Application form guidance

This document includes the definitions and explanation of the data fields to be completed when submitting a record for registration on ISRCTN. The information requested is based on the definitions and set requirements for study registration from the World Health Organization (WHO) Trial Registration Data Set and the International Committee of Medical Journal Editors (ICMJE). Definitions of terms used are available at the ISRCTN definitions page.

To ensure your study is registered as soon as possible, please refer to the Rapid Registration Checklist at the end of this document.

Part 1 - Study Overview	
Section 1 – Initial information	
Responsible Registrant Declaration	Please confirm through ticking the box that you are the appropriate representative of the study's Primary Sponsor and understand your responsibilities.
Does this study include participants from UK centres?	Please select 'Yes' if your study has any study sites within the UK (England, Northern Ireland, Scotland, Wales), or 'No' if your study only has study sites outside of the UK.
Is this study interventional or observational?	Please select whether your study is observational (participants observed without any variables being manipulated) or interventional (treatments or actions are tested).
Section 2 – Title & additional identifiers	
Public title	We expect the public title to contain enough information so that the main aim of the study is easily understood by the public. The public title is usually used for the general public and may be the title given on patient information sheets. It should be brief but contain enough information so that a member of the lay public would easily understand the main aim of the study. Please note that the

	public and scientific titles should not be the same.
Scientific title	The scientific title is intended for use in grant and ethics applications. It should be in the PICO format, containing information on the **P**articipants in the study, its **I**ntervention(s) and the **C**omparisons and **O**utcomes of the study. If you use an acronym for your study, use upper case for the corresponding letters.
Study acronym	Optional field. An abbreviation of your scientific title. This can be made up from individual letters from your title or parts of a word from your title. Alternatively, you can supply a short name that you use to refer to your study.
Secondary identifying numbers	Secondary identifying numbers could include IRAS numbers, CPMS numbers, NIHR numbers (all UK only), identification numbers from other clinical study registries if your study is also registered anywhere else, or internal reference numbers assigned by the sponsor or funder. Select 'Yes' if you wish to add any secondary identifying numbers, or 'No' if you do not have any to add. From the dropdown, select the type of Secondary identifying number you wish to add from the options listed, and then enter the number. Multiple secondary identifying numbers can be added here if required. For a UK-recruiting study's IRAS number, this will be a seven-digit code for a Clinical Trial of a Medicinal Product, or a six-digit code for other types of study. For a UK-recruiting study with a CPMS number, the format is a five-digit number. If your study is also registered in the European Clinical Trial (EudraCT) database or Clinical Trials Information

	System (CTIS) and you have a unique EudraCT/CTIS number, the format will be YYYY-123456-78 for EudraCT and EU-CT 2022-50xxxx-xx-xx for CTIS. If your study is also registered in ClinicalTrials.gov, the format of the number assigned to your study will be NCT12345678. You can also enter any internal reference given to the study by the researcher, the funder, the sponsor etc. under the 'Other' category'.
Section 3 – Study dates	
Date of first enrolment	The date, or planned date, of enrolment of the first participant to the study, i.e. first participant in. If your data is historical, please use the date that you will start collecting data from records as the date of first enrolment.
Date of final enrolment	The end date, or planned end date, of enrolment of participants for the study, i.e. last participant in.
Completion date	The end date of your study. In many cases, it is the last date that data is collected. The correct format is dd/mm/yyyy.
Section 4 – Study design	
Allocation	Interventional studies only. Select the method of allocation which is most appropriate for your study from the drop-down list. For a single-arm study, select 'N/A'. View more information on the allocation types here.
Masking	Interventional studies only. Select whether the study is Open (masking is not used, clinicians are aware of which intervention participants are receiving) or Blinded (masking is used, clinicians are not aware of which intervention participants are receiving). View more information on the masking types here.
Control	Interventional studies only. Select whether the study uses a placebo, active, historical, or dose comparison control, or whether no control group is used. View

