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Trainees' Corner BJUI BJU International

Research Letter

Global comparison of research ethical review protocols: insights from an international research collaborative

Scientific ethical review is a cornerstone of conducting medical research. It aims to ensure human subject research is conducted in a manner that safeguards and respects participants' rights and well-being. Research ethics committees (RECs) or institutional review boards (IRBs) are responsible for ethical evaluations before approval. This entails assessing potential risks and benefits associated with the research. For effective international research collaboration, researchers must be cognisant of participating countries' ethical and regulatory requirements. Although these processes may be managed at various levels—local, regional or national; their implementation across countries often remains opaque and varies significantly. The British Urology Researchers in Training (BURST) Research Collaborative houses a network of international representatives to guide prospective study sites within their countries in acquiring ethical approval. We provide an overview of the ethical approval processes across 17 countries, emphasising on approvals for audits, observational studies, and randomised controlled trials (RCTs).

A brief structured questionnaire was sent to all international representatives of BURST (Appendix S1). BURST is an international research group leading major collaborative urological research studies, both interventional and non-interventional, engaging hospitals from multiple countries [1–3]. The international representatives are from 17 countries (United Kingdom, Ireland, Italy, Spain, Germany, France, Belgium, Portugal, Montenegro, Slovakia, USA, India, Hong Kong, Vietnam, Indonesia, Mexico, and Ethiopia). Additionally, data on ethical approval procedures were collected from the top 15 countries with the highest case contributions to BURST's recent 'Transurethral REsection and Single instillation intra-vesical chemotherapy Evaluation in bladder Cancer Treatment' (RESECT) study, which enrolled 19 505 patients across 230 hospitals from 41 countries [3]. A link to the questionnaire was sent by e-mail to the international representatives in May 2024. The survey encompassed questions relating to local ethical and governance approval application processes, projected timeline, financial implications, challenges, and regulatory guidance.

Of the 24 questionnaires distributed, 18 (75%) were completed and returned by respondents across 17 countries. Table S1 summarises the questionnaire results for each country. All countries confirmed the role and existence of established decision-making committees tasked with overseeing the ethics of human subject research within their countries.

The core of the ethical approval process lies in the clarification and preparation of necessary information for the REC. Applications typically require the study protocol, which defines the research plan, allowing the REC to assess and classify the study. Additional documentation may be requested, including a conflict-of-interest statement, consent forms, or a data transfer agreement. Certain institutions may charge fees for ethical approval submissions, particularly for-profit studies and RCTs. A checklist outlining common documents required by collaborating hospitals can enhance the efficiency of conducting collaborative studies (Table S2).

Ethical approval decisions generally take 1–3 months, resulting in approval, rejection, or a clarification request. While ethical approval permits the study to proceed, compliance with REC directives, including obtaining additional approvals, may be required.

Among the 10 European countries surveyed (UK, Belgium, Spain, Italy, France, Portugal, Ireland, Montenegro, Slovakia, and Germany), the majority—excluding the UK, Montenegro, and Slovakia—required formal ethical approval for all study types (Table S1). In the UK, local audit department registration remains necessary for audits, whereas other study types require a formal ethical review. In Montenegro, all studies are subject to an initial formal review by the National Scientific Council to determine whether they qualify as research or audit. If deemed an audit, local audit department registration of participating sites is the only requirement. In Slovakia, the requirement for formal REC approval is limited to interventional studies. In the majority of the 10 European countries, RECs primarily function at the local hospital level, excluding Italy, Montenegro and Germany. Montenegro conducts ethical approval evaluations nationally, while Italy and Germany perform these assessments regionally. Regional REC evaluations in both countries chiefly serve a particular group of hospitals in each region. In the latter instance, they have affiliations with medical faculties, associations, or universities. Written informed consent is mandatory for all types of formal research studies in Belgium, France, Portugal, Germany, and the UK. Clinical audits also require written informed consent in Portugal and Germany, but this requirement is waived in Belgium, France, and the UK. Additional authorisation apart from ethical approval is needed in several European countries. This includes the UK (for research studies), France, Portugal and Belgium for all types of studies.

Of the Asian countries (Hong Kong, India, Indonesia, Vietnam), only India and Indonesia require formal ethical

review for all study types (Table S1). For Hong Kong, audits have to be submitted for initial review by regional IRBs to assess eligibility for a waiver of formal review, while in Vietnam, audits require local hospital's audit department registration. In Indonesia, further authorisation is required for all studies involving international collaboration, entailing an additional foreign research permit application to Indonesia's National Research and Innovation Agency (Badan Riset dan Inovasi Nasional [BRIN]). RECs across these Asian countries function locally in India, Indonesia, Vietnam, and regionally in Hong Kong. Ethical approvals for interventional studies and clinical trials in Vietnam must be submitted to a National Ethics Council, rather than a local ethics approval.

Our results highlight considerable heterogeneity in the ethical approval processes for research studies and audits across the world. While all mentioned countries align with the Declaration of Helsinki, the discrepancies demonstrate that some enforce more stringent review regulations. Across the countries, European countries like Belgium and the UK appear to have the most arduous process in terms of timeline duration (>6 months) for gaining ethical approval for interventional studies. Conversely, review processes for observational studies and audits in Belgium, Ethiopia, and India may be most lengthy, extending up to more than 3–6 months. Delays in attaining ethical approval can be a barrier to research, particularly low-risk studies, curtailing medical research efforts. This has historically been a point of critique on ethical approval mechanisms, with previous studies highlighting their deterring effect on research endeavours [4,5]. From a collaborative research viewpoint, non-involvement of hospital sites from certain countries in collaborative studies reflects inadequate representation of their patient populations, potentially limiting the applicability of study findings to these groups.

