Hi, my name is Julie. As a relatively inexperienced postgraduate researcher based in a non-clinical department, I found the NHS ethical approval process especially challenging; however, I hope that this case study will help others to prepare a successful application by providing some insight into my experiences, highlighting the issues and difficulties I faced and how I dealt with them. However, please be aware that there have been some changes to the details of the process since I encountered it so please ensure you refer to the National Research Ethics Service (NRES) website at http://www.nres.npsa.nhs.uk/ for definitive information.

A Basic Guide to the Application Process

1. **Getting help** - Committee administrators are a useful source of knowledge about the application process in general, and their specific committee; their details can be found on the NRES website. It is also a good idea to familiarise yourself with the NRES web pages so you have an awareness of the whole process from the outset.

2. **Preparing the documents** – The first step is to set up an application form: go to the NRES website and register with the Integrated Research Application System (IRAS) to create your own online account, from which you can manage your application form (you will be asked a series of questions to generate the relevant form, and you can save and go back to the form as much as you like until you are ready to submit it).

   **TIP:** PAY CLOSE ATTENTION TO ANY INSTRUCTIONS ON THE FORM: particularly in relation to not copying and pasting details from one section to another; although it may seem like a lot of work and that you are repeating yourself, it is due to the way the form is prepared for review by different members of the committee and if you do not adhere to these rules you risk the application being deemed unsuitable for submission.

The following points highlight the main requirements of the application form:

- **Research & Development approval** – this is required in order for your research to go ahead; the necessary forms will be generated automatically and are submitted as part of your ethics application form. Requirements can be found within your online IRAS account. You can contact the relevant R&D department if you have any questions (contact details can be found on the NRES website).

- **Applicant checklist** – shows what additional documents are required in your application (some are compulsory, but you can add others).

   **TIP:** CONSULT THE CHECKLIST EARLY SO YOU KNOW WHAT TO EXPECT FROM THE OUTSET: the committee will want to see all documents to be used during the course of the research (consent forms, information sheets, interview guides etc), as well as documents relating to verification of the credibility of the research (letters securing funding, statement proving scientific quality of proposed research etc).

- **Research proposal** – you will need to provide a document covering the aims and methodology of the project in detail and discussing how you will deal with ethical
considerations such as confidentiality. You need to convince the committee that your research is important, timely and relevant, as well as methodologically sound, so include sections outlining the significance of the potential outcomes. Ensure it is written in clear, lay terms and that everything is explained carefully in detail to show you have thought everything through.

**TIP: NUMBER ALL THE ADDITIONAL DOCUMENTS AS APPENDICES AND CROSS-REFERENCE THESE IN YOUR RESEARCH PROPOSAL: this will make it easier for the reader to understand what each document is and how it will be used in the context of the research.**

**TIP: TRY TO WRITE IN A WAY THAT ALLOWS REVIEWERS TO SEE THAT YOU CAN PLACE YOURSELF IN THE SHOES OF YOUR PARTICIPANTS: this will help you to show that you have considered how the research will affect participants; include how they will be recruited, what they will have to do, how you will obtain their informed consent, etc.**

**TIP: TRY TO JUSTIFY EXPLICITLY THE CHOICES YOU HAVE MADE ABOUT RESEARCH DESIGN AND ETHICAL CONSIDERATIONS: cite relevant literature to support your theoretical and methodological explanations.**

3. **Finding your committee** – Identify where to submit the completed application (do this early on, whilst you are preparing the documentation). You will either need to submit to your local NHS research ethics committee, or via a centralised allocation system (CAS) where you will be allocated a specific committee. This depends on various factors and guidance is provided on the NRES website.

**TIP: ONCE YOU KNOW WHICH COMMITTEE WILL BE REVIEWING YOUR APPLICATION, FIND OUT THEIR MEETING DATES AND HAVE A TARGET DATE IN MIND: this will help you to plan timescales for your application, but be aware that the whole process can take some time (6 months in my case from preparation to approval).**

4. **Submitting the application** - once your application form, research proposal and all additional documents are complete:
   a. **Contact the relevant committee** to let them know you need to submit an application: if applying to your local committee, telephone the committee administrator (using contact details on the NRES website) and let them know you will be submitting an application; if applying via the Central Allocation System call 0845 270 4400 and you will be allocated to a committee;
   b. **Submit the application form** within the timeframe agreed with the committee, usually within 4 working days, electronically via your IRAS account (you will not be able to amend it once submitted);
   c. **Forward hard copies** of the entire application to the committee; details of how many copies of each document are required are outlined on the form checklist.

