Activities

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

## Activity 18.1

Access the following video clip about a cancer trial conducted in 1957 in which prisoners were injected with living cancer cells:

Britishpathe.com/video/heroic-convicts-aid-cancer-tests

What are the ethical issues arising from this study?

## Activity 18.2

In order to access the Nuremberg Code and the Declaration of Helsinki see:

Nuremberg Code:

BMJ 1996; 313 DOI: https://doi.org/10.1136/bmj.313.7070.1448a (Published 07 December 1996)

Declaration of Helsinki:

*JAMA.* 2013;310(20):2191–2194. doi:10.1001/jama.2013.281053

## Activity 18.3

See the following additional information about research governance and addressing the needs of specific client groups:

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>

Sammons, H.M. Wright, K. Young, B. and Farsides, B. (2016) Research with children and young people: not on them, *Archives of Disease in Childhood*, 101(12):1086–1089

Mental Health Research Network (2013) *Good Practice Guidance for Involving People with Experience of Mental Health Problems in Research*. London: Mental Health Research Network

Goldsmith, L. and Skirton, H. (2016) Research involving people with a learning disability – methodological challenges and ethical considerations, *Journal of Research in Nursing,* 20(6): 435–446. <https://doi.org/10.1177%2F1744987115591867>

## Activity 18.4

For more information about IRAS see:

<https://www.myresearchproject.org.uk/help/hlphraapproval.aspx>

This website includes a range of useful resources such as templates for consent forms and participant information leaflets.

## Activity 18.5

For details about GCP course content and training see:

<https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm>

## Activity 18.6

For more detailed information about factors to consider when conducting research involving children see:

<http://childethics.com/>

## Activity 18.7

Read the following paper:

Cheah, P.Y. and Parker, M. (2014) Research consent from people in resource-poor settings. *Archives of Disease in Childhood.* doi:10.1136/archdischild-2014-307121

The authors suggest there is an argument for taking consent from children under the age of 16 for their participation in research; particularly children from low-income countries.

What do you think about the ethical issues raised in these papers?

What do you think are the risks and benefits of adopting the strategies outlined in these papers?

## Activity 18.8

The following paper describes a study involving participants with learning disabilities and the strategies used in order to obtain ethical approval for the study. This included involving people with learning disabilities on the research team:

Northway, R. Howarth, J. and Evans, L. (2015) Participatory research, people with intellectual disabilities and ethical approval: making reasonable adjustments to enable participation. *Journal of Clinical Nursing.* 24(3-4): 573–581

The following paper gives further insight into the Mental Capacity Act and its application to practice:

Andrews, A. (2015) In whose best interests? *Midwives.* 19 Summer: 64–65

## Activity 18.9

For guidance on lone working see:

<https://www.suzylamplugh.org/>

## Activity 18.10

For guidance on working in partnership with research participants see:

<https://www.involve.org.uk/>

<http://www.jla.nihr.ac.uk/>

## Activity 18.11

Before making a submission for indemnity insurance and ethics committee approval, the following checklist may be useful in determining information to clarify:

Checklist

* Who will provide indemnity insurance and ethics committee approval?
* Do I need permission to access potential participants?
* Who is the gatekeeper regarding access to potential participants?
* Do I need permission to use information that I already have access to as part of my current role, for research purposes?
* Do I need an honorary contract, research passport or Disclosure and Barring Service (DBS) clearance?
* Do I need to undertake Good Clinical Practice (GCP) training?
* Can I guarantee participant anonymity?
* What strategies can be put in place to minimise any breaches of anonymity?
* Can I guarantee participant confidentiality?
* What strategies can be put in place to facilitate safety reporting?
* When and from whom will I obtain informed consent?
* Do I need to devise a participant information leaflet/sheet and consent form?
* Will the research involve babies, children, adults lacking mental capacity or vulnerable adults? If so:
* What specific documentation and strategies do I need to put in place if my research involves babies, children, adults lacking mental capacity or vulnerable adults?
* Are there any potential power relationships that may impact the research?
* What strategies can be put in place to minimise the impact of any power relationships?
* Is written permission required to access locations for data collection?
* Do lone worker strategies /policies need to be put in place?
* What strategies need to be in place to ensure the secure storage of data?
* Do participants need to be reimbursed for expenses they have incurred?
* Do participants need to be paid in acknowledgement for their time, effort and commitment to the study?
* Is follow-up support required for participants?
* Is an information sheet regarding follow-up support required for participants?
* Is written confirmation required of the availability of follow-up support for participants?