



Registered Reports

Study Protocol (Stage 1) submission template

A guide for authors preparing the first stage of their
Registered Report for submission to F1000Research

F1000Research

Contents

About	3
1 Title page	4
Authors	4
Title	4
Abstract	4
2 Introduction	5
Research question: background, importance and relevance	5
Hypotheses	5
Timeline	5
3 Methods	6
Basic methodological framework / identification strategy	6
Intervention	6
Sample and statistical power	6
Data collection and processing	7
Variations from the intended sample size	7
Pilot data	7
Statistical methods	7
Statistical model	7
Multiple outcome and multiple hypothesis testing	7
Heterogeneous effects	8
Interpreting results	8
Software	8
Dissemination of information	8
Study status	8
4 Data availability	9
5 Other required information	10
Funding	10
Ethics policies	10
Competing interests	10
Registration	10
Systematic reviews	11
Acknowledgments	11
5 References	11
Reporting checklist	12

About

This template is a guide for authors preparing the first stage of their Registered Report for submission to **F1000Research**.

Stage 1 Study Protocols typically include the following elements:

- Description of the key background literature
- Motivation for the study
- Hypotheses
- Study procedures
- Proposed statistical analysis plan
- Pilot data (as applicable)

Please note: not all fields included in this template will be applicable to your research, so you may need to modify or delete sections accordingly.

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

More information

For more detailed information about Registered Reports on F1000Research, please visit think.f1000research.com/registered-reports.

The [article guidelines](#) for Registered Reports contain more information specifically about this article type. Further information about the F1000Research publishing model is available on [our website](#), and any additional questions might be answered by our online [FAQs](#).

For editorial questions, please contact us on research@f1000.com.

1 Title page

Authors

- List all authors who played a significant role in developing the points presented in the article.
- Provide full affiliation information (full institutional address and ZIP or postal code, and email address) for all authors.
- Indicate who is/are the corresponding author(s).

Title

- The title must begin with 'Stage 1 Registered Report'.

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.
- Citations should not be used in the abstract.
- Abbreviations, if needed, should be spelled out.
- For clinical trials, registration information must be included in the abstract; this should indicate the registry, registration number and date of registration.

2 Introduction

Research question: background, importance and relevance

- What is the main problem/question motivating the study? Why is this question important?
- How has this question been addressed thus far in the relevant literature? What are the competing theories for explanation of this question? How is this study different from prior research on this problem/question?

Hypotheses

- What are the main outcomes of interest? Which outcomes are primary to the analysis, which are secondary, and why?
- How will the main outcomes of interest be defined in your dataset? If applicable, how will they be aggregated?
- Please include all hypotheses which will be tested, specifically linking each outcome to how it will be measured. These should be reported as main results in the Stage 2 submission.

Timeline

- What is the estimated timeline for completion of the study, and proposed submission date if Stage 1 peer review is successful?

Please note: once peer review is complete, the Introduction section cannot be altered apart from correction of factual errors, typographic errors, and changing the tense from future to past for Stage 2.

3 Methods

Methods sections should provide sufficient details of the materials and methods used so that the work can be repeated by others.

Basic methodological framework / identification strategy

- What is the basic methodological framework of the study (e.g. RCT, pre-post, simple comparison, difference-in-difference, systematic review, etc.)?
- Why is it suitable to address this research question?

Intervention

- What type of an intervention does the study involve? Elaborate in detail when, where, and by whom it will be delivered. Please provide enough detail to allow for replication of the study.
- How will individual observations be assigned to treatment and control conditions¹?
- How is participation in the program defined for the purpose of your study?
- How will participants be identified and recruited?
- Are there multiple treatment arms involved and if so, are they exclusive or overlapping?
- What is the source of exogenous variation in your study?
- If applicable, what observations will be blinded² after assignment to interventions and how? If blinding is not possible, what measures will be taken to minimize the potential for performance and expectancy biases (e.g. keeping participants unaware of trial hypotheses, measuring participant and provider expectations of benefit at baseline, etc.)?
- How will exclusion criteria be defined? How and under what conditions will data be replaced?

Sample and statistical power

- What is the unit of analysis for this sample (e.g. individuals, organizations, etc.)?
- What is the expected sample size? Please include statistical power calculations to justify sample size, and indicate any software used (with version number) and input source(s). How does your statistical power compare to other contributions in the literature?
- What is the minimum effect size you will be able to detect?
- State any covariates or regressors.

