



# The General Data Protection Regulation (GDPR) : using personal data for scientific research

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# Focus

## Key provisions for biobanking research

Principles

Lawful bases for processing

Consent

New rights if consent is the lawful basis

Not covering organisational compliance or the Data Protection Bill

# Scope and definitions

- GDPR covers all processing of personal data
- Definition of personal data
- Does not apply to anonymous information
- Restrictive in many areas of data processing but seeks to be more enabling in the context of scientific research

# Preparing for the General Data Protection Regulation (GDPR)

## 12 steps to take now

1

### Awareness

You should make sure that decision makers and key people in your organisation are aware that the law is changing to the GDPR. They need to appreciate the impact this is likely to have.

2

### Information you hold

You should document what personal data you hold, where it came from and who you share it with. You may need to organise an information audit.

3

### Communicating privacy information

You should review your current privacy notices and put a plan in place for making any necessary changes in time for GDPR implementation.

4

### Individuals' rights

You should check your procedures to ensure they cover all the rights individuals have, including how you would delete personal data or provide data electronically and in a commonly used format.



5

### Subject access requests

You should update your procedures and plan how you will handle requests within the new timescales and provide any additional information.

6

### Lawful basis for processing personal data

You should identify the lawful basis for your processing activity in the GDPR, document it and update your privacy notice to explain it.

7

### Consent

You should review how you seek, record and manage consent and whether you need to make any changes. Refresh existing consents now if they don't meet the GDPR standard.

8

### Children

You should start thinking now about whether you need to put systems in place to verify individuals' ages and to obtain parental or guardian consent for any data processing activity.

9

### Data breaches

You should make sure you have the right procedures in place to detect, report and investigate a personal data breach.

10

### Data Protection by Design and Data Protection Impact Assessments

You should familiarise yourself now with the ICO's code of practice on Privacy Impact Assessments as well as the latest guidance from the Article 29 Working Party, and work out how and when to implement them in your organisation.

11

### Data Protection Officers

You should designate someone to take responsibility for data protection compliance and assess where this role will sit within your organisation's structure and governance arrangements. You should consider whether you are required to formally designate a Data Protection Officer.

12

### International

If your organisation operates in more than one EU member state (ie you carry out cross-border processing), you should determine your lead data protection supervisory authority. Article 29 Working Party guidelines will help you do this.

## Article 5

### Principles of processing personal data

- (a) Lawfulness, fairness and transparency
- (b) Purpose limitation
- (c) Data minimisation
- (d) Accuracy
- (e) Storage limitation
- (f) Integrity and confidentiality



## Article 5 Principles

Personal data shall be:

processed fairly  
and lawfully and  
in a transparent  
manner  
(lawfulness,  
fairness and  
transparency)

Collected for  
specified and  
legitimate purposes  
and not further  
processed in a  
manner which is  
incompatible with  
those purposes  
(purpose limitation)

Further processing  
for **scientific**  
**purposes** shall not be  
considered to be  
incompatible with  
the initial purpose  
(purpose limitation)

## Article 5 Principles

Personal data shall be:

Kept in a form which permits identification for no longer than is necessary for the purposes (storage limitation)

Personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, **scientific** or **historical research** purposes or statistical purpose (storage limitation)

## Articles 6 & 9

### The lawfulness of processing

- Requirements for lawful processing depend on category of data
- 2 categories of data:
  - Personal data (Article 6)
  - Special categories of personal data (Article 9)
    - Racial or ethnic origin
    - Political opinions, religious or philosophical beliefs
    - Trade union membership
    - **Genetic and biometric data**
    - **Health data**
    - Sex life and sexual orientation



## Articles 9

# The lawfulness of processing

Processing data in special categories prohibited unless one of the Article 9 provisions applies:

a. The data subject has given **explicit consent** to the processing of those personal data for **one or more specified purposes**

j. Processing is necessary for purposes in the public interest, **scientific or historical research purposes** or statistical purposes

- Must be in accordance with Article 89 (1)

## Article 89 (1)

### safeguards relating to processing for scientific research purposes

Processing for scientific research purposes shall be subject to appropriate safeguards in accordance with this regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to respect the principle of **data minimisation**. These measure may include **pseudonymisation** provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which **does not permit or no longer permits the identification** of data subjects, those purposes shall be fulfilled in that manner



## Articles 6 & 9

### The lawfulness of processing

Data controllers must establish and publish the lawful basis that they are relying on to process personal data



## Article 4

### Definitions - consent

Consent of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by statement or by clear affirmative action, signifies agreement to the processing of personal data relating to him or her

The GDPR does not give a definition of 'explicit consent' required under Article 9



# Article 7

## Conditions for consent

Where processing is based on consent the controller must demonstrate the data subject has consented

If consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from other matters

Data subject shall have the right to withdraw consent at any time. It must be as easy to withdraw consent as giving it

# Consent

Consent is one way to comply with the GDPR

It is not the only way

In some contexts GDPR compliant consent may be difficult

Consent is not preferred over the other legal bases and there are practical implications where an organisation relies on consent

# Consent

GDPR requirements do not affect the common law duty of confidence  
organisations do not need to change their consent practices in order to comply  
with the GDPR in order to maintain confidence

However consent obtained or assumed for reasons of confidentiality may not  
comply with the GDPR

It is only if the organisation relies on consent as the basis for lawful processing  
under Article 9 that the consent needs to be GDPR compliant

Existing good consent practices for clinical research will probably comply with  
the consent requirements under Article 9 GDPR



# Consent

What does this mean for the concept of broad consent under the GDPR?

V Chico and M J Taylor [Using and Disclosing Confidential Patient Information and the English Common Law: What are the Information Requirements of a Valid Consent?](#) *Medical Law Review*

‘It is often not possible to fully identify the purpose of personal data processing for **scientific research purposes** at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of **scientific research** when in keeping with recognised ethical standards for **scientific research**. Data subjects should have to opportunity to give their consent only to certain areas of research’

Recital 33



## Articles 12-22

### Rights of the data subject

In addition to setting a high standard, where processing is based on consent the data subject enjoys a number of rights linked to consent:

- The right to withdraw consent
- The right to data portability

Alternatives to consent

## Article 9

### The lawfulness of processing

The prohibition under Article 9 does not apply to:

(j) Processing necessary for scientific research purposes

Must be in accordance with the safeguards in Article 89(1) – data minimisation

Article 89(2) derogations where the rights are likely to render impossible or seriously impair the achievement of the specific purposes

## Rights of the data subject

### Derogations under Article 89(2):

Article 15 – Right of access

Article 16 – Right to rectification

Article 18 – Right to restriction of processing

Article 21 – Right to object

Further there is a specific provision in Article 17 – the Right to erasure that limits the application of that right where processing is necessary for achieving **scientific research purposes** (again subject to the safeguards in Article 89 (1) data minimisation

The UK Data Protection Bill



# Conclusion

- Centred around key principles of lawfulness, fairness transparency and accountability
- Significant exemptions for scientific research
- Consent may be arduous to achieve and may not be the most appropriate legal basis for processing of personal data for achieving scientific research purposes