City Research Online

City, University of London Institutional Repository

Citation: Bockhold, S., McNulty, J., Abdurakman, E., Bezzina, P., Drey, N., England, A., Flinton, D., Khine, R., McEntee, M., Mekiš, N., et al (2022). Research ethics systems, processes, and awareness across Europe: Radiography research ethics standards for Europe (RRESFE). Radiography, 28(4), pp. 1032-1041. doi: 10.1016/j.radi.2022.07.002

This is the published version of the paper.

This version of the publication may differ from the final published version.

Permanent repository link: https://openaccess.city.ac.uk/id/eprint/28667/

Link to published version: https://doi.org/10.1016/j.radi.2022.07.002

Copyright: City Research Online aims to make research outputs of City, University of London available to a wider audience. Copyright and Moral Rights remain with the author(s) and/or copyright holders. URLs from City Research Online may be freely distributed and linked to.

Reuse: Copies of full items can be used for personal research or study, educational, or not-for-profit purposes without prior permission or charge. Provided that the authors, title and full bibliographic details are credited, a hyperlink and/or URL is given for the original metadata page and the content is not changed in any way.

City Research Online: http://openaccess.city.ac.uk/ publications@city.ac.uk

Radiography 28 (2022) 1032–1041

Contents lists available at ScienceDirect

Radiography

journal homepage: www.elsevier.com/locate/radi

Research ethics systems, processes, and awareness across Europe: Radiography research ethics standards for Europe (RRESFE)

S. Bockhold [a, 1, *], J. McNulty [a, 1], E. Abdurakman [b], P. Bezzina [c], N. Drey [d], A. England [e], D. Flinton [b], R. Khine [f], M. McEntee [e], N. Mekiš [g], H. Precht [h], L. Rainford [a], C. Sá dos Reis [i], A. Santos [j], V. Syrgiamiotis [k], S. Willis [l], J. Woodley [m], C. Beardmore [n], R. Harris [n], T. O'Regan [n], C. Malamateniou [b]

[a] Radiography and Diagnostic Imaging, School of Medicine, University College Dublin, Ireland
[b] Division of Midwifery and Radiography, School of Health Sciences, City University of London, United Kingdom
[c] Radiography, Faculty of Health Sciences, L-Università ta' Malta, Malta
[d] Division of Nursing, School of Health Sciences, City University of London, United Kingdom
[e] Discipline of Medical Imaging and Radiation Therapy, School of Medicine, University College Cork, Ireland
[f] School of Health Care and Social Work, Buckinghamshire New University, United Kingdom
[g] Medical Imaging and Radiotherapy, Faculty of Health Sciences, University of Ljubljana, Slovenia
[h] Diagnostic and Treatment and Radiography Education, Health Sciences Research Centre, UCL University College, Denmark
[i] Radiological Medical Imaging Technology, School of Health Sciences, University of Applied Sciences and Arts Western Switzerland, Lausanne, Switzerland
[j] Medical Imaging and Radiotherapy, ESTESC-Coimbra Health School, Instituto Politécnico de Coimbra, Portugal
[k] CT-MRI Department, General Children's Hospital of Athens Agia Sophia, and University of West Attica, Greece
[l] Health Education England, National Health Service, London, United Kingdom
[m] School of Health and Social Wellbeing, Faculty of Health and Applied Sciences, University of the West of England, Bristol, United Kingdom
[n] Society and College of Radiographers, London, United Kingdom

ARTICLE INFO

Article history:
Received 23 February 2022
Received in revised form
29 June 2022
Accepted 2 July 2022

Keywords:
Research ethics
Radiography
Standards
Processes

ABSTRACT

Introduction: The Radiography Research Ethics Standards for Europe (RRESFE) project aims to provide a cross-sectional snapshot of current research ethics systems, processes, and awareness of such, across Europe together with identifying the associated challenges, education, and training needs.
Methods: A cross-sectional online survey targeting radiography researchers in Europe was conducted. Data collection took place between April 26 and July 12, 2021, using a snowball sampling approach. Descriptive and analytical statistics were used to identify trends in research ethics frameworks across Europe.
Results: 285 responses were received across 33 European and 23 non-European countries. Most (n = 221; 95%) European respondents stated ethics approval is required before commencing research in their country. Requirements around research ethics approval and awareness of such requirements varied by European region (X^2 (2, n = 129) = 7.234, $p = 0.013$) and were found to differ depending on the type of research participant and study design. Additionally, European respondents reported ethics approval is a national requirement more often than their non-European counterparts (X^2 (1, n = 282) = 4.316, p = 0.049). Requirements for ethics approval were also associated with the undergraduate programme duration (2-year vs. 3-year vs. 3.5 year vs. 4-year vs. multiple programme durations; X^2 (4, n = 231) = 10.075, $p = 0.016$) and availability of postgraduate training (postgraduate training available vs. postgraduate training not available; X^2 (1, n = 231) = 15.448, $p = <0.001$) within respondents' country.
Conclusion: Respondents from countries with longer programme durations/availability of multiple programme lengths, availability of postgraduate training, and establishment of European Qualifications Framework Level 6 were generally associated with less uncertainty and more comprehensive research ethics requirements.