**TIP: SET ASIDE A DAY TO ORGANISE ALL THE PAPER COPIES TO BE DELIVERED TO THE COMMITTEE ADMIN OFFICE – BE PREPARED FOR LOTS OF PAPER AND PAPERCLIPS!**
5. **Attending the meeting** – once you have submitted the application, the committee administrator will check that your application is complete and is therefore eligible to be reviewed, and if it is, will book a place for you at the next available committee meeting. You are encouraged to attend the meeting to clarify any issues and answer any questions about the research. I discussed my proposal with the committee for about 20-25 minutes.

6. **Receiving the decision** – the committee will contact you with its decision some time after the meeting; this may detail any amendments that they require to be made to the application before they can grant approval.

**TIP:** THE QUICKER YOU CAN RESPOND TO A REQUEST FOR CHANGES, THE QUICKER THE FINAL DECISION ARRIVES (HOPEFULLY APPROVAL!)

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**Reflections on my experience of the NHS ethics review process**

I found that overall, although there are certain issues relating to the NHS ethics review process which are difficult to manage and reconcile – especially for researchers applying from non-clinical departments and using certain methodological approaches – the intensity with which the application process makes you think about carrying out your research is ultimately useful. It represents an opportunity to prepare thoroughly for your research and to think about best practice (and not just in terms of ethics) in a very in-depth and constructive way.

A document containing the full reflection of my experience is available here:

[Reflections on experience of NHS ethics review process](#)

However, the following table summarises some of the main experiences and problems I faced and what the outcome was/what I learned during the process:

<table>
<thead>
<tr>
<th>Experience/Problem/Concern</th>
<th>How it was addressed/outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Being from a non-clinical department with little experience of the NHS ethical review process made it difficult to understand the requirements</td>
<td>Being pro-active about finding out what the process involved was essential</td>
</tr>
<tr>
<td>Anxiety that the qualitative methodological approach I aimed to use would not be valued and that I would have to change it, especially as the application process seems to be more aimed at medical research</td>
<td>Anxiety made me more thorough in my preparation, contributing to a successful outcome. I spent time justifying my research in ethical and methodological terms, not just what I was going to do, but why and how, and ensuring that the committee felt the project was do-able and worthwhile. Hopefully the example documents in this case study will help others to go about this.</td>
</tr>
<tr>
<td>Time taken to prepare the application, including negotiating the confusing process, was significant (3-4 months) and took time away from reviewing literature during first year of PhD</td>
<td>There was no clear explanatory checklist to show all the processes involved and how they interrelated; I kept coming across more things I needed to do. Hopefully this case study will help you to be more aware of the full requirements and plan your time accordingly.</td>
</tr>
<tr>
<td>Rigid approach to research design required in</td>
<td>The ethics review process does require a</td>
</tr>
</tbody>
</table>
the application process which did not fit with a more qualitative research approach

| significant level of predictability but I did manage to convey some of the need for flexibility which the committee generally accepted, by understanding the implications of this issue very clearly whilst preparing, and underlining in my proposal why a certain amount of ‘give and take’ was essential. However the committee insisted that if I wanted to change my interview guide I would have to submit an amendment to the committee for further review; also I was required to miss opportunities to recruit participants where it involved recruiting them in a manner different from that stipulated in the application. It is therefore important to be aware of the possible restrictions that may be imposed on your research through this issue. |

| An accident causing harm to a participant despite all the work thinking about all possible causes of harm in the application process! |

| It is important to recognise that once ethical approval is granted, what happens during the research and any decisions to be made still need to be considered in terms of ‘how do I stand with regard to my ethics approval?’ |

**LINKS TO FURTHER INFORMATION:**

To see a separate Word document containing my full guide to the application process, please click here: [Basic Application Guide](#).

To see my completed application form, please click here: [Example Application Form](#). PLEASE NOTE that the layout and questions on the form have altered since my application was made; however, some of the questions remain the same or are similar and the manner in which questions are answered may help indicate the type of response required (NB. personal information/identifying details have been removed).

To see my completed research proposal, please click here: [Research Proposal](#) (NB. personal information/identifying details have been removed).

To see examples of the additional documents provided as part of my application, please use the links below. Please note, this is just a small sample; specific versions of documents such as covering letters and information sheets were provided for all the different types of participant involved (ie. adults, younger children, older children and hospice staff) along with documents explaining the activities I planned to undertake with participants as part of the research.

[Example Interview Guide](#)

[Example Information Sheet](#)

[Example Consent Form](#)