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Recruiting and Engaging With Study Participants: Practical Advice and Guidance Applicable to Health Care Research for Early Career Researchers

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Abstract

It is now widely acknowledged that qualitative research has a valid place within health care research and often adds context and further insights to the quantitative model of health care research. The importance of engaging with patients and service users for health care research is often cited as a key factor in the success of research studies within the United Kingdom. Although it is often easy to identify a research topic and gaps in knowledge for further exploration, engaging and recruiting participants for a study often presents challenges for the neophyte as well as experienced researchers. Although we would be classed as early career researchers in that we completed our PhDs in health care research within the last 10 years, we have between us gained insights into a variety of health care research within the U.K. health care systems and teach a variety of modules on research methodologies and professional health care practice. This case study aims to share some of the challenges and provide tips on how to engage with potential participants to health care research. Our aim through reading this case study is to ensure that your brilliant research topic and research questions are fully explored and don't fail due to lack of participant engagement and recruitment. The case study focuses on one recent research study, but we draw upon other examples to demonstrate the often unspoken and unpublished difficulties of engaging and recruiting participants.

Learning Outcomes

By the end of this case, students should be able to

- Demonstrate and apply principles for the successful engagement of study participants in health care research
- Recognize and understand the methodological challenges involved in recruiting participants
- Judge the importance of gatekeepers and identify key stakeholders in the recruitment process
- Examine a wide range of tools and resources to successfully recruit participants for a wide range of health care research

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Project Overview and Context

In 2014, National Health Service (NHS) funding was received by the principal investigator (PI), Rachael Spencer, to conduct an empirical study in a locality in the United Kingdom that had below national rates of breastfeeding for first-time mothers (referred to as primiparous). A research team was formed with the PI, a leading midwife and researcher Dr. Denis Walsh as an advisor, and Dr. Kathryn Hinsliff-Smith was the field researcher.

Several international initiatives have been instigated over the past 25 years in an effort to increase breastfeeding rates, including the World Health Organization (WHO) code of marketing breast milk substitutes (WHO, 1981), the *Innocenti Declaration on the protection, promotion and support of breastfeeding* (WHO, 1991), the WHO/UNICEF Baby Friendly Initiative, and the WHO Global statement on infant feeding (WHO & UNICEF, 2003). WHO and UNICEF launched the Baby-friendly Hospital Initiative (BFHI) in 1992, to strengthen maternity practices to support breastfeeding. In the United Kingdom, breastfeeding is a key public health priority. On a population basis, exclusive breastfeeding for the first 6 months of life is the optimal way of feeding infants (Kramer & Kakuma, 2012; WHO, 2011).

The aim of the commissioned research was to develop an understanding of primiparous women's experiences of breastfeeding. The study focused on first-time mothers living in one large rural area in the United Kingdom and included those who succeeded in establishing and maintaining successful breastfeeding and those who breastfed initially but then discontinued (6-8 weeks postpartum). The secondary aim of the study was (a) to determine primiparous women's perceptions of infant feeding and (b) to identify the factors that influence breastfeeding duration and cessation.

Ethical approval was granted by the University of Nottingham and the National Research Ethics Committee.

Research Practicalities

To access suitable participants, the research team agreed that the recruitment materials, including an invitation letter, information sheet, and recruitment posters, would state that we were seeking first-time mothers who were intending to breastfeed. By clearly stating this, we immediately excluded mothers who were planning on formula feeding their babies after delivery. This clarity enabled us to actively recruit mothers who were able to share their breastfeeding experience. Our clear and stated aim was to only engage with women who declared that they were intending to breastfeed and for the study to gain a better understanding about mothers' actual feeding experience including participants' desire to breastfeed. It also saved time by not having contact with pregnant women who were not intending to breastfeed.

The participant inclusion and exclusion criteria are often chosen for pragmatic reasons or due to identified gaps in the literature. For the purposes of this study, our criteria directly linked to the current local data about breastfeeding rates and the extensive literature on breastfeeding difficulties (Beake, Pellowe, Dykes, Schmied, & Bick, 2012). The criteria for our study were as

follows:

- *Inclusion criteria*. Women who have given birth to their first baby, who is a healthy full-term (>37 completed weeks' gestation) infant. Written consent to participate given freely without coercion.
- *Exclusion criteria*. Women identified as illicit drug users, women with a mental health condition or learning difficulties (who are unable to give informed consent), women with an identified pregnancy condition (i.e., gestational diabetes), any women who experience a neonatal death or stillbirth, women with no written consent, and women aged younger than 16 years.