* Corresponding author. Radiography and Diagnostic Imaging, School of Medicine, Health Sciences Centre, University College Dublin, Belfield, Dublin 4, Ireland. Fax: +353 1 716 6547.
E-mail addresses: sophie.bockhold@ucd.ie (S. Bockhold), jonathan.mcnulty@ucd.ie (J. McNulty), christina.Malamateniou@city.ac.uk (C. Malamateniou).
[1] Sophie Bockhold and Jonathan McNulty are co-first authors.

https://doi.org/10.1016/j.radi.2022.07.002
1078-8174/© 2022 The Author(s). Published by Elsevier Ltd on behalf of The College of Radiographers. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

Implications for practice: Results are informative of the current status of research ethics within evidence-based radiography.

© 2022 The Author(s). Published by Elsevier Ltd on behalf of The College of Radiographers. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

Introduction

Active engagement with the evidence base underpinning Radiography, and contribution to such evidence through undertaking high-quality research is essential for radiographers in medical imaging, nuclear medicine or radiotherapy, in clinical practice, academia, or industry.[1–5] Aligned with the World Health Organization's (WHO) definition of a health professional, radiographers have a responsibility to maintain health in humans through applying the principles and procedures of evidence-based medicine and caring.[6] The WHO further state that health professionals must also "conduct research and improve or develop concepts, theories and operational methods to advance evidence-based health care".[6] This is supported by the European Federation of Radiographer Societies (EFRS) through the *EFRS Statement on Radiography Research in Europe*[7] which sets out their position on encouraging, supporting, and developing high-quality radiography and radiographer-led research to strengthen the knowledge base underpinning the profession. They also emphasise the importance of having a clear research focus within radiography programmes as vital to the profession and patient care.[8–10]

Growth in research and a lack of standardisation concerning ethical review runs the risk of research with poor ethical and moral underpinnings entering the evidence base.[11] The European Congress of Radiology (ECR) is the official scientific congress of the European Society of Radiology (ESR) and the EFRS for medical imaging and has seen radiographer participation growing year on year to a record of 2591 radiographers and 740 radiography students at ECR 2022.[12] This growth has also been echoed in the steady annual increase in abstract submissions by radiographers for this congress. Similarly, in *Radiography*, the official journal of the Society and College of Radiographers (UK) and the EFRS, article submissions reached a record high in 2021 at over 400.[4] With this growth in research activity, there is an increased probability for research employing poor ethical practices with suboptimal research ethics consideration, which can be disseminated and propagated, if not detected at the source.[11,13–15] Research undertaken without proper ethical consideration can be presented at conferences, submissions can be considered by journals, and work could be presented during teaching sessions or journal clubs as evidenced in the literature and through author's anecdotal experiences.[13] Thankfully, poor research practices are often identified and/or reported as a result of the ethical frameworks put in place over the past 80 years.[13,16,17] The *Radiography Journal* clearly states that all research involving human subjects (patients, volunteers, staff, students) should be carried out following the *Code of Ethics of the World Medical Association (Declaration of Helsinki)*[16] and that submissions should be in line with the International Committee of Medical Journal Editors (ICMJE) *Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals*.[17] Studies on patients or volunteers require ethics committee approval and informed consent to be documented in journal submissions.[18] Though, despite ethical safeguards in place, ethical concerns around transparent reporting and ethical conduct can persist.

The issue of autonomy and informed consent, or lack thereof, presents a prominent concern in clinical research and is nuanced by the unique considerations of varying participant types and study designs.[19–22] Other ethical issues that might be evident include a lack of formal research training and insufficient ethical and moral conduct training. Continuing professional development (CPD) is also essential. The research ethics committee review and approval processes can be variable and change over time, and the associated legislation is complex and challenging to follow.[22] Unethical and uninformed decision making presents potential risks to both research participants and researchers, elicits inequity in the provision of healthcare resources, and manifests distrust of the radiography research profession, among other risks.[19] A lack of proper understanding and insufficient adherence to sound ethical practices for radiography research is thus unacceptable, even when one's unethical actions are not intentional, as the possible consequences of such behaviour are far too significant. Given the ethical issues and associated risks in radiography research, a robust ethical framework must permeate all aspects of the profession at the institutional, regional, and international levels.

The Radiography Research Ethics Standards for Europe (RRESFE) is led by City, University of London, endorsed by the EFRS, and steered by a consortium of research radiography and research ethics academics and experts. RRESFE aims to provide a cross-sectional snapshot of current research ethics systems, processes, and awareness of such, across Europe together with the associated challenges, and education and training needs. Experienced radiography researchers' expertise and opinions will be sought to achieve this aim.

Methods

A cross-sectional open survey study design was employed targeting radiography researchers in Europe. Ethical approval was granted for this project by the City, University of London SHS Research Ethics Committee (Reference: ETH1920-0977) before study commencement. Gatekeeper's approval was received from the European Federation of Radiographer Societies (EFRS) Executive Board to approach their member organisations. A survey form comprising various questions asking about the research ethics systems, processes, and associated challenges, education, and training in respondents' country was then developed within the SurveyMonkey® online platform. Subsequently these questions were piloted to a small group of radiography researchers ($n = 21$) to review and comment before the survey launch. The final version of the questionnaire comprised 42 open-ended and closed type questions across six sections and included multiple-choice, checkbox, Likert rating scale, and free-text question types (see Supplemental Material). Inclusion criteria required that all participants were involved in radiography research; therefore, skