Exeter Clinical Research Facility

University of Exeter Medical School

NHS National Institute for Health Research

Exeter Clinical Trials Support Network

Event 16, 15th November 2018

UKTMN Annual Meeting 2018 – feedback

Workgroup 1: 'Implementing the General Data Protection Regulation'

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Data Protection legislation

- GDPR Europe-wide, includes derogations for research
- Data Protection Act 2019 (UK)

Both apply in the UK - GDPR will continue to apply after Brexit

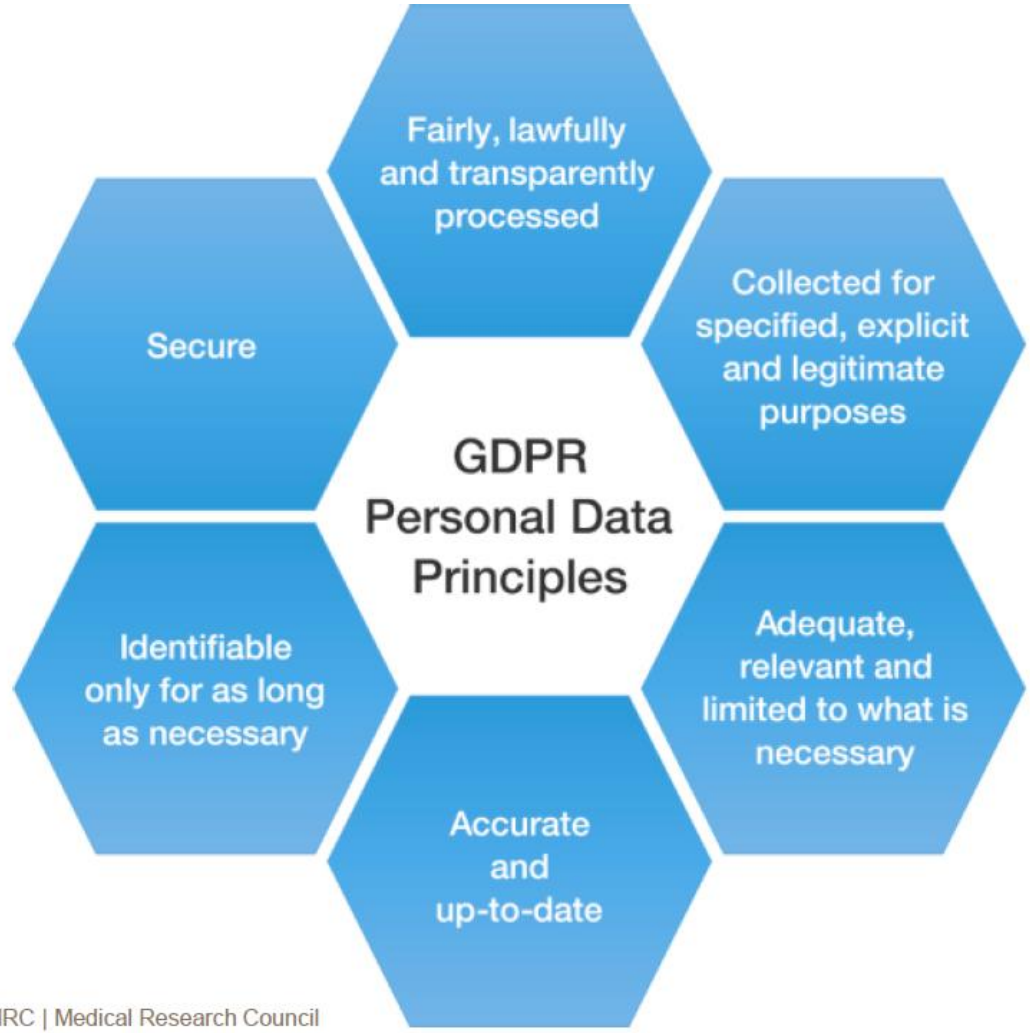
Processing (collecting, holding, using) of personal data

What is personal data?

- Structured information
- Relates to a living person
- Identifiable*

* ICO hasn't yet released new definition of identifiable – this may change!

GDPR Principles



MRC | Medical Research Council

The expectation is for organisations:

- To have a **lawful** basis
- To treat us **fairly**
- To be **transparent**
- Meet these principles

GDPR - lawful basis for research

- You must have a valid lawful basis in order to process personal data
- There are six available lawful bases for processing – no single basis is better
- Processing must be 'necessary' to achieve your purpose
- If you are processing special category data you need to identify both a lawful basis for general processing and an additional condition for processing this type of data.

