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Ethical challenges in research faced by master's students in anesthesiology

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Highlights

- Ethical approval is a fundamental step in research for anesthesiology master's students.
- Conflicts between ethical approval timelines and clinical training schedules hinder research progress.
- Lengthy review periods can delay research completion and dissertation submission.

Abstract

Ethical approval is the first essential step for medical master's students to officially initiate research. This article discusses the ethical issues encountered in various types of research projects conducted by professional master's students, the preparation of ethical application materials, conflicts between the timing of ethical applications and the clinical training rotation schedules, and the continuity of ethical applications among students within the same cohort and across different cohorts.

Keywords: Ethics, professional master's, application, approval, standardized training, retrospective analysis

Introduction

The current training system for medical master's students in China divides them into two categories: research-oriented and clinical-oriented programs [1]. Among these, the clinical-oriented master's program, commonly known as the professional master's track, emphasizes practical skills development, focusing on clinical practice relevance and teamwork cultivation. This program also has stringent evaluation standards to assess students' academic and practical competencies [2, 3]. Consequently, professional master's students must complete clinical training while also racing against time to fulfill their research requirements [4]. Ethical approval is a critical first step in formally launching a research project, making it essential for students to have a solid understanding and proficient application of ethical principles. This study aims to: (1) comprehensively explore the ethical challenges faced by anesthesiology master's students in various research projects; (2) analyze how the ethical application process impacts their research progress, especially with respect to conflicts between approval timelines and clinical training schedules; and (3) propose and evaluate effective strategies to address these challenges. The research questions include: What specific ethical issues arise in anesthesiology clinical and basic research? How do current ethical application procedures affect the research process? What are the most practical and efficient ways to optimize rotation schedules to balance clinical training and ethical approval waiting time? This article will discuss the concept of ethical approval, its importance, the ethical challeng-

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es encountered in different types of research projects by professional master's students, and the difficulties in preparing ethical application materials and managing their timing.

Concept of ethical applications in research

Ethical applications in scientific research refer to a structured process designed to identify and address ethical issues and risks within a research project [5]. This process typically requires researchers to provide detailed information, ensuring adherence to ethical principles and legal regulations throughout the study. Ethical applications are based on core principles such as respect for human dignity, informed consent, privacy protection, research justice, honesty, and transparency. These principles ensure that research activities do not harm participants, society, or the environment and that research integrity and fairness are maintained. Informed consent, a key principle, mandates that researchers provide participants with clear, sufficient information about the study, enabling voluntary and informed decisions regarding participation. Ethical applications also involve comprehensive risk assessments, requiring researchers to evaluate and address potential risks their projects may pose to participants, society, or the environment. Research design must meet ethical standards, with a clear outline of study methodologies and data collection practices that respect ethical guidelines. Effective data management is crucial, as researchers must detail how research data will be stored and protected to safeguard participant privacy and data security. Often, ethical applications require review and approval by an ethics board or committee to ensure compliance with ethical principles and protection of participant rights. Additionally, transparency in reporting is essential; researchers must present findings honestly and accurately, including both positive and negative results, maintaining the integrity and reproducibility of scientific research. In essence, ethical applications provide a framework guiding scientific research within ethical and legal boundaries, protecting participant rights, ensuring research integrity, and fostering public trust in research findings. This process strengthens the reputation of the research community and supports sustainable progress in science.

Ethical issues in different types of scientific research

Ethical issues in anesthesiology research vary across different research types, with clinical and basic research each requiring distinct ethical considerations [6]. In clinical research, which involves direct interventions and observations on human subjects, informed consent is essential. A patient-centered clinical trial concept must be developed [7]. Participants must be fully informed about the study's purpose, methods, and potential risks, and their consent must be documented through a signed form. For individuals unable to consent, such as children, the elderly, or those with disabilities, consent must be obtained from a legal guardian or representative [8].

Confidentiality is also crucial, with personal information must be protected from unauthorized access [9]. Additionally, participant safety must be prioritized, with anesthetic doses carefully calculated based on factors like medical condition, age, and weight, and vital signs closely monitored to prevent adverse effects. Balancing benefits and risks is critical, ensuring that the study's potential benefits outweigh its risks, with harm minimized. Justice and fairness must also be ensured by adopting an unbiased approach to participant selection and allocation.

In anesthesiology basic research, which typically involves animal and cell experiments to investigate drug mechanisms, efficacy, pharmacokinetics, and toxicology, distinct ethical standards are required. Ethical approval from relevant institutions is necessary to ensure compliance with research standards, and animal welfare must be protected [10]. This includes minimizing harm and suffering by using minimally invasive methods, regularly monitoring animal health, and providing adequate nutrition, water, and sanitary conditions. Researchers are encouraged to explore alternative methods, such as computer simulations or cell cultures, to reduce or replace animal use whenever possible, thus minimizing harm. The balance of benefits and risks remains crucial, as researchers must ensure the study's value justifies any potential harm to animals. Furthermore, researchers must prioritize data and privacy protection, implementing measures to prevent unauthorized access to research data.

