Participant engagement and consent

In this series we will explore how to apply the principles of data protection to your research study as well as how to engage with and take informed consent from your research participants.

# Introduction

Many people associate the words ‘research ethics’ with red tape and think of it as just another tick-box exercise that they have to complete in order to begin their research.

However, the concept of research ethics first came to the forefront of people’s minds because of the Nuremburg trials and the horrendous atrocities that were committed on innocent human beings. After the trials, the Declaration of Helsinki was drafted. It outlines the basic ethical principles that researchers must adhere to when conducting their studies. Put simply it is protection and respect for other people, something that we should all be thinking about when designing and conducting our studies.

If you automatically tend to associate research ethics with burdensome requirements, you need to change focus and remember why these principles are important: to keep people safe.

The University of Manchester fully supports the creativity and ingenuity of our research community, but we also take the safety, rights, well-being and confidentiality of our research participants extremely seriously.

To support this, we have a wealth of guidance information available to help you meet the balance between methodologically sound yet groundbreaking research that is safe, well managed and committed to the protection of those who take part.

Take a look at each of the posts in this series which explore the ways in which you can ensure your study is designed and conducted in a way that also supports this balance and ultimately leads to good quality research.

# Recruitment of research participants

In this guide we will look at the recruitment of participants to your research study including approaching them and your research materials.

## Introduction

An essential part of any research study that involves human participants is recruiting individuals to take part. These may be members of the general public or those with specific attributes that you’re interested in, such as being members of a particular organization, within a particular age group or those with specific medical conditions.

## Approaching participants

No matter who your participants are you need to think about how to advertise your study so you gain sufficient interest whilst also ensuring that you’re not intrusive or aggressive in your approach.

Your approach should be inviting but you must ensure that potential participants don’t feel pressured or obligated to take part. Some common methods for approaching potential participants include the use of:

* Posters
* Telephone or Video calls
* Letters
* Social media posts

**It is important to be aware some methods can be more intrusive than others.**It’s always best, if possible, to approach potential participants indirectly rather than directly.

Using posters, flyers, leaflets or social media adverts are all excellent ways to gain interest without people feeling pressured into taking part. Other good methods include using emails or letters addressed to either large groups (distribution lists) or publicly available contact details. A [fuller list of methods organised by how intrusive they are can be found here](https://education.library.manchester.ac.uk/mre/recruitment-research-participants).

## Using Gatekeepers

Gatekeepers might be another option that could help facilitate your recruitment strategy. Gatekeepers, as the terms suggests, act as a channel for conveying information for a large group of potential participants and sometimes you may need to seek their permission before you’re able to access a specific group.

## For example:

This might be a professional organization where you’d like to speak with the employees. It’s likely that you’ll need permission from a manager or even CEO before you could approach these individuals.

Gatekeepers are not only able to provide access to an otherwise difficult to reach group, but they can also help with your recruitment strategy by circulating details of the study to the group on your behalf.

There are of course other potential methods for recruitment that involve contacting people directly through telephone calls, video call, instant messaging, chat groups or even in person. However, many times these are considered to be ‘cold calling’ techniques as the potential participant is often caught off guard by the invitation and may not feel as though they can decline. For this reason, it is advisable to choose a less intrusive method of approaching participants so they have both time and space to consider your invitation and decide if they wish to take part.

## A word of caution if using gatekeepers:

One must be aware of the possible power dynamic that may exist in organisations and make efforts to mitigate this and ensure that possible participants are free to choose if they would like to take part.

For example, if the gatekeeper is a manager who agrees to circulate the information to those they directly line manage, the employees may feel obligated to take part to either be viewed in a more favourable light or out of fear for possible repercussions for not taking part.

To help mitigate this, it is recommended that the person who circulates the information is impartial and that the message which is circulated re-iterates that participants are free to make their own decision, without any possible negative repercussions should they decline.

## Recruitment materials

When approaching your potential participants, you should use recruitment materials (also known as advertisements) to explain the purpose of your study as well as what’s involved and any specific requirements.

Recruitment materials may include items such as posters, flyers, leaflets, social media text, letters, emails or videos. They should strike a balance between capturing someone’s attention, and ensuring they are not overly coercive or promise unrealistic benefits. Materials should also be short and to the point, you will have an opportunity to provide more detailed information at a later date.

### ****The essential elements of a good advertisement include:****

* **What the study is about:** **Describe in general terms what your study is investigating**, such as: ‘ The study is about the correlation between blue light emissions from hand held devices (e.g. mobile phones) and a lack of quality sleep.’

### What will participants be asked to do: **Specify any tasks that the participants will be asked to do**during the study, such as: ‘You will be asked to take part in a one time, 1 hour long Zoom interview about your views on mobile phone usage and the quality of your sleep. You will also be asked to complete a diary for 7 days prior to the interview about mobile phone usage and your sleep patterns.’

