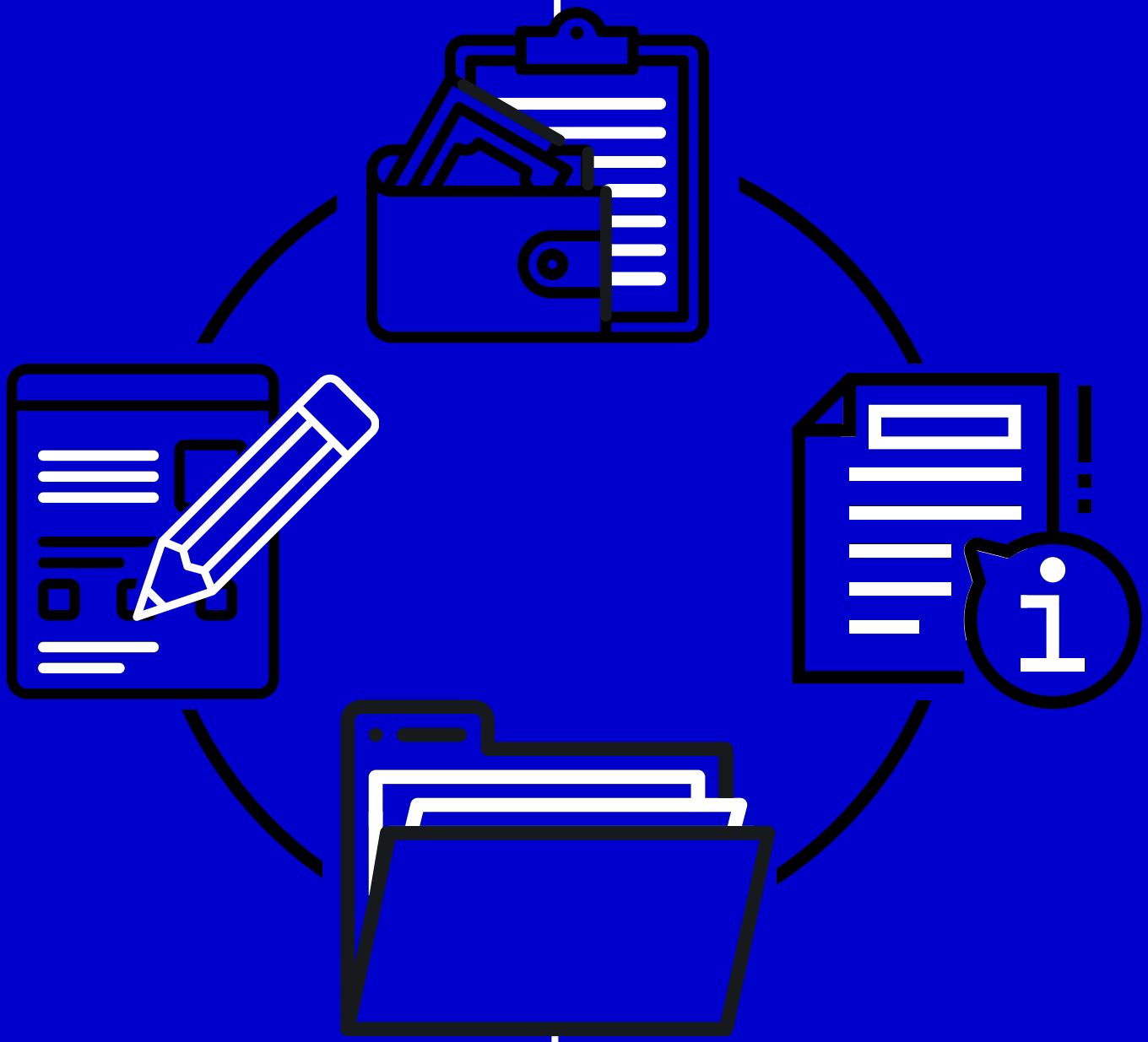
IMPERIAL

MedTechONE

HOW TO WRITE STUDY DOCUMENTS



MT1

COLLABORATIVE

www.imperial.ac.uk/medtechone/

HOW TO WRITE STUDY DOCUMENTS

This resource is designed to give you an overview of how to draft participant-facing study documents, including information sheets and consent forms.

A big part of recruiting participants to a clinical trial or research project involves writing clear, informative participant study documents.

Information sheets and consent forms perform the crucial role of both providing information to your participants, but also acting as a record of their informed consent.

Ensuring your participants are properly informed about what their participation in your project involves can be vital to participant safety, as well as having a smaller part in participant recruitment and retention.

