

**PCPIE Support Application Form**

In order for the Group to be able to evaluate your research proposal effectively please kindly supply the following additional information. If you already have other study documentation such as study protocol or patient information sheet, please submit it along with this form.

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| **Study Title** |
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| **Chief Investigator** |
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**Section 1: Overview of research proposal**

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| 1. **Lay Summary (500 words max.)**   *Please write a brief lay summary of your research proposal (maximum 500 words).Click* [*here*](http://www.niaa.org.uk/article.php?newsid=637) *for advice on how to write a lay summary. You may wish to copy & paste the existing lay summary from your funding application.* |
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| 1. **Principal Research Question**   *What are your main aims and objectives?* |
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| 1. **Study design**   *Describe your study design and reasons for choosing it.* |
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| 1. **Background and justification for study**   *What is already known on this topic and what will this study add? Why is the study needed now? How does your study address research priorities? Please include relevant literature review of what is known, other relevant on-going studies.* |
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| 1. **Patient group (inclusion and exclusion criteria)** |
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| 1. **Intervention, or observation, and comparator**   *Describe study intervention. Is there a control group?* |
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| 1. **Primary and secondary outcome measures** |
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| 1. **Study setting including number and type of sites**   *Where will patients be recruited from?* |
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| 1. **Proposed sample size and justification** |
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| 1. **Potential ethical issues**   *Are there any risks or disadvantages to taking part? What have you done to minimise these? Is the study recruiting vulnerable patients?* |
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| 1. **Confidentiality**   *What procedures are in place to safeguard data protection and patient confidentiality? How will sensitive data be stored? Who has access to this data? How long is data kept for?* |
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| 1. **Study time-lines (proposed start date and duration)** |
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| 1. **Study team expertise** |
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| 1. **Higher degree project?** |  | **Yes** |  | **No** |

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| **xv. Funding stream applied for (if known)** |
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| **xvi. Date of pending submission (if known)** |
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| **xvii. Amount of funding applied for** |
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**Section 2: Participant experience in the research project**

Please give a detailed account of a study participant’s experience of the proposed study using the following headings if relevant. If this study does not involve recruiting human participants, please outline how you think this research may ultimately have an impact on patients:

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| 1. **Initial contact with participants**   *Where and by what means will this happen? What information – written, verbal or other – will be given? If a patient information sheet has been developed, please attach this in email.* |
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| 1. **Consent process**   Who will take consent? How long will potential participants be given to consider the study? Will patients lacking capacity be recruited and if so, what arrangements will be made? |
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| 1. **Participant contact during the study**   Please include details on the number of study visits and to what degree these will be integrated with routine clinical care. How long will each visit take and what will be involved? |
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| 1. **Impact on participants**   If the study involves any inconvenience or cost to patients, will this be compensated for, e.g. by paying travel costs? Please quantify any potential risks to study participants and outline how these will be dealt with. How will you support participants and their relatives and/or carers before, during and after the trial? If there is an adverse event related to study participation, how will this be dealt with? How will the participants find out about the overall outcome of the study? |
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**Section 3: Patient and public involvement in planning and conducting the research**

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| 1. **Patient and public involvement work already undertaken**   Please outline any other involvement of patients / public in the research planning to date. How have you made contact with relevant lay members? |
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| 1. **Planned patient and public involvement**   *Please note that in many cases in addition to HSRC PCPIE review it may be beneficial to involve local service users in research planning and conduct, i.e. patients and carers with direct experience of the relevant healthcare area. Are any plans in place for consulting these service users?* |
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**Section 4: Additional Information**

Please feel free to include any additional information regarding your proposal that you think would be useful:

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Please send completed form plus any existing **patient-facing information** for review (e.g. patient information sheets, CRFs) to [info@niaa.org.uk](mailto:info@niaa.org.uk)