### What are the inclusion or exclusion criteria: **Clarify any specific attributes the participants must have or activities they must do**in order to take part, such as: ‘You must use a mobile phone daily.’

### How can participants contact the researcher: **Provide contact details such as an email address or telephone number so those interested in taking part can contact you.** You may also choose to use a QR code that can be read by one’s smartphone that takes them to your website or automatically populates an email. For example, ‘You can contact the researcher by email: sleep@manchester.ac.uk; or by phoning 0161–777–7777’.

### Monetary amounts are not permitted: You may clarify that one will be compensated for their time or entered into a prize draw, but **you must not include details of how much as this is deemed to be coercive**. For example, ‘You will be compensated £20 for your time’ is deemed to be potentially coercive. Instead, this should be written as ‘you will be compensated for your time’ and the specific amount included in other study documentation.

## Case study example:

‘You’re conducting a research study about the impact of the COVID pandemic on the parents or guardians of school aged children.

As your child also attends school, you’re part of a WhatsApp group with all the other parents or guardians from your child’s class. Some of the parents or guardians you know and others you’ve never met before. As you already have their numbers, you’d like to send the advertisement to the group to see if anyone would be interested in taking part.

Part of this message would ask that if anyone is interested that they send an email to your generic research email address as opposed to replying in the group chat.

You would also make it clear that they are under no obligation to reply to the group text.’

## Summary

In this guide we explored how you might approach and recruit participants to your study.

Once potential participants respond to your advertisement and express an interest in taking part, you need to provide them with more specific information about what the study involves. This is done through the use of a participant information sheet.

# Participant Information Sheets

In this post we will explore best practices for providing further information to participants after they have applied to your research study.

## Introduction

In this guide we will be looking at providing potential participants with more detailed information about the study so they can decide if they wish to take part.

## Providing information after initial contact

Once potential participants respond to your advertisement and express an interest in taking part, you need to provide them with more specific information about what the study involves. This is done using a participant information sheet (PIS).

A good PIS is comprehensive, yet concise and written in lay language that members of the general public will be able to easily understand. You want to avoid participants needing to read a lengthy, complex document as this may result in them losing interest and hindering recruitment to your study.

If detailed, supplementary information needs to be made available to participants, such as the [Research Privacy Notice](https://www.manchester.ac.uk/discover/privacy-information/data-protection/privacy-notices/), you can provide a hyperlink to the relevant digital document or have paper copies available upon request.

The PIS serves an important purpose as it’s your opportunity to outline your research and specifically what you’d like the participant to do. Potential participants then need to have the opportunity to consider this information before deciding whether or not they want to take part. For this reason, the PIS should be given to participants **at least 24 hours before any activities are due to begin** (e.g. interviews).

## Components of a good PIS

In order to ensure that the Participant Information Sheet has all of the essential information needed for the participant to make an informed decision about participating, it should include the following key sections:

### 1. About the Research

* Who will conduct the study?
* What is the purpose of the research or what does it hope to highlight or achieve?

### 2. What would my involvement be?

* What will the participant be asked to do?
* How long will it take?
* Is participation a one-off event or part of a series?
* Will they be compensated for their time?
* What happens if they change their mind part way through?

### 3. Data protection and confidentiality

* What data will be collected about the participant?
* What is the legal basis for processing this data?
* What are the rights of the participant in relation to their data?
* Will their participation be confidential or will data be shared with others?
* What happens if something is revealed during the study that means the researcher needs to alert another person or group of people or provide support via charities or other organisations?

The last question in the list is often one of the most difficult to plan for.

## For example:

‘If you’re conducting interviews with members of the general public about their experiences during the COVID pandemic lockdown and they express concerns about their current state of mental health and well-being, you may need to provide them with support via mental health charities or encourage them to speak with their GP.

If they become very upset during the interview, you may need to call a family member or friend to come and meet with them or contact another professional organization for additional support.’

Another example involves disclosures and needing to report these to the relevant organisation or authority.

## For example:

If during the course of an interview a participant reveals child safeguarding concerns, you must report these following the University’s Child Protection Policy and note this requirement in the PIS.

### 4. What if I have a complaint?

* Contact details of the supervisor or first point of contact.
* Contact details of the Research Governance, Ethics and Integrity Team (if not satisfied with response from first point of contact).
* Contact details of the Data Protection Office and Information Commissioner’s Office (if complaint is in relation to UK GDPR).

### 5. Researcher contact details

* Should be the telephone number and or email address of the student.

### 6. Version number and date

* Version numbers and dates should appear in the header, footer or just below the title of all supporting documents and is required under UK GDPR.