In summary, anesthesiology research, whether clinical or basic, requires strict ethical standards that prioritize participant welfare, data confidentiality, research safety, and fairness, ensuring the research's reliability, compliance, and ethical integrity. Anesthesiology basic research must also respect animal welfare and rights, ensuring research reliability and legal compliance [11]. Efforts should be made to adopt alternative methods to reduce harm to animals and safeguard animal welfare to the

greatest extent possible. Additionally, appropriate measures should be implemented to protect the confidentiality of research data and participants' privacy.

The importance and necessity of research ethics applications

The importance and necessity of research ethics applications lie in ensuring that scientific research is conducted within ethical and legal boundaries, thereby safeguarding the integrity, fairness, and safety of research activities [12]. At their core, ethics applications focus on protecting the rights of participants—whether human or animal—by requiring researchers to provide detailed plans on how they will safeguard privacy, autonomy, and safety [13]. This includes securing informed consent and ensuring that participants have the freedom to withdraw.

Ethics applications also play a critical role in preventing scientific misconduct by mandating transparency in reporting methods and findings [14]. This transparency enhances the credibility of research, reducing the likelihood of biased or dishonest practices, thereby upholding the reputation of the research community. By requiring clear descriptions of study designs, methodologies, and data handling processes, ethics applications promote openness, enabling independent validation and replication, which strengthens the reliability of findings.

Compliance with legal regulations is another crucial aspect, as many countries and institutions have established laws governing research ethics. Ethics applications ensure adherence to these regulations, helping researchers avoid legal disputes and penalties [15]. Additionally, they help protect the environment and biosecurity by requiring researchers to assess and mitigate any potential ecological or societal harm. This not only preserves ecosystems but also aligns with broader societal responsibilities. Ethics applications further contribute to improving research quality by prompting researchers to consider the ethical and societal impacts of their work, leading to more credible and sustainable outcomes [16].

Beyond practical measures, these applications foster a culture of ethical awareness and moral responsibility, strengthening ethical standards within the scientific community. In sum, research ethics applications are essential for ensuring adherence to ethical principles and legal requirements, protecting participants, promoting transparency and integrity, and cultivating a responsible and ethically aware research environment.

Current status of ethical applications in graduate research

Institutions have established Institutional Review Boards (IRBs) and standardized approval procedures to ensure ethical compliance in graduate research projects, marking a significant advancement in research integrity [17]. However, the ethical application process for graduate students remains notably complex. When applying for ethics approval, students must provide comprehensive details on their project's objectives, research design, data handling, and participant protection measures. Specific templates are required depending on the research type. For instance, in our teaching group, projects involving human genetic resources or non-drug research are initially reviewed by the institution's science office before advancing to the IRBs, while drug and device trials must go through the clinical trial office. These drug-related studies require additional documentation—such as consent forms, questionnaires, and, when applicable, insurance arrangements—before being submitted on platforms like Wetrail.

The IRBs approval process may involve either an expedited review for simpler studies, such as retrospective analyses, or a full review that requires written submissions and an oral defense. The committee's decision may range from approval to conditional acceptance or suspension, highlighting the process's rigor. This IRB framework has also heightened advisors' ethical awareness, prompting them to prioritize ethics training for graduate students, especially those involved in human-subject research. Such rigorous oversight not only strengthens ethical considerations but also enhances the credibility of research findings by requiring adherence to ethical guidelines, thus improving the trustworthiness of outcomes.

Furthermore, most institutions now mandate that ethics approval be obtained before any research begins, prohibiting reviews for ongoing studies. This policy encourages students to begin the ethics application process promptly after preliminary experiments, ensuring proper review without risking study termination. Overall, the ethics application process has become a critical regulatory step in graduate research, and its importance will continue to grow as ethical standards and technological advancements evolve.

