Study Protocol - Guidelines

The **Study Protocol** is a detailed outline of your proposed work. It will contain more in-depth background, methods and terminology surrounding your study and cover aspects during and after the study has concluded. The **Study Protocol** is both for your own reference and for the Ethiclear committee to review. It will never be shown to participants. The **Study Protocol** helps the committee understand what you plan to do, how, and determine if it has been designed in an ethical way.

💡***You are welcome to use your own Study Protocol forms, but for a simple and streamlined submission, we recommend you follow this form as a guideline when creating your own Study Protocol***.

💡***There is a template which complements this form which can be found here.***

The sections below indicate what you need to provide in a typical Study Protocol. We've included tips for you to better understand what the committee's expectations might be.

✅ Actions / Checklist

👉 Create your Study Protocol (You can begin by using **this template** if you want to).

👉 Use the *guidelines* below to populate your form (or web form or app if the Study Protocol will be digitally distributed to participants).

👉 Save it, and add it to your application with all other relevant files with your application here: https://www.ethiclear.com/new-application. Accompanying documents will include an Informed Consent Form (ICF), Participant Information Sheet (PIS) and other files, such as CVs of key personnel and any recruitment information (e.g. flyers, email invitations etc.).

Study Protocol Content Guidelines

💡*Remember, you can access a template containing these fields here.*

Document date	Document version number
💬 **Tip**: Date format DD/MM/YYYY	💬 **Tip**: For version tracking throughout the review process.

Study title (**≤30 words**)

💬 **Tip**: A short title which describes what the study is about - in lay terms for anyone to be able to understand.

Brief summary (**≤500 words**)

💬 **Tip**: Provide a summary of your study. What are you looking to achieve? Why is it important that you undertake this work? Is there any background information or are there previous studies which have led to this moment?

Primary and secondary outcomes (**≤300 words**)

💬 **Tip**: Explain what your desired primary outcome is. Are there any additional secondary outcomes you are interested in achieving as well as this?

Group allocation and study arms (**≤300 words**)

💬 **Tip**: Outline the key item/s you're studying and assessing. Will it be observational (looking at what has or is already happening)? Or intervention-based (giving something to someone to take or use)? If it's an intervention you will need to explain what it is, what it is made of and what it does or might do. Does it have a certificate of analysis (CoA) which attests to its quality and safety? Where was it produced and how should it be stored? Will there be a placebo? What is that made of? How many different groups will be allocated? Will a randomisation strategy be used – if so, how?
⚠ **When thinking about intervention studies, pay careful attention to the nature and intent of your intervention and whether it might be considered a clinical trial of an investigational medicinal product (CTIMP). Guidance by the MHRA can be found here.**

Chief Investigator (CI), Principal Investigator/s (PI) or Study Co-ordinator (**≤200 words**)

💬 **Tip**: The Chief Investigator (CI) has responsibility for the entire study – not just locally at a single site. The Principal Investigator (PI) is responsible for participants that they engage with directly. In studies with multiple sites or locations, there might be multiple PIs. They

remain the appropriate point of contact and retain responsibility for local activities where appropriate. The CI and the PI can be the same person. For much less or non-clinical-style studies, the person overseeing the project can be listed as the Study Co-ordinator.
⚠ **When submitting your application online, you will also need to attach a CV for the personnel listed here so the committee can see that they are competent to undertake the role.**

Biological sampling (≤350 words)

💬 **Tip**: If appropriate, outline here what samples will be taken or provided by the participant. Also detail how these samples will be collected – where and how? How should they be stored? You will also need to outline any safety precautions undertaken to ensure safety?

Wearables sampling (≤350 words)

💬 **Tip**: If any wearables (e.g. smart watches or continuous glucose monitors) are to be used in the study, outline what they will be – include any relevant model numbers and software to be used with them. Explain how data will be collected for analysis and how you aim to collate and compile this to achieve your outcome/s. Where will this data be stored? In the UK or EU? How will it be protected from unauthorised access.

Sponsor and collaborators (≤200 words)

💬 **Tip**: Explain who is funding this work and what their role is in this study. Will the study involve any other entities? Describe who they are, if they are collaborators and what they will be doing in full as part of this study.

Participant eligibility (≤300 words)

💬 **Tip**: Describe who your participants will be. Will they be a specific sex, sexual orientation, religion or ethnicity? Will they work in a specific job role? What age range will they need to be? Does it matter if they are pregnant? What if they are taking antibiotics? Where relevant, be specific in defining your cohort as much as you can here. You can split your points into inclusion criteria and exclusion criteria here if helpful.
⚠ **When thinking about eligibile participants, consider the appropriateness of their attributes and any regulations or mandatory HRA/NHS ethics review that might be relevant to specific groups of people. E.g. disability/ies, disease cohorts, children, prisoners, adults lacking capacity etc. The HRA/NHS decision-making tool can help you with this which can be found here.**

Recruitment strategy and enrolment (≤300 words)

💬 **Tip**: How will you find suitable people to take part in this study? Will you use social media ads? Leaflets? Flyers? Emails? Whether you're using a multi-modal approach or not, explain it here in detail. Once you've found your target population, how many people do you think you need and why? What is the cut-off? Have you used a power calculation to know what number of people you need to achieve your primary outcome?

Data collection (≤300 words)

💬 **Tip**: To answer your question you will need to collect data. Will it be personally identifiable information (PII)? What methods will you use to collect data in your study? Will it be paper- or digital-based questionnaires? On the web or an app? Outline which ones, why, and how often will need this data.

Data privacy and security (≤300 words)

💬 **Tip**: If you're collecting any PII, you need to explain how can it is handled properly in line with the general data protection regulation (GDPR). What measures are you taking to make sure that it is stored correctly and kept away from unauthorised individuals? Where PII is to be collected, who will be the Data Controller for the study and who will be the Data Processor? Do you have a dedicated Data Protection Officer (DPO) – who are they? This information is essential when PII and GDPR apply.

Study timeline (≤300 words)

💬 **Tip**: When will your study aim to start, and what will be the duration of the study? It is helpful to provide a Gantt chart. This can be a small grid of rows which include key activities or study benchmarks (e.g. "Initial questionnaire"), and columns of timepoints. You can fill the grid with blocks of colours to indicate when activities are due. As you won't have specific dates for starting, you can label timepoints as, for example "Day 0", "Day 14", "Month 4" etc.

Risks and risk management (≤400 words)

💬 **Tip**: What risks are there during the study? Are they risks to health? To data? To the environment? To animals? Describe all perceived risks here and how you plan to mitigate them during your study.

Reporting (≤300 words)

💬 **Tip**: What do you plan to do with the results? Explain here how they might be analysed, summarised and disseminated elsewhere. For example, in scientific publication, conferences or events, on social media and more.

If you have any questions, feedback or comments about this form, get in touch with the Ethiclear team at hello@ethiclear.com