### 7. Ethics committee and reference number

* The name of the ethics committee that granted approval (if applicable) and the reference number of your study

### 8. Additional sections that may be applicable

* Will the research project be published?
* Is the research project being funded?
* Disclosure and Barring Service (DBS) Check

## Constructing your PIS

Having all of these essential sections will help to ensure that your participants have detailed information about your research and can therefore make an informed decision about whether or not they want to take part.

Some other useful advice to remember when constructing your PIS is:

* Always use a UK GDPR compliant template, which can be downloaded from the research ethics website.
* Ensure that any other essential sections are also included. For example, if working with children or young people you should also include the section relating to a [DBS check](https://www.staffnet.manchester.ac.uk/compliance-and-risk/dbs/).
* If any information in the template is not relevant to your study (e.g. if you’re not planning on sharing data with others) then ensure it is removed to avoid potential confusion.
* The template contains words in red that need to be changed to the specifics for your study. It also contains guidance notes (e.g. in the header) that should be removed in your final version.
* Ensure you update the footer with a correct version number and date for your document. This will help to ensure that your participants are receiving the most up to date version, should you choose to make changes in future.
* Ensure you write the PIS in lay language. You should also consider the average reading age of your potential participants as you may need to simplify this further. For example, if you are planning on recruiting those with significant learning difficulties or those recovering from a stroke, you may wish to consider presenting your PIS in a more simplified format and even using pictures.
* You may need to have different PIS documents if you are recruiting more than one group of participants (e.g. teachers and parents)

## Summary

In this guide we explored best practice for providing information to participants after they express an interest in taking part in your research study.

# Obtaining Informed Consent

In this guide we explore types of consent and best practice for constructing a written consent form.

## Introduction

Once your participants have had the opportunity to review the information in your Participant Information Sheet (PIS), they may decide to take part in your study. This agreement to take part is known as informed consent and must be recorded by the researcher.

There are a number of different ways of recording consent, depending on the type of study being conducted and the specific groups of individuals who are taking part.

## The main types of informed consent are:

### 1. Written consent

Written consent is provided by signing or marking (e.g. thumbprint) a written consent form.

### 2. Verbal consent

Verbal consent is provided by asking the participant a series of questions (through the use of a consent script) and recording their verbal agreement to each statement. The recording can be done either by audio recording or through the use of detailed field notes. If field notes are used, you must include the participant’s name, the date on which consent is being taken and the specific statements they are agreeing to.

### 3. Implied consent

Implied consent is provided by ticking a box at the beginning of a questionnaire or survey in order to verify consent. In some cases, more than one tick box may be required if there are specific inclusion or exclusion criteria that you need to verify for your study (i.e. the participant being over 18 years of age, from a specific background or the user of a specific service) Please note that a full participant information sheet must still appear before the tick box.

However, there are cases where it is not possible to seek informed consent from participants such as when using publicly available data sets from Twitter or performing large scale observational studies in public spaces (e.g. parks).

In these cases, although informed consent will not be taken, it’s important to **consider how you will protect the confidentiality of participants**. If conducting observational studies, you should produce an information sheet and have this available in case you are approached by a member of the public.

## Written versus verbal consent

Depending on the study you’re undertaking and the specific group of participants you hope to recruit, you may need to decide whether written or verbal consent is more appropriate.

**Written consent** is the preferred method of the ethics committees as it assures a standardized written record of specifically what the participant agreed to. This method uses a standard template of initialled or checked boxes that correspond to specific statements which may be compulsory in order to take part in the research or optional.

**Compulsory:** ‘I agree to take part in the study.’

**Optional:** ‘I agree that my anonymized data may be shared with other researchers at the University of Manchester.’

It is recommended that you ensure all optional statements are last to avoid any potential confusion.

**Verbal consent**may be appropriate for studies conducted with vulnerable groups or those who require that the information is read out to them. For example, if your research focused on the lived experiences of undocumented migrants in Manchester, the participants may be leery of signing any official document. In this case, it may be more appropriate to take verbal consent. If using this method, you can adapt the template for the written consent form into a consent script where you read aloud each statement and then ask the participant to agree.

## One off versus ongoing consent

Another important consideration regarding informed consent is how many times you should seek it. For most studies, consent is sought and confirmed once at the beginning of the study and before any data collection takes place.

However, if your research study involves multiple visits, follow-up interviews or you’re involving vulnerable groups, you may choose to seek ongoing consent.

**Ongoing consent** is the re-affirmation that a participant is still happy to take part in your study. It can be given before each research activity (e.g. an interview or focus group) or can be incorporated as part of a longitudinal study.

Should you choose to take ongoing consent for your research, you’ll need to consider at which time points this should be done, how it will be recorded and what you will do if you are unable to contact the participant or they wish to withdraw from the study.