Research lawful basis: **Task in the public interest (university, NHS) or legitimate interest (charity, commercial company)**

Most health and social care research uses special categories of personal data (health, sexual orientation, genetics etc) so we need an additional condition: **necessary for scientific research purposes**

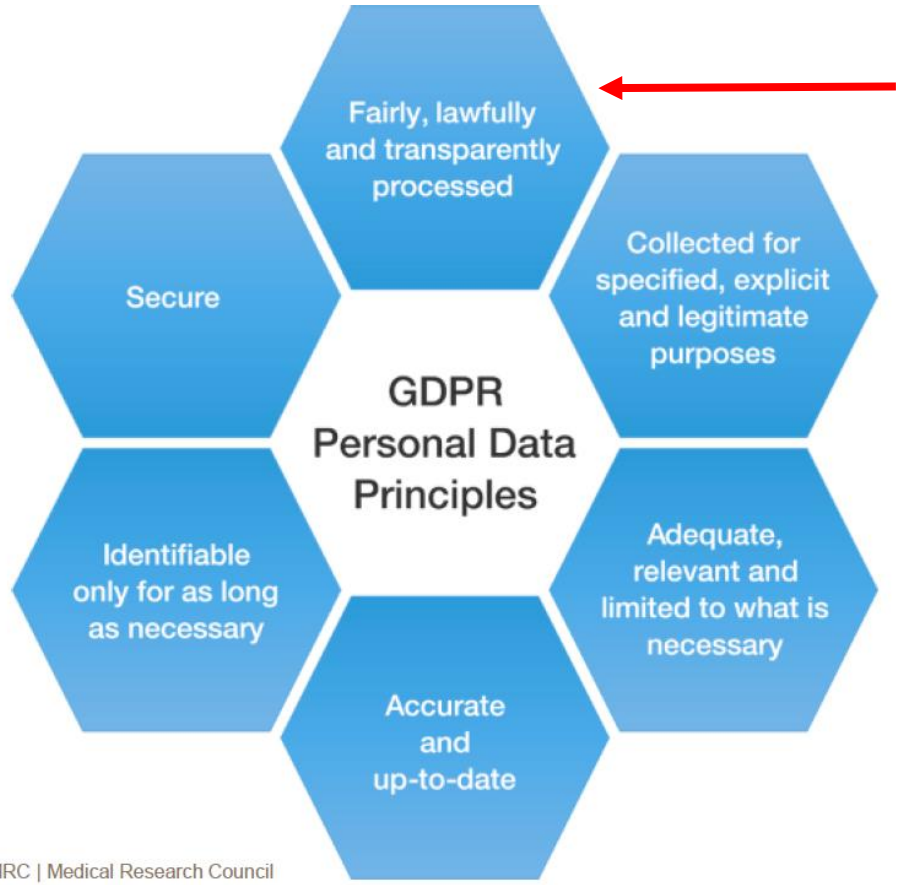
Lawful – complying with other relevant laws

- Common Law of Confidentiality
- Clinical Trials Regulations
- Human Tissue Act, etc

These have not changed as a result of GDPR - continue to apply to our research

GDPR Principles

Good news = research is already well-ahead with these principles!