	more information on the control types here.
Assignment	Interventional studies only. Select whether the study uses single, parallel, crossover, factorial or sequential assignment, or another method or assignment. If 'Other' is selected, please briefly explain the method of assignment. View more information on the assignment types here.
Purpose	Interventional studies only. Select an option from the dropdown which most closely explains the purpose of this study. If 'Other' is selected, please briefly explain the purpose of the study. View more information on the Purpose types here.
Observational study design	Observational studies only. Select an option from the dropdown which most closely explains the observational design of this study. If 'Other' is selected, please briefly explain the observational study design. View more information on the observational study design types here.
Section 5 – Eligibility criteria	
Health condition(s) or problem(s) studied	Please specify the name of the disease, condition, or healthcare domain being studied. If you would like to add more information on the condition being studied, then this information can be placed in the plain English summary of protocol section.
Healthy volunteers allowed?	Please select whether healthy volunteers (human volunteers who are not part of the target population, i.e. do not have the condition being studied) can be considered as participants for this study, for example for a preliminary safety study.
Key inclusion criteria	Provide a numbered list of all the characteristics that all potential participants must have to take part in the study.
Lower age limit	Enter a number and select a unit from the drop-down for the lower age limit for the inclusion criteria. If there is no lower limit, please enter '0'.

Upper age limit	Enter a number and select a unit from the drop-down for the upper age limit for the inclusion criteria. If there is no upper limit, please enter a hyphen '-'.
Sex	Please select the biological sex of the participants taking part in your study from the drop-down.
Key exclusion criteria	Provide a numbered list of the characteristics that exclude potential participants from taking part in the study. Do not include the opposite of your inclusion criteria.
Target sample size at registration (numeric)	This is the target total enrolment of participants for the study (across all arms and all sites if a multicentre study). If your study is a cluster randomised controlled trial, please include the number of clusters and how many participants are included on average in each cluster.
Final enrolment number	Optional field if date of final enrolment is in the future, mandatory field if date of final enrolment is in the past. If this is a retrospective registration and enrolment has already ended, the final number of participants taking part in the study can be entered here. If recruitment is ongoing or has not yet begun, this field can be updated at a later date.
Section 6 – Study description	
Study objectives	The principal questions, objectives or hypotheses addressed by the study. For example, a study's objectives might be "Ascertain whether Drug X reduces blood pressure more than Drug Y". For observational studies, if no objectives are available, please enter the aims of the study. Multiple objectives, hypotheses or aims should be in a numbered list.
Interventions/Methodology	**For interventional studies**, please provide a brief methodology for each of your study arms, giving a summary of the treatment given to each group applicable (name, dose, how it is administered), the total duration of treatment and follow-up for all study arms, as well as details of

	the randomisation process if applicable (e.g. sealed envelope). **For observational studies**, please provide a simple and brief methodological description of what happens to participants taking part in this study (from enrolment to the end of their participation), including the total duration of observation and the total duration of follow-up. Please write in the third person and present or future tense.
Intervention type	Interventional studies only. Please select the intervention type from the drop-down that most accurately describes that used in your study. View the list here.
Phase	Conditional field, appears based on answer selected for Intervention type. Drug, device, and biological/vaccine studies are commonly carried out in a series of phases. Please select which option is appropriate from the drop down or select 'Not applicable'. View the list here.
Drug/device/biological/vaccine	Conditional field, appears based on answer selected for Intervention type. I f the intervention uses one or more drugs or biologicals, use the international non-proprietary name (INN) for each drug or other generic name if possible (not brand/trade names). For an unregistered drug, the generic name, chemical name, or research code is acceptable. For devices and vaccines, use the trade name or research code.
Primary outcome(s) **Outcome name** **Metric or method of measurement** **Timepoint(s)**	The primary outcome(s) of a study are the data, or results, from which the main aims of the study can be assessed. The outcome(s) can be used to decide whether a hypothesis has been proven or principal question answered. Please enter the primary outcome(s), the method used to measure (specific name required if medical test or questionnaire) the outcome(s), and the exact time points at which the outcome will be measured. For example: [Outcome A] measured using [method B] at [time C].

	For more information, see the COMET initiative.
Key secondary outcome(s)	Optional field. The key secondary outcome(s) of a study are the data, or results, that answer questions relevant to the study but secondary to those assessed by the primary outcome measures. Please enter a numbered list of the key secondary outcomes, the method used to measure each outcome, and the exact time points at which each outcome will be measured. For example: 1. [Outcome A] measured using [method B] at [time C] 2. [Outcome X] measured using [method Y] at [time Z]. For more information, see the COMET initiative.
Part 2 - Information for participants	
Plain English summary of protocol	Required field for studies recruiting participants in the UK, optional field for other studies. The plain English summary describes your research to the lay public and should be written in easily understood plain English in 1000 words or fewer. Please include all the following subheadings (further guidance here): Background and study aims Who can participate? What does the study involve? What are the possible benefits and risks of participating? Where is the study run from? When is the study starting and how long is it expected to run for? Who is funding the study? Who is the main contact? Please see the HRA's guidance on writing a plain language (lay) summary for more information on this.
Countries of recruitment	Please select all the countries where recruitment for the study is expected to take place. If you are registering a study taking place in the UK NHS, it may be eligible for inclusion in the NIHR portfolio