## Components of a good consent form

When constructing your consent form (or script for seeking verbal consent), it’s important to include statements that outline any specific requirements of the study as well as any optional requests that you want participants to consider agreeing to.

Some examples of statements that outline specific requirements might include:

* ‘I confirm that I have read the attached information sheet (Version 2, Date 20/8/2020) for the above study and have had the opportunity to consider the information and ask questions and had these answered satisfactorily’.
* ‘I agree to the interviews being audio recorded’.
* ‘I agree that any data collected may be published in anonymous form in academic books, reports or journals’.
* ‘I understand that there may be instances where during the course of the interview information is revealed which means that the researchers will be obliged to break confidentiality; and this has been explained in more detail in the information sheet’.
* ‘I agree to take part in this study’.

Some examples of statements that include optional requests might include:

* ‘I agree that any anonymised data collected may be shared with researchers at other institutions’.
* ‘I agree that the researchers may contact me in future about other research projects’.
* ‘I agree that the researchers may retain my contact details in order to provide me with a summary of the findings for this study’.

## Important tips to remember

Ensuring you have outlined all the specific requirements of participation as well as any optional requests will help your participants understand exactly what they are or are not agreeing to. To support this, please ensure you ask the participant to complete two copies of the consent form, one for you as the researcher and one for the participant to keep.

When constructing your consent form try to remember this best practice advice:

* Always use a UK GDPR compliant template, which can be [downloaded from the research ethics website](https://www.manchester.ac.uk/research/environment/governance/policies-guidelines/).
* Any points that are essential to participation in the study should be listed first with any optional points grouped together at the end. For additional clarity consider separating optional points into a new table.
* Remove any statements which are not relevant to your study to avoid confusion. For example, if you’re not planning on sharing data with others.
* The template provided on the [research ethics website](https://www.manchester.ac.uk/research/environment/governance/policies-guidelines/) contains words in red that need to be changed or deleted to match the specifics for your study. It also contains guidance notes (e.g. in the header) that should be removed from your final consent form.
* Update the footer with a correct version number and date for your form. This will help to ensure that your participants are receiving the most up to date version, should you choose to make changes in future.
* Number statements chronologically.

## Summary

In this post we explored best practice and considerations for obtaining informed consent including types of consent and constructing a written consent form.

# Research with children and young people

In this guide we will explore consent vs assent and what additional considerations you may have in obtaining assent where your research is with children and young people.

## Introduction

Consent is the agreement to take part that is provided by your participant. If your participant is aged **16 years or older, we use the term consent** but if they are **under the age of 16 years, we would use the term assent** to describe this agreement.

The possible methods for obtaining assent from a person under the age of 16 are the same as those used for obtaining consent: written, verbal or implied. However, the templates to help you draft assent forms/scripts use simpler language and often contain suggestions of pictures or other images to support understanding.

The method for obtaining assent will also differ depending on the age of the child. For example, a child of 4 years wouldn’t be able to read and understand an information sheet so verbal would be the preferred method for obtaining assent. Just as for recording consent, you must ensure that you document all instances of verbal assent appropriately in case of future query or concern.

## Obtaining parental consent

When you are planning to recruit children and young people under the age of 16, you must not only consider how you will obtain assent from those individuals but also how you will obtain consent from their parents/guardians to take part.

In most cases, assent from a child is not sufficient for them to be able to take part in a research study and you must also obtain parental/guardian consent. To do this, researchers will often liaise with the school/nursery/organization where the children are being recruited from for assistance with contacting parents/guardians. In this capacity, the school/nursery/organization is acting as a gatekeeper and will usually distribute study materials directly to parents.

It is recommended that information should be distributed to parents/guardians by at least two different methods to ensure the information is received. These may include:

* Information placed into the child’s backpack
* Emails/newsletters
* Text messages or messages on social media
* Information handed out by teachers directly to parents at the school gates

## Types of parental consent

Obtaining consent from parents/guardians can take place in two different ways but there are specific University requirements and stipulations to these methods.

The first way is called opt-in which means that the parents/guardians receive detailed information about the study and then sign a consent form or indicate agreement verbally to the researcher. This is the preferred method of the University ethics committees as it ensures there is no discrepancy between the parent’s/guardian’s understanding of what their child will be asked to do and what will realistically occur during the research.

For ethical purposes, opt-in consent is also required for the following types of studies:

* Those involving invasive procedures (e.g. dental exams)
* Those using audio/video recordings or photographs
* Those which will likely result in the child becoming distressed or upset

The other method for obtaining parental/guardian consent is called opt-out. In this method, detailed information about the study is sent to parents/guardians along with an opt-out form that has a specified deadline for completion. The opt-out form is an opportunity for the parent/guardian to indicate that they are not happy for their child to take part in the research. Should the parent/guardian complete this form and return it to the researcher, the child will not be able to take part in the research. However, if no form is received by the researcher, it is assumed that the parent/guardian is happy for their child to take part.

