Flowchart to assist with the use of the templates

You can't find the right template for writing a protocol or the right template for writing a patient information and consent form? This Flowchart (decision tree) can help you.

If you still can't find the template you are looking for, contact swissethics or one of the seven ethics committees.

Not all available templates are listed in this decision tree.

Ordinances:
- Clinical Trial Ordinance, ClinO
- Ordinance on Clinical Trials with Medical Devices, ClinO-MD
- Human Research Ordinance, HRO

Start here: Is the research project a project involving living persons?

Yes

Is the research project a clinical trial, i.e. testing the effects of an intervention or investigating the performance and/or safety of a medical device?

Yes

Is the clinical trial investigating a medicinal drug or transplant product?

Yes

Protocol template according to ClinO-MD: Clinical Investigation Plan (CIP) - clinical trial with medical devices (MD), according to EU-MDR, ISO14155: EN

Clinical Performance Study Plan (CPS) - medical device, according to EU: IVD, ISO20916: EN

Patient information and consent form: DE, FR, IT

Is the research project an observational study, i.e. research with persons involving measures for sampling of biological material or collection of health-related personal data?

Yes

Is this a clinical trial on and with children and adolescents?

Yes

Study information for relatives/parents/legal representatives: DE, FR, IT

Checklist: Research on and with children and adolescents under the age of 18: DE, FR, IT

Guide to the study information: DE, FR, IT

Is the research project a project with already existing biological material or already collected health-related personal data? (so-called further use research project)

Yes

Protocol template further use with consent: DE, FR, IT

Note: submit the general consent or the project specific patient information and consent to the ethics committee.

If applicable, exemption and approval by ethics committee possible (Art. 34 HFG).

Protocol template further use without consent: DE, FR, IT

Partially with and without consent

Is the research project a project with consent for the further use of biological material or with consent for the further use of health-related personal data?

Yes

No

Is the research project a project involving deceased persons?

Yes

Protocol template research involving deceased persons: DE, FR, IT

No

Is the research project an observational study, i.e. research with persons involving measures for sampling of biological material or collection of health-related personal data?

No

Is the research project with deceased persons?

Yes

Protocol template research involving deceased persons: DE, FR, IT

No

Is the research project an observational study, i.e. research with persons involving measures for sampling of biological material or collection of health-related personal data?

Yes

Is the clinical trial investigating an investigational drug or an IVD device?

No

Is the research project a project involving living persons?

Yes

Is the clinical trial investigating an investigational drug or transplant product?

No

Protocol template research project according to ClinO: EN

Patient information and consent form: DE, FR, IT

Is the research project a clinical trial, i.e. testing the effects of an intervention or investigating the performance and/or safety of a medical device?

No

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Yes

No

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Clinical Performance Study Plan (CPS) - medical device, according to EU: IVD, ISO20916: EN

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Study information for relatives/parents/legal representatives: DE, FR, IT

Checklist: Research on and with children and adolescents under the age of 18: DE, FR, IT

Guide to the study information: DE, FR, IT

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Protocol template further use without consent: DE, FR, IT

Partially with and without consent

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Protocol template research involving deceased persons: DE, FR, IT

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Protocol template research project according to ClinO: EN

Patient information and consent form: DE, FR, IT

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Clinical Performance Study Plan (CPS) - medical device, according to EU: IVD, ISO20916: EN

Patient information and consent form: DE, FR, IT

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Protocol template further use without consent: DE, FR, IT

Partially with and without consent

Is the research project involving deceased persons?

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Protocol template research involving deceased persons: DE, FR, IT

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