An evaluation of university research ethics oversight in Islamic Republic of Iran

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Abstract

Background: Regular evaluation of the performance of research ethics committees is vital to ensure their effectiveness in protecting the rights of research subjects and increasing public trust in biomedical research.

Aim: To evaluate the performance of research ethics committees (RECs) at Tehran University of Medical Sciences and identify key challenges in carrying out their functions.

Methods: Using the WHO ethics oversight benchmarking tool, we interviewed 18 secretaries of research ethics committees, 7 bioethics experts and 14 researchers at Tehran University of Medical Sciences and reviewed relevant documents. We performed a content analysis of the text and interview transcripts to identify key operational mechanisms and challenges.

Results: Of the 26 indicators for structure and composition, resources, procedures, mechanisms to promote transparency and accountability, and mechanisms to monitor self-performance, only 8 were fully implemented, 8 were partially implemented, and 4 were not implemented by all the 18 RECs. There were variations in implementation of the remaining 6 indicators. The most prominent challenges in implementation were absence of post-approval monitoring of research, inadequate conflict of interest management and inconsistent adherence to procedures. The RECs had limited ethics training and there were no policy and procedures for managing conflict of interest.

Conclusion: The WHO tool effectively identified strengths and weaknesses in the performance of RECs at Tehran University of Medical Sciences. A tiered oversight system is recommended to enhance support for, and harmonization among, RECs. Key improvements should focus on post-approval monitoring, conflict of interest management, and institutional accountability. Addressing these gaps will strengthen ethics oversight and increase trust in biomedical research.

Keywords: research ethics, ethics committee, ethics oversight, coordination, conflict of interest, Iran

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Background

Review and approval of research protocols by research ethics committees (RECs) have become a standard and widespread practice in many countries, although achievement of the primary goal of safeguarding the rights and welfare of research participants remains controversial (*1–5*). Like other regulatory entities, there is a need for regular evaluation of RECs to ensure their effectiveness and that their activities contribute to ethical research conduct (*6*). Continuous evaluation of their performance is crucial in protecting the rights of participants and fostering public trust in biomedical research. It will ensure compliance with established standards and regulations, enhance the quality of decision-making processes and promote transparency and accountability. Such oversight can help identify challenges and foster a culture of continuous improvement (*3*).

The National Committee for Ethics in Biomedical Research of Iran (NCEBR) was established in 1998 by the Deputy for Research and Technology of the Ministry of Health and Medical Education (MOHME) following the 18th Regional Committee meeting of the World Health Organization in the Eastern Mediterranean. One year later, guidelines for the establishment of research ethics committees were issued (*7*). With the advancement of research activities and increased experience, these guidelines were revised in 2013 and 2020 by MOHME's Deputy for Research and Technology. The latest version of the guidelines provides detailed explanation of the procedures for establishing ethics committees at various levels and outlines the processes for ethical review of research proposals (*8*). It emphasizes the importance of monitoring compliance with ethics standards throughout all stages of research.

The national guidelines delegates the review of research proposals and oversight of ethical research conduct to RECs. RECs operate under the supervision of the Regional Research Ethics Workgroups (RREWs), which are typically established by medical universities.

Currently, there are 63 RREWs and 228 RECs in Islamic Republic of Iran, and all RREWs are supervised by NCEBR, which operates under the Research Deputy of MOHME (*8*).

Tehran University of Medical Sciences (TUMS)is the largest university in Islamic Republic of Iran and it has an extensive research portfolio and a RREW overseeing 18 RECs. These RECs collectively review up to 4000 research proposals annually, with individual workloads varying from 13 to 779 projects per year. At TUMS, every research proposal is reviewed by at least one REC, and ethics oversight coverage of research proposals is 100%. The university's RREW is responsible for monitoring the performance of these committees, addressing their challenges and resolving their complaints.

This study was conducted to assess the performance of RECs at TUMS and identify their strengths and weaknesses. The findings are expected to help improve their performance and the oversight of research ethics by TUMS.