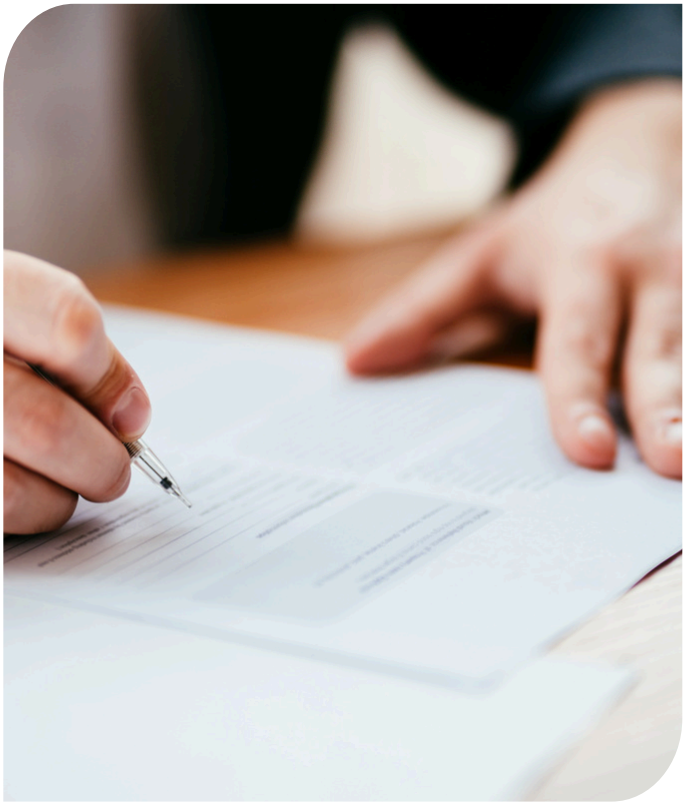
CONTENTS

HOW TO WRITE AN INFORMATION SHEET

The information sheet must include all information about the project including:

- The project title and aims.
- Project methodologies.
- Funding sources, details of sites and host organisations, and any potential conflicts of interest.
- Institutional affiliations of the researchers involved, including senior team such as the Chief Investigator.
- Anticipated benefits and potential risks, including any discomfort it may entail.
- The time commitment required of participants and any expected burdens related to the participant's use of the intervention.
- Any remuneration or compensation available to participants, such as travel expenses, and any limitations (including maximum amounts for expenses claims).
- Post-study provisions, such as access to the novel intervention if it is demonstrated to be superior to the control/placebo.
- Any other relevant study information.

Where the intervention being studied is shown to be more beneficial than its control group counterpart (e.g. the current NHS intervention for the same condition), the research team or host organisation must make provision for participants in the control group to receive the new intervention after their participation is complete. Where necessary, this provision can specifically be after the project is complete, to ensure the most accurate outcome is being adhered to.



HOW TO WRITE AN INFORMATION SHEET

- You should **include information on how you plan to disseminate the results** after the completion of the study. As a researcher, you have an ethical obligation to make the results of a project publicly available, and it is recommended that you make an additional effort to make the results available to the participants of the project.

- **Disclosing information on any risks involved in participating is vital to participant safety** – This is particularly important in studies utilising interventions that involve exposure to radiation and X-rays, novel pharmaceuticals, and novel surgical technologies.

You **must** openly disclose any risks involved in participating as clearly as possible.

- **Contact information for the project**, including the general contact details where participants can reach the project team for further information about the project, plus the contact details of the Chief Investigator, and any specific details of sites such as addresses and opening hours. You should state that any complaints can be directed to the Chief Investigator.

- **A statement that the research team will confidentially share information about a person's participation in the project with their GP** and other healthcare providers or clinicians and that any changes in their health related to this project will be communicated accordingly. N.B. Participants do have a right to object to this information sharing. You should make clear any possible consequences of not sharing this information with their healthcare provider, but ultimately if they persist in declining to share this information, you should adhere to the participant's wishes.

HOW TO WRITE AN INFORMATION SHEET

N.B. All information must be provided in an easy-to-understand format. This may mean tailoring the presentation of information sheets, summaries, and consent forms to your project's sample group.

This could mean:

- Providing documents in an appropriate language and utilising translation services for appointments.
- Providing documents in non-text formats such as braille or audio format or providing other visual aids as needed.

Ensure you engage your PPIE consultants when drafting your participant-facing documents as it's crucial to make sure that the participants you hope to recruit will be able to properly understand the information you're providing.

Visit this resource's accompanying piece, "Accessible Writing", available on the webpage for this resource.

HOW TO WRITE AN INFORMATION SHEET SUMMARY

The Information Sheet Summary should encapsulate the main parts of the information in a shortened format. The summary should usually only be one side of A4 long (with a reasonable text size e.g. 11pt or 12pt).

