Preparing a Study Protocol Article

This page provides information about writing a Study Protocol for Wellcome Open Research, including the key sections that must be present in the article and details of figure and table formats. Please also refer to Wellcome Open Research’s editorial policies.

Criteria

Wellcome Open Research’s scope covers all original research in any of the areas funded by Wellcome, including biomedical science, population health, and applied research, as well as humanities and social science. The peer review focuses on whether the paper is fully scientifically sound, not on interest or novelty, and we welcome protocols for any study design in these Wellcome-funded areas. Study pre-protocols (i.e. discussing provisional study designs) may also be submitted and will be clearly labelled as such in the title when published. If specific feedback is being requested from reviewers and/or other readers from the community, this should be included in the article.

Study protocols for pilot and feasibility studies will also be considered.

All protocols for randomised clinical trials must be registered and follow the SPIRIT guidelines; ethical approval for the study must have been already granted. Protocols for systematic reviews should be registered and follow the PRISMA guidelines.

Language

All articles must be written in good English. Please note that the article will not undergo editing by Wellcome Open Research before publication and a manuscript may be rejected during the initial checking process if it is deemed unintelligible and hence not suitable for peer review.

For authors whose first language is not English, it may be beneficial to have the manuscript read by a native English speaker with scientific expertise. There are many commercial editing services that can provide this service at a cost to the authors.

Main Sections

1. Authors

Please list all authors that played a significant role in the research involved in the article. Please:
- provide full affiliation information (full institutional address and ZIP code, and e-mail address) for all authors, and
- indicate who is/are the corresponding author(s).

Criteria for authorship are based on the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Being an author implies full responsibility for the article's content and that the work conforms to our editorial policies. For large, multi-centre collaborations, the individuals who accept direct responsibility for the manuscript must be listed as authors.

Details of each author’s contribution must be listed in the Author Contributions section. Anyone who has contributed but does not meet the criteria for authorship should be listed in the Acknowledgments section. The involvement of any professional medical writer assistance must be declared.

2. Title

Please provide a concise and specific title that clearly reflects the content of the article.

3. Abstract

Abstracts should be up to 300 words long and provide a succinct summary of the article. Although the abstract should explain why the article might be interesting, the importance of the work should not be over-emphasized. Abstracts formatted with bullet point lists and separate headings are allowed, but the text will be included in the overall word limit. Citations should not be used in the abstract. Abbreviations, if needed, should be spelled out.

4. Keywords

Authors should supply up to eight relevant keywords that describe the subject of their article. These will improve the visibility of your article.

5. Main Body

The format of the main body of the article is flexible: it should be concise, making it easy to read and referee, and presented in a format that is appropriate for the type of study presented.

For most Study Protocols, the following standard format will be the most appropriate.

- Introduction
- Protocol
- Conclusions/Discussion

Please include a clear rationale for the study, as well as a detailed description of the protocol, including:

- How the sample is to be selected
- Interventions to be measured
- Sample size calculation - i.e. expected number of participants to make the outcome significant
- Primary outcomes to be measured, as well as a list of secondary outcomes
- Data analysis and statistical plan
- Details of any ethical issues relating to the study (and of the ethical approval received).
- Plans for dissemination of the study outcome (including the associated data) once completed.

**Ethics policies:** All research must have been conducted within an appropriate ethical framework. For studies involving humans or animals, details of approval by the authors' institution or an ethics committee must be provided in the Methods section. Please refer to the detailed ‘Ethics’ section in our editorial policies for more information.

**Clinical trials:** If the data associated with your article relate to a clinical trial then the Trial Registration details must be provided: name of registry, registry number, and URL of the trial in the registry database. We support the public disclosure of all clinical trial results (as mandated in the US FDA Amendments Act, 2007), for example on a public website such as clinicaltrials.gov. The disclosure of results on such sites does not preclude the publication of articles reporting and/or analyzing the same datasets in Wellcome Open Research. For further details about trial registration, see our editorial policies.

### 6. Author Contributions

The individual contributions of each author to the manuscript should be detailed in this section. Anyone who has contributed but does not meet the criteria for authorship should be listed in the Acknowledgments section.

We recommend using author initials and then stating briefly how they contributed; e.g.

‘AH, JS and IT conceived the study. MJ designed the experiments. AH, JS and MJ carried out the research. UGT contributed to the design of experiments and provided expertise in genomics. JS and IT prepared the first draft of the manuscript. UGT and MJ contributed to the experimental design and preparation of the manuscript. All authors were involved in the revision of the draft manuscript and have agreed to the final content.’

### 7. Competing Interests

Articles published in Wellcome Open Research must not contain content that could be perceived as ‘advertising’ and must include a Competing Interests section. Any financial, personal, or professional competing interests for any of the authors that could be construed to unduly influence the content of the article must be disclosed and will be displayed alongside the article. More information on what might be construed as a competing interest is available in our editorial policies.

If you do not have any competing interests, add the text ‘No competing interests were disclosed’.
8. Grant Information

Please provide the following details of your Wellcome funding:

- the grant number and
- the name of the grant holder

If you have other funding that is relevant to this specific piece of research, please provide the funder’s name, the grant number where applicable, and the author to whom the grant was assigned.

