

# Study protocol

## Study protocol

Now that the research question has been decided, and it has been checked that sufficient patients should be available to enrol into the study, it is time to prepare the detail of the trial. At this stage, a study protocol should be constructed to define the research plan. It should contain the background of the definitions of population and sample sizes and methods of proposed analysis. It should include the patient numbers, inclusion and exclusion criteria and the timescale for the work. The protocol should be detailed enough for another party to come along in the future and theoretically replicate the study. It is useful to construct a flow diagram giving a clear summary of the research protocol and its requirements (Figure 13.1). It is helpful to imagine the paper that will be written about the study before the study is performed. This may prevent errors in data collection. When a study is planned, sufficient time should be reserved at the beginning for fund-raising and obtaining ethical, regulatory and other approvals (e.g. HRA). Time for data analysis and preparation of publication needs to be included in funding applications. The cost of any non-routine investigations and extra treatments should be identified and covered by the research grant in line with national guidance (in the UK, the *Research and Development [AcoRD] guidance*; <https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research>). A data collection form should be designed or a computer collection package developed. If data are collected on a computer, appropriate safeguards for privacy, confidentiality and data quality will be necessary to comply with legislation. At this stage it is important to consider any validation requirements and needs for open access, either in a recognised archive (e.g. the UK Data Archive) or in an institutional repository. Any form of data collection needs to be quality assured. The quality assurance process will include training, standard operating procedures as well as monitoring and checking a certain sample of the data. At the end of data collection and analysis, a final database with all data should be locked and kept for future reference in a safe location. A data-archiving policy with a nominated data custodian should be in place. Research is no longer confined by institutional or even geographical boundaries. Collaborative research groups in surgery at a national or international level have come together to undertake high-quality surgical research in recent years, aided by online communication and the availability of secure electronic databases such as REDCap™. The SUNRRISE trial shown in Figure 13.1 was undertaken by researchers from two trainee-led research collaborative groups across the UK, in conjunction with a parallel collaborative group in Australia. All patients were included within the same study cohort in real time: the Australian sites were effectively identical to those in the UK because of online electronic randomisation systems and online live data capture via REDCap. Some publishers require registration of a study at the time it is set up on a publicly available database (e.g. the World Health Organization's recognised registries such as ISRCTN, EudraCT and ClinicalTrials.gov). It is becoming increasingly popular to consider publication of a protocol paper. Study protocol

Now that the research question has been decided, and it has been checked that sufficient patients should be available to enrol into the study, it is time to prepare the detail of the trial. At this stage, a study protocol should be constructed to define the research plan. It should contain the background of the definitions of population and sample sizes and methods of proposed analysis. It should include the patient numbers, inclusion and exclusion criteria and the timescale for the work. The protocol should be detailed enough for another party to come along in the future and theoretically replicate the study. It is useful to construct a flow diagram giving a clear summary of the research protocol and its requirements (Figure 13.1). It is helpful to imagine the paper that will be written about the study before the study is performed. This may prevent errors in data collection. When a study is planned, sufficient time should be reserved at the beginning for fund-raising and obtaining ethical, regulatory and other approvals (e.g. HRA). Time for data analysis and preparation of publication needs to be included in funding applications. The cost of any non-routine investigations and extra treatments should be identified and covered by the research grant in line with national guidance (in the UK, the Health Research Authority's [AcORD] guidance; <https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research>). A data collection form should be designed or a computer collection package developed. If data are collected on a computer, appropriate safeguards for privacy, confidentiality and data quality will be necessary to comply with legislation. At this stage it is important to consider any validation requirements and needs for open access, either in a recognised archive (e.g. the UK Data Archive) or in an institutional repository. Any form of data collection needs to be quality assured. The quality assurance process will include training, standard operating procedures as well as monitoring and checking a certain sample of the data. At the end of data collection and analysis, a final database with all data should be locked and kept for future reference in a safe location. A data-archiving policy with a nominated data custodian should be in place. Research is no longer confined by institutional or even geographical boundaries. Collaborative research groups in surgery at a national or international level have come together to undertake high-quality surgical research in recent years, aided by online communication and the availability of secure electronic databases such as REDCap™. The SUNRRISE trial shown in Figure 13.1 was undertaken by researchers from two trainee-led research collaborative groups across the UK, in conjunction with a parallel collaborative group in Australia. All patients were included within the same study cohort in real time: the Australian sites were effectively identical to those in the UK because of online electronic randomisation systems and online live data capture via REDCap. Some publishers require registration of a study at the time it is set up on a publicly available database (e.g. the World Health Organization's recognised registries such as ISRCTN, EudraCT and ClinicalTrials.gov). It is becoming increasingly popular to consider publication of a protocol paper. Study protocol

Now that the research question has been decided, and it has been checked that sufficient patients should be available to enrol into the study, it is time to prepare the detail of the trial. At this stage, a study protocol should be constructed to define the research plan. It should contain the background of the definitions of population and sample sizes and methods of proposed analysis. It should include the patient numbers, inclusion and exclusion criteria and the timescale for the work. The protocol should be detailed enough for another party to come along in the future and theoretically replicate the study. It is useful to construct a flow diagram giving a clear summary of the research protocol and its requirements (Figure 13.1). It is helpful to imagine the paper that will be written about the study before the study is performed. This may prevent errors in data collection. When a study is planned, sufficient time should be reserved at the beginning for

fund-raising and obtaining ethical, regulatory and or other approvals (e.g. HRA). Time for data analysis and preparation of publication needs to be included in funding applications. The cost of any non-routine investigations and extra treatments should be identified and covered by the research grant in line with national guidance (in the UK, the *Researcher Attributing the costs of health and social care Research and Development [AcoRD] guidance*; <https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research>). A data collection form should be designed or a computer collection package developed. If data are collected on a computer, appropriate safeguards for privacy, confidentiality and data quality will be necessary to comply with legislation. At this stage it is important to consider any validation requirements and needs for open access, either in a recognised archive (e.g. the UK Data Archive) or in an institutional repository. Any form of data collection needs to be quality assured. The quality assurance process will include training, standard operating procedures as well as monitoring and checking a certain sample of the data. At the end of data collection and analysis, a final database with all data should be locked and kept for future reference in a safe location. A data-archiving policy with a nominated data custodian should be in place. Research is no longer confined by institutional or even geographical boundaries. Collaborative research groups in surgery at a national or international level have come together to undertake high-quality surgical research in recent years, aided by online communication and the availability of secure electronic databases such as REDCap™. The SUNRRISE trial shown in Figure 13.1 was undertaken by researchers from two trainee-led research collaborative groups across the UK, in conjunction with a parallel collaborative group in Australia. All patients were included within the same study cohort in real time: the Australian sites were effectively identical to those in the UK because of online electronic randomisation systems and online live data capture via REDCap. Some publishers require registration of a study at the time it is set up on a publicly available database (e.g. the World Health Organization's recognised registries such as ISRCTN, EudraCT and ClinicalTrials.gov). It is becoming increasingly popular to consider publication of a protocol paper.

---

Revision #1

Created 2025-12-31 15:08:54 UTC by Omar Ayman

Updated 2025-12-31 15:08:54 UTC by Omar Ayman