You should include:

- The project title and aims.
- The project methodologies.
- Anticipated benefits, and potential risks, as well as any burdens related to participating.
- Details of any remuneration or compensation plans e.g. travel expenses.
- Post-study provisions (as previously described).
- Contact information for the study and for the Chief Investigator.
- Site details including addresses and opening times.

HOW TO WRITE A CONSENT FORM

A consent form is usually comprised of three sections:

- A header section containing any affiliation logos, the title of the project, a short description of the project and explainer on what a consent form is, and the sentence "I, insert name here, understand that..."
- A full itemised list of the information the prospective must understand about their participation in this project, what it will entail, risks, and other important information, with boxes for the person's initials next to each item.
- A space for the participant's name, signature, and the date consent was received, along with space for the researcher's name, signature and the date consent was received.

As with all study documents, the consent form should also contain a footer that incorporates page numbers, and the document title, version number, and version date.

The main section of a consent form is the second point above. Each item in the list should be phrased to make grammatical sense where the full sentence is "I understand that... insert item here."

A few of the stock phrases that you could include in your consent form are:

- "I understand that I am expected to attend all appointments associated with participating in this project."
- "I understand that I am expected to adhere to the intervention as prescribed by the research team for the duration of the project."
- "I understand that my data will be securely stored for the duration of the project, and that biological samples (specify as needed) will be stored for X years after the end of the project."
- "I understand that my data will be stored for, and may be used for, future research purposes."
- "I understand that I can withdraw from, or end my participation in, this project at any point, without needing to give a reason, and without compromising my ongoing and future care."
- "I understand that this project presents Y risk."

HOW TO WRITE A CONSENT FORM

It can sometimes be useful to include a consent refusal option. At the end of the aforementioned list, add an option that states “I do not consent to participate in this study, and would like to be withdrawn”.

You should always **aim to tailor your consent form to your specific project**, carefully consider the risks participants will face as part of their participation, and make sure you fully describe both the responsibilities of the participant, and the process their data will go through as part of the current project and beyond (e.g. data storage for future applications).

The original copy of the consent form must be kept in the participant’s file, with copies backed up onto at least two secure external hard drives. **Consent forms should be checked at regular intervals to ensure compliance with the protocol and with ethics standards.**

Refer to the appendices of this resource to see a template consent form example.

It can be helpful to **read through the consent form with the participant**, to ensure they understand what they’re agreeing to.

EXPENSES & HOW TO CREATE AN EXPENSES FORM

Remuneration and compensation for research participants is a contentious topic. It is generally considered unethical to offer financial incentives to participants as there are common circumstances where it could act as a form of coercion, i.e. a person who would not otherwise have freely chosen to participate in a project may decide to participate for the sole purpose of acquiring the monetary reward.

You should also remember that you cannot legally offer incentives of any kind to participants under the age of 16 years, or to adults who lack capacity / their representatives.

The exceptions to these rules are:

- Financial compensation where participating in the study would cause significant loss of earnings for the participant. This is generally the case for disease studies where the participant will be hospitalised / in a controlled environment for the duration of their participation and will be unable to work.
- Covering the costs of any additional financial burden that the participant would experience as a direct result of participating in the project. This usually means the coverage of travel expenses to and from project-related appointments but can also cover other finances specific to the study (e.g. a study about diet may cause a participant to have an increased grocery bill, so the project may cover the difference between their usual grocery bill and the increased amount). These expenses are often covered to prevent the exclusion of participants who would not otherwise be able to afford to participate.
- The provision of any project-specific equipment that the participant may not otherwise have access to (e.g. FitBits or smart watches, blood pressure monitors, weighing scales etc). This serves the dual purpose of not burdening participants with a high cost of entry to the project, but also ensures that the equipment used by participants is of a suitable standard and consistency.

EXPENSES & HOW TO CREATE AN EXPENSES FORM

Depending on how the funding for your project is handled, you will be able to draw on the budget for expenses related to the project (provided that participant expenses have been accounted for in said budget). **It is recommended to design a standardised expenses form for participants to complete at, or after, their visits.**

A participant expenses form should include:

- Participant ID number/code
- Project title
- Date (form completed / submitted)
- Date of visit/s the expenses relate to
- Nature of expense e.g. travel – This should be specific enough to identify the purpose, so stating “travel” is not necessarily enough, but “taxi travel to and from appointment at X hospital on Y date” would be sufficient. If you have multiple expense types, you can stratify the form e.g. a section for travel, a section for accommodation, a section for other costs, etc.
- Individual Expense amount (GBP)
- Total expense amount

Refer to the appendices of this document for a template example.

