INTERNAL CHECKLIST TO USE AFTER OR ALONGSIDE THE NIHR BRIEFING DOCUMENT

This checklist has been developed based on a review of applications made to the National Institute for Health Research (NIHR) Research for Patient Benefit (RfPB) funding made by Sussex Partnership Foundation Trust staff from 2007-2013. This list is designed to help researchers avoid common pitfalls that have led to unsuccessful bids in the past. What follows is not an exhaustive list and by no means does it replace the published NIHR RfPB guidance.

Note that applicants are more likely to get funding if they have involved the NIHR Research Design Service (RDS) early and have been peer reviewed.

General overview:

- State what you are planning to do early on in the text.
- Use strong and decisive language rather than tentative.
- Use plain English throughout – there will be a wide range of reviewers: 14 members in total, 1 lay Dr, one lay non-Dr, 5 professors and 7 academics without professorships.
- Make sure the proposal is easy to follow –
  - Break-up the description of the plan into phases/steps.
  - Use lots of headings – helps the reviewer to check key points have been covered.
- Don't use lots of acronyms; write the phrase in full the first time it is used.
- Make sure the title fits the research.
- Have a clear design and rationale for using this approach.

Applicant & Co-applicant

- Is the research team appropriate and can they demonstrate capability and is the lead applicant supported?
  - Is there national and international recognition?
  - Have field experts been included?
    - RfPB panel will 'Google' the names to look for presence in journals.
  - Are there experienced researchers in the team – methodological support?
  - Are there a lot of publications?
  - Is there previous experience of conducting successful research or running a successful clinical trial or support from Clinical Trials Unit (CTU)?
  - Is there support from design team?
  - Is the research team large enough and stable to cope with staff changes?
  - Make sure everyone's role is described clearly- ensuring 'big names' aren't included in the application to make it 'look good'.
  - Is there a clear structure to manage and co-ordinate growing research team members?
  - Is it clear who is going to do the day-to-day management?
  - Does the team have a track record of working together, and does the application build on past work?

Patient and Public Involvement (PPI)

- Is the patient voice prominent – what do they say about their experience, what is their input into every stage of the research and dissemination.
  - Proof of ongoing involvement – not just the beginning and end; PPI should be interweaved throughout the application and embed into the protocol – use a PPI consultant to get you started.
  - Has the Lived Experience Advisory Forum (LEAF), Service User Research Forum (SURF) or similar service user advisory group been involved.
  - Have researchers, clinicians and services users with a lived experience been involved?
  - Have peers been involved? Consider as interviewers, deliver training, co-facilitate sessions, analysis, interpretation and dissemination of findings. Not all studies require involvement at every step as this varies according to problem and method. Consider your rationale for involvement across the research cycle.

- Have self help groups, service user, caregiver or support forums been involved.
- How will beneficiaries be able to engage with the research or the results?
- Have you explained how they will be supported or paid?
- Primary Care Research Network (PCRN)/Mental Health Research Network (MHRN) involvement.
- Do not use the term 'focus groups' when you mean consultation say 'discussion group'
  - How many people, who, specific recommendations
- Use the INVOLVE payment guide/calculator.
- There should be a clear distinction between the abstract and the lay summary with evidence of lay voice in the latter.

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Aims & Objectives

- Be clear about what the issue is and why?
  - Why should we or NHS care?
  - What is the problem and how big is the problem?

- Set the scene - include what's known about the study population
  - Incidence rates
  - Prevalence
  - Numbers in the population – nationally, locally
  - Known characteristics
  - Refer to evidence base, past research, recommendations from experts

- What's available to service users now?
  - What are the service gaps – what is the evidence of this?
  - Have problems between need and delivery been highlighted?
  - What are the research gaps – what do we need to know more about, why, and what impact will it have?

- Who will benefit and how will things be different?
  - Have service users and caregivers indicated what is important to them?
  - What will be the improved primary/secondary outcomes on a day-to-day basis, medium term, long term e.g.
    - Improved health and wellbeing
    - Reduced suicide rates
    - More likely to take medication & reduced relapse
    - Improved service engagement
  - It is very important that the results are generalisable within NHS and this needs to be clearly demonstrated.

- What are the potential savings for NHS and social care – Value for Money?
  - Spend to save ideas,
  - Reduced hospital admissions/A&E,
  - Reduced visits to GP,
  - Low cost innovation,
  - Social care costs?

- How will it reduce inequality?
  - Will it engage the most vulnerable who are usually excluded or who don't access services?
  - Have you addressed potential language barriers, communication difficulties or other protected characteristics such as Gender, Race, Lesbian Gay Bisexual or Transgender, and disability?

