Case Studies

# Chapter 18: Research governance in clinical research: Addressing ethical issues

Simone and Darren from the case study students are planning their studies and are considering the ethical issues that they must address.

Simone wants to explore the effect of a new non-pharmacological intervention to reduce perineal discomfort following episiotomy by comparing this with conventional treatment. Simone will be using a between participants post-test only design. The study will be undertaken at one NHS maternity hospital. Simone is going to recruit newly delivered mothers who have had an episiotomy. The mothers will be randomised to either receive the new non-pharmacological intervention or the conventional treatment. Wound healing will be monitored by hospital and community midwives. To measure perineal discomfort, the mothers will also be asked to complete three questionnaires; the first at 3 days after delivery, the second at one week and the third two weeks after delivery. What ethical factors should Simone address before she can begin her study?

**To reveal the answer toggle the show/hide button (¶) or press Control + Shift + 8.**

These will include:

* Securing indemnity insurance approval from the academic institution.
* Securing ethics committee approval for the study. This should probably be provided by the RES using the IRAS system. If the study site suggests this is not required, Simone will need to secure ethics committee approval from the academic institution.
* Obtain permission from the study site to access participants.
* Establish participant inclusion and exclusion criteria; this will determine whether Simone needs to put strategies in place that would be necessary if participants will include girls under the age of 16 or vulnerable adults.
* Decide who will obtain participant consent and ensure they have appropriate training and permissions for access.
* Decide when participants will be approached to obtain consent.
* Establish strategies to obtain informed consent from participants. This will include the production of participant information leaflets and consent forms.
* Ensure appropriate strategies are in place to securely store participant identifiers such as names and contact details.
* Ensure appropriate strategies are in place to securely store participant data.
* Develop strategies for the delivery and return of questionnaires.
* Decide how the situation will be managed if a participant decides to withdraw from the study.
* Decide how the situation will be managed if a participant reveals information on her questionnaire that Simone feels should be reported.

Darren wants to explore the lived experience of teenage girls who have anorexia. The participants will be recruited via an out-patient clinic at a local hospital. Darren is going to conduct semi-structured qualitative interviews with participants about their anorexia. The interviews will either be conducted at the participants’ homes or at the study site.

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These will include:

* Securing indemnity insurance approval from the academic institution.
* Securing ethics committee approval for the study. This should probably be provided by the RES using the IRAS system. If the study site suggests this is not required, Darren will need to secure ethics committee approval from the academic institution.
* Obtain permission from the study site to access participants.
* Establish participant inclusion and exclusion criteria. If Darren plans to include teenagers under 16 he will need to ensure appropriate strategies are put in place.
* Decide who will obtain participant consent and ensure they have appropriate training and permissions for access.
* Decide when participants will be approached to obtain consent.
* Establishing strategies to obtain informed consent from participants and their parents if appropriate. This will include the production of participant information leaflets and consent forms.
* Consider where the interviews will take place. Permission will be required to access facilities within the study site. If in the participant’s home, Darren will need to implement lone worker policies/guidelines. There may also be an issue regarding Darren interviewing girls on their own. Darren may need to consider involving a chaperone, asking one of their parents to be present or asking a female researcher to conduct the interviews
* Ensure appropriate strategies are in place to securely store participant identifiers such as names and contact details.
* Ensure appropriate strategies are in place to securely store participant data.
* Ensure strategies are in place to support participants who become distressed during or as a consequence of the interviews.
* Decide how the situation will be managed if a participant decides to withdraw from the study or if the participant’s parent wants their daughter to withdraw.
* Decide how the situation will be managed if a participant reveals information to Darren that he feels should be reported.
* Decide how the situation will be managed if a participant’s parent asks to know the content of the interviews.