The wide variations in review timelines for audits and observational studies internationally highlight a key factor: the necessity of formal ethical review. Countries like the UK, Hong Kong and Vietnam, with shorter lead times, only require local audit department registration before study initiation. Additionally, a prevailing limitation is the inconsistency and ambiguity in defining and classifying studies, which can differ between countries and sites, often being determined only after review by the appropriate RECs in some countries. The decision-making tool established by the UK's Health Regulatory Authority (HRA) is designed to identify the nature of the proposed study, determining the need for formal ethical approval. This tool serves as a valuable self-assessment tool to facilitate decision-making and enhance clarity for researchers, which may be adopted by other countries to enhance their respective regulatory frameworks.

This article highlights the diverse regulatory guidance across countries on different continents, aiming to provide readers with a clearer understanding of the said regulations. Familiarity with regulatory variations enables researchers to effectively coordinate international research studies. From the BURST perspective, our experience indicates that international representatives are well-positioned to understand local contexts and guide regulatory approvals for participating sites. A limitation of this study is the variability in research guidelines, which may fluctuate within individual countries. This may be particularly significant in countries where RECs are locally governed, suggesting a potentially even greater variability in local REC guidelines than reflected here, given the limited respondent pool of individuals per country. The differences across countries suggest a pressing need for further improvement and standardisation in the context of an expanding landscape of international collaborative research.

Disclosure of Interests

The authors declare no conflicts of interest.

Bing Jie Chow[1,2], Alexander Light[1,3], Arjun Nathan[1,4], Loic Baekelandt[5,6], Gautier Marcq[7], Stefanie Croghan[1,8], Fortis Gaba[1,9], Francesco Esperto[10], Luca Orecchia[11], Carlos Toribio-Vázquez[12], Juan Gómez Rivas[13], Adrian Chi-Heng Fung[14], Kaleab Habtemichael Gebreselassie[15], Eduardo Felicio[16], Aria Danurdoro[17], Nikolaos Pyrgidis[18], Vukovic Marko[19], Jan Svihra Jr.[20], Mohamed Javid[21], Andrés Salas[22], Tran Trung Thanh[23], Cameron Alexander[1,24], Nikita Bhatt[1,25], Sinan Khadhouri[1,26,27], Veeru Kasivisvanathan[1,4], Kevin Byrnes[1,4] and in collaboration with the European Association of Urology Young Academic Urologists Urothelial Carcinoma Working Group

[1]British Urology Researchers in Surgical Training (BURST), [2]Barts and the London School of Medicine and Dentistry, Queen Mary University of London, [3]Department of Surgery and Cancer, Imperial College London, [4]Division of Surgery and Interventional Science, University College London, London, UK, [5]Department of Urology, University Hospitals Leuven, [6]Organ Systems, KU Leuven, Leuven, Belgium, [7]Urology Department, Claude Huriez Hospital, CHU Lille, Lille, France, [8]Department of Surgery, Royal College of Surgeons in Ireland, Dublin, Ireland, [9]Department of Urology, Albany Medical Center, Albany, NY, USA, [10]Department of Urology, Campus Bio-Medico University, [11]Urology Unit, AOU Policlinico Tor Vergata, Rome, Italy, [12]Urology Department, Hospital Universitario La Paz, [13]Department of Urology, Hospital Clínico San Carlos, Madrid, Spain, [14]Department of Surgery, School of Clinical Medicine, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Hong Kong, Hong Kong, [15]Urology Unit, Department of Surgery, Worabe Comprehensive Specialized Hospital, Worabe, Ethiopia, [16]Urology Department, Hospital Professor Fernando Fonseca, Amadora, Portugal, [17]Division of Urology, Department of Surgery, West Nusa Tenggara Province General Hospital/Faculty of Medicine, University of Mataram, Mataram, Indonesia, [18]Department of Urology, University Hospital of the LMU Munich, Munich, Germany, [19]Department of Urology,

Clinical Centre of Montenegro, Podgorica, Montenegro, [20]Jessenius Faculty of Medicine, Comenius University, Martin, Slovakia, [21]Chengalpattu Medical College, Chengalpattu, India, [22]Hospital de Oncología Centro Médico Nacional 'Siglo XXI', Mexico, Mexico, [23]Department of Urology, Hanoi Medical University Hospital, Hanoi, Vietnam, [24]Luton and Dunstable University Hospital, Luton, [25]Freeman Hospital, Newcastle Hospitals NHS Foundation Trust, Newcastle upon Tyne, [26]School of Medicine, University of St Andrews, St Andrews, and [27]Victoria Hospital, Kirkcaldy, NHS Fife, UK

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Correspondence: Arjun Nathan, British Urology Researchers in Surgical Training (BURST), London, UK.
e-mail: arjun.nathan@ucl.ac.uk

Abbreviations: RCT, randomised controlled trial; BURST, British Urology Researchers in Training; IRB, institutional review board; REC, research ethics committee.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Questionnaire.

Table S1. An overview of the process for obtaining ethical approval for audits and research studies across 17 countries.

Table S2. Checklist of relevant research documents for study approval.