For ethical purposes, **opt-out consent is only permitted for low-risk studies where parents/guardians receive the detailed study information by at least 2 different methods**. The opt-out consent method involves a level of assumption, so as a researcher, you must ensure you have a plan of what you will do should a parent/guardian contact you to complain that they did not receive the study information and are not happy about the fact that their child took part.

## Information sheets for children and young people

Depending on the age of the child, an information sheet may be appropriate in order to help the child understand what they are being asked to do and what will happen to the information that they share with the researcher.

The information sheet should include simple language that is easy to understand, and if appropriate include pictures or figures for further clarification.

However, you must be cautious not to overly simplify the sheet for older children as this may interpreted as patronizing and result in the child not wanting to take part.

**If the child is aged 13 years or over, you must also ensure that the information relating to GDPR is included**. For ease, simple wording that relays this information has been included as part of the [information sheet template](https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/ethics/app-prep/).

## Summary

In this post we have explored what considerations there are for obtaining assent if your research is with children.

# Research with additional considerations

In this guide we will look at additional considerations around research with potentially vulnerable groups and research in a language or format other than English.

## Introduction

If your research will involve potentially vulnerable groups or will be conducted in a language or format other than English (i.e. British Sign Language or Braille) then there are a number of other considerations that you need to make when designing your study and supporting documentation. We will explore both these groups in this guide.

## Identifying potentially vulnerable groups

Vulnerability is a subjective term which means that whether or not specific groups of individuals are vulnerable will depend upon the individual circumstances of the participants. As an example, those aged over 60 are not automatically classed as vulnerable simply due to their age.

Some examples of potentially vulnerable groups may include, but are not limited to:

* Refugees/asylum seekers/undocumented migrants.
* Those with severe learning difficulties.
* Those with mental health difficulties.
* Those suffering from dementia/Alzheimer’s.
* Those recovering from strokes or other medical conditions.
* Those in emergency situations (e.g. A&E admissions).

If participants will be from potentially vulnerable groups, you will need to develop a plan of how informed consent will be taken and how you will continue to assess whether the participant has the capacity to provide informed consent. In order to plan for this, the researcher must have sufficient experience of working with participants from these groups or you will need to enlist the assistance of a carer or care team.

If the participants lose the capacity to provide informed consent during the research, you must withdraw them from your study. Any participant who does not have the ability to provide informed consent would fall under the Mental Capacity Act and therefore cannot take part in a research study unless that study has been approved by the [NHS Research Ethics Committee](https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/).

In addition to this, information sheets and supplementary information (e.g. research privacy notice) will need to contain more simplistic language. To assist researchers with this the [University has templates for both information sheets and the research privacy notice called ‘easy-access’](https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/ethics/app-prep/) that contain simple, one lined statements accompanied by a picture to provide additional clarity.

## Research in a language or format other than English

If conducting the research in a language or format other than English, you may need to provide translated documents to your research participants. Although translating documents can be a challenging task, we encourage researchers to use the easy access versions of supporting documents to make this process easier. You may also need to consider whether you need to have an interpreter accompany you throughout your interactions with participants.

If conducting the research in a remote community, you may need to seek permission from a village elder or family member before you can approach other members of the community. Ensure you are familiar with all cultural expectations before embarking on your research.

Another important consideration when working with these groups of participants is how many visits are required in order to complete the study. You want to ensure that you make the most of each visit, while not overburdening your participants. This may mean that you need to make multiple trips in order to ensure they do not become fatigued, or you take up too much of their time.

Finally, you need to consider the location of the research and whether you are able to travel to meet your participants as opposed to asking them to come to see you. If conducting interviews, focus groups or observations, you should make every effort to reduce the burden on participants by travelling to a location that is convenient for them. If, however, your research involves specific tests that must be done at a hospital for example, it may be

## Summary

In this post we have explored research with additional considerations such as research involving potentially vulnerable groups and research in a language or format other than English.

# Research with human participants: your responsibilities under UK GDPR

In this post we will explore the six principles for data protection when conducting research with human participants.

## Introduction

The UK General Data Protection Regulation along with the Data Protection Act 2018 concerns the collection of, holding, processing and using of information about individuals or more (‘personal data’).

The legislation balances the individual’s right to privacy with the legitimate interests of organisations wanting to process their personal data. UK GDPR gives extensive rights to individuals. When undertaking research with human participants it is important you understand what responsibilities you have in relation to how you collect, process and use your participants’ data.

Breaches of the UK GDPR may result in investigations by the Information Commissioners Office ([ICO](https://ico.org.uk/)), potentially leading to significant fines, civil or criminal liability, adverse publicity and could damage your reputation as a researcher.