	database. Please click here for further information. If the UK does not show up as an option, this is because you have not selected 'Yes' for "Does this study include participants from UK centres?" on the first page.
UK study participating centres	Conditional field, appears based on answer selected for "Does this study include participants from UK centres?". Enter the name and address details of all participating centres/sites in the UK where the study recruits, submitting the details of the lead centre first. You can add another centre by clicking on 'Add another centre'. Please include details of all sites where the research is taking place rather than where it is administered from. For NHS sites in the UK, enter the first few characters of the name and select from the list to auto-complete all fields. For the address, include the department, faculty, or NHS trust here, not in the name field. The state or county can also be included here. If there is no post/zip code, enter a hyphen (-) in this field.
Study participating centres outside the UK	Optional field. A study may take place in many countries and have many participating centres/sites. Enter the name and address details of all participating centres/sites where the study recruits, submitting the details of the lead centre first. You can add another centre by clicking on 'Add another centre'. Please include details of all sites where the research is taking place rather than where it is administered from. For the address, include the department, faculty, or trust here, not in the name field. The state or county can also be included here. If there is no post/zip code, enter a hyphen (-) in this field.

Part 3 - Contacts, Sponsor, Funder and Ethics	
Contact	
Type, Title, Name	The principal investigator is the person responsible for leading the study. (In the UK this person is known as the chief investigator). The scientific contact is the person who will respond to scientific queries about the study. The public contact is the person who will respond to general queries, including information about the current recruitment status. At least one of each type of contact must be added (these can be the same person, but we encourage adding more than one person). To add another person click on "Add" below the Telephone and Email address fields. All persons listed will receive emails from ISRCTN regarding the publication and updating of the study record.
ORCID ID	An ORCID ID is a unique digital code for researchers that can be used to identify all their publications and grant applications. If you are interested in obtaining one, please visit the ORCID website for further information.
Address	The name of the institution and street address. The state or county can also be included here.
City	The contact's city
Country	The contact's country
Postcode	The contact's post/zip code. If there is no code, use a hyphen [-] in this field.
Telephone	An institutional telephone number must be used (if available). Add international calling code.
Email address	An institutional email address must be used (if available).
Sponsor	

Primary sponsor organisation	The sponsor is the organisation (rather than an individual) taking primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. Enter the first few characters of the sponsor institution and select the correct name from the drop-down list. If the name is not available, please enter the full name of the institution.
Secondary sponsor organisation	Optional field if you have more than one sponsor. Click "Add" if you wish to add a secondary sponsor.
Source(s) of monetary or material support	
Funder **Organisation**	All studies will have some form of source of monetary or material support, even if they are self-funded. Please list all the funders or sources of monetary or material support for this study, providing an English translation for names of institutions/organisations as appropriate. You can use the Funder Registry (formerly FundRef) functionality to select the names and contact details of major funders. If the name of your funder does not appear in the list, input it manually. Please enter "Investigator initiated and funded" if self-funded. If your sponsor is paying for incidental costs incurred by the study during its lifecycle, please list them as the funder of the study. You can add another funder by clicking on 'Add another funder'.
Ethics approval	
Ethics approval required	Please select whether ethics approval is required for your study or not.
Ethics committee approval – Approval status	Conditional field, appears if answering 'Ethics approval required' to the previous question. Please select whether your ethics approval has been submitted, not yet submitted, or approved.