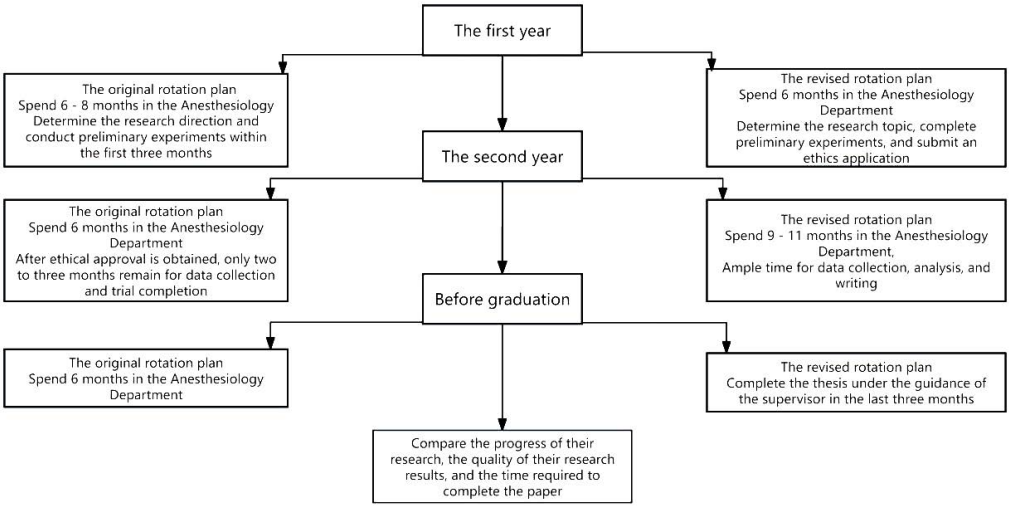

Figure 1. Clinical training rotation plan.

In anesthesiology, the clinical training for professional master's students lasts 18-20 months, usually organized into three rotations: 6-8 months in the anesthesia department in the first year, 6 months in the second year, and 6 months before graduation [18]. This schedule demands that students determine their research direction and conduct preliminary trials within the first three months of their first rotation. However, by the time ethical approval is obtained-often more than halfway through their second-year anesthesia rotation-students may have only 2-3 months remaining for data collection and trial completion. This tight timeline can impede research progress and postpone thesis writing and publication.

To tackle this issue, our department suggests adjusting the rotation schedule. Students should be given 6 months in the anesthesia department during the first year to finalize research topics, complete preliminary trials, and submit ethics applications. During the waiting period for approval, students can rotate through other departments, review literature, and draft initial results. In the second year, 9-11 months should be allocated in the anesthesia department for data collection, analysis, and writing, with the last three months set aside for thesis completion under the advisor's guidance (**Figure 1**).

Assessing the effectiveness of the proposed rotation schedule

To evaluate the usefulness and effectiveness of the proposed rotation schedule, investigations can be conducted to determine if the new plan better aligns research activities with the ethical approval process [19]. First, a longitudinal study could be carried out on a group of anesthesiology master's students following the adjusted rotation schedule. By comparing their research progress, the quality of their results, and the time required to complete their dissertations with students following the traditional schedule, we can quantitatively assess the impact of the new schedule on research efficiency.

Second, feedback from students, advisors, and relevant teaching staff could be gathered through questionnaires and interviews. Their subjective experiences and opinions on the new rotation schedule—such as whether it facilitates learning and research—could provide valuable qualitative insights into its effectiveness. Additionally, we could track the success rate of ethical approvals during the implementation of the new schedule and monitor how many research projects avoid disruption due to ethical issues.

Furthermore, since an IRBs decision to suspend or terminate a clinical trial can cause graduation delays, we recommend strategies to mitigate these challenges [20]. Advisors should encourage students to explore multiple aspects within the same research area, enabling later students to use existing ethical approvals. Students could also apply for multiple ethical approvals simultaneously, ensuring that unused approvals are available for subsequent cohorts. Finally, submitting retrospective analysis applications early is advisable, as these typically bypass full review, allowing faster approval. Retrospective analyses may also identify promising areas for future prospective studies, fostering a beneficial research cycle for successive cohorts.

While the proposed adjustment of the rotation schedule seeks to improve the balance between clinical training and research activities, several potential limitations should be considered. One challenge is the feasibility of implementing this schedule across all institutions, as it may require significant adjustments to existing clinical training frameworks and teaching resources. Some hospitals or medical schools may face difficulties in reallocating clinical training time, especially in departments with high patient volumes or limited faculty capacity. Additionally, ensuring that students receive adequate mentorship and research support during extended research periods may place an additional burden on faculty members, who might already have heavy workloads. Moreover, the proposed schedule may require more funding for research support, such as laboratory resources and data analysis tools, which could be a constraint for institutions with limited financial resources. Finally, resistance may come from students who prefer a more traditional, clinically focused training model, as well as from clinical departments that might feel the adjusted schedule reduces their access to students for clinical duties. These challenges should be carefully considered when implementing the revised rotation plan.

Conclusion

Ethical approval is a key step in the research training of anesthesiology master's students, underscoring the need for robust ethics education. Our teaching group recommends aligning non-anesthesiology rotations with the ethical review waiting period to maximize students' time and ensure ethical compliance in their research. This adjustment may help improve clinical training programs by better balancing research and clinical duties. Future research could examine the long-term impact of such adjustments on academic performance and ethical research practices. Additionally, policymakers may consider integrating more structured ethical training into the curriculum to better prepare students for clinical research challenges.

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