- Has extensive background research been carried out?
  - If a claim such as 'widely known' is made do not be vague, explain who said this and in what context - reference from literature.

- Demonstrate that a thorough literature review been conducted – don't just rely on Cochrane review.
- Consult with experts in the field and check if similar research has been proposed or conducted before – make sure proposal doesn't overlap with other funded research.
- Run a last minute rapid review to check for new publications before the application.
- It is good practice to carry out preliminary work to support rationale – when you describe this in your application don't assume that the reader knows anything about your results; RfPB panel want to see evidence of solid foundation work and a trajectory.

- Sustainability
  - Explain how will things be different in the future and what would be needed to support this.
  - What is the proposed after story – the research has been conducted…now what?

- Why should the funding be granted?
  - Is the topic important to the NHS?
  - Is the topic important to service users and caregivers?
  - Could the reviewers argue any of the following: Interesting but not important/Difficult to explore/Not valid research?
  - Will an identified gap be addressed?
  - Adds to limited research – is there an agreement that it's needed or little is known about a subject?
  - Relevant to clinical practice.
  - Will it lead to a pilot or a Randomised Controlled Trial (RCT) – think ahead do not wait until the last person has been through the intervention programme before preparing for the next grant?

- Abstract & plain English section
  - This is the first thing reviewers read especially when they are not familiar with the topic so make it clear, persuasive and punchy: sell the problem, tell them why they should care, how the research should be carried out and how you are going to make a difference.
  - Describe what is the issue and why.
  - Keep the description focused - get to the point quickly.
  - Refer to evidence base/past research.
  - Set the scene – describe how many people are affected locally.
  - Describe the research question clearly.
  - What is the hypothesis?
  - What difference can be made to patients & carers?
  - What is the Value for Money angle?
  - The plain English summary needs a clear lay voice, - ask lived experience consultants to review or help with this.

Research Plan & Design

- State your research question and keep coming back to this.
  - Is the research question and design in harmony?
- The funders appreciate research which is novel or innovative but it needs to be relevant too
- Will the outcome facilitate 'patient choice'?
- Are you describing what you think you are describing – is this a feasibility study, a pilot study, a main study or a RCT?
- Provide sufficient details of informed consent procedures.
- Have clear rationale behind inclusion and exclusion criteria.
- Have all potential harms and risks been noted?
- Is the intervention clearly defined?
  - Is there certainty that the effect of the treatment is isolated enough to test – will the reviewer be able to argue that there is a third factor involved that accounts for the outcome that is not a result of the treatment. Or that a placebo effect has been observed?

- If the intervention is complex e.g. Therapy in a Group for a condition. Then present the evidence and rationale for why the elements are better than other available options and why you've brought them all together.
- Is there a control group – reviewers have generally been unsupportive of designs where no control group exists? RfPB panel strongly favour RCTs.
- Explain what type of control group is being set up and appropriateness? E.g. Placebo Treatment as Usual (TOU), standard care. Follow with a clear definition of what TOU/standard care means in practice.
- What is already known about the effect of the intervention in the same or different settings (e.g. health issues, age groups, clinics) and how is this knowledge built in to the study?
- Can the intervention be replicated?
- What does best practice guidance (e.g. NICE Department of Health, WHO policy) say about the intervention?
- Is there potential for participants to have been treated before or currently receive medication? Could this impact negatively on your research?
- Is there a clear link to patient benefit?

- Are your primary and secondary outcomes clear?
  - How do they relate to your research question? – have you selected the right ones? Will this be enough to show a significant difference?
  - Are the outcomes standardised and reliable?
  - What are your Patient Reported Outcomes – has what is important to patients been included?
  - How will outcomes be measured and then used and what is the rationale?
  - What tools will be used and what's the rationale?
  - Be aware of participant fatigue, is the number of measurements being taken reasonable - ask lived experience experts to review this if required.
  - State the possibility of negative outcomes/observations.

- Use of tools/instruments
  - Why this tool – what's the evidence base – sensitivity & specificity?
  - Who will use the tool and how, frequency, what will happen to the outputs?
  - Use of surveys – self administered, how do they receive them, by post or Face-to-face?
  - Is there a risk of survey fatigue, leading to drop-out, non participation, non compliance ask lived experience experts to review this.
  - Data collection/storage/protection – are all the who/what/where's covered?
  - Completeness of data – how will any analysis problems be handled?
  - Is any training involved –who and how? What support will they receive?

- Is there randomisation?
  - How is it administered?
  - For an RCT, RfPB panel favour CTU involvement.
  - Use stratification to ensure you have the right comparison groups.
  - Perhaps not necessary for a feasibility study.

