


Project Ref No/ID:

Research Office
1st Floor, Gloucester House
Queen Alexandra Hospital
Cosham
Portsmouth
PO6 3LY

Tel: 023 9228 6236
Fax: 023 9228 6037
Email: research.office@porthosp.nhs.uk

DESIGN REVIEW FORM

Front sheet details are confidential

▪ Name of Reviewer:	Dr Fraser Brims
▪ Institution/Organisation :	Lung Institute of Western Australia
▪ Reviewer's Signature:	

Project Ref No/ID:

RESEARCH DESIGN REVIEW FORM

Thank you for agreeing to provide a Design Review of the enclosed research proposal on behalf of the Portsmouth Hospitals NHS Trust. Please complete your assessment on this form and qualify your views where possible. The R&D Office staff can be contacted at any time should you have questions or concerns about the peer review process. Please note that the R&D Office will arrange for a separate review of strategic relevance or 'Topic Area'. Your assessment will be passed unattributed to the research team.

On completion of your review **please sign the front sheet** and return this form to the R&D Office.

R&D Office Use Only			
Project Details:		Dates:	
Title:	The SENSOR Study: A mixed-methods study of <u>SE</u>lf-management checks to predict exacerbatio<u>Ns</u> of Pseudomonas aeruginosa in patients with long-term re<u>SpiratORy</u> conditions.	Sent to Reviewer On:	
Local Ref No:		To be Returned By:	
Principle Investigator Details:		Enclosures:	
Name:		Protocol:	
Institution:		C.V. Details:	
		Other:	

RESEARCH DESIGN REVIEW FORM

Please provide your views on any aspect of the project proposal, commenting specifically on the numbered areas identified in the left-hand column. Please then provide a summary of your views in the table overleaf. Both assessments will be copied and passed, unattributed, to the lead researcher.

1. Research Quality	
<p>Please give your opinion on the overall quality of the design.</p> <p>Prompts:</p> <p>Background and literature: Is the current state of knowledge outlined, well structured, coherent and well -referenced?</p> <p>Question: Is there a clear research question/ purpose, which leads on from the background and literature?</p> <p>Objectives: Are the objectives clearly stated, appropriate and achievable?</p> <p>Design: Is there a rationale for the approach? Are the methods chosen suitable and appropriate? Is the sample population described with reasons given for sample size? Will the sample size provide meaningful data once analysed? Are the research tools (such as questionnaires /interviews) well structured, informed, and suitable for analysis?</p> <p>Analysis: Is there an effective analytical plan?</p>	<p>Yes</p> <p>Yes</p> <p>Yes</p> <p>Yes. What is the likelihood of drop out from the study? Should this be incorporated - or will the numbers allow for this?</p> <p>Covered briefly - A formal statistical analysis plan needs to be developed to better define the analysis plan.</p>

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Any General Comments/Overall Assessment

Please clearly state any **specific changes** you would require to the protocol/research team

Suggest consider defining 'worsening symptoms' in the primary endpoint - (eg worsening SOB, cough, sputum production)

Inclusion criteria - is it correct to use the term 'infected with PA or HI' - should this be 'previous culture or colonised with ' ?

Is it OK to assume an equal exacerbation rate for those with PA and HI ?

Thank you for taking the time to complete this design review on behalf of Portsmouth Hospitals NHS Trust.

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