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Preparation of an ethics application

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Abstract

The purpose of writing an ethics application as part of a scientific study is to ensure that the study adheres to ethical standards and guidelines. This work must be done with care and accuracy, and can be a tedious and time-consuming task that may involve multiple amendments and revisions. This is where guidance such as the SMART (specific, measurable, achievable, realistic, and time-bound) criteria can be used. This article is intended to support you in approaching the submission process with preparation of the application in a structured and standardized manner.

Keywords
Ethical review · Clinical protocols · Research · Patient rights · Quality assurance

Introduction

The purpose of preparing an ethics application as part of a scientific study is to ensure that the study adheres to ethical standards and guidelines. The following are some reasons why an ethics application is important:

- Protection of participants: an ethics application ensures that the protection, welfare, and rights of participants are safeguarded. The study should not pose unnecessary risks or burdens for participants, and their informed consent should be obtained.
- Accountability: through an ethics application, researchers disclose their plans and methods and subject them to review. This promotes transparency and accountability in the research community.
- Trustworthiness of research: ethics applications contribute to the trustworthiness and credibility of research. Adherence to ethical standards ensures that the results and conclusions of the study are based on a solid foundation.
- Consideration of moral and social aspects: ethics applications help to incorporate moral and social aspects into research planning. This includes consideration of justice issues, possible bias or discrimination, and the potential impact on specific groups or society in general.
- Compliance with legal and institutional requirements: many institutions and countries have specific ethical guidelines and regulations for conducting studies. An ethics application demonstrates compliance with these guidelines and ensures that the study complies with legal requirements.
- Promotion of research ethics and quality assurance: the need for an ethics application raises awareness of ethical issues in research and promotes compliance with ethical standards. This contributes to quality assurance and the further development of research ethics.

An ethics application is submitted to the institutional review board (IRB). The IRB is an independent administrative body re-

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Table 1 SMART criteria for defining a research question		
S	Specific	The objective is concrete, unambiguous, and described in detail
M	Measurable	The target can be assessed qualitatively and quantitatively
A	Achievable	The goal is appropriate and achievable for everyone involved
R	Realistic	The goal can realistically be achieved with the available resources
T	Time-bound	The goal can be realized at a certain point in time

sponsible for reviewing and approving research involving human subjects in order to protect the rights and welfare of the study cohort. The IRB is charged with ensuring that proper informed consent is obtained and documented, risks to subjects are minimized, the research design is sound, and subjects are not unnecessarily exposed to risk. The IRB also verifies that the selection of patients is fair, that appropriate data monitoring measures are enforced, and that the privacy and confidentiality of subjects are maintained. The IRB also has the authority to terminate or suspend any research that does not comply with the guidelines. The IRB is composed of scientists, laypersons, physicians, and lawyers, and the average size is approximately 14 members [5].

Drafting an ethics application must be done with care and accuracy and can be a tedious and time-consuming task that may involve multiple changes and revisions. Sufficient time should therefore be allowed [1]. A study from the UK found that only 24% of submitted studies were approved without amendments [2]. Common reasons for rejection of an application were an improperly drafted consent form, poor study design, unacceptable risk to subjects, and ethical and legal reasons. Therefore, young researchers are advised to write their first ethics applications in collaboration with an experienced mentor or at least discuss them prior to submission to the IRB. Below is a guide on how to proceed in this process.

Guide to writing an ethics application

Background

Begin with a concise introduction explaining the purpose and aim of the study. Also describe the context in which the study is being conducted and emphasize the need for ethical evaluation. Explain the background and scientific justification for conducting the study. Explain the potential benefits of the study, both for the individual participants and for society in general. Emphasize the contribution to medical research and the potential benefits for patient care or public health.

The current state of knowledge on the topic, relevant previous research findings, and the significance of the proposed study should be included in this section.

Research questions, hypotheses, and objectives

Clearly formulate your research questions and hypotheses. Make sure that they are specific, measurable, achievable, realistic, and time-bound (SMART criteria; ◘ **Table 1**; [5]).