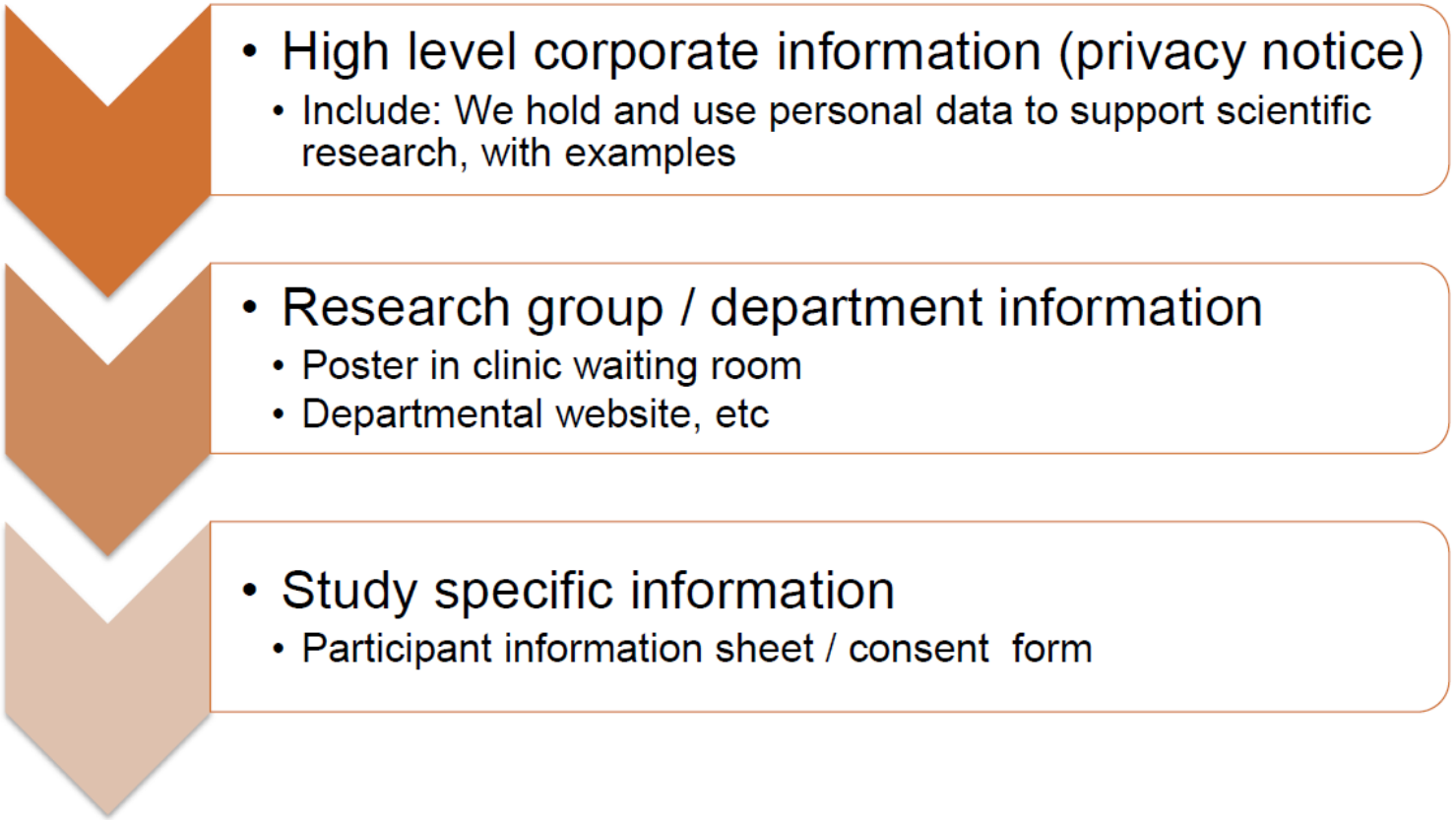
Key area of current concern = **transparency**

Fairness and Transparency – in our research

- Open and honest with participants – we have nothing to hide, research depends on trust
- Clear, concise, understandable information about what data we collect, why and how it is processed (collected, used and stored)
- Easy to find – doesn't have to be in one place. Important things can be in many places.