For example, in a current study that is recruiting community mental health service users, participants are screened by clinicians and invited to take part based on their current mental health status.

As this breastfeeding study aimed to understand women's experiences of infant feeding, mothers in the early postpartum period (6-8 weeks after giving birth), we agreed that mothers needed to be recruited in the antenatal period but after 34 weeks of pregnancy. The agreed time period of 34 weeks for actively recruiting mothers links to the literature around feeding decisions made by new parents (Swanson & Power, 2000) and likelihood of successful delivery.

Within your own study, it would be helpful to ensure that you clarify and agree on the parameters that might affect the inclusive and exclusion reasons for participants. For example, another recent study of ours regarding the U.K. Mental Capacity Act of 2005 required access to informal carers (usually family members) of patients who had a cognitive disability such as Alzheimer's disease or dementia. To access these carers and engage with them about the study, we had to engage with local support groups. Such groups, which can be referred to as third sector organizations or informal support groups, can be research active and may have members who are engaged in research through local or national patient and public groups or forums. Their value in engaging in meaningful studies, particularly in health care, has now been more widely recognized (Ennis & Wykes, 2013; Sadler, Lee, Lim, & Fullerton, 2010).

When utilizing support groups or forums, you should mention this intent in your ethics applications, detailing how you plan to recruit participants and, if necessary, measures you will take to address participant distress resulting from taking part in the study (e.g., participant support). Seeking ethical approval for studies conducted in health care is not covered in detail in this case study but advice is widely available, a good source is the NHS Health Research Authority web site, and we would strongly suggest speaking with your supervisors, PI, or, if you

are a university student, your module lead.

Because our study was exploring the experiences of women in one region of the United Kingdom, we needed to ensure that women interested in the study were actually planning on receiving maternity care in the study site. Women who were out of the care area were neither eligible to take part in the study nor were women who had known birth complications (e.g., gestational diabetes). Our study site covered one NHS Trust and three hospitals, but a number of specialist maternity services were available in two neighboring NHS Trusts which were not part of our focus or approvals.

This is an important dimension to studies as often there are geographic considerations for recruitment. For example, in our study, participants who lived in one region may deliver out of the region due to birth complications or be transferred for care; therefore, they would not be able to share their experiences on the services received in the study site as per our research objectives. For instances where this occurred (two mothers initially recruited), we excluded their data because their feeding experiences related to the professional care in the first few weeks outside of the study site. If we were to include their data, we would have to consider applying for ethical approval from the relevant NHS Trust prior to recruitment.

Research Design

We based the design of the study and subsequent ethical approval on a model of participant recruitment by community midwives. The study design was such that community midwives would introduce the study with mothers at their planned antenatal appointments and mothers would then receive a study information pack. This information pack invited the mothers to contact us by phone or email to register their interest in participating in our study.

Because this was the agreed recruitment route, we had to conduct much work to engage community midwives with the study. This included ensuring that they were aware of the study, the rationale for the study, and their part in the recruitment of suitable participants. We had to ensure that we had their “buy-in” to meet the recruitment target which was set at 40 primiparous women living in the locality, receiving antenatal care in the region and due to birth within the study site. This sample size was first set for pragmatic reasons based on limits of time and resources availability rather than anything more substantial. We had to be cognizant of having a sample size that was too small to support claims of having achieved theoretical saturation. This refers to the point when the data provide no new themes or emerging data and the researcher is able to demonstrate that further sampling would reveal no further insights. Likewise, we were conscious of not collecting a plethora of data that would be difficult to

provide a deep and meaningful understanding of the phenomena within the timescales. The importance of engaging with community-based professionals was paramount to the successful recruitment of primiparous women. To gain access to potential participants, we organized meetings with the community midwifery teams and breastfeeding steering groups within the locality to discuss the proposed study. We asked all community midwives in the locality to identify antenatal women who were at least 34 weeks pregnant and ask them whether they might be interested in participating in this study, and we provided a participant information sheet outlining the purpose and details of the study. If prospective participants were interested in discussing the study further or participating, they would then contact us directly using contact details on the participant information sheet.