N.B. Expenses forms are usually not kept completely anonymised as the participant will need to provide the banking or payment information they would like to receive the reimbursement to. **Treat expense forms as one of the most confidential documents, as they could link participant identities and project ID numbers, as well as containing sensitive information in the form of banking details.**

If your project is Sponsored by Imperial College London, you will submit your participant’s expenses on their behalf. This will likely mean transcribing the form the participant has filled in, into the standardised form provided by Imperial. To do this, you must know the Project Code that your expenses will be paid out from. You Chief Investigator will be responsible for approving expenses as they move through the system, so liaise with them to check for any issues with workload or availability.

EXPENSES & HOW TO CREATE AN EXPENSES FORM

Record keeping is vital to good budget management. As part of your expenses process you should be keeping a comprehensive spreadsheet of all expenses claimed and financial outgoings that you handle – It is recommended to at minimum stratify this by splitting the items into "participant expenses" and "trial expenditures".

In your spreadsheet you should be keeping records of:

Participant Expenses

- Date expense form was submitted / processed by yourself
- Participant ID number / code
- Type of expense, expense details
- Expense total (GBP)
- Any document ID numbers e.g. expense form #XXXX
- PO numbers as they are received
- Date PO received
- Notes – Keep a record of anything unusual or anything that might help you understand queries that may arise about expenses.

Other Trial Expenditures

- Date item was ordered / expense was submitted
- Details of the expenditure type e.g an item name (such as an item ordered from a stationers)
- Expenditure cost (item) (GBP)
- Expenditure total cost (GBP) – Where there is more than one item on an order.
- PO number
- Date PO received
- Date order / item received
- Notes – Keep a record of anything unusual or anything that might help you understand queries that may arise about expenses.

EXPENSES & HOW TO CREATE AN EXPENSES FORM

Tailor your spreadsheet to your project, but **ensure you are keeping detailed enough records to be able to quickly and accurately answer any queries about expenditure** that may arise.

A well-maintained record will also help you support the budget for the project, as you will be able to accurately keep track of spending. You should be completing regular audits of your records too, the frequency would depend on how many participants you are enrolling and how long the project is running for, to ensure that all of your records match up.

You must keep detailed records of project-related expenditures. **Audits will assess your financial records.**

As part of the audit exercise you should be checking:

- Expenses submitted match records of expenses paid.
- Hard copies of forms or POs are filed neatly, in a logical order, and are complete.
- POs have been received / evidence of payment has been received for all submitted expenses (older than a given date – of course newly submitted items may still be being processed).
- All goods have been received for submitted orders.
- Any totals tally up correctly, and match what has been submitted.
- Any digital records such as spreadsheets have been completed accurately and fully.
- Any budget documents have been updated with accurate records of expenditure for good budget tracking.

TEMPLATE: CONSENT FORM

[Project Title] Consent Form

I, _____,

TICK		INITIAL
☐	Have read and understood the provided Information Sheet and Information Sheet Summary.	☐
☐	Have had the opportunity to ask questions and am satisfied with the answers I have received.	☐
☐	Understand the purpose of this study, and the purpose of the intervention.	☐
☐	Understand that participating in this project will require the dedication of [insert number / amount] of my time.	☐
☐	Understand that I am expected to attend all appointments associated with participating in this project.	☐
☐	Understand that I am expected to adhere to the prescribed intervention for the duration of my participation.	☐
☐	Understand that participating in this study will pose X risk, and I understand that the study team will do their best to minimise my discomfort.	☐
☐	Understand that my biological samples will be stored for the duration of the project, and for a further Y years after the end of the project.	☐
☐	Understand that my data will be securely stored for the duration of this project.	☐
☐	Understand that my biological samples, and other data from my participation in this project may be used for future research purposes.	☐
☐	Understand that I can withdraw from this project at any time, without giving a reason, and that my continued care will not be diminished if I withdraw.	☐
	OR	
☐	I **do not** wish to participate, and request that I am withdrawn from this project.	☐

Print name: Signature: Date:

Clinician name: Signature: Date:

TEMPLATE: EXPENSES FORM

Project Title
Participant Expense Form

Participant name	Date of birth	Home address
Bank name	**Sort code**	**Account number**
Appointment name	**Appointment date**	**Appointment location**

Travel Expenses		
Expense e.g. train ticket	**Purpose of expense**	**Total cost**
	Total	**£**

Other expenses		
Expense e.g. food, accommodation	**Purpose of expense**	**Total cost**
	Total	**£**

Signature	Date

IMPERIAL

MedTechONE

CONTACTS

https://www.imperial.ac.uk/medtechone/

mt1-info@imperial.ac.uk

LinkedIn@MedTechONE