The UK Midwifery Study System (UKMidSS)

Guidance for Submitting an Application for Inclusion of a Study or Survey of Practice

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Approved by	**UKMidSS Steering Committee**

1. Submitting applications to UKMidSS

Applications for supporting a project within the UKMidSS programme are considered in two stages (Figure 1 and Figure 2) which vary depending on whether the application is for an observational (case control or cohort) study (referred to below as 'studies') or for a survey of practice (referred to below as 'surveys').

For a study or survey, preliminary applications (Appendix A) are considered by the Head of UKMidSS and the UKMidSS Research Midwife.

For a **survey of practice** that fulfils the criteria for support within the UKMidSS programme (below), the application will then be considered by the UKMidSS Steering Group, which meets every four months. A full application will not be required.

For a **study**, once a preliminary application is approved by the Head of UKMidSS and the UKMidSS Research Midwife, applicants will be notified and will then need to complete and submit a full application (Appendix B) that will be reviewed by the Steering Group.

It is an expectation that applicants demonstrate Public Patient Involvement (PPI) in the design and conduct of the studies or surveys when submitting an application. Public involvement improves the quality and relevance of research as it can provide personal knowledge and experience relevant to the research topic, or it can provide a more general societal perspective[1]. Further guidance on PPI involvement is available on the NIHR website[2].

Applicants whose studies and surveys are accepted to be supported by the UKMidSS programme will be expected to obtain funding where necessary, and appropriate ethics approval should be sought before the commencement of the study. For studies, UKMidSS has NHS Research Ethics Committee (REC) approval (15/SW/0166) and a substantial amendment will be submitted to include any new study. For surveys, NHS REC approval is not typically required, but we expect applicants to obtain other appropriate research ethics approval, e.g. the University of Oxford Central University Research Ethics Committee or other institutional ethics approval as appropriate.

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

2. External investigators' responsibilities

Investigators whose studies/surveys are supported by UKMidSS are expected to fulfil certain undertakings. UKMidSS is dependent entirely on the time and effort of reporting midwives.

2.1 Dissemination

It is extremely important that information obtained through UKMidSS studies and surveys is fed back to midwives in a timely manner in order that it may be used to make practical improvements and allow for more effective service planning. Each study/survey must therefore nominate a researcher to act as guarantor who will undertake to make certain that the study/survey results will be disseminated within two years of completion of data collection. Outside of this time limit, UKMidSS reserves the right to analyse and publish the data itself.

[1] Briefing notes for researchers - public involvement in NHS, health and social care research. Available at: https://www.nihr.ac.uk/documents/briefing-notes-for-researchers-public-involvement-in-nhs-health-and-social-care-research/27371

[2] PPI (Patient and Public Involvement) resources for applicants to NIHR research programmes. Available at https://www.nihr.ac.uk/documents/ppi-patient-and-public-involvement-resources-for-applicants-to-nihr-research-programmes/23437#Standards_for_Public_Involvement

2.2 Reports to other relevant bodies:

If studies are included in research portfolios, the UKMidSS office should be notified. Provision and uploading of accrual data, as required by the portfolio, remain the external investigator's responsibility.

3. UKMidSS' responsibilities

In return for a fee, UKMidSS will undertake the following:

- For all studies/surveys:
    - Peer review of study/survey proposal by UKMidSS Steering Group
    - Assistance with developing a data collection instrument (electronic case report form for studies and electronic data collection form for surveys)
    - Study publicity throughout, including with the results, through UKMidSS newsletter and mailings to reporters
    - Provision of mentorship from Steering Group members, if required
- For studies:
    - Obtain NHS REC approval
    - Case report form programming by NPEU programmers
    - Monitoring case reporting and data entry and sending chasing and status report emails to reporters as required
    - Data gathering, validating and cleaning
    - Querying of missing or invalid data
    - 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 within six months after completion of the study
- For surveys:
    - Support to obtain appropriate research ethics approval
    - Support to programme data collection form
    - Sending survey invitation and reminder emails to reporters

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

4. Fees

Each UKMidSS study will have an initial bespoke costing of around £20,000. The cost of each study will be determined by individual study requirements (for example whether any data analysis is required by the UKMidSS team) and will also depend on the study funder. For studies where the investigator is applying for external funding (e.g. from NIHR) UKMidSS will provide a full economic costing (FEC) of the time and work involved. UKMidSS reserves the right to charge a higher amount for labour-intensive studies and for commercial organisations, and to make additional charges for any study that is extended beyond the initial agreed study period.

For surveys, there will be a charge of around £2000, which may be open to negotiation, for example for student projects.

5. Criteria for inclusion of studies/surveys in the UKMidSS programme

Studies/surveys are expected to fulfil the following criteria:

5.1 The research project must be in line with the UKMidSS research objectives and priorities [3]
5.2 The inclusion within the study programme of UKMidSS will not impose too great a burden on reporting midwives.
5.3 The research questions posed by the study can be suitably addressed using the UKMidSS platform
5.4 For surveys of practice, the questions can be reasonably answered by UKMidSS reporters.

6. Application acceptance and rejection

Following final acceptance of the application and before commencement the investigator and guarantor will be asked to sign a letter indicating agreed responsibilities in relation to the project (Appendix C). **Please note** that final acceptance of the study/survey by the Steering Group does not necessarily mean that the project can commence immediately. The timing of study inclusion in the UKMidSS programme will depend on existing burden on reporters and commencement may be delayed because of programme balance considerations. The Head of UKMidSS will be able to give an indication of a provisional commencement date at the time of acceptance.

Applicants whose surveys/studies are rejected will be sent a letter detailing the Steering Group'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 Group explaining the reasons why they disagree with the grounds for the rejection stated in the Steering Group letter. If the Chair feels that these reasons are valid, the project may be brought before the Steering Group for further review.

7. Information and contact details

Preliminary enquiries are welcomed. Please contact:

Associate Professor Rachel Rowe (Head of UKMidSS)
Tel: 01865 289713 Email: rachel.rowe@npeu.ox.ac.uk

Alessandra Morelli (Research Midwife)
Tel: 01865 617774 Email: alessandra.morelli@npeu.ox.ac.uk

[3] Rowe, R.E., Kurinczuk, J.J., Hollowell, J. and Knight, M., 2016. The UK Midwifery Study System (UKMidSS): a programme of work to establish a research infrastructure to carry out national studies of uncommon conditions and events in midwifery units. *BMC Pregnancy and Childbirth*, *16*(1), pp.1-6.

Figure 1.Process for submitting an application for inclusion of a survey of practice

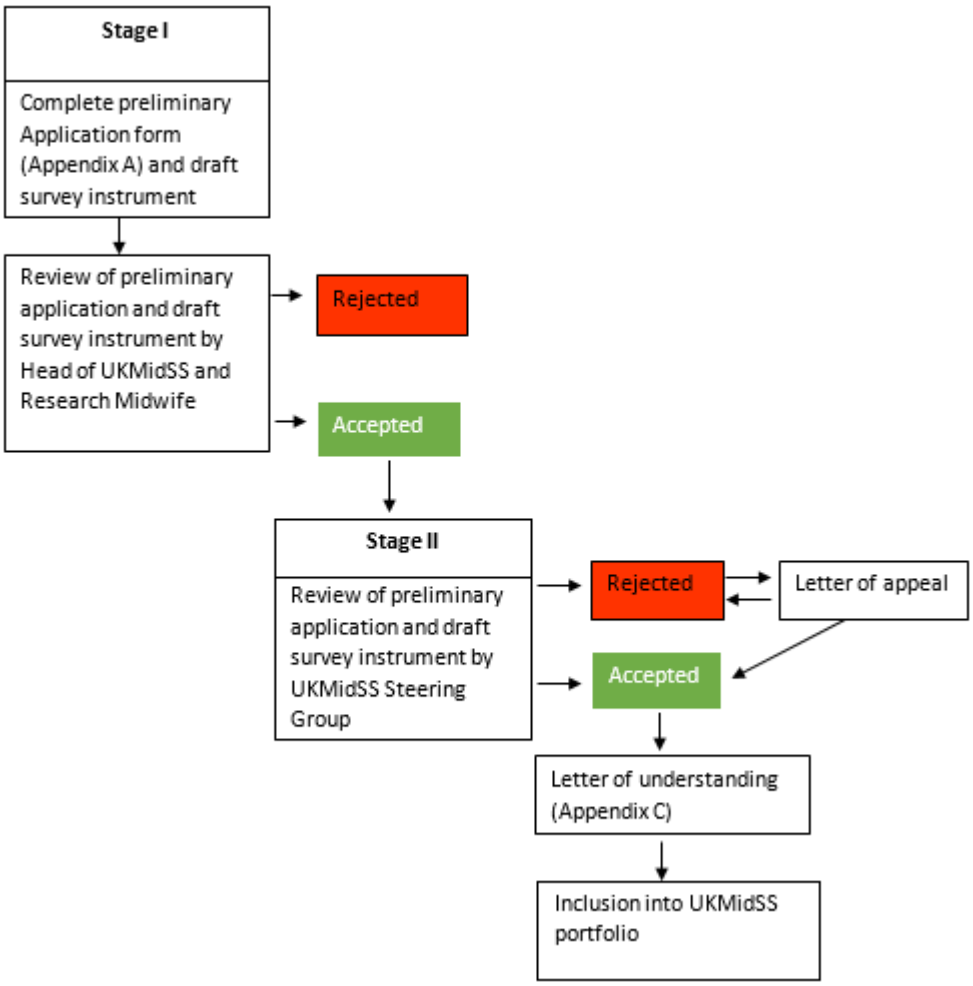
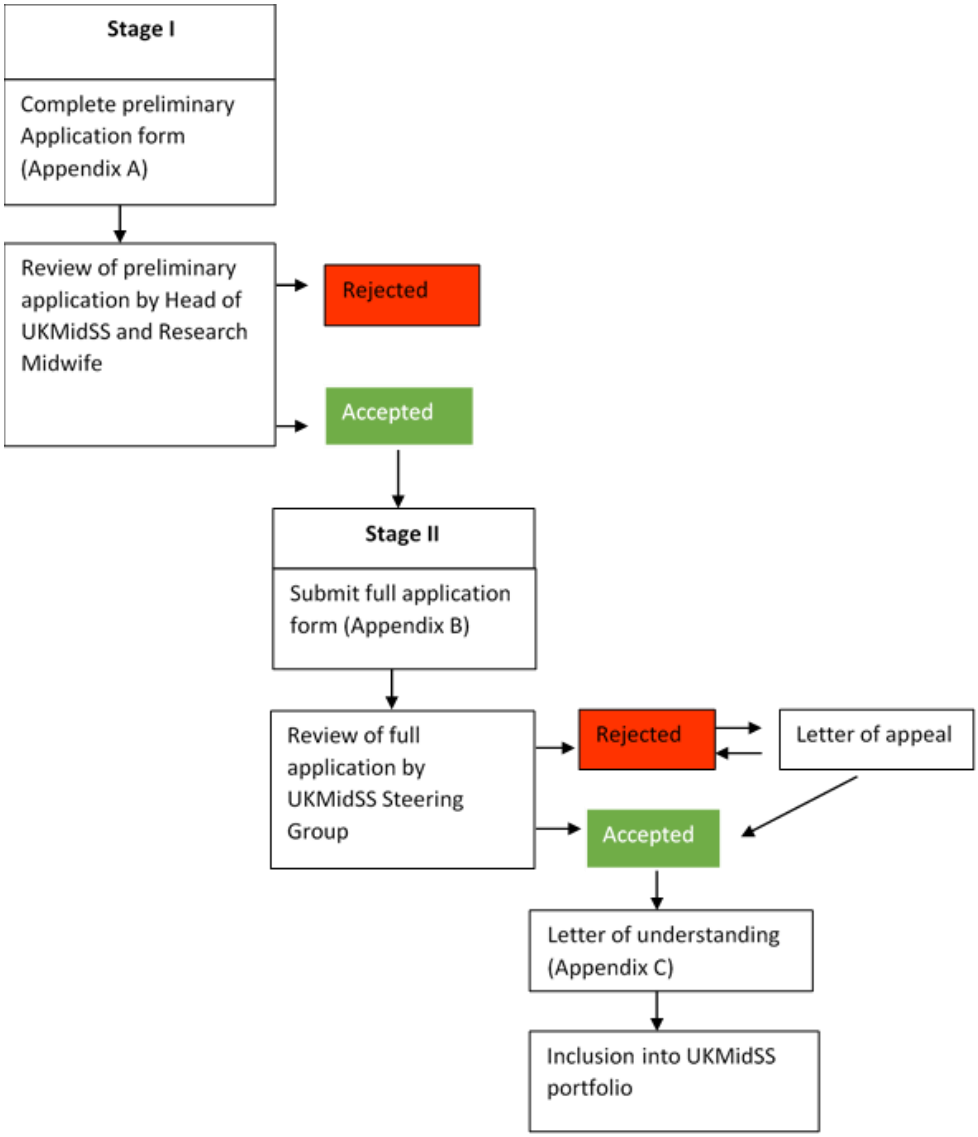


Figure 2.Process for submitting an application for inclusion of a study (cohort or case-control)



8. Completion of preliminary application form (Appendix A)

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. **Investigators**
   Please list all investigators and indicate the Principal Investigator, principal contact and guarantor. Please provide a full postal address, telephone number and email address for the principal contact. For student projects, please list all academic supervisors and indicate the lead supervisor.

3. **Background information**
   This should include a brief assessment of the state of current knowledge and indicate the need for the study/survey including scientific and public health importance. This section should clearly demonstrate PPI involvement in the design of the research project.

4. **Research questions**
   State the aims of the study/survey and list clearly the questions that will be answered.

5. **Justification for use of UKMidSS**
   Briefly outline your reasons for believing that UKMidSS is the appropriate platform to use for this research. For surveys of practice this will include consideration of why UKMidSS reporters are appropriate people to be completing the survey.

6. **Funding**
   For surveys of practice only, indicate what funding is available to support the project.

7. **Additional documents required**
   For surveys of practice only, attach a draft data collection form.

9. 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: ukmidss@npeu.ox.ac.uk

10. Completion of full application form (Appendix B)

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 or event to be studied**
   Give the full name with any recognised abbreviation.

3. **Researchers/Investigators**
   Please list all researchers/investigators and indicate the Principal Investigator, principal contact and guarantor. Please provide a full postal address, telephone number and email address for the principal contact. For student projects, please list all academic supervisors and indicate the lead supervisor.

4. **Background information**
   This should include a brief assessment of the state of current knowledge and indicate the need for the study/survey including scientific and public health importance. This section should clearly demonstrate PPI involvement in the design of the research project.

5. **Research questions**
   State the aims of the study and list clearly the questions which that will be answered.

6. **Proposed methodology**
   Give an overview of the type of research design for the project. 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.

7. **Expected numbers**
   Please give an estimate of the expected number of cases/answers.

8. **Proposed duration of study**
   Please provide a proposed duration for the study

9. **Alternative sources of information**
   Describe any other sources of information (e.g. MBRRACE-UK, hospital episode statistics) for the project in question.

10. **Justification**
    Describe why UKMidSS is the best mechanism for conducting your research and justify why this project should be included in the programme.

11. **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.

12. **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, PPI involvement, 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 UKMidSS and ethical guidelines. Please include a copy of the checklist on the front of your draft data collection form(s).

	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 UKMidSS 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).	
Are the questions comprehensible to all UKMidSS reporting midwives?	
Are any unusual or non-standard terms defined at the end of the form?	
Are the questions arranged in the standard UKMidSS form sections?	
Do the questions cover no more than 12 pages of A4 in word format?	

Appendix A

Preliminary application for UKMidSS study/survey

Title of research
Investigators (Indicate Principal Investigator and principal contact with name, address, telephone number and email address. For student projects include all academic supervisors and indicate lead supervisor)
Background information (a brief assessment of the state of current knowledge and indicate the need for the study/survey including scientific and public health importance)
Research questions (explain the aims of the study and the questions you think this study might answer)
Justification for use of UKMidSS (outline your reasons for believing that UKMidSS is the appropriate platform to use for this research. For surveys of practice include consideration of why UKMidSS reporters are appropriate people to be completing the survey)
Funding (for surveys of practice only, indicate what funding is available to support the project)
Additional document to be submitted (for surveys of practice only, draft data collection form)

Appendix B

Full application for a UKMidSS study

Title of research
Condition/event to be studied
Researchers/Investigators (Indicate Principal Investigator and principal contact with name, address, telephone number and email address. For student projects include all academic supervisors and indicate lead supervisor)
Background information (a brief assessment of the state of current knowledge and indicate the need for the study/survey including scientific and public health importance)
Research questions (explain the aims of the study and the questions you think this study might answer)
Planned methodology
Expected numbers (please supply an estimate of the expected number of cases per year)
Proposed duration of the study
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 (Explain why you think this condition/event is of importance and why it should be included in the UKMidSS programme)
Funding (Outline possible funding arrangements and name the bodies to which a grant application will be submitted)
Additional documents to be submitted (CV of the Study Guarantor (maximum 2 pages), detailed research protocol and draft data collection form(s))

Appendix C

UKMidSS Letter of Understanding

Dear Investigator,

UKMidSS Letter of Understanding

The UKMidSS Steering Group has approved the 'XXX'. There are some particular points that need to be agreed between the investigator and UKMidSS.

Conduct of the survey/study

UKMidSS is based at the NPEU, in the University of Oxford. The University of Oxford has obtained REC approval for the study (15/SW/0166). Ethics approval for a survey of practice carried out using UKMidSS is the responsibility of the researcher. The researcher is expected to provide the Head of UKMidSS with such assistance and information as is reasonably required to be able to conduct the study.

The draft data collection form, once approved by the UKMidSS Steering Committee, will be reformatted to the UKMidSS standard design where appropriate.

Reporting Survey/Study Findings

The survey/ study has been approved by UKMidSS because important clinical or public health issues are being addressed, so dissemination of the findings is expected. All researchers are expected to provide a short summary of the outcomes of the project for UKMidSS in the year following completion of data collection.

Researchers, where applicable, are expected to submit full results for publication in a peer-reviewed journal within two years of the completion of data collection. One or more members of the Steering Group will be identified to closely monitor the study prior to the commencement of the project, and they will be expected to be co-authors on relevant papers. The UKMidSS 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 UKMidSS methodology has been prepared and should be used as the basis for the description of the UKMidSS methodology in any publication based on the UKMidSS system, available via the UKMidSS office.

References to all completed studies will be listed on the UKMidSS website, and requests for reprints will be addressed to the study investigators where these are received by UKMidSS. Investigators will be asked to supply copies of any completed papers.

Content and title of papers and presentations are subject to approval of the Head of UKMidSS. UKMidSS requires its acknowledgement in the title of a paper or collectively in the list of authors. The Steering Group 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.

UKMidSS 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 midwives reporting to UKMidSS".

Associate Professor Rachel Rowe acts as overall guarantor for UKMidSS. However, each survey/ study must nominate a researcher to act as individual study guarantor who

will undertake to make certain that the results are submitted for publication, where appropriate, within two years of completion of data collection. Outside of this time limit, Associate Professor Rachel Rowe will take on this role and UKMidSS 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,

Associate Professor Rachel Rowe

Head of UKMidSS

UKMidSS LETTER OF UNDERSTANDING

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

Signed:

Date:

APPENDIX D: UKMidSS Dissemination Strategy

1. Background

UKMidSS has been set up to establish an infrastructure for investigating uncommon events and conditions in midwifery units, and carrying out national surveys of practice, with a view to providing robust evidence on the quality, safety and benefits of midwifery-led intrapartum care. Effective dissemination of the results of UKMidSS studies is key to the success of the system. In addition, UKMidSS relies on a network of collaborating midwives for notification of cases and data collection. Regular communication with these midwives and prompt reporting of the results of studies will help engage them with the research and enable them to use the information provided to inform their clinical practice.

2. Dissemination methods

2.1 Studies/surveys in progress

Quarterly newsletters describe the background and aims of UKMidSS studies/surveys in development and in progress. Before studies/surveys commence, a short article describing the background and aims will be included in the UKMidSS newsletter. They will also provide up-to-date information on cases notified and data collection completeness. This newsletter will be distributed to all reporting midwives, Steering Group members, RCM Heads and Heads of Midwifery and will be freely available on the UKMidSS website.

2.2 Completed studies

The results of UKMidSS studies and surveys will be submitted for publication in peer-reviewed journals and for presentation at appropriate national and international conferences, e.g. Normal Labour & Birth, British Maternal & Fetal Medicine Society, International Confederation of Midwives. Authorship will follow standard academic rules. For each study/survey, a subgroup of the UKMidSS Steering Group, which will be agreed at the time that the inclusion of the study/survey is approved, will work closely on the named study/survey and co-author the related paper. The UKMidSS Steering Group will receive a draft copy of any manuscript before submission for publication, and similarly a copy of the final version of the paper upon acceptance.

A short summary of the results of UKMidSS studies will be posted on the UKMidSS website and disseminated through the UKMidSS Twitter account.

Researchers leading external studies, where appropriate, 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.

Where the Steering Group 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 Understanding on acceptance of their study.