9. Acknowledgments

This section should acknowledge anyone who contributed to the research or the writing of the article but who does not qualify as an author; please clearly state how they contributed. Please note that grant funding should not be listed here.

10. Supplementary Material

There are no figure or table limits for articles in Wellcome Open Research. Additional information that is not absolutely required in order to follow the study design and analysis of the results, e.g. questionnaires, extra or supporting images or tables, can be submitted as supplementary material; descriptions of the materials and methods should be in the main article.

If you have any supplementary files, please include a section entitled 'Supplementary Material' at the end of the manuscript and provide a title and short description for each file. Please also include citations to the supplementary files in the main body of the article.

The Wellcome Open Research editorial team will liaise with the authors to determine the most appropriate way to display this material.

11. References

References can be listed in any standard referencing style as long as it is consistent between references within a given article. However, basic requirements include:

- Journal abbreviations should follow the Index Medicus/MEDLINE abbreviation approach.
- Only articles, books and book chapters, datasets and abstracts that have been published or are in press, or are available through public e-print/preprint servers/data repositories, may be cited. Unpublished abstracts, papers that have been submitted but not yet accepted, and personal communications should instead be included in the text; they should be referred to as 'personal communications' or 'unpublished reports' and the researchers involved should be named. Authors are responsible for getting permission to quote any personal communications from the cited individuals.
- Web links, URLs, and links to the authors’ own websites should be included as hyperlinks within the main body of the article, and not as references.
- References to trials on a clinical trial database should be as follows: [Authors/name of group], [title of the trial], In: ClinicalTrials.gov [cited year month date], Available from [URL of the link from ClinicalTrials.gov].
- Datasets published or deposited elsewhere (for example, in figshare, Dryad, etc.) should be listed in the ‘References’ section and the citation to the dataset should follow one of these examples.

12. Figures and Tables

All figures and tables should be cited and discussed in the article text. Figure legends and tables should be added at the end of the manuscript. Tables should be formatted using the ‘insert table’ function in Word, or provided as an Excel file. For larger tables or spreadsheets of data, please see our Data Preparation guidelines. Files for figures are usually best uploaded as separate files through the submission system (see below for information on formats).

Any photographs must be accompanied by written consent to publish from the individuals involved. Any distinguishing features, including medical record numbers or codes in the case of clinical images that could be used to identify the patient or participant concerned must be removed from the images.

Titles and legends: Each figure or table should have a concise title of no more than 15 words. A legend for each figure and table should also be provided that briefly describes the key points and explains any symbols and abbreviations used. The legend should be sufficiently detailed so that the figure or table can stand alone from the main text.

Permissions: If reusing a figure or table from a previous publication, the authors are responsible for obtaining permission from the copyright holder and for the payment of any fees (if applicable). Please include a note in the legend to state that: ‘This figure/table has been reproduced with permission from [include original publication citation]’.

Figure formats: For all figures, the color mode should be RGB or grayscale.

Line art: Examples of line art include graphs, diagrams, flow charts and phylogenetic trees. Please make sure that text is at least 8pt, the lines are thick enough to be clearly seen at the size the image will likely be displayed (between 75-150 mm width, which converts to one or two columns width, respectively), and that the font size and type is consistent between images. Figures should be created using a white background to ensure that they display correctly online.

If you submit a graph, please export the graph as an EPS file using the program you used to create the graph (e.g. SPSS). If this is not possible, please send us the original file in which the graph was created (e.g. if you created the graph in Excel, send us the Excel file with the embedded graph).

If you submit other forms of line art such as flow charts, diagrams or text to be displayed as an image, please export the image as an EPS file (e.g. if creating phylogenetic trees with specialized programs), or send us the original file that was used to create the image (e.g. EPS or AI files if Adobe Illustrator was used, or a DOC, DOCX, PPT, PPTX or equivalent file if Word or PowerPoint was used).
If none of the above options is possible then we also accept uncompressed TIFFs with a resolution of at least 600dpi at the size they are likely to be displayed at (see above).

**Photographs and microscopy images:** Photographs and microscopy images should be submitted as uncompressed TIFFs with a resolution of at least 300dpi at the size they are likely to be displayed (see above).

**Mixed images:** Images that are a mix of half-tone images and line art (e.g. annotated gels or images with scale bars) should be submitted as TIFF files at a resolution of 500dpi or vector files (e.g. EPS or Adobe Illustrator files). Please ensure that the text size is at least 8pt and lines are thick enough to be clearly visible at the size the image will be displayed.

**Images to be used as data:** If you are submitting photographic images as part of your raw dataset, please submit them as uncompressed TIFF files.

**Electronic manipulation of images:** The clarity of figures may be improved using image-editing software, but this must be done transparently and without misrepresenting the data (and the original, unaltered source data must be provided with the article). Brightness, contrasts or colour balance may be used to enhance electronic images, but such changes must be applied to the whole image; any non-linear adjustments must be made explicit in the figure legend. Specific features within an image must not be added or changed (e.g. amplified, removed or obscured); and if figures are composed from images that have come from different sources, such a different gels, or from different parts of the same source, this must be made clear on the figure (e.g. by adding dividing lines).