Methods

This study used the WHO tool for benchmarking ethics oversight of health-related research involving human participants (*9*) to evaluate RECs at TUMS. The user guide for the tool outlines various methods for assessing RECs (*10*) and the external evaluation method was used for this study. The method recommends that an independent individual, unaffiliated with the RECs, should conduct the assessment. We conducted interviews with committee members and reviewed available relevant documents.

Data collection

The tool was translated into Persian. Five research team meetings were held to discuss the appropriate data sources for each category of the tool (Table 1). During these meetings, the national guidelines and regulations were reviewed and discussed to evaluate the indicators in Category 1 of the tool. For Categories 2 to 6, relevant interview questions based on the tool's indicators were designed for 3 target groups: secretaries of the institutional ethics committees, ethics experts and researchers. The required documentation for assessing the performance of the committees in these categories was identified (Box 1). The secretaries were chosen because they had very good knowledge of REC procedures and the ethics experts were included because they review all research proposals, including expedited reviews. The researchers were included because of their insights into the interactions between committees and researchers. For Category 7, which assesses the responsiveness of TUMS as an institute, evidence was provided by the university's research manager and the lead expert for the university's electronic research management platform. Evaluation of indicators in this category was finalized through consensus among members of the research team.

For categories 2 to 6, we interviewed the secretaries of all the 18 RECs, 7 bioethics experts, who serve as ethics expert members of RECs, and 14 clinic and basic science researchers whose proposals had been reviewed by the committees. The questions were prepared during the study team meetings based on the WHO tool indicators. They were mostly structured, but respondents were allowed to elaborate on their responses to the questions, particularly the challenges they faced within the RECs and the reasons for not meeting certain indicators. At the end of each interview session, we asked an open-ended question on the other challenges they encountered in providing ethics oversight.

All the interviews were one-on-one, face-to-face and recorded and each lasted 45 minutes on average. The interviewers ensured that participants understood each question and gave appropriate responses.

Data analysis

The research team met to discuss and reach consensus on the status of the RECs for indicators in categories 1 to 7. For categories 2 to 6 indicators, the interviewers evaluated the status of each REC after conducting the interviews and reviewing the documents provided. A content analysis of interview transcripts was conducted to identify challenges RECs faced in provoding ethics

Table 1 Data sources for each category of the WHO tool for benchmarking ethics oversight of health-related research involving human participants

Main category	Category	Data gathering method
Indicators for assessing legal and regulatory context	1: Legal provisions and regulatory framework	Review of national and university-level guidelines by the research team
Indicators for assessment of RECs	2: REC structure and composition	Interviews with ethics committee secretaries, ethics experts and researchers, as well as a review of documentation provided by the committees
	3: REC resources	
	4: REC procedures	
	5: Mechanisms to promote REC transparency and accountability	
	6: Mechanisms for RECs to monitor their performance	
Indicators for assessing research institutions	7: Responsible research institutions	Documentation provided by the university's research manager and research system specialist

REC = Research Ethics Committee

Box 1. Documents requested for assessment of research ethics committees

1. REC's meeting minutes for the past year (December 2022 to December 2023)
2. Educational requirements and courses for staff and members of committees
3. Internal procedures for conducting meetings and ethics clearance decision-making
4. Completed conflict of interest forms for each meeting session
5. Procedures for receiving research protocol from outside the university
6. Survey documents assessing the performance of RECs gathered from committee members, staff, researchers, and research participants
7. Evaluations of the quality of committee meetings and ethical review of research proposals
8. Performance evaluations for committee staff members
9. Procedures for post-approval monitoring of research projects
10. URL of the ethics committee's website
11. Complaints or concerns raised by researchers and research participants
12. Process for addressing the complaints

oversight. The texts were reviewed multiple times for accuracy, and initial codes were extracted and organized into subcategories based on similarities. The results were then compared and any disagreements were resolved through face-to-face meetings before reaching a consensus.

Ethics approval

Informed consent was obtained from all participants after explaining the objectives of the study to them. The study protocol was reviewed and approved by the Faculty of Medicine REC, approval number IR.TUMS.MEDICINE.REC.1402.291.

Results

For category 1 indicators on legal and regulatory framework, the regulations were sufficient to ensure ethics oversight of research. Only 2 of the 14 indicators in this category were not fully implemented (Table 2). Of the 26 indicators for structure and composition, resources, procedures, mechanisms to promote transparency and accountability, and mechanisms to monitor self-performance, only 8 were fully implemented, 8 were partially implemented, and 4 were not implemented by all the 18 RECs. There were variations in implementation of the remaining 6 indicators. Performance was consistent in most of the indicators because of the electronic research management platform, centralized procedures and coordination among the RECs, which were overseen by the university's RREW.

The major challenges that required attention were identified, analysed and organized into 7 categories and 14 subcategories (Table 3). In Islamic Republic of Iran, RECs are not authorized to develop many of the processes listed in Table 2. The responsibility lies with the university's RREW and NCEBR. Therefore, challenges related to these processes can be considered as part of the broader challenges under the category of university accountability.

Category 7 lacks an indicator specifically addressing the monitoring of the performance of RECs. From the perspective of stakeholders, oversight of the performance of RECs is the responsibility of the university's RREW, a task that has been overlooked. Consequently, this challenge has been included under university accountability category (Table 3).

Discussion

We discuss the challenges in providing ethics oversight by the RECs at TUMS and lessons learnt, based on our findings.

Post-approval monitoring of research projects

The main goal of the ethics committee is to protect the rights of research participants (*3*). The national guidelines assign the responsibility of continuous monitoring of studies to the RECs, however, only few of the RECs do so, as indicated by committee members and researchers. The main reasons for the lack of post-approval monitoring are the absence of formal procedures for such monitoring, insufficient training for REC members, limited resources, and potential conflicts of interest. Similarly, most RECs in Europe do not conduct post-approval monitoring for some reasons, including limited resources and issues related to governance structures (*11*). Lack of post-approval monitoring has also been reported in India (*12*). Adequate funding and human resources are needed to improve post-approval monitoring by RECs (*13,14*). Pickworth suggests that there could be resistance to post-approval monitoring because it could negatively affect the relationships between REC members and researchers, therefore, significant changes are needed for RECs to carry out post-approval monitoring duties effectively (*15*). Implementing post-approval monitoring by a higher-ranking committee, such as the university's RREW, could help prevent tensions and conflict of interest faced by local committees.

Oversight of committee performance

Domain 6 of the WHO's tool on self-evaluation and self-monitoring of RECs was not implemented by all the RECs

Table 2 Evaluation of research ethics committees at Tehran University of Medical Sciences based on WHO tool for benchmarking ethics oversight

No.	Indicator	Implemented		
		Fully	Partially	Not
	Legal provisions and regulatory framework			
1.1	Legal provisions that require health-related research involving humans to be reviewed and approved by RECs	18		
1.2	Legal provisions that require RECs to review proposed research to determine whether it is consistent with the ethics standards in WHO guidelines	18		
1.3	Legal provisions that require RECs to conduct continuous review of research at intervals appropriate to the risk to humans		18	
1.4	Legal provisions that authorise RECs to suspend or terminate health-related research involving humans if they determine that the study no longer meets the criteria that justified its initial approval	18		
1.5	Legal provisions that require REC members to declare any conflicts of interest and prohibit members from participating in the review of any study in which they have a conflicting interest	18		
1.6	Legal provisions that ensure that a REC's decision not to approve a study cannot be overruled, except in cases of abuse of authority as determined by a regulatory agency or court	18		
1.7	Legal provisions establishing minimum standards for RECs' archiving of documents, including the length of time that records must be retained and requirements for maintaining data security and confidentiality		18	
1.8	Legal provisions that make institutions and their RECs responsible for ensuring that RECs have the resources described in category 3 of this document	18		
1.9	Legal provisions to ensure that research participants have access to medical treatment for any injuries that result directly from their participation and that participants and their dependants are protected from any financial consequences that could directly result if the participants suffer injury or death as a result of their participation	18		
1.10	Legal provisions that require clinical trials to be registered in a registry that complies with the WHO registry criteria before recruitment of participants begins	18		
1.11	National, subnational, multinational and/or local oversight authorities support RECs and ensure that they adhere to applicable ethical and legal requirements	18		
1.12	Legal provisions that require all RECs in the country to be registered, with the name and contact information of the REC chair or other responsible person, and require a list of registered RECs to be made publicly available	18		
1.13	Legal provisions to suspend or revoke the registration of RECs that do not adhere to applicable laws, regulations and guidelines	18		
1.14	Updated, publicly available information, on laws, regulations and official guidelines for the ethics oversight of health-related research involving humans	18		
	Structure and composition			
2.1	REC membership satisfies the requirements of ethics principles in WHO guidelines and of any national laws or policies consistent with those principles	15	3	
2.2	The roles and responsibilities of REC members are clearly defined		18	
2.3	REC members and their chairs are appointed for fixed terms rather than indefinitely, and terms are staggered so that they do not all expire at the same time		18	
2.4	REC members and chairs may not be removed before the expiration of their terms unless they have been found to have substantially breached their duties	18		
2.5	REC invites relevant non-members to contribute to the review of research that raises issues beyond the scope of members' experience or expertise	17	1	
	Resources			
3.1	REC has sufficient, competent staff with appropriate education, skills and experience to support its activities	15	3	
3.2	REC members and staff receive training in ethics issues in health-related research involving humans		18	
3.3	REC has adequate facilities and equipment	18		
3.4	REC has adequate technological support for its needs	18		
3.5	REC has adequate and stable financial resources		18	
	Procedures			
4.1	REC provides adequate guidelines for submission and screening of applications for ethics review of health-related research involving humans	1	17	
4.2	REC has written procedures to ensure that its deliberations adhere to ethical criteria for review in WHO guidelines	18		
4.3	REC members have adequate time before and during meetings for meaningful review of research proposals	15	3	
4.4	REC has procedures to ensure that decisions are made in a timely manner and are promptly communicated to principal investigators		18	

No.	Indicator	Implemented		
		Fully	Partially	Not
	Procedures			
4.5	REC has procedures for ensuring fast-track review of research proposals in public health emergencies			18
4.6	REC engages in and/or contributes to monitoring ongoing research at intervals appropriate to the degree of risk to humans			18
4.7	The REC maintains a good document management system.	18		
	Mechanisms to promote transparency and accountability			
5.1	Updated information on REC's guidelines and procedures is publicly available	1	10	7
5.2	Updated information about REC's sources of funding is publicly available			18
5.3	Updated list of all the REC members is publicly available or available on request	18		
5.4	A list of the titles, principal investigators and dates of approval of all research proposals approved by the REC is publicly available or available on request	18		
5.5	REC enables current and prospective research participants to ask questions, raise concerns or lodge complaints about their rights as research participants and about the ethics review process, and it responds to questions and complaints in a timely manner		18	
5.6	REC enables investigators to question, raise concerns or lodge complaints about the ethics review process, and it responds to questions and complaints in a timely manner	18		
	Mechanisms to monitor self-performance			
6.1	REC has a mechanism for obtaining feedback from investigators and research participants about their experience of the research study			18
6.2	REC monitors its adherence to its standard operating procedures		18	
6.3	REC regularly conducts internal reviews of its performance		18	
	Responsible research institution			
7.1	The institution verifies that all proposals for health-related research involving humans are submitted to a registered REC if any part of the research is to be conducted by a researcher affiliated with the institution	*		
7.2	The institution has policies and procedures for declaration and management of conflict of interest of researchers affiliated with the institution and of the institution itself			*
7.3	Institutions with their own RECs have policies and procedures for declaration and management of conflict of interest of REC members and non-member participants in REC meetings		*	
7.4	The institution has a policy that requires that all researchers affiliated with it be trained in their responsibilities for ethical conduct of research			*
7.5	The institution has its own REC, it ensures that the REC has the resources described in category 3 of this document	*		
7.6	The institution facilitates lodging of complaints by research participants and prospective research participants about studies conducted by researchers affiliated with the institution, either through the institution itself or at national or regional level. If the complaint system is established within the institution, the institution has a process for reviewing and responding to complaints.		*	
7.7	The institution has a process for investigating allegations of unethical conduct by researchers and for imposing consequences when unethical conduct is determined to have occurred		*	

**Responsibility status of the university*

at TUMS because of the lack of guidelines or written procedures on how to implement them. Performance monitoring and accreditation help standardize ethics oversight and ensure adherence to policies by RECs (3). RECs have been criticized for delaying or obstructing life-saving research, for excessive bureaucracy and for expansion of their responsibilities to low-risk activities (*16*,*17*).

The WHO tool serves as a maturity framework for benchmarking and enhancing the performance of RECs, however, challenges like limited resources, inadequate training and conflict of interest have hindered such self-evaluation. Review processes were prolonged, there were inconsistencies in the review methods used by different RECs and no post-approval oversight. RECs should make efforts to reduce the duration of their review and approval processes and embrace self-evaluation and performance monitoring as opportunities for reflection and improvement rather than burdens (*18*).

Conflict of interest

The national guidelines stipulates that a REC cannot review a proposal for which the principal investigator is a member of that REC and that such proposal must be sent to another REC. There are no restrictions if any of the co-investigators is a member of the REC. In practice, conflict of interest often arises, particularly in smaller institutions where members frequently interact and collaborate. Although guidelines require members to disclose conflicts and recuse themselves, our findings indicate that many members fail to declare conflict or excuse themselves even when they are involved in a

Table 3 Challenges faced by RECs in performing their duties (perspectives of REC secretaries, ethics experts and researchers)

Theme	Subtheme	Code
National regulations and standards		Lack of mandatory regular reporting by researchers to the REC
		No requirement to reference or cite previous reviews
		Absence of contact information for the committee chair or other responsible persons
		No requirement for at least one non-affiliated member
		Operational issues in the guidelines on sample transfer abroad
		Lack of ethics standards for the preparation and use of big data
Structure		No epidemiology experts in some committees
		Absence of young researchers in the committees
		Frequent absence of some committee members
		No member turnover after 2 years
		Non-staggered terms for members
Resources	Human resources	No full-time or dedicated staff
		High workload
	Financial resources	Inadequate funding
		No dedicated physical space for REC at the hospitals
		Insufficient incentives
	Knowledge of committee members	Lack of awareness among members about their roles
		No specific training programmes for committee staff
		Inadequate familiarity of ethics experts with clinical procedures and routines
Processes	Continuous monitoring process	No after-approval monitoring
		No access to the submitted project by ethics experts to read its reports
	Meeting process	Irregular meeting sessions
	Decision-making process	No documented internal decision-making processes
		No procedures to address uncooperative principal investigators
		Need for exemption from ethics review for certain projects
		Inconsistency in ethics review across RECs
	Complaint handling process	Slow complaint resolution process
		No documented procedures for complaint handling
		No feedback to RECs about complaint-handling outcomes
		No platform or method for participants or potential participants to submit complaints or express concerns
	Conflict of interest management	No policy or procedure for declaring conflict of interest by researchers
		Conflict of interest among scientific consultants
		Personal ties with research team members
		Following their institutional interests by requiring projects to include a collaborator from the clinical setting
	Evaluation process	No quality control for committees
		Delays and slow ethics review processes
		Excessive administrative bureaucracy
		Low quality evaluation of the reviewers
Transparency		No written policy outlining compensation to committee members and staff
		No clear procedures for researchers outside the university to submit their proposals
		Insufficient communication about processes
		No access for participants to the committee approving the proposal
Researchers	Knowledge	Lack of awareness about research ethics
		Lack of awareness about the ethics review process
	Attitude	Non-acceptance of scientific and methodological critiques from the ethics committee
		Carelessness in revising proposals

Table 3 Challenges faced by RECs in performing their duties (perspectives of REC secretaries, ethics experts and researchers)

Theme	Subtheme	Code
University accountability	Research council issues	Approval of incomplete proposals
		Lack of thorough scientific review of proposals
		Approval of projects lacking social value
	Lack of Policies and Procedures	No requirement for researchers to complete research ethics training or learn about RECs role and responsibilities
		No requirement for researchers to declare conflict of interest
		No policy or procedure for declaring a relationship with private companies
		No procedures for monitoring the performance of RECs
		No procedures for complaint handling
	Frequent changes	Frequent changes in some processes
	Electronic research management platform	Inappropriate content of the template consent forms for parents of children
		No option to create multiple consent forms in the system for different groups of participants
		No option to view the average proposal retention time in different environments
		Inability to generate meeting agenda or minutes for RECs
		No access from other countries
		No access for non-affiliated researchers to the system

proposal that is being reviewed by their REC (Table 2). A study in the USA found that one-third of RECs did not require members to disclose industry relationships and a quarter lacked formal conflict management procedures (*19*). Another study reported that 15% of committee members reviewed protocols supported by companies they had relationship with (*20*). Conflict of interest in our study was often linked to personal friendships and collaborations rather than industry ties. In small research centres and academic faculties, close relationships may impact the ability of REC members to deliver unbiased evaluation.

Review processes

Self-monitoring shows that RECs at TUMS have the weakest procedures in the country. Across universities nationwide, local committees do not have the authority to develop their own procedures or deviate from those established by the RREW or the national REC. Therefore, it is crucial for the university to develop common procedures for its RECs. We identified procedures that the university's RREW should address in collaboration with RECs (Table 3), to help standardize RECs' practices. Czarkowski emphasized the need to develop processes, and recommended the establishment of an association of RECs that will draft standardized procedures, ensure coordination and promote uniformity across all committees (*21*).

Institutional responsiveness

We found significant deficiency in category 7 on institutional responsibility, particularly the lack of policies for managing conflict of interest. The absence of clear policies and procedures for the management of conflict of interest in universities and research institutions undermines scientific integrity (*22*). Universities should establish transparent conflict of interest policies for individuals and their institutions to maintain public trust (*23*).

At TUMS, the process for managing complaints is centralised within the RREW. This leads to a heavy workload and feedback on the resolution of complaints is usually not communicated to the approving REC. There is no mandatory training on research ethics that could help researchers understand the principles of research and publication ethics. Some researchers perceive the identification of flaws by RECs as an infringement of their rights, as already noted in other studies (*24*).

Recommendations for improving the use of the WHO tool

Numerous studies have reported similar challenges faced by RECs around the world, including structural and resource-related deficiencies, inconsistent operations, reviews conducted by unqualified or excessively rigid personnel, bureaucratic procedures, unwarranted interference in research processes, and unethical manipulation (*25–30*). Several measures have been suggested to address these challenges and improve the efficiency, consistency and accountability of RECs, including simplifying and standardizing procedures, implementing accreditation systems and enhancing post-approval monitoring (*27*).

The WHO tool for benchmarking ethics oversight can be used as a maturity framework and self-assessment tool for RECs, however, the value of its components varies and, sometimes, relying solely on self-assessment is inadequate. For example, researchers in one study

questioned the validity of the responses given by RECs to certain questions about post-approval monitoring of studies (*30*). In many low- and middle-income countries, including Islamic Republic of Iran, RECs often lack the resources and workforce to conduct post-approval monitoring effectively (*29,31*). Financial dependence on their affiliated institutions limits the independence and capacity of RECs for reform. Therefore, performance evaluations of RECs should be managed by a central regulatory entity such as NCEBR. The WHO tool for benchmarking ethics oversight provides clear guidance for regulatory bodies on the documentation and questions for REC evaluations.

Islamic Republic of Iran currently has an accreditation system for RECs, but it is limited to assessing the qualification of REC members and not supervision of the quality of ethics clearance. Although centralized oversight of all RECs by NCEBR is impractical, a tiered oversight system, as suggested in UNESCO's guidelines for establishing ethics committees (*18*), could enhance support and harmonization of REC performance while providing a practical and efficient oversight mechanism. Unlike the WHO tool for benchmarking ethics oversight, which assumes that RECs operate independently with internal responsibility for processes, training and performance monitoring, UNESCO's model proposes a structured, hierarchical approach at national, regional and local levels. In this system, local RECs are evaluated by regional RECs, which are in turn overseen by a national REC, enhancing support and accountability. The RREW at TUMS has a supportive and harmonizing role for local RECs by paying the reviewers and developing procedures to improve and unify RECs practices.

Although there is a tiered approach for receiving REC reports in Islamic Republic of Iran, higher-level committees typically do not actively assess the performance of the RECs they oversee. Our study highlights the importance of external oversight, training, support, and centralized procedures by the university's RREW office.

The success of RECs should not only be defined by the mechanisms and infrastructure they create but also by their outputs, to ensure effective protection of research participants' rights (*3,32*). The WHO tool provides valuable criteria for assessing the minimum necessary infrastructure and mechanisms for the optimal performance of a REC; however, it lacks the indicators to monitor the ultimate outcomes for participants. This limitation has been reported for many other evaluation tools as well (*33,34*). Incorporating clauses to evaluate the performance of RECs based on outcomes can help address this challenge. Gathering feedback from research participants is vital, especially in health systems where studies occur in health care settings and researchers also act as providers. This dual role may affect how information is presented to participants and influence participants' ability to make fully informed and independent decisions (*35*).

Study limitations

This study has some limitations. The findings cannot be generalized nationally because TUMS has more faculty members with medical ethics training, which improves the quality of ethics reviews. Conducting similar studies in other RECs across the country could offer a more comprehensive understanding of the overall performance of RECs nationwide.

Conclusion

This study indicates the need for enhancements in post-approval monitoring, conflict of interest management and institutional accountability for RECs at TUMS. Addressing these gaps will help improve ethics oversight and build trust in biomedical research. Our study shows that although the WHO tool is good for identifying the challenges and shortcomings of RECs and can function as a maturity framework for all RECs, the varying capacities and performance levels among RECs indicate the need for a tiered approach. We suggest categorizing RECs into tiers for improved oversight, support and training. This would help ensure optimal performance, particularly at the regional level where disparities in capacity and resources may exist.

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Évaluation de la surveillance de l'éthique de la recherche universitaire en République islamique d'Iran

Résumé

Contexte : Une évaluation régulière des performances des comités d'éthique de la recherche (CER) est essentielle pour garantir leur efficacité dans la protection des droits des sujets de recherche et renforcer la confiance du public dans la recherche biomédicale.

Objectifs : Évaluer les performances des CER de l'Université des sciences médicales de Téhéran et identifier les principaux défis liés à l'exercice de leurs fonctions.

Méthodes : À l'aide de l'outil d'analyse comparative de la surveillance éthique de l'OMS, nous avons mené des entretiens avec 18 secrétaires de comités d'éthique de la recherche, sept experts en bioéthique et 14 chercheurs de

l'Université des sciences médicales de Téhéran. Nous avons également passé en revue les documents pertinents. Nous avons analysé le contenu des textes et des transcriptions d'entretiens afin d'identifier les principaux mécanismes opérationnels et défis rencontrés.

Résultats : Sur les 26 indicateurs relatifs à la structure et à la composition, aux ressources, aux procédures, aux mécanismes visant à promouvoir la transparence et la responsabilité ainsi qu'aux mécanismes de suivi de l'auto-évaluation, seuls huit ont été entièrement mis en œuvre, huit autres l'ont été partiellement et quatre n'ont pas été appliqués par l'ensemble des 18 CER. La mise en œuvre des six indicateurs restants variait d'un comité à l'autre. Les principaux défis identifiés durant ce processus étaient l'absence de suivi post-approbation des projets de recherche, une gestion inadéquate des conflits d'intérêts et une application irrégulières des procédures. Les CER disposaient d'une formation limitée en éthique et ne disposaient ni de politiques ni de procédures de gestion des conflits d'intérêts.

Conclusion : L'outil de l'OMS a permis d'identifier efficacement les atouts et les faiblesses de la performance des CER à l'Université des sciences médicales de Téhéran. Un système de surveillance à plusieurs niveaux est recommandé pour renforcer le soutien aux CER et harmoniser leurs pratiques. Les axes prioritaires d'amélioration devraient porter sur le suivi post-approbation, la gestion des conflits d'intérêts et la responsabilisation institutionnelle. La correction de ces lacunes contribuera à renforcer la surveillance éthique et à accroître la confiance dans la recherche biomédicale.

تقييم مراقبة الالتزام بأخلاقيات البحوث في إحدى المؤسسات الأكاديمية الجامعية في جمهورية إيران الإسلامية

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الخلاصة

الخلفية: يكتسي التقييم المنتظم لأداء لجان أخلاقيات البحوث أهمية بالغة لضمان فعاليتها في حماية حقوق الأشخاص الخاضعين للبحوث وزيادة ثقة الجمهور في بحوث الطب الحيوي.

الأهداف: هدفت هذه الدراسة الى تقييم أداء لجان أخلاقيات البحوث في جامعة طهران للعلوم الطبية والوقوف على التحديات الرئيسية التي تعوق أداء هذه اللجان لمهامها.

طرق البحث: باستخدام أداة المنظمة المرجعية لمراقبة الالتزام بأخلاقيات البحوث، أجرينا مقابلات مع 18 أمينًا للجان أخلاقيات البحوث، و7 خبراء في أخلاقيات البيولوجيا، و14 باحثًا في جامعة طهران للعلوم الطبية، واستعرضنا الوثائق ذات الصلة. وأجرينا تحليلاً لمحتوى محاضر المقابلات ونصها لتحديد الآليات التشغيلية الرئيسية والتحديات التي تعترض التشغيل.

النتائج: من بين 26 مؤشرًا للهيكل والتكوين، والموارد، والإجراءات، والآليات الرامية إلى تعزيز الشفافية والمساءلة، والآليات الرامية إلى رصد الأداء الذاتي، نُفِّذت 8 مؤشرات فقط تنفيذًا كاملاً، ونُفِّذت 8 مؤشرات تنفيذًا جزئيًا، ولم تُنفَّذ 4 مؤشرات من جانب جميع لجان أخلاقيات البحوث البالغ عددها 18 لجنة. وكانت هناك تفاوتات في تنفيذ المؤشرات المتبقية البالغ عددها 6 مؤشرات. وتتمثَّل أبرز التحديات التي تواجه التنفيذ في عدم متابعة البحوث بعد الموافقة عليها، وعدم كفاية إدارة تضارب المصالح، وعدم انتظام الالتزام بالإجراءات. وكان التدريب على الأخلاقيات لدى لجان أخلاقيات البحوث محدودًا، ولم تكن هناك سياسة وإجراءات لإدارة تضارب المصالح.

الاستنتاجات: أداة منظمة الصحة العالمية حددت بشكل فعال نقاط القوة والضعف في أداء لجان أخلاقيات البحث. يُوصى بنظام رقابة متدرج لتعزيز دعم لجان أخلاقيات البحث وتوحيدها. يجب أن تركز التحسينات الرئيسية على مراقبة ما بعد الموافقة، وإدارة تضارب المصالح، والمساءلة المؤسسية. معالجة هذه الفجوات ستعزز الرقابة الأخلاقية وتعزز الثقة في البحث الطبي الحيوي.

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