Methods Section I: Expectations and Reviewers' Concerns

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THE METHODS SECTION: QUESTIONS REFEREES MAY ASK

This is not a comprehensive list, but will ensure that you think about a number of important things that reviewers will be looking out for in the methods section of your application. You need to pre-empt possible criticism by answering any questions reviewers may think of within your written application. When you are ready, use the checklist as you develop your own methods section, to help make your project reviewer-proof!

Overall, consider:

- ☐ Will the methods proposed answer the research question?
- ☐ Are they appropriate?
- ☐ Are they scientifically rigorous?
- ☐ Are they feasible?
- ☐ Will they deliver useful outputs?
- ☐ Have weaknesses been acknowledged & removed or mitigated where possible?
- ☐ Importantly, do referees have sufficient detail to gauge the quality of your work? Consider an external review (e.g. from the RSS) to ascertain this.

STUDY DESIGN ISSUES	
☐	Is the design clearly stated?
☐	Will the design answer the research question?
☐	Is the justification / rationale for the design clear?
☐	Are the theoretical underpinnings of the design suited to the nature of the question?
☐	Have the relative strengths & weaknesses of the design been considered?
☐	How does the design compare to alternatives?
☐	Have appropriate methodologists been consulted in deciding on the design?
☐	[Where necessary] Is a clinical trials unit on board?
☐	Have patients/ carers/ service users/ other relevant stakeholders been involved in the design?
☐	Have the practical aspects of implementing the design been considered?
☐	What methods are used to ensure rigour ('trustworthiness', validity, reliability, reproducibility etc.) in the design? E.g. Where relevant, does the design use more than one method of data collection to facilitate cross-checking (triangulation) of findings?
☐	[If comparative study] Is there any chance of contamination between intervention & control arms?
☐	[Where other things can influence outcomes] Are relevant confounders accounted for in the design (e.g. through randomisation)?
☐	[Where used] Is the randomisation procedure suitable?
☐	[If qualitative] What is the ontological (nature of reality) & epistemological (theory of knowledge) position of the work?
☐	Where necessary, are researchers familiar with the culture of the participating organisations?
☐	Are there any ethical issues in relation to the study design that need to be considered?

SAMPLING & RECRUITMENT	
☐	Is the population of interest clearly stated?
☐	Is the setting of the research clearly stated?
☐	Does the stated population & setting relate sensibly to the research question?
☐	Are the sampling method/s clearly stated?
☐	Are the sampling methods consistent with the objectives?
☐	Is the sample size clearly stated?
☐	Is the rationale/ justification (statistical or theoretical) for the sample size clear?
☐	Are the eligibility criteria clearly stated?
☐	Is it clear how, when & by whom eligibility criteria will be applied?
☐	Is it clear how potential participants will be accessed, approached, consented & enrolled?
☐	Is the recruitment process ethical & suitable?
☐	Is recruitment likely to meet targets? Have the researchers presented any evidence to support the likely recruitment rate stated?
☐	Have patients/ carers/ service users been consulted about the recruitment process?
☐	'Have issues relating to equality, diversity & inclusion been addressed?

INTERVENTION	
☐	Is the intervention clearly described/ explained?
☐	Is the intervention novel? In what ways?
☐	What is the evidence to support the intervention?
☐	Does the intervention make sense for the patient/ carer/ service user group?
☐	What is the ‘dose’ for the intervention & the rationale for it?
☐	Is the timing of the intervention clear?
☐	What is the likelihood that the intervention will have an effect, relative to other factors?
☐	What are the implications of the intervention for the NHS?
☐	Can the intervention be applied properly & consistently?
☐	Can staff administer the intervention appropriately?
☐	Are staff training plans adequate & clear?
☐	Will staff be happy to administer the intervention?
☐	Are staff experiences & preferences an issue for the intervention?
☐	How will the fidelity of the intervention (ensuring it is delivered as intended) be ensured?
☐	Will patients/ carers/ service users be happy to do the intervention?
☐	Will patients/ carers/ service users adhere to the intervention?
☐	[Where relevant] Has the comparator been clearly explained, including ‘treatment as usual’?
☐	[Where relevant] Is the comparator sensible (e.g. in relation to potential biases/ confounders)?
☐	Should/ can participants be ‘blinded’ to the intervention? Is a placebo necessary/ possible?
☐	Are there any ethical issues in relation to the intervention that need to be considered?