- HRA wording - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/

Transparency – the right to be informed



Various levels to transparency and many opportunities to do this appropriately

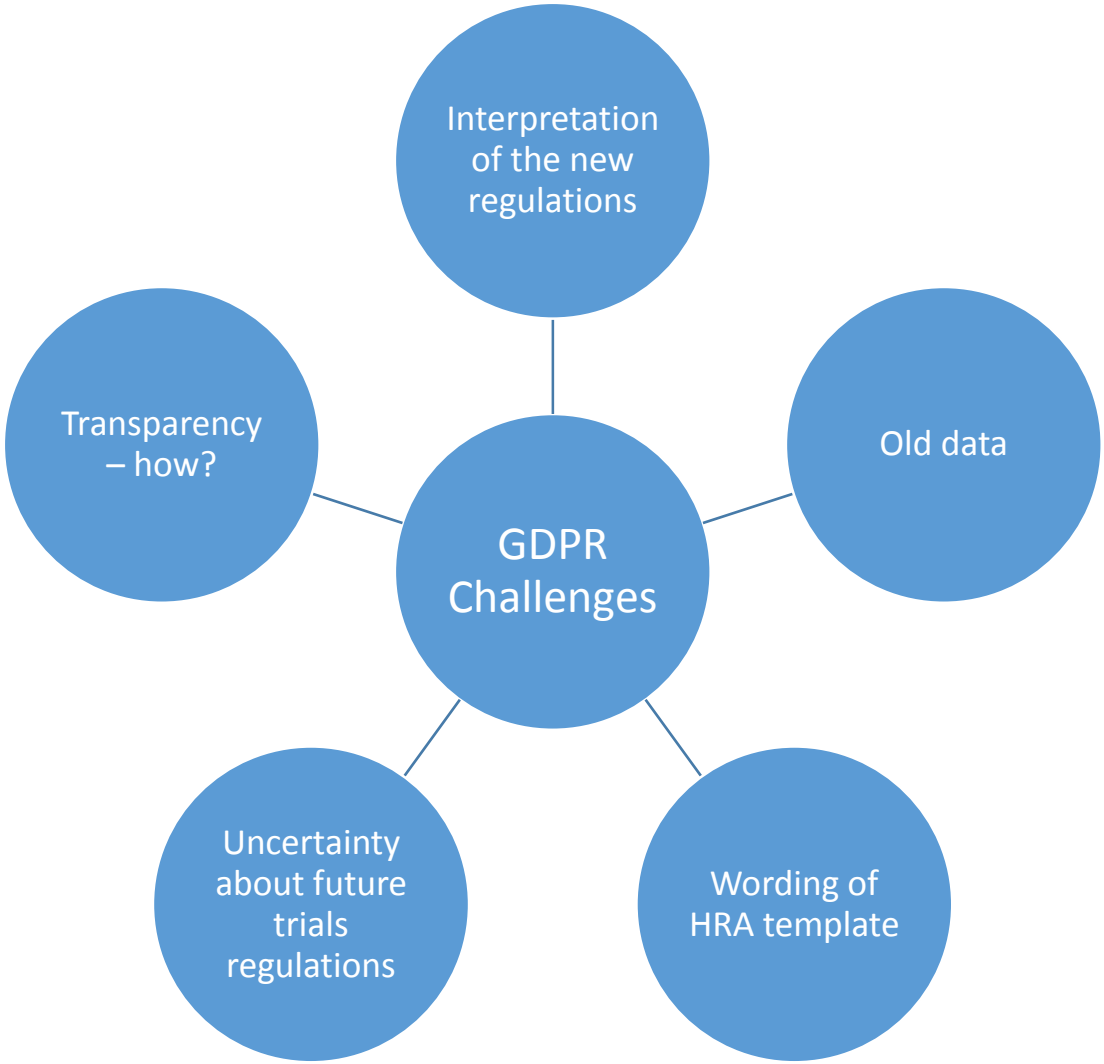
Transparency – helping people notice the info

Not enough to have notices on websites – you need to let people know the information is there

How:

- Depends on opportunities for contact in the study (consent discussions, visits, newsletters)
- Contacting individuals carries risks – old details, unintended disclosures
- Use best endeavours – measures that are appropriate for your study and your population

GDPR session – main feedback



General Data Protection Regulation – Key Points

- 28th May 2018 was the STARTING point – organisations need to demonstrate efforts toward compliance not a finished process
- Information is available, but there are still a lot of unknowns
- Research is well-advanced compared to other industries
- Consent is NOT the legal basis for processing research data
- There are different interpretations (legal teams, different organisations, DPOs, researchers, Sponsors) - encourage dialogue, don't get stuck in the middle as the researcher
- Don't struggle alone - GDPR is a corporate responsibility (UOE/RD&E):
  - Data Protection Officer (DPO)
  - Research Governance Office

Most importantly = DON'T PANIC

GDPR wasn't aimed at clinical research - look at the principles, we already do these!

GDPR Help

There are good sources of information:

Original slides from TMN GDPR workgroup - Dr Sarah Dickinson
https://www.tmn.ac.uk/global_engine/download.aspx?fileid=CB72B748-D4D8-407B-A423-525F519DC568&ext=pdf

MRC Regulatory Support Centre: https://mrc.ukri.org/research/facilities-and-resources-for-researchers/regulatory-support-centre/gdpr-resources/

MRC GDPR animation: Likely lawful basis for research:
https://www.youtube.com/watch?v=8A0wo4QYyJQ

HRA Guidance: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/

Information Commission's Office: https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/