1 For useful information on what to report on randomization, see Bruhn and McKenzie (2009).

2 Blinding or masking refers to methods of withholding information about assigned interventions post-randomization from those involved in the trial, when knowledge of this information could influence their behavior in a way that would later prove integral to interpreting the results.

Data collection and processing

- What are the pre-processing steps (if any)?
- What are the key data sources? What data collection procedures and instruments will be used?
- Where using questionnaires, please indicate whether the questionnaire is validated, and if not, provide details of pre-testing.
- What is the rule for terminating data collection (e.g. number of observations, available funds, available time, etc.)?
- How long will the data collection process take?
- If data will be collected at multiple points (longitudinal design), what is the proposed schedule (including enrollment, intervention delivery and outcome assessment)?
- For analysis decisions that are contingent on the outcome of prior analyses, please specify the contingencies and how these will be adhered to.
- Cite the corresponding data management plan, where available.

Variations from the intended sample size

- Do you anticipate any challenges in collecting data (e.g. attrition, non-compliance with the assigned treatment, etc.)? What measures do you plan to take to address these challenges?

Pilot data

- Summarize any pilot data used in preparation for this submission. These can be included to establish effect size estimates, feasibility, or proof of concept.

Statistical methods

- What statistical methods will be used to analyze the data and what are their underlying assumptions?
- How will the study deal with missing values?
- How do you define and handle outliers?

Statistical model

- Provide the model in its functional form, submitting equations as text and not as images.

Multiple outcome and multiple hypothesis testing

- How will the study address false positives from multiple hypothesis testing?
 - If you plan to adjust your standard errors, what adjustment procedure will you use? (e.g. Family Wise Error Rate, False Discovery Rates, etc.)
 - If you plan to aggregate multiple variables into an index, which variables will you aggregate and how?

Heterogeneous effects

- Which groups do you anticipate will display heterogeneous effects? What leads you to anticipate these effects? Specify which baseline variable(s) will be used for heterogeneity analysis.

Interpreting results

- Depending on the outcome of the test(s), how will you interpret the results in the light of competing theories?
- How do they contribute to the literature?
- What are the potential implications for policy?

Software

- Details of all software to be used (statistical, imaging etc.) must be provided; please state the version to be used (where known), details of where the software can be accessed, and any variable parameters that could impact the outcome of the results.
- Where software will be coded by the authors of the paper, please provide details of this software including the version control system to be used. To continue with F1000Research at Stage 2, it is imperative that software coded by the authors is openly available.
- If you plan you use a proprietary software, an open alternative to replicate this methodology should also be provided.

Dissemination of information

- A statement regarding how you plan to disseminate the findings, and underlying data generated by your study, must be provided.
- Cite the corresponding data management plan, where available.

Study status

- Indicate the current status of your study at time of writing; data collection must not have started.
- If you have provided a study timeline, indicate where on this timeline your study currently is.

4 Data Availability

All articles must include a Data Availability statement, even where there is no data associated with the article. Pilot data files should be appropriately time stamped. No other data acquired prior to the date of publication of the Study Protocol is admissible in the Stage 2 submission.

Raw data must be accompanied by guidance notes, where required, to assist other scientists in replicating the analysis pipeline.

To continue with F1000Research at Stage 2, it is imperative that the data underlying the study is openly available (where it is safe to do so).

Please refer to the F1000Research data [guidelines](#) and [policies](#) for more information.

5 Other required information

Funding

Please state who funded the work, whether it is your employer, a grant funder etc. Please do not list funding that you have that is not relevant to this specific piece of research. For each funder, please state:

- The funder's name
- Grant number (where applicable)
- The individual to whom the grant was assigned

If your work was not funded by any grants, please include the section entitled 'Grant information' and state: 'The author(s) declared that no grants were involved in supporting this work'.

Ethics policies

All research must have been conducted within an appropriate ethical framework. Details of approval by the authors' institution or an ethics committee must be provided in the Methods section. This should also provide details of your planned consent process where applicable.

Please refer to the detailed Ethics section in the F1000Research [editorial policies](#) for more information.

Competing interests

Articles published on F1000Research 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 the F1000Research [editorial policies](#).

If you do not have any competing interests, please include the section entitled 'Competing interests' and state: 'No competing interests were disclosed'.

Registration

Clinical trials

If the Study Protocol relates to a clinical trial, then the following trial registration details must be provided:

- Name of registry
- Registry number
- Registration date
- URL of the trial in the registry database

For further details about trial registration, please refer to our [editorial policies](#).

