Manchester
Academic Health Science Centre
Trials Co-ordination Unit

Trial Adoption Request for Collaboration Form

CHIEF INVESTIGATOR		
Surname	First Name	Initials
Address		
Town/City	County	Postcode
Phone No.	E-mail Address	
Current Employer		
Honorary Contracts		
GCP Training	No ○ Yes ○	Date of GCP Training
Have you previously acted as CI?	No ○ Yes ○	Please indicate number / type of studies

STUDY DETAILS		
Title		
Acronym		
Name of Sponsor(s)		
Has the study been discussed with the Sponsor?		No ○ Yes ○
If 'yes' please provide details	Date	Meeting held with:
Has the study been discussed with MAHSC-CTU?		No ○ Yes ○
If 'yes' please provide details	Date	Meeting held with:

STUDY TYPE – Please complete the relevant section	
Is the study a Clinical Trial of an Investigational Medicinal Product (CTIMP)?	No ○ Yes ○ Don't know ○

Clinical Trial of an Investigational Medicinal Product		
Name of IMP(s)		
Is the IMP licensed for this disease indication?	No ○ Yes ○	
Is the IMP provided by a company/funder?	No ○ Yes ○	Name of company
Will the IMP provider provide labelling, QP release and distribution of the IMP?	No ○ Yes ○	Details and/or comments

Clinical Trial of a Medical Device		
Is the medical device licensed for this disease indication?	No ○ Yes ○	
Is the medical device CE marked?	No ○ Yes ○	
Is the medical device provided by company/funder?	No ○ Yes ○	Name of company

Other Clinical Trial or Clinical Investigation		
☐ Screening and Prevention	☐ Complex Intervention	☐ Surgery
☐ Diagnostic Test Evaluation	☐ Radiotherapy	☐ Psychological and behavioural
☐ Human Tissue (Sample and Data)	☐ Questionnaires Only	☐ Qualitative Study
☐ Other	Please specify:	

Translational work	
Will the study involve any translational work?	No ○ Yes ○
Please state which labs will be used:	
Please state what samples will be analysed:	

PHASE/TYPE		
☐ I	☐ II	☐ III
☐ Translational	☐ Pilot	☐ Feasibility
☐ Open Label	☐ Blinded	☐ Randomised
☐ Cluster Randomised	☐ Placebo Controlled	☐ Observational
☐ Single Centre	☐ Multicentre	☐ Other
Please Specify:		

STUDY SYNOPSIS
Background/Brief Summary of Evidence
Aims
Methods

PICOS (Participant, Intervention, Control and Study/Statistical design)	
P– Participant group(s)	
I – Intervention(s)	
C– Control	
O – Outcome and follow up period	
S – Study/Statistical design (e.g. RCT)	

TRIAL DEVELOPMENT AND SAMPLE SIZE CALCULATIONS	
An estimate of your primary study outcome measure for the control group (e.g. response rate expected without the new intervention)	
The clinical significant difference you would want to observe between groups for the study to be convincing (e.g. be worthwhile for funders and patients, change practice)	
Please provide sources/ justification for these estimates from pilot work/ literature	
Proposed sample size	

RECRUITMENT	
Anticipated number of UK sites	
Anticipated number of European sites	
Number and names of sites already identified as willing to participate	
Age range of participants	
Please describe your recruitment plan and how do you arrived at this recruitment rate/figures? Please provide sources/justification for these estimates from pilot work/literature	
What are the plans to address potential recruitment issues? (E.g. opening of additional/ international sites)	

Have you made contact with a research network or national specialty group(s)?	No ○ Yes ○
Does the trial intend to recruit any vulnerable participants? (e.g. elderly, those with mental capacity issues, prisoners)	No ○ Yes ○
Are there likely to be any recruitment issues? (e.g. where the participant will be recruited, who will recruit the participant)	No ○ Yes ○
Please specify	

ESTIMATED STUDY TIMELINES	
Estimated total trial duration in months (First participant first visit – Last participant last visit)	
Estimated study set-up duration in months	
Estimated recruitment duration in months	
Estimated follow-up duration in months	
Estimated duration of the intervention per participant in months	

Planned trial duration per participant in months	
Estimated close-out (analysis and study report duration) in months	
Estimated start of set-up date	
Estimated recruitment start date	
Estimated end of follow up	

INDUSTRY INVOLVEMENT		
Is this study part of industry collaboration?	No ○ Yes ○	Comments
Will the results of this study be used for marketing authorisation or CE marking?	No ○ Yes ○	Comments

RESEARCH DESIGN SERVICE	
Has the study design been discussed with the RDS?	No ○ Yes ○

HEALTH ECONOMICS INPUT (*Please note that the CTU cannot provide this and if the input of health economics is required please inform the CTU).*		
Does the study require Health Economics input?	No ○ Yes ○	
Has a Health Economist already been consulted?	No ○ Yes ○	Please provide contact details

NIHR/CRN CLINICAL STUDIES GROUP SUPPORT	
Has the study been discussed/approved or due to be discussed at the relevant CSG?	No ○ Yes ○

PATIENT AND PUBLIC INVOLVEMENT		
Is PPI planned?	No ○ Yes ○	
Please specify		

MAHSC-CTU SUPPORT REQUESTED		
Methodology support	No ○ Yes ○	
Trial coordination	No ○ Yes ○	
Central data management	No ○ Yes ○	
Randomisation service	No ○ Yes ○	
Statistical support	No ○ Yes ○	Please clarify if not required
Study Monitoring (Consent, data, SDV, ISF etc.)	No ○ Yes ○	
Other (please specify)		

FINANCE		
Is funding already in place?	No ○ Yes ○	Funding amount and funder
Will this study proposal be subject of a grant funding application?	No ○ Yes ○	Grant application submission deadline
Grant funding body (e.g. NIHR, CRUK MRC etc.)		
Funding stream (e.g. RfPB, EME etc.)		
Details of competition call (e.g. Themed, commissioned, open)		

Type of application? Full, Outline, EOI	
Deadline for submission	
Proposed (target) submission date	
Expected date when outcome known	
Expected date of start of award	
Estimated potential grant total (if known)	
Has this study been discussed with your Research Support Manager?	No ○ Yes ○