Informed Consent Form (ICF) - Guidelines

The Informed Consent Form - or "ICF" - is essential for allowing prospective participants to provide consent to undertake your study activity/ies. It contains a list of declarations which the participant will sign to confirm their understanding and willingness to undertake the study, as it was described to them in the Participant Information Sheet (PIS).

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

💡***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 ICF. We've included tips for you to better understand what the committee's expectations might be.

⚠️ It's important to remember that the committee will need to see all of your submission forms ***as is*** – whether this is a .docx, .pdf, or a screenshot – of how it will appear to a potential participant in a document, on a web browser or app. In this way, the documents you provide to the Ethiclear committee as part of your submission will be the ***same ones*** you will show the participants (including any dates, text, images, version numbers, logos, styling, fonts etc.).

✅ Actions / Checklist

👉 Create your ICF (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 ICF 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 a Participant Information Sheet (PIS), Study Protocol and other files, such as CVs of key personnel and any recruitment information (e.g. flyers, email invitations etc.).

💡 **Don't forget, the ICF you submit should be "as is", and exactly what the prospective participants will see.**

ICF 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.
⚠️ **This should be identical to the title in your Study Protocol**

Organisation name

💬 **Tip**: This will typically be the name of the organisation with the primary interest in performing the study – usually the sponsor or funder.

Chief Investigator, Principal Investigator/s or Study Co-ordinator

💬 **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.

Statements of declaration

💬 **Tip**: These should be separate individual statements which the participant will agree to before taking part. They should be written in the first person. Example styles might include: “I have read and understand all of the information presented to me in this study.”, “I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason and without my legal rights being affected.”, “I understand what participation in this study involves.”, “I have had enough time to ask any or all the questions I have and, if so, have had them answered satisfactorily.”, “I understand all of the potential risks and benefits of taking part in this study.”, “I give permission for my data to be stored and processed in the ways that have been described to me”.

Optional add-ons which might be relevant to your study could include statements on transfer of data to other entities, countries or collaborators, being contacted about future studies, permissions around audio and video footage of the participant (if relevant), processing and storage of biological samples (and the duration/life span of this), things that might relate to insurance and/or anything else.

⚠️ **Each statement should be followed by an initials box for the participant to initial each point they will provide consent for.**

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