- Is there blinding – if not why not?
- What is the justification for proposed length of follow-up time
  - Interview participants after the study to gain feedback on how they found participation.

- Bias & Confounders
  - Have confounders been identified based on evidence/expert opinion – is there a description of how to account for these in the design or analysis stage.
  - Has bias been thought through, identified and minimised.
  - Can an adjustment be made for non-compliance.
  - Could there be a between therapist/rater effect?
  - Will patients current treatment/medication confound the results.
  - Is there any bias related to recruitment. E.g. only recruiting through a known support group.

- Feasibility
    - Do you know how many participants are out there that can potentially be recruited.
    - Have you demonstrated how you will recruit centres?
    - Is there a pilot study/previous related research that demonstrates that a reasonable number of people will be likely to give consent or be followed-up?
    - What do lived experience experts advise about enablers and disablers to recruitment in your study? Would they want to take part in it?
    - Keep the project realistic
        - Set up time
        - Recruitment dates
        - Study period
        - Follow-up rates – is there enough time to follow everyone up
        - Time for analysis
        - Overall write up and dissemination
        - Time for writing proposal for next grant application

- Is the question answerable within the time frame of the grant
    - Is there enough follow-up time to make full use of all potential data?

- How will deviations from the protocol be dealt with?

- Include Sample size & Power
    - Why this sample size number? – Link back to the research question.
    - Has drop-out been considered?
    - What is the minimal clinical difference which is considered important
    - Power – what information do you need, has an effect size been published elsewhere
    - Is this a feasibility study - is it appropriate to start discussing power
    - Are you using this study to work out an effect size or to explore the feasibility of a larger study
    - Are you preparing for an RCT – include a cost analysis
    - RfPB favour 90% power

- Analysis methodology
    - Is there sufficient details on the methodology – RfPB commented that it's often lacking
    - Is there appropriate application of qualitative and quantitative methodologies in line with research question
    - Will the results answer the research question and support or disprove the hypothesis
    - Describe analysis techniques e.g. ANACOVA, Regression, Intention to treat, multilevel modelling for multiple site
    - Has the RDS been consulted – consult with them early in the process of developing the protocol
    - Are you planning to involve lived experience experts in the analysis and interpretation of findings? What is your rationale for this?

Project outputs and dissemination

Do not imply here that you will only 'write a report' and publish in a journal – the panel are looking for evidence of how the outcomes of the research will be translated into patient benefit, NHS and wider healthcare community to provide improvements in service delivery, patient health and/or well being:

- Are the outcomes & outputs practical and tangible such that they can be disseminated?
- RfPB panel want you to specify what the NHS outcomes will be.
- Will patient satisfaction improve?
- Will clinics be run in a different way?
- Will the care pathway change?
- Will there be a new model of service delivery?

- What are the plans for dissemination and proposed changes to clinical practice?
    - How will it develop best clinical practice, knowledge and transfer?
        - Service improvement?
        - How will it the research be made available & how?
    - Who do you want to take note of the research results?
        - Patients/Service users & Carers
        - INVOLVE
        - NHS/Health Policy makers
        - General public
    - Build dissemination into the time scale.

- Think about commercial exploration – intellectual property, education materials (or free resources offered to open systems more ethical and information gets to the right people more quickly)
- Will the results improve awareness of what's needed to improve engagement in services?
- What are your thoughts about future research, does this potentially lead to an RCT (considered by many as the gold standard)?

Management and governance

- Roll over of staff on long studies – is there a contingency plan.
    - Is the team of researchers large and stable enough?
- What are the risks?
- What are the general management procedures?
- Ethical review considerations
    - Could participation potentially raise health issues which remain untreated?

Intellectual property & innovation

- Possible elements include
    - Early identification tools
    - Screening tools
    - Pamphlets/booklets
    - Recommendations for …clinicians/NHS policy makers…protocol
    - Manuals for new intervention
    - Targeting – how?
    - Training
    - Improved technology

Involvement with NIHR Infrastructure & Other Partner Organisations
(as described in the application form)

- Demonstrate how linked to NIHR networks and the benefits
- Successful bids are more likely to have involved the Research Design Team as part of the process – get in contact with them early.
- Describe Partnerships and very briefly explain why relevant.

Finances

- Is time/money properly apportioned between data collection and analysis, write-up – is it CSO, RA, therapist or PI intensive?
- Who is covering treatment costs? Will there be any after the study?
- Have costs for the control arm been considered?
- Is the overall amount too much/little?
- Is there clear description of what participants are paid for?
- Has the ACCORD been consulted to breakdown costs by study/treatment/support?
- Is it necessary to train a research nurse, or better to employ someone who is already qualified?