Describe the primary and, if applicable, secondary objectives of the project. What is to be analyzed by the evaluation of the data or the evaluation of the biological material? The primary objective must be clearly and precisely defined. Describe the endpoint for the primary objective and, if applicable, describe the endpoints for the secondary objectives. Endpoints are the parameters that are measured to check whether the objective has been achieved. If you do not define endpoints, describe the relationship between the parameters you are evaluating and what conclusions this should allow you to draw [4].

Design, methods, and time schedule

Describe in detail the planned study design and the methods that will be used. This includes information about the participants, the data collection methods, the planned interventions (if any), and the planned data analysis.

What is the specific procedure? What analysis methods/techniques will be used? For example, "the measured values are generated from the existing x-ray images. Data already collected from the medical history are also analyzed" [4].

The intended statistical methods for assessing the primary endpoint and, if applicable, the secondary endpoints should be clearly stated. If possible, formulate a hypothesis. Please use standard statistical methods whenever possible. It must be stated what is to be measured or evaluated using which method.

Specify the sample size and justify the amount of data and biological material to be analyzed for the primary endpoint and, if applicable, secondary endpoints. Has a sample size been calculated? In any case, the quantity of data and material to be analyzed must be justified. In the case of multiple endpoints, statistical adjustments for multiple testing should be considered.

If different statistical methods (e.g., descriptive statistics or artificial intelligence/algorithms) are used to confirm or refute a hypothesis instead of statistical tests, these should be described and justified.

Indicate which statistical software package(s) are to be used [4].

A detailed timetable for the conduct of the study should be presented. Show that adequate time is planned for ethical evaluation and approval.

Origin of the data/biological material

What is the source of the data/biological material? Is the data source public, private, or industrial? Is the data source trustworthy and of good quality?

Which population should be investigated based on the data/biological material to be reused? Does this population belong to a particularly vulnerable population (e.g., minorities, minors, persons incapable of judgment)? Identify possible risks or burdens for the study participants. Discuss both physical and psychological risks, and explain how you intend to minimize or manage them (risk assessment).

Indicate here the "period of collection" for this research project. For example, "personal and medical data and all imaging material (computed tomography, magnetic resonance imaging, etc.) of the operated knee joint from January 1, 2021, to December 31, 2025 …"[4].

Table 2 "Recipe" for an ethics protocol	
Introduction	Description of the state of knowledge on the topic, the relevant previous research results, and the significance of the proposed study
Hypotheses and objectives	Formulate your research questions and hypotheses. Make sure that the SMART criteria are met
Design, methods, and schedule	Describe the planned study design, timeline, and methods (information on participants, data collection methods, planned interventions, and planned data analysis)
Origin of the data/biological material	Who is the source of the data/biological material? Is the data source public, private, or industrial? Is the data source trustworthy and of good quality?
Inclusion and exclusion criteria	What criteria must the data/biological material fulfill in order to be used for this evaluation?
Consent and data protection	Explain in detail the process of obtaining informed consent from participants
Information on the storage of data and samples	What is being done to protect the privacy of participants?
Ethical and regulatory requirements	Refer to the relevant ethical guidelines and standards that apply in your field of research
Financing, data exchange, declaration of interests	Describe the sources of funding, the publication policy of the project, the handling of data exchange, and possible conflicts of interest

Inclusion and exclusion criteria

Which criteria must the data/biological material fulfill in order to be used for this evaluation? Which datasets would falsify the evaluation if they were included? For example, "data records without a confirmed diagnosis, etc."

Consent and data protection

Explain in detail the process of obtaining informed consent from participants. Describe how you will ensure that participants are sufficiently informed and can consent voluntarily. It must be ensured that fair and understandable information is provided. How will information be provided? Refer to the information leaflet and declaration of consent or the assurance of consent obtained. Also note data protection and explain how personal data are collected, stored, and protected.

For example, "all data originate from our daily clinic routine and were collected between 2020 and 2022. All patients have signed the general consent of the university hospital (copy enclosed)" [4].

For non-anonymized data/biological material

Clinical projects almost always involve non-anonymized data. The anonymization process of the data must be correctly documented for evaluation. Please mention where the key to the anonymization is kept.

For anonymized data/biological material

If the data or biological material is already encrypted for evaluation, e.g., in a research register or a research biobank, this must be explained, as well as the location at which the key is securely stored.

Reporting

Any change in project management must be reported to the responsible ethics committee in advance.