## The six principles of Data Protection

Researchers must process all personal data in accordance with the following principles.

Personal data must:

1. Be processed lawfully, fairly and in a transparent manner; **(Lawful, fair and transparent).**
2. Be collected only for specified, explicit and legitimate purposes, and not be further processed in any manner incompatible with those; **(Legitimate and limited purpose).**
3. Be adequate, relevant and limited to what is necessary in relation to the purposes for which it is processed; **(Data minimisation).**
4. Be accurate and, where necessary, kept up to date; **(Accurate and up to date).**
5. Not be kept as identifiable data for longer than necessary for the purposes concerned; **(Storage limitation).**
6. Be processed securely **(Integrity and confidentiality).**

In the remainder of this guide, we will explore each principle in more detail.

### 1. Lawful, fair and transparent processing

This is an overriding objective of UK GDPR and when sufficiently met, it will help to ensure you meet the requirements for the other principles.

The **processing of personal data must have a lawful basis** (a legally acceptable reason for processing the data). There are six legal bases specified in the UK GDPR; the three that are important to understand from a research perspective are outlined below.

**Research being a ‘Public interest task’ covers the majority of The University’s research work** and likely be the most common legal basis for processing. It applies where the processing is necessary for the performance of a task carried out in the public interest. **As a result, personal data can be processed without consent.**

**Consent as one of UK GDPR’s lawful bases for legally processing personal data**is different to, and should not be confused with, consent that researchers usually seek from people to participate in a project. The need to seek consent from participants in research in order to satisfy [ethical considerations](https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/ethics/app-prep/) is necessary, but it is separate from the requirement under the UK GDPR. You can learn more about [participant consent in this post](https://medium.com/%40myresearchessentialswriter/obtaining-informed-consent-c0636df7740c).

UK GDPR sets a very high standard for valid consent and it may be difficult to rely on consent as your basis for processing. Consent can be withdrawn by participants at any time, so if a research participant exercised this right, the research team would need to stop processing that individual’s data. The University would therefore, not usually recommend that researchers rely on consent as their lawful basis for processing.

**As a public authority, The University cannot rely on legitimate interests for any processing it does to perform its public interest tasks**. However, legitimate interests may be the appropriate legal basis where it is difficult to demonstrate that the research is necessary to meet a public interest. For example, because it is funded by a private company and is commercial in nature.

**When processing special categories of data,** for example personal data about health, ethnicity, political opinions, religious beliefs, etc., you must meet an additional legal basis for processing. In these cases, the most likely condition for researchers will be that such processing is ‘necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with safeguards’.

**The fairness and transparency requirements** give control to participants; they have greater awareness of how their data is being used and can object if they wish. ‘Fair’ processing requires researchers to consider how their use of personal data affects the interests of the individual concerned; if it’s likely to cause them detriment, you must consider whether it is justified.

When you are collecting personal data from individuals you must be clear, open and transparent with those individuals, by explaining what you intend to do with their data. For research this information is most often provided to data subjects in the form of a [privacy notice or participant information sheet](https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/ethics/app-prep/). Transparency information must be concise, easy to understand and easy to find.

Good research transparency should help participants understand that data is commonly linked with other data sources, kept for a long time, reused to address important research questions and how their interests are protected.

**Privacy Notices** for research participants (full version and a simplified version are available on the [Ethics website](https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/ethics/app-prep/)). Links to them are also provided in the Participant Information Sheet templates.

You’ll need to choose the relevant one depending on the type of research you are doing.

### 2. Legitimate and limited purpose

This principle explains that personal data shall be collected only for specified, explicit and legitimate purposes, and not further processed in a manner incompatible with those purposes. Where you have obtained personal data for a specified purpose, you should not then be allowed to use it for other purposes (i.e., ‘further processing’) that are incompatible with that original purpose.

However, the UK GDPR states that the further processing of data for research purposes will be considered compatible with the original purpose for which the data was collected. In addition data collected for a non-research purpose may be reused for research purposes provided the necessary information is provided to the data subjects, and to do so before the further processing takes place.

### 3. Data Minimisation

This principle outlines the need for personal data collection to be adequate, relevant and limited to what is necessary for the intended purpose for which it is processed, i.e., collect only what you need to fulfil your research purpose.

This principle does not just apply to the amount of data you collect but who has access to it. This could apply to all aspects of the research work, e.g. consider whether all members of a research team and collaborators need access to the full data set, can anonymisation or pseudonymisation be utilised before sharing. Take a look at this post on [Data protection considerations](https://medium.com/%40myresearchessentialswriter/data-protection-considerations-post-6-d7427afacc39) for further information.

### 4. Accurate and up to date

If data is not kept up to date and inaccuracies amended, it may no longer be relevant. However, the purpose of some research projects might be to create a point in time archive, where updating would defeat the purpose. In this case researchers do not need to keep the personal data up to date.

