

11.4_C



Figure 1

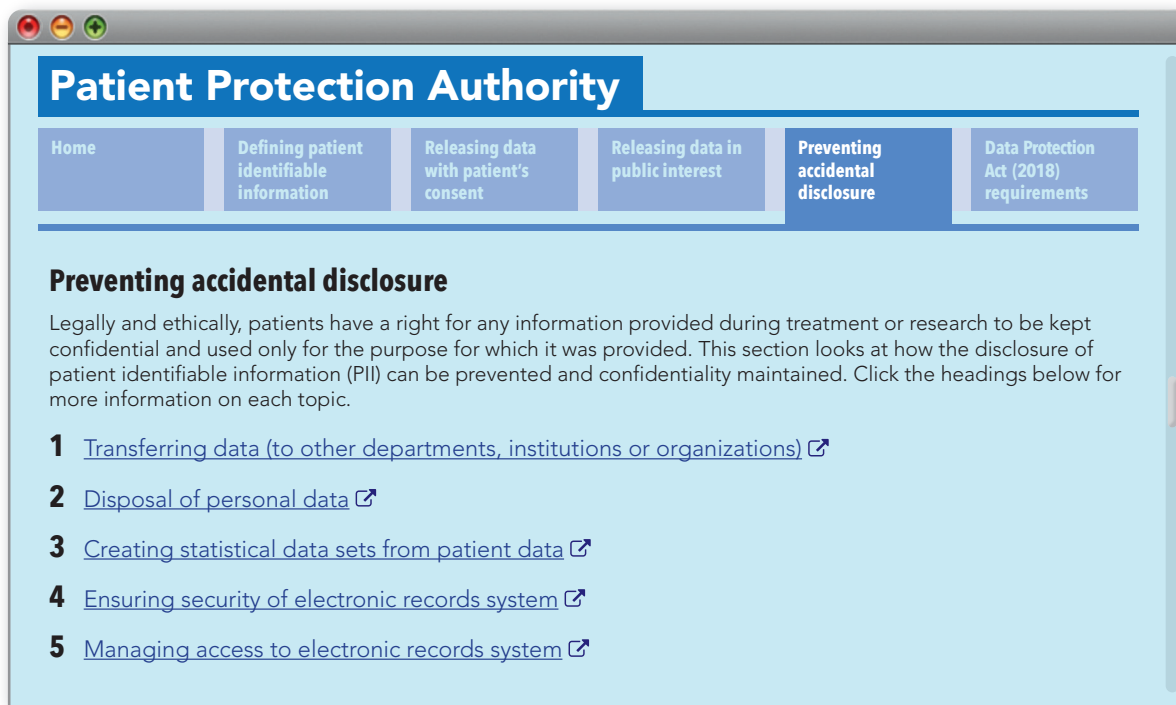


Figure 2

11.4_C



Hadmore Research Ethics Committee
Resources and guidance

These pages contain resources to help applicants produce good-quality applications for clinical trials. To ensure a successful application, it is essential that these examples are followed carefully.

1 **Extracts from successful trial applications**

- Clinical justification
- Implications of trial outcome for target patient group
- Societal benefits of trial outcome
- Economic justification
- Statement of conflict of interest

2 **Guidelines on legal compliance**

- Human Tissue Act (2004)
- The Human Fertilisation and Embryology (Parental Orders) Regulations (2010)
- Data Protection Act (2018)

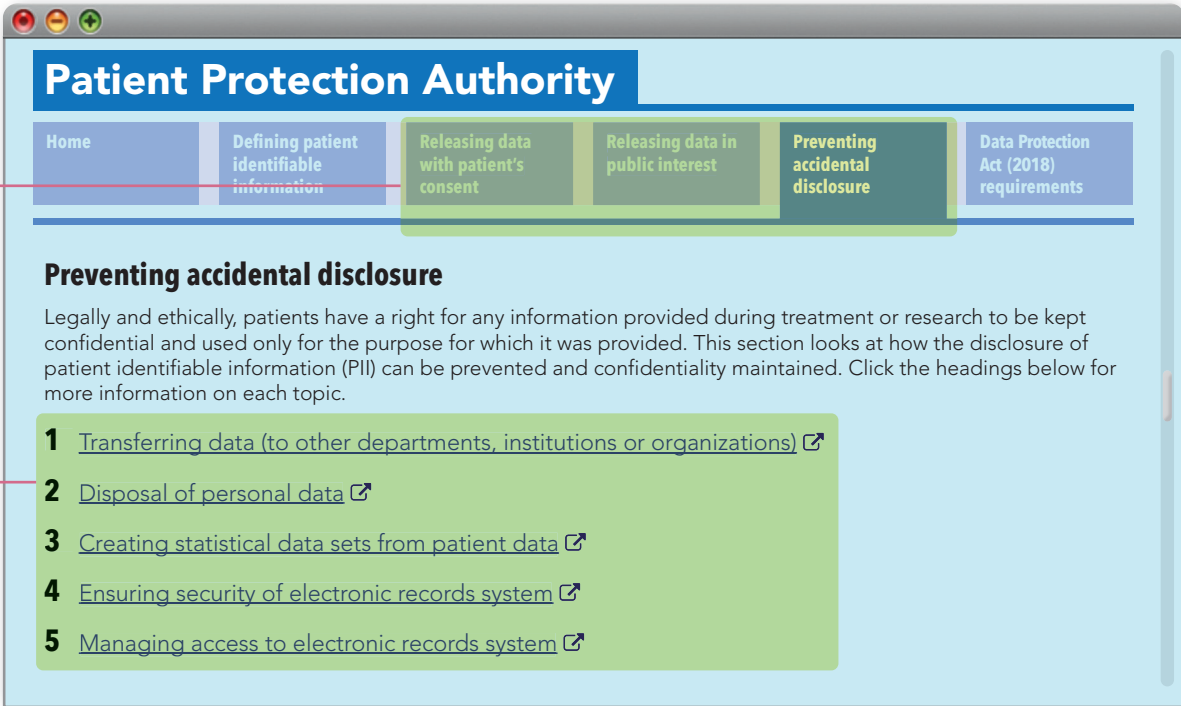
Useful research papers

- Jones AM, Bamford B. The other face of research governance. *BMJ*. 2004 Jul 29; 329: 280. Available from: <https://doi.org/10.1136/bmj.329.7460.280>
- Luyckx VA, Biller-Andorno N, Saxena A, Tran NT. Health policy and systems research: towards a better understanding and review of ethical issues. *BMJ Global Health*. 2017; 2(2): e000314. Available from: <https://dx.doi.org/10.1136/bmjgh-2017-000314>

Patient consent and safety sample documents

- Patient information sheet
- Consent form
- Current health status checklist
- Checklist for preclinical testing

Figure 1



Patient Protection Authority

3 Home | Defining patient identifiable information | **Releasing data with patient's consent** | Releasing data in public interest | Preventing accidental disclosure | Data Protection Act (2018) requirements

Preventing accidental disclosure

Legally and ethically, patients have a right for any information provided during treatment or research to be kept confidential and used only for the purpose for which it was provided. This section looks at how the disclosure of patient identifiable information (PII) can be prevented and confidentiality maintained. Click the headings below for more information on each topic.

4

- 1 [Transferring data \(to other departments, institutions or organizations\)](#)
- 2 [Disposal of personal data](#)
- 3 [Creating statistical data sets from patient data](#)
- 4 [Ensuring security of electronic records system](#)
- 5 [Managing access to electronic records system](#)

Figure 2