**Title of Study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| ***For research involving the NHS:******IRAS ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_******Participant ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*** |

**Invitation and Brief Summary**

You are being invited to take part in a research study. Before you decide whether or not you wish to take part it is important that you understand why the research is being done and what it will involve. Please read this information carefully and discuss it with others if you wish. Take time to decide whether or not you wish to take part. If you do decide to take part, you will be asked to sign a consent form. However, you are free to withdraw at any time, without giving any reason and without any penalty or loss of benefits.

**What is the purpose of the research?**

*What is already known/not known and how will this study help you learn more?*

*Is the research educational/therapeutic?*

**What does taking part involve?**

*How long will the participant be involved in the research?*

*How often will the participant need to meet the researcher/attend a research session?*

*What exactly will happen?*

**What information will be collected and who will have access to the information collected?**

*What information will be collected? Will personal information be collected, and for what purpose?*

*Will participants be asked for information on particularly sensitive issues?*

*Who will have access to the information during collection, analysis and on study completion?*

*What are the data storage plans?*

*What plans are there for re-use of the data after completion of this study? It is important to inform potential participants of data sharing.*

*How will participants’ confidentiality be protected? For how long will any personal information be retained?*

*Will personal data be used in machine learning or other technologies that will result in a decision about the individual, e.g. a diagnosis?*

We will use your name and contact details [telephone number, address] to contact you about the research study. We will use [insert other identifiers e.g. date of birth] in order to [insert reason for processing]. Individuals at Newcastle University may look at your research data to check the accuracy of the research study. The only individuals at Newcastle University who will have access to information that identifies you will be individuals who need to contact you to [insert reason] or audit the data collection process.

If you agree to take party in the research study, your data will become part of a dataset which can be accessed by other users running other research studies at Newcastle University and in other organisations. These organisations may be universities, NHS organisations or [insert as applicable]. Your information will only be used by organisations and researchers to conduct research.

*AND TO SUPPORT DATA SHARING:*

*If you agree to take part in the research study the data provided will be de-identified and made available as “open data” through a research data repository [state the repository, guidance:* *https://research.ncl.ac.uk/rdm/sharing/). This means the de-identified study data will be publicly available and may be used for purposes not related to this study. It will not be possible to identify you from the “open data”.*

**Why have I been invited to take part?**

*Why has this participant been invited? Who is the study group?*

**What are the possible benefits of taking part?**

*It is usually not possible to promise any direct benefits of taking part to potential participants. The most likely benefits may be experienced by others, in the future, as a consequence of discovery through research.*

**What are the possible disadvantages and risks of taking part?**

*Potential participants must be informed of the likelihood and level of any harm AND of any potential risk to their confidentiality.*

**(For research involving high risk) What procedures are in place if injury were to occur?**

*Is any compensation or medical treatment available? If so, what does this involve?*

**Who is the sponsor and data controller for this research?**

*Enter the research sponsor here [e.g. Newcastle University/NHS], and information regarding how the sponsor will look after the information collected. If Newcastle University…*

Newcastle University is the sponsor for this study based in the United Kingdom. Newcastle University will be using information from you [and/or your medical records] in order to undertake this study and will act as the data controller for this study. This means that Newcastle University is responsible for looking after your information and using it properly.

The lawful basis for carrying out this study under GDPR is Task in the Public Interest, (Article 6,1e) as research is cited as part of the University’s duties. *(If applicable:) The lawful basis for processing any special categories of personal data is Scientific Research (Article 9,2j).*

Your rights to access, change or move your information are limited, as Newcastle University need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, Newcastle University will keep the information about you that has already been obtained. To safeguard your rights, the minimum personally-identifiable information will be used.

You can find out more about how Newcastle University uses your information at [insert URL] and/or by contacting their Data Protection Officer [DPO name, rec-man@ncl.ac.uk].

**(If applicable) Who is funding this research?**

*Name of funder(s)*

**Has this study received ethical approval?**

This study has received ethical approval from XX Committee on XX/XX/XXXX.

**Who should I contact for further information relating to the research?**

*Principal Investigator Name, Contact Details*

**Who should I contact in order to file a complaint?**

*Research Study: Name, Contact Details*

If you wish to raise a complaint on how your personal data is handled, you can contact the Data Protection Officer who will investigate the matter: DPO Name, Contact Details

If you are not satisfied with their response you can complain to the Information Commissioner’s Office (ICO): <https://ico.org.uk/>