Ethics committee approval – Status date	Conditional field, appears if answering 'yes' to Ethics approval required. If approved, please provide the date of approval in an 8-digit format (DD/MM/YYYY). If submitted, please provide the date of submission in an 8-digit format (DD/MM/YYYY). If not yet submitted, please provide today's date in an 8-digit format (DD/MM/YYYY)
Ethics committee approval – Ethics committee name	Conditional field, appears if answering 'yes' to Ethics approval required. Please provide the name of your ethics board, providing an English translation of the name if appropriate.
Ethics committee approval - Address	Conditional field, appears if answering 'yes' to Ethics approval required. Please provide a street address for your ethics board.
Ethics committee approval - City	Conditional field, appears if answering 'yes' to Ethics approval required. Please provide the city your ethics board is located in.
Ethics committee approval - Country	Conditional field, appears if answering 'yes' to Ethics approval required. Please provide the country your ethics board is located in.
Ethics committee approval – Postcode	Conditional field, appears if answering 'yes' to Ethics approval required. Please provide a post/zip code for your ethics board. If there is no code, use a hyphen [-] in this field.
Ethics committee approval - Telephone	Optional field. Conditional field, appears if answering 'yes' to Ethics approval required. Please provide a telephone number for your ethics board, if they have one.
Ethics committee approval – Email address	Conditional field, appears if answering 'yes' to Ethics approval required. Please provide an email address for your ethics board.
Ethics committee approval – Reference number	Conditional field, appears if answering 'yes' to Ethics approval required.

	Please provide a reference number attached to your ethics submission.
Part 4 - Uploads and outputs	
Third-party confirmation of study	Optional field, this can be emailed to us later but is a necessary prerequisite for us to have received before your study record will be published online. If you wish to upload now, choose a file from your computer showing third-party evidence that your study exists. This may include letters from ethics committees, funding agencies or government regulatory authorities. We will record that this information has been provided and store the document, but the evidence will not be publicly displayed. If you wish to upload later, tick the box to confirm this.
Do you plan to share individual participant data?	Please select the most appropriate option(s) for whether you plan to share participant-level data (sometimes referred to as raw data).
Individual participant data (IPD) sharing plan	Conditional field, appears if answering 'yes' to previous question. Please add details of your plan for sharing participant-level data (sometimes referred to as raw data). For further information on the details required please click here.
Do you wish to upload anything else?	Optional field. This may include a Participant Information Sheet, Statistical Analysis Plan, Protocol or Consent Form. Please note that these files will be displayed publicly as part of your study record.
Part 5 - Payment	
After your study registration has been curated by our in-house editorial team, you will be required to pay a one-off fee of GBP 250 (plus tax when applicable) for registering a study with an ISRCTN. This fee helps to cover the cost of editing and curation, data conversion, and permanent online hosting.	

Prompt payment is advised as the ISRCTN will not be assigned, and the study will not be registered until payment is received. This might affect whether the study is prospectively or retrospectively registered, which could then affect publication of the results. For individual submissions, offline payment has an administrative surcharge of GBP 20 (plus tax when applicable). When paying online with a credit card, a receipt will be sent by email once payment has been processed.	
Payment method	
Payment method	Choose whether you wish to make an online payment using a credit or debit card (this method means that the study record will be published immediately on payment) or an offline payment (we will send an invoice and your institution can pay by bank transfer). Offline payment costs an extra GBP 20 (plus tax when applicable) to cover administration costs and may mean a delay to study registration. The 'Funded registration' option is only for UK-based studies where the funder has an agreement with ISRCTN.
Miscellaneous questions	
Why did you choose ISRCTN to register your study?	Please select an option from the drop-down list.
Invoice Details (if offline payment selected)	
First name	Enter the contact details of where you would like the invoice to be sent. Please note that an invoice will not be generated until you have been informed that your record is ready for publication by a member of our editorial team.
Last name	
Institution	
Address	
City	
Zip	
Country	
Email	
Purchase order number/reference numbers	If this application is funded by your institution, you may need a purchase order (PO) from the finance department before an invoice can be paid. Check with them and enter the reference our invoice should quote in this field.
VAT number	Getting a study ID may be subject to VAT (value added tax or sales tax) depending on the applicant's country. Enter the relevant VAT identification number in this field.

Rapid Registration Checklist

If you would like to register your study as quickly as possible, please take note of the following:

- Ensure that the public title is in the required format.
- Ensure that the 'Intervention'/'Methodology' field contains all the required information.
- Ensure that the primary outcome(s) and key secondary outcome(s) are in the required format.
- Ensure that all the dates are entered as specified above, in the DD/MM/YYYY format.
- Select the online payment option and be prepared to make payment once you have been notified that your application is ready to publish.

Please note – offline payment (invoicing) is subject to delays, particularly if edits need to be made to the invoice, or if Purchase Orders need to be raised. If you are unable to proceed with an online payment, please ensure you supply us with accurate details for your invoice and are ready to raise a Purchase Order if your departments processes deem this necessary.