F1000Research articles that report randomised clinical trial protocols must follow the [SPIRIT guidelines](#). For reporting of the intervention methodology itself, F1000Research endorses the [TIDieR checklist](#), an extension of the CONSORT statement. We ask authors to include a completed SPIRIT checklist with their Study Protocol, which will be included in the 'Reporting guidelines' section of the article when published.

Systematic reviews

F1000Research encourages authors to register the protocol for their Systematic Review prospectively in the PROSPERO database. Details of the protocol registration should be included in the final systematic review article.

F1000Research endorses the PRISMA-P Statement; protocols for systematic reviews and meta-analyses must follow the PRISMA-P guidelines. Authors should include a completed PRISMA-P [checklist](#) with their Study Protocol and this will be included in the Reporting Guidelines section of the article when published.

When completing checklists, as the page numbers will likely change following production, please refer to section by name using the section headings rather than page numbers.

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. Authors should obtain permission to include the name and affiliation, from all those mentioned in the Acknowledgments section. Please note that grant funding should not be listed here.

If your author list includes a collective a full list of members should be provided here.

References can be listed in any standard referencing style as long as it is consistent between references within a given article.

6 References

References can be listed in any standard referencing style as long as it is consistent between references within a given article.

Checklist for authors

Checklist for authors: what to report in your Stage 1 Study Protocol

Section	Item	Details	Reported?	Section
Title page	Title	Informative title specifying the study design, population, and interventions. Must begin with 'Stage 1 Registered Report'.		
	Authors	Names and affiliations of all authors who played a significant role.		
Abstract	Abstract	Summary of research question, outcome variables, methodological framework and contribution in less than 300 words.		
		For registrations, the name of the registry, registration number and date of registrations must be provided (if applicable).		
Introduction	Background and relevance of the study	Brief overview of previous research, and relevance of the research question(s) for the field.		
	Research question(s)			
	Expected completion date	Expected date for completion of the pre-specified research design.		
Methods	Basic methodological framework	Outline of the identification strategy in the study (experimental/non-experimental).		
	Hypotheses	Pre-specified hypotheses to be tested in the study and reported as primary findings in the Stage 2 full manuscript.		
	Outcome variable(s)	Definition of the main outcome variable(s) and (if applicable) secondary outcome variable(s).		
		Specification of how outcome(s) will be constructed from the dataset.		
	Intervention(s)	Details of the intervention (when, where, how, by whom).		
		Number of treatment arms and whether they are exclusive or overlapping.		
		Randomization strategy.		
		Blinding strategy (if applicable).		
		Instructions and supporting materials for administering the intervention.		
		Source(s) of exogenous variation.		

Section	Item	Details	Reported?	Section
Methods (continued)	Theory of change	How and why the intervention is predicted to lead to certain effects.		
	Sample	Specification of unit of analysis (individuals, organizations, countries, etc.).		
		Data source(s).		
		Projected sample size and statistical power calculations.		
	Variations from the intended sample	Specification of the degree of attrition that may threaten the robustness of the study.		
		Strategies to deal with attrition, non-compliance with the assigned treatment, etc.		
	Data collection and processing	Type of data, collection method/data source(s), and timeline for collection.		
		Rule for terminating data collection / stopping rule.		
		Data management plan.		
		Pilot data and experiments run in preparation of the Stage 1 submission.		
	Statistical method(s)	Main evaluation method(s) and underlying assumptions.		
		Rules for handling missing values.		
		Definition and rules for handling outliers.		
	Multiple hypothesis testing	Strategies to prevent false positives.		
	Heterogeneous effects	Anticipated heterogeneous effects and theoretical justification.		
	Statistical model	A functional (mathematical) form of the causal mechanism explored in the study.		
		Specification if regression model is linear, generalized linear, or other.		
		How will standard errors be calculated.		
	Challenges in the study implementation	Potential objective circumstances that might jeopardize the implementation of the proposed study design.		

Section	Item	Details	Reported?	Section
Methods (continued)	Software	Details of all software to be used (statistical, imaging etc.) must be provided.		
	Dissemination of information	A statement regarding how you plan to disseminate the findings, and underlying data generated by your study, must be provided.		
	Study status	The current status of your study at time of writing should be indicated; data collection must not have started.		
Data availability	Data Availability statement	See our data guidelines and policies .		
Other required information	Funding	Funding sources in the suggested format.		
	Ethics approval	Statement confirming that all necessary ethics approvals are in place.		
	Acknowledgments	List of (non-author) individuals who provided help to the research project.		
	Registration	Registration details of clinical trials or systematic reviews.		
References	Reference list	References can be in any style or format, provided the style is consistent.		

Learn more about Registered Reports: think.f1000research.com/registered-reports
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