### 5. Storage limitation

This principle refers to not keeping personal data for longer than necessary for the purposes concerned. The UK GDPR does not specify how long personal data should be held for, although a specific retention period may be required by a research funder or sponsor, or as a result of regulatory or policy considerations. If this is the case, ensure it is included in your [Data Management Plan](https://www.library.manchester.ac.uk/using-the-library/staff/research/research-data-management/planning/). In all cases the research participants should be told about the likely retention period. The University of Manchester Records Retention Schedule can be accessed [here](http://documents.manchester.ac.uk/DocuInfo.aspx?DocID=6514).

### 6. Integrity and Confidentiality

Personal data must be processed securely; information security breaches may cause serious harm or distress to individuals, cause embarrassment or be highly inconvenient. Individuals are entitled to be protected from all forms of security breach which requires researchers to ensure they are using appropriate ‘technical and organisational measures’ to gather, process and store personal data.

Depending on the nature of the research and associated risks, researchers should consider the technology to be used and liaise with [Research IT](https://www.itservices.manchester.ac.uk/research/) and or [Information Governance](https://www.staffnet.manchester.ac.uk/igo/) teams as appropriate.

## Summary

In this post we explored the six Data Protection principles for dealing with personal data and your responsibilities as a researcher to adhere to UK GDPR.

# Data Protection Considerations

In this section we explore what you need to know about data protection when conducting research with human participants.

## Introduction

We have discussed how information sheets and consent forms/scripts are important supporting documents for your research study. Both contain information not only about what you’re planning to do but also about what information you want to collect and what you’re planning to do with it. They also contain information related to UK General Data Protection Regulation (GDPR).

In this post we explore how UK GDPR applies when constructing information for your research study.

UK GDPR relates to personal information that makes it possible to identify a person directly or indirectly (i.e. through contextual elements or when linking multiple sources of data).

### ****Examples of personal information include:****

* Names, addresses, contact information
* Dates of birth
* Records of consent
* Audio/video recordings
* Photographs

UK GDPR also refers to **special category information** which is sensitive personal information about a person. These pieces of information are classed as special category as they require additional protections to ensure the information is only accessed by authorised individuals.

### ****Examples of special category data include:****

* Race
* Ethnic origin
* Political affiliation
* Religious beliefs
* Trade union membership
* Genetics/biometrics
* Health information
* Sexual orientation

## What does UK GDPR mean?

Now that we know what type of information is included under UK GDPR, we can explore what we need to do to ensure that information is kept safe and secure.

The requirements of UK GDPR stipulate that we must tell participants the legal reason why we are collecting and processing their personal information. **This reason is called the legal basis** and for the purposes of research at the University, this reason is listed as **public interest** and **a process necessary for research purposes**. More information about these specific reasons can be found in the [University’s Research Privacy Notice](https://www.manchester.ac.uk/discover/privacy-information/data-protection/privacy-notices/) and a copy of which (either digitally as a hyperlink/URL or physically as a separate handout) must be included as part of any information that you provide to your participants.

Another requirement is UK GDPR stipulates that we must explicitly list the personal and special category data that we plan to collect in the participant information sheet. Remember, personal information includes names, records of consent and any demographic information. By following the [University template for the participant information sheet](https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/ethics/app-prep/), you’ll see the information listed under the section related to confidentiality.

Finally, UK GDPR stipulates that we must be clear with research participants about how their data will be used, stored and shared. This is why specific information must be included in the participant information sheet and consent form in relation to these details.

## Data protection considerations

In order to be able to provide participants with detailed information about how their data will be used, stored and shared, you need to develop a data management plan. A data management plan (DMP) contains specific information in relation to the data generated from your research study including what you plan to record, how you will use the information, where the information will be stored, who will access it, how it will be published and when it will be destroyed.

Data management plans are created using the [DMPonline](https://www.library.manchester.ac.uk/using-the-library/staff/research/research-data-management/planning/) system and a copy of the plan should be submitted as part of any ethics application.

In order to construct your plan, you’ll need to consider the following:

### Collection

* How will the data be initially collected? Will this be on paper or electronically?
* Will you be taking audio/video recordings or photographs? What device will be used? How will these be stored?

### Use

* How will the data be used? Will it be identifiable, pseudonymised or anonymised?
* Will the data be shared with others at University of Manchester or those at other institutions? In what format will it be shared?
* How will the data be published? Will individuals be identifiable?

### Retention/Storage

* How and where will the data be stored and archived?
* Will you use a central repository and make the data openly available?
* Will you be retaining contact details to provide them with a study summary or to invite them to take part in a future study?

### Destruction

* When and how will the data be destroyed?