DATA COLLECTION	
☐	Is it clear what type of data are being collected?
☐	Are the data types appropriate for addressing the research question, aims & objectives?
☐	What methods are being used to collect data (e.g. postal, online, telephone)?
☐	Who will collect the data?
☐	From whom & where are data being collected?
☐	When are data being collected & does the timing make sense (e.g. in relation to intervention)?
☐	Is data collection sensible in relation to NHS structures & pathways?
☐	Have other options for data collection been considered?
☐	Have potential weaknesses in the data collection approach been identified & addressed?
☐	Is the data collection feasible? Can data be collected successfully (is there evidence to support this)?
☐	Have the ethical implications of data collection been considered?
☐	Will missing or poor quality data be an issue?
☐	[If routine data/ 'big data'], have permission & timelines for these been considered?
☐	Are the data collection methods & schedule acceptable to patients? E.g. Are they burdensome? Are they realistic with regard to continued participant involvement?
☐	[Where applicable] Should, & can, data collection be 'blind' to intervention group?
☐	Is there sufficient expertise on the team to ensure data of suitable quality?

OUTCOME MEASURES	
☐	Are the outcome measures being used appropriate for the research question, aims & objectives?
☐	Are the outcome measures relevant/ appropriate to the patient/ carer/ service user/ staff to whom they will be administered?
☐	Will the specific measures be acceptable to patients/ carers/ service users/ staff? Have patients/ carers/ service users/ staff been consulted?
☐	Are the outcome measures valid & reliable?
☐	Is there a good rationale (& is it explained) for using particular outcome measures (e.g. over alternatives)?
☐	Will the outcome measures be sensitive to the intervention?
☐	If proxy measurements are being used, are they appropriately correlated to important outcomes?
☐	Are outcome measures properly referenced?
☐	Where relevant, is there a clear primary outcome?
☐	Where relevant, are outcome measures sensibly timed in relation to the intervention?

DATA ANALYSIS	
☐	Will the data analysis proposed address the research question, aims & objectives?
☐	Are the methods suitable, based on the type of data collected?
☐	Are the methods suitable, based on the sampling approach?
☐	How will the data be prepared for analysis?
☐	Is the analysis plan thorough?
☐	Will relevant guidelines/ references be followed & are these highlighted?
☐	Has an appropriate methodologist been consulted?
☐	Should/ can the data analyst be blinded to the intervention group?
☐	Does the analysis take into account confounding variables?

PROJECT MANAGEMENT	
☐	Does the study have an appropriate sponsor?
☐	Is it clear that ethics & governance principles will be upheld?
☐	Are all other relevant permissions & approvals in hand?
☐	Is the proposed work feasible in the time allocated?
☐	Are the study stages in a sensible order?
☐	Has sufficient time & funding been allocated for each step?
☐	Are the right researchers in the right place at the right time?
☐	Will all the materials, equipment & space required be available?
☐	How will data be entered & managed (including storage)?
☐	Do all aspects of data processing (e.g. storage, transcription) meet GDPR?
☐	Have all quality assurance issues been considered appropriately?
☐	[Where necessary] Have the logistics of sample transport & storage been considered appropriately?
☐	Has provision been made for issues relating to intellectual property, e.g. do researchers have 'freedom to operate'?
☐	Have Gantt charts/ flowcharts been used where these will be helpful/ have been requested? Do they make sense?
☐	Is appropriate support from other relevant organisations (e.g. collaborators, clinical research network) assured?
☐	Overall, will the project be well-managed? Will it deliver?