.

Please let me know of any problems that arise and of any other advice or assistance you may require.

Yours sincerely,

Professor Marian Knight

Head of UKOSS

UKOSS LETTER OF UNDERSTANDING

I have read and agreed to the conditions outlined in the UKOSS letter of understanding.

Signed:
Date:

11. APPENDIX 2: UKOSS Dissemination Strategy

1. Background

The UK Obstetric Surveillance System has been developed to address important clinical and public health issues concerning different rare disorders of pregnancy. One of the main aims of UKOSS is to provide information which can be used to improve prevention and treatment of these rare conditions. In order to achieve this aim, appropriate dissemination of study results is key[1]. Additionally, UKOSS relies on clinicians to report cases and complete data collection. It is vital to maintain the enthusiasm for reporting to UKOSS by providing prompt and timely feedback of study results to these clinicians in order that they may use the information gained to help in day to day clinical practice.

2. Dissemination methods

2.1 Studies in progress

Before studies commence, a short article describing the background and aims of the study will be included in the UKOSS newsletter. This newsletter will be distributed to all reporting clinicians, steering committee members, Directors of Public Health in Strategic Health Authorities and Health Boards, Chief Medical Officers, Voluntary Groups in the Perinatal Field, the UK Department of Health, the Patient Safety Observatory and will be freely available on the UKOSS website. During data collection, study updates in terms of cases collected will be included in the newsletter.

In order to facilitate testing of analysis strategies and presentation at appropriate scientific conferences, investigators will be provided with an interim dataset to include information on all cases reported before the mid-point of the study. These data will be provided four months after the mid-point of the study in order to allow sufficient time for completion of data collection forms.

2.2 Completed studies

All investigators may be asked to provide a short summary of the outcomes of the project for the UKOSS Newsletter in the year following completion of data collection. Where appropriate, and with agreement of the chapter authors, summary results will be included where appropriate in the MBRRACE-UK Confidential Enquiry into Maternal and Child Health ‘Saving Lives, Improving Mothers’ Care’ report.

Pending submission of the final results for publication, investigators will be encouraged to present the results at appropriate conferences, noting particularly the annual meetings of the British Maternal Fetal Medicine Society (BMFMS) and the Obstetric Anaesthetists’ Association (OAA). Where such abstracts are presented, the UKOSS Steering Committee should be supplied with a copy of the abstract upon acceptance.

[1] Canadian Health Services Research Foundation. Developing a dissemination plan. Ottawa: CHSRF. Available at: http://www.chsrf.ca/knowledge_transfer/communication_notes/comm_note_dissemination_plan_e.php

Study investigators will be asked to give an undertaking to submit full results for publication in a peer-reviewed journal within two years of the completion of data collection. The UKOSS Steering Committee should be supplied with a draft copy of any report before submission for publication, and similarly a copy of the final version of the paper upon acceptance. References to all completed studies will be listed both in the UKOSS newsletter and on the UKOSS Website, and requests for reprints will be addressed to the study investigators where these are received by UKOSS. Investigators will be asked to supply copies of any completed papers for the Department of Health, the Scientific Advisory Committees of the Royal College of Obstetricians and Gynaecologists (RCOG), the Royal College of Midwives (RCM), OAA and the Child and Maternal Health Observatory (ChiMat).

Where the Steering Committee judges it appropriate, in consultation with the investigators and appropriate journal, a news release may be made to the media upon publication of particularly notable results.

3. Adoption

Study investigators will be asked to agree to abide by this dissemination strategy as part of the Letter of Agreement on acceptance of their study.

Prof. Marian Knight