In addition to accessing potential participants via the local community midwives, we recruited some participants via snowball sampling (Parahoo, 2006), whereby participants who had been recruited via their community midwife asked whether they could pass on our contact details and the participant information sheet to women they knew who fulfilled the inclusion criteria. Although participants were not asked directly to undertake recruitment, women were keen to talk about the study with friends and family and a number of women made contact with the study team directly as a result of word and mouth. We were also invited to discuss our study with local breastfeeding support groups, which also generated interest to participate from a number of women who fulfilled the inclusion criteria.

Other methods for recruitment included posters placed in locations that provided services for pregnant women—these comprised antenatal clinics at the two obstetric units in the locality. If prospective participants were interested in discussing the study further or participating, they would then contact us directly using contact details on the poster. Be aware, though, that you must ensure that you remove these after your recruitment period has closed to avoid participants contacting you and then having to advise that they are too late to participate.

We regularly attended the regional breastfeeding steering group meetings that were widely attended by community midwives, health visitors, and infant-feeding specialists from the study site. In addition, the chair for the breastfeeding steering group locally was a keen advocate of the study and had engaged with local stakeholders to fund the study. We were conscious of any conflict of interest among the chair, steering group members, and funders and managing their study expectations against our overall findings and recommendations. This can be a common occurrence when expectations of results and recommendations may differ from their aims and objectives of the study. Stakeholders may have specific outcomes and aspirations that the study findings and overall recommendations may not demonstrate or support. Likewise what may be judged as significant by the study team could have little or no immediate impact

on local services or policies but can still add value to a regional or national perspective. In our case, the chair was able to ensure that those working in the area of infant feeding locally were fully aware of the study brief, the overall aims and objectives and the rationale for its commissioning. It is important to consider how you might provide feedback to funders regarding difficulties within your study, or similarly for a student research study how your supervisors may help you engage with potential participants. The opportunity to attend these key meetings enabled us to provide feedback to stakeholders, including community midwives and infant-feeding specialists, about the participant recruitment and provided a dialogue about the preliminary findings of our study.

In addition to attending the regional steering group meetings, Kathryn and Rachael met with all the community midwife teams, a total of six teams, across the study site. This involved attending their team meetings, providing additional information, and ensuring that the study information packs were being distributed to potential participants. It also allowed for any local difficulties or misunderstandings about the study to be discussed. This was followed up with repeated visits to community midwife teams, weekly visits to three maternity units, including assessment clinics, maternity wards, and children's centers.

Again this could be a factor for some planned research where there is a long timeline between initial discussions and agreements to be engaged in a study. This can be protracted due to gaining ethical approvals, recruiting researchers, and actually commencing the study. A major factor to consider is that often health care professionals move sites, teams, and regions in addition to many staff working flexible or part-time hours. Therefore, study advocates who were fully engaged and committed to the study may no longer be in situ. It is therefore imperative that constant updates and contact with those engaged in the study (i.e., as recruiters) and contact with potential participants are maintained. Within the field of health care it is common to see staff changes, promotions, and flexible part-time work; for these reasons consideration needs to be given and planned on how to ensure that everyone in the site has some knowledge about the study.

The research design was such that two methods of data collection were used: participant diaries and interviews. Diaries are typically used when particular activities or events are expected to change over time and contextual information, such as the circumstances leading up to or following an event, is deemed important (Travers, 2011). We considered using only interviews to collect data, but reflected that the presence of an interviewer can cause the "halo" effect, in which participants wishing to be perceived in a favorable light provide socially desirable responses (Holloway & Fulbrook, 2001). We then considered using diaries, along with interviews with a subset of participants, as we were keen to minimize the effects of researcher

interaction to ensure that the participants determined the content of their own diaries (O'Brien & Clark, 2012). So that participants could feel free to express their sense of the world, both the interviews and the diaries would need to be unstructured (Hinsliff-Smith & Spencer, 2015). Using two data or multiple data collection tools is common to gain an understanding of a phenomena. This is referred to as "triangulation," and many researchers generally use this technique to ensure that an account is rich, robust, comprehensive, and well developed (see Denzin, 1978; Patton, 1999).