### Specifying data protection

The detailed information that you include as part of your data management plan must be consistent with the information you provide participants in the information sheet and consent form. This will ensure that what you tell the University you are planning on doing with the data matches with what you tell participants you will do with their information and what they agree you are permitted to do with it.

## Magic triangle of data protection

This triangulation of requirements is best described here as the Magic Triangle of Data Protection. It simply shows how for ethical purposes, the details of all three of these documents must match and the specific areas where these statements are usually misaligned.



The Magic triangle of data protection — The images is indicating the information in the middle (data sharing, contact details, future use and results summary) must match for the consent form, participant information sheet and data management plan.

The most important areas to cross check for consistency between your supporting documents are:

* Sharing the data with other researchers.
* Using the data in future research.
* Retaining contact details to provide participants with a study summary.
* Retaining contact details to invite participants to take part in future studies.

## Confidentiality

When it comes to confidentiality, you have some important choices to make in terms of the data you have collected and what you will do to ensure that the identity and other detailed information about your participants is kept safe. Most researchers will either pseudonymise or anonymise their data sets to ensure that the confidentiality of their participants is protected when the information is published. Although these terms appear similar, there are some important differences that you need to note before deciding on which method is most appropriate for your study.

### Pseudonymising

Pseudonymising refers to the process of removing identifying information from your data set (usually names) and providing each participant with a random ID number. A key is then created which lists the identifying information for each participant along with their corresponding ID so that individual contributions to the data set can be identified by the researcher in future. It is important that the key is stored in a separate location to the rest of the data.

### Anonymising

Anonymising refers to the process of removing all identifying information from the data set such that no link remains to make it possible to identify a participant. You may find that simply removing the name is not sufficient to make the data truly non-identifiable and therefore you need to change the information (e.g. using pseudo names or fictitious details) or in the case of audio/video recordings, use voice masking software.

You also need to consider any circumstances which would mean that you need to break confidentiality (i.e. a participant reveals that they are at risk of harming themselves/others or they reveal something that requires reporting to the relevant authorities).

**Should it be likely that there will be circumstances that arise during the course of the research, that would result in you needing to break confidentiality, you must provide details of this in the Participant Information Sheets and Consent form.**

## Withdrawal of data

How you choose to manage confidentiality will have implications on the ability of your participants to request that their information is withdrawn from the study.

If you pseudonymise the data, you are always able to maintain a link between the participant and their data. You must therefore consider how you will handle any withdrawal requests that may arise. Ensure you make it clear in the information sheet and consent form when it will no longer be possible for a participant to request that their data is withdrawn from the dataset (i.e. point of publication or once your thesis is submitted).

If you anonymise the data, you won’t be able to withdraw data from a specific participant as you’re unable to identify their specific contributions. Ensure you make this clear in the information sheet and consent form and highlight the time period that is available before you will anonymise the information (e.g. two weeks after the interview). If data will be anonymised immediately upon collection, ensure this is specifically mentioned.

## Data sharing

If you have clarified in the information sheet and consent form that you would like to share research data with either researchers at University of Manchester or researchers at other institutions/organisations, you must provide additional details regarding your plans, including:

* What data will be shared? All of it or only selected portions?
* In what format will the data be shared? Raw? Pseudonymised? Anonymised?
* With whom will the data be shared?
* For what purpose will the data be shared? To inform future work? To enable additional analysis?
* Will the data be shared outside of the UK?

It’s important to note that **sharing of data should always be an optional point on the consent form**and**if participants choose not to agree to this you must respect their decision**.

## Retention

You must also ensure that you clarify in the information sheet what data you will be retaining and for how long. You should follow the University’s [Records Retention Schedule](https://www.library.manchester.ac.uk/using-the-library/staff/research/research-data-management/policies/) which outlines the minimum amount of time that specific pieces of information should be kept. When retaining information, you must follow the University’s guidelines and expectations regarding appropriate storage facilities and backing up of data.

As with data sharing, the retention of data for future studies or the retention of contact details should be optional requests for participants as opposed to mandatory requirements. Again, if they choose not to agree to one or both then the researcher must respect this decision and ensure the information is destroyed appropriately.

## Summary

In this guide we have explored what you need to know about data protection when conducting research with human participants, including confidentiality and withdrawal of data.

# Frequently Asked Questions

Further detailed information on all of the topics that are covered in this series are available on the [Research Ethics website](https://www.manchester.ac.uk/research/environment/governance/) and via the [Frequently Asked Questions document](https://www.manchester.ac.uk/research/environment/governance/ethics/approval/). If after reading these resources you still have specific queries related to your research study, we would encourage you to first speak with your supervisor or Ethics Signatory.

The central ethics team are also available to assist with complex ethical queries from supervisors or Ethics Signatories.

# Thank you to our contributors

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