The completion or termination of the research project must be reported to the ethics committee within a defined period.

Information on the storage of data and samples

What is done to ensure that the privacy of participants remains protected?

When storing health-related personal data and/or biological material for research purposes, their protection must be ensured by means of suitable operational and organizational measures (see HRO Art. 5) [3]. Unauthorized or inadvertent disclosure, modification, deletion, or copying of health-related personal data must be prevented.

A paper data collection form or suitable data management software, e.g., SecuTrial® (interActive Systems, Berlin, Germany) or REDCap (Vanderbilt University, Nashville, USA), allows changes to be tracked.

All identifying data (names, addresses, date of birth, and patient number at the hospital, etc.) must be stored separately from the actual study data. All digital documents are password protected. It must be possible to securely lock away paper data.

Biological material must also be encrypted or anonymized accordingly. The technical requirements for proper storage must be guaranteed, and the necessary resources for storage must be available. Unauthorized persons are denied access to the material. The measures required to protect the biological material must be described in this section.

As mentioned, if anonymization takes place, the anonymization process must be described (e.g., destruction of the key) [4].

The place and period of storage must be defined.

Ethical and regulatory requirements

Refer to the relevant ethical guidelines and standards that apply in your field of research, such as the Declaration of Helsinki or national and institutional guidelines [5]. Demonstrate how you intend to meet these standards.

Ethical risk–benefit assessment

Carefully weigh up the benefits and risks. Some information is particularly necessary for big data projects, for example:

- What benefits are expected from this project? Is there a social and/or personal benefit? Who will benefit from the results? Is the benefit only for the clients of the project? Do the study participants also receive a benefit? Do the benefits outweigh the risks? For example, will inferior or discriminatory data be processed?
- What data risks are associated with the project and how are they prevented or mitigated? How is the data linkage

controlled? How can you prevent the data from being made accessible to unintended recipients? Could this result in personal disadvantages for the participants and/or inaccurate assumptions or predictions from the project? Are any particularly vulnerable groups affected?
- What harm could arise from these risks (e.g., physical, emotional, financial, etc.)? What would be the extent of the damage? Do the risks and harms affect all those involved equally? Will some risks or damages remain?
- Who will assume liability, e.g., for data damage? The project management is obliged to take appropriate precautions (note: separate project insurance is usually not required) [4].

Financing, data exchange, declaration of interests

Describe the sources of funding, the publication policy of the project, the handling of data exchange, and possible conflicts of interest. If conflicts of interest exist, explain how you will deal with potential conflicts of interest to ensure the integrity and objectivity of the study. If applicable, refer to contracts or documents in which this information is recorded.

Bibliography

Include a complete bibliography that lists all sources cited and references used.

Conclusion

The purpose of writing an ethics application as part of a scientific study is to ensure that the study adheres to ethical standards and guidelines. This work must be done with care and accuracy, and can be a tedious and time-consuming task that may involve multiple amendments and revisions. This is where guidance such as the SMART criteria can be used. This instructive article is intended to support you in approaching the submission process with the preparation of the application in a structured and standardized manner (see ◘ **Table 2** for a concise summary).

Zusammenfassung

Erstellung eines Ethikantrags

Das Verfassen eines Ethikantrags im Rahmen einer wissenschaftlichen Studie dient dazu sicherzustellen, dass in der Studie ethische Standards und Richtlinien eingehalten werden. Diese Arbeit muss mit Sorgfalt und Genauigkeit erfolgen und kann eine mühsame und zeitraubende Aufgabe sein, die mehrere Änderungen und Überarbeitungen mit sich bringen kann. Hierbei können Orientierungshilfen wie die SMART-Kriterien („specific, measurable, achievable, realistic, and time-bound") herangezogen werden. Dieser Artikel soll dabei unterstützen, das Einreichungsverfahren mit Erstellung des Antrags strukturiert und standardisiert anzugehen.

Schlüsselwörter
Ethikprüfung · Klinische Protokolle · Forschung · Patientenrechte · Qualitätssicherung

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Declarations

Conflict of interest. D. Mathis and the AGA Research Committee declare that they have no competing interests.

For this article no studies with human participants or animals were performed by any of the authors. All studies mentioned were in accordance with the ethical standards indicated in each case.

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