Honor Nicholl (2010) provided a useful checklist for researchers on aspects of diary structure, analysis of content, and decisions on purpose. We chose to provide a simple A5, lined hardbound notebook with the University logo, an introduction page, and further details about the study. As an alternative to writing, when recruiting participants, we also provided participants with the option to use an audio recorder as a method for recording their diary entries. There was no set format for using the diaries or daily questions to be answered by participants. We simply requested daily documentation (written or verbally recorded) from participants about their experiences of feeding. All entries were self-selected and the participants were aware that they were not obliged to make an entry at every feed, as the aim was to capture events around breastfeeding that were significant to them. They were free to document as little or as often as they felt able.

These two methods were designed to capture mothers' experiences of infant feeding (whether that was planned breastfeeding or formula feeding) in the early postpartum period (6-8 weeks). For our study, this time frame was used as it linked to the extensive literature on early cessation of breastfeeding (McLeod, Pullon, & Cookson, 2002) as well as the literature for encouraging longer term breastfeeding (Hodnett, Gate, Hofmeyr, & Sakala, 2007). The period of 6-8 weeks is also used as a measure and recorded by the U.K. Office of National Statistics (ONS). From the ONS data, we were aware that the study site was falling below the national rates of initiation and continuation rates of breastfeeding. Referring back to the study objectives, we were exploring the issues of infant feeding from the mothers' perspectives and what barriers existed for these primiparous mothers, of which we were aware that the initiation and continuation of breastfeeding was a key target for the three accredited BFHI maternity facilities in the study.

Method in Action

The study aimed to recruit 40 primigravid women over a study period of 12 months. This timescale included all aspects of the study including participant recruitment, collection of data from participant diaries and interviews, data analysis, and report writing.

In total, we received consent from 48 primigravid women more than 34 weeks' gestation. Our funding allowed the research team to recruit more than the minimum number of participants as well as the associated costs with higher numbers of participants (i.e., material costs, transcription services, and gratuities).

The 48 participants were all recruited antenatally (as per our protocol) and invited to complete detailed daily diaries of their infant feeding experiences in the 6- to 8-week postnatal period. Our protocol enabled us to have a clear structure on the participants we were intending to recruit and was especially useful when the team was approached by women after they had given birth who had seen our publicity material and wanted to share their infant-feeding experiences. As per our protocol, we were not able to recruit these women postnatally to our study.

From the 48 consented participants, we gathered 22 completed diaries (a response rate of 46%). Their diaries provided daily accounts of infant feeding, whether that was the mothers planned breastfeeding or whether this changed to formula feeding after giving birth. There are numerous challenges with using diaries as a data collection tool, which we are not including in this case study but details can be found in our published journal article (Hinsliff-Smith & Spencer, 2015).

In addition to the written diaries, the research design included conducting interviews with at least 10 participating mothers. The number chosen to be interviewed was purely for pragmatic reasons of time within the study (a total of 12 months) and costs (researcher costs, interview transcription).

After the birth, all mothers were invited to take part in a one-to-one interview with one of us at the participant's home. When mothers were given their diaries in the immediate postnatal period, they indicated their preferred contact method for us to maintain contact over the data collection period: email, text message, or letter. This enabled us to remain in contact with mothers and to encourage them to continue to write in their diaries as well as enable us to recruit to the interview.

A sub-sample of 13 mothers consented to participate in a face-to-face interview at the end of the initial 6-week postnatal period. The in-depth qualitative interview aimed to explore, in detail, their experiences and to identify the contextual factors that affected their decision to continue or to discontinue breastfeeding in the first 6- to 8-week period after giving birth (our findings were reported in two peer-reviewed journal articles).

As per research ethics, all participation was voluntary, and those who decided to take part were free to withdraw at any time and without giving reason. We received no requests to withdraw from the study. Written consent was required prior to taking part in the study, on the understanding that anonymity and confidentiality were assured.

Practical Lessons Learned

With every research study undertaken, there should be an element of reflection and post-study evaluation. Although the experiences gained during a study are useful, it is one's ability to reflect upon, draw conclusions, and use this reflective practice that enables future career development and progression. We are referring here to researcher and research team reflection as often researchers quickly move to another study or focus and it is only when dissemination occurs that such reflection takes place. We suggest that more research reflection be structured within study timescales. We are grateful that in compiling this case study, we have been able to reflect again about our research journey, and in particular this research study on breastfeeding.

So, what lessons do we take away from our study and what can we helpfully pass onto our colleagues and other early career researchers. In no particular order, we summarize the practical lessons learned as follows.

Time Required to Engage With Stakeholder Groups, Develop Networks, and Meet Potential Participants

A great deal of time and effort was required during the early part of the study period (12 months) to ensure that the community midwives were engaged with the study and likely to hand out the study information packs. It was imperative that the community midwives fully understood the participant inclusion and exclusion criteria. For example, during their routine appointments, they needed to allow time to discuss the study and assess women's eligibility (such as only primiparous women, those intending to breastfeed and likely to deliver in the study site). Indeed, these aspects are further elaborated on by Stuart, Barnes, Spiby, and Elbourne (2015) when involving community teams, including midwives. They described the difficulties for midwives to assess eligibility and often midwives are unclear about their role within the research process. They concluded that health care studies may require a dedicated research lead working in the community to facilitate the recruitment.

A further requirement was for one of us to be available to talk with potential participants about the study. This could occur after the potential participants received the study information pack from their community midwife or after they saw the study publicity material (e.g., posters). Often this could be conducted over the phone but on some occasions we were asked to attend an antenatal class to discuss the study prior to women consenting to participate.

One of us worked within the locality as an academic midwife researcher and both of us are parents who had breastfed our babies, in essence making us "*insiders*" to the community involved in the study. Sonya Corbin and Jennifer Buckle (2009) discuss the relationship of researchers conducting qualitative studies and the complexities that this may present for the researcher and for the participants. A useful advantage of being an "*insider*" is that you have shared knowledge, a common language, and identity, although researchers have to mindful of how they declare this insider knowledge and what power this may exert over the study. These aspects have been considered in a number of articles, particularly with regard to devising methods to build trust in the research participant relationship. Elliott, Watson, and Harries (2002) employed a strategy of peer interviewers to access drug users. They observed that the value of these peer interviewers was their ability to introduce and vouch for outside researchers because they were trusted by those the researchers wished to access.

In our experience, we spent considerable amount of time with "gatekeepers" (Devers & Frankel, 2000). Gatekeepers is the term often used to refer to those in power that can provide access to research participants; they could be organizational leaders, or the head of a department/ward. In our study, the gatekeepers were the midwifery team leads who gave permission for us to access community midwives. We therefore ensured that we attended community midwifery team meetings, frequently arranged to meet staff on the maternity wards and attended antenatal clinics to establish relationships with the midwives. From these relationships, we were invited to attend various community groups such as antenatal classes where we were provided with opportunities to speak about our research study to potential participants. Being invited by the community midwives with whom the pregnant women already had a trusting relationship provided us with further credibility, and we would suggest this facilitated recruitment. Indeed, these meetings often resulted in a flurry of emails in the days following from women volunteering to participate.

Predetermined Study Period of 12 Months

Our study period and grant funding was for a period 12 months; this timescale was intended to cover the recruitment period, data collection, and funders report. This required due consideration, preparation, and planning and a need for very clear parameters for each stage of the study to meet the funders' requirements and to ensure that we delivered within the agreed timescales. We would add that the funders report was completed within the timescale, but the study dissemination through the usual academic channels (i.e., academic journals, conference presentations) was completed outside of the 12 months' study time. Funders are often reluctant to fund for the dissemination period so thought needs to be given to how, when, and by whom study dissemination will occur.

Lead Time for Participants

Participant lead time, where you recruit participants with a long lead time before the study intervention or event occurs, was a particular feature for this study but could occur in a number of health care–related studies. Although we were actively recruiting women from 34 weeks' gestation, this clearly had implications of waiting for the mother to give birth, anywhere from 6 to 8 weeks from recruitment. There was then the possibility of participant withdrawal or forgetting about the study. To compensate for such scenarios, we agreed, and stated in our information pack, that we would remain in contact with the women once consent was received. We kept in contact with the women on a weekly basis via email addresses provided and mobile phone text messages. This approach enabled us to remain in contact with all participants as an attempt to keep them engaged and continue their participation. We strongly believe that this approach ensured that women continued to be engaged with the study and that no participant asked to be withdrawn although one participant was withdrawn due to birth complications and was therefore ineligible to continue in the study as per our study protocol.

Non-eligible Participants

Unfortunately, researchers often have to let potential participants know that they are not eligible to take part in a study. Although it is often easy to refer to the study protocol, those interested, often as lay members of the public, may appear very keen to engage with health care research. It is therefore important to take time and care to ensure that by letting individuals understand why they are not eligible and the study rationale will help to safeguard future positive responses to health care research recruitment in the future. It is therefore imperative that from the outset of a study design, the participant eligibility and timescales are agreed upon. One example is a Kathryn's PhD involving mature pre-registration nursing students at one institution (Hinsliff-Smith, 2013). The inclusion criteria stated that participants had to undertake a specific entry qualification to their nursing program gained from a local provider college. These inclusion criteria were agreed due to the nature of the research questions and therefore including participants that did not meet these requirements could potentially bias the results and subsequent findings.

Participant Engagement With the Study and the Data Collection Tools

A woman's decision on whether or not to participate in any health care research is often not made arbitrarily but is likely to be based on careful and rational consideration of a number of factors (e.g., perceived value of the research, time commitment, and perception of researchers). To aid recruitment, we were aware that we needed to emphasize the value of our research and

its relevance for both the participant and the advancement of infant-feeding services, locally and nationally.

Our infant feeding study sets out to explore the experiences of infant feeding in the first 6 weeks after the baby's birth, and we were cognizant that new mothers would be adjusting to their new role of parenting while potentially experiencing severe sleep disruption. We hoped to balance collecting meaningful qualitative data while also minimizing the commitment required from our participants. Although we had decided upon the use of a diary as a data collection tool, we provided two options (audio or written book) for participants to choose which was most appropriate for them while maximizing the chances of gaining a record of their experiences.

Our diary instructions about their daily entry were simply to document (recorded or written form) their experiences of infant feeding. We chose not to provide detailed requirements of diary structure, format or questions to be answered. We hoped for one entry per day, but anticipated that this would diminish as participant fatigue set in over the 6-week period. However, we did not find this to be the case: for those who returned their diary, diary entries were maintained through the full 6-week period. Although one could hypothesize that those who did not return their diary did not maintain it throughout the data collection period, our completion rate was 46%. We also found that when stressful situations had arisen such as infant weight loss, the mothers wrote considerably more, often illustrated and augmented with verbatim quotes and detailed reflections.

Conclusion

We hope that this case study on participant engagement and recruitment has allowed you to reflect on some of the pitfalls and solutions of participant recruitment and engagement at the very outset of your research proposal.

It is often very easy to get carried away with your research ideas and research aspirations without fully considering not only who your potential research participants are but how to recruit them to and engage them in your study.

You may come across serial research participants, individuals who are engaged in a number of studies and may be research active within public and patient involvement forums. However, the majority of participants have never engaged in research studies and therefore researchers need to consider "why would someone want to be involved in this study?"

The good news is that using the examples provided in the case study it is possible, with careful thought and planning, to engage and recruit participants into health care research. A useful

starting point is to engage with stakeholders, those in the setting, who are invaluable in shaping and directing your study.

Think carefully about the gatekeepers within your setting and how you might engage with these individuals, organizations, and community groups. In our experience, these are the individuals and groups that are pivotal in recruiting participants, particularly when initial participant responses may be lower than you envisaged!

Our key messages are, think about your research topic: How might this topic be of interest to members of the public? Would they be interested in helping you understand the problem better? If so, then you are more likely to engage with them and finally consider how you might successfully recruit them.

Exercises and Discussion Questions

1. Reflect upon your current study or previous work and consider the importance of obtaining gatekeeper approvals to enable recruitment of participants. What were the barriers and what would have made this easier?
2. Consider research that has been conducted in your field of expertise that has experienced difficulty in recruiting participants. Reflect on and discuss what were the difficulties and how could they be overcome. This might be an under recruitment from an agreed target or an over recruitment.
3. Consider your own research and discuss whether the recruitment materials and convenience of engaging with your study were suitable for your targeted audience.
4. What do you consider to be the influencing factors for recruiting participants to your own work?

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Web Resources

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Sue Ryder Care Centre: http://www.nottingham.ac.uk/research/groups/ncare/projects/everyday-decisions.aspx

Health Research Authority: http://www.hra.nhs.uk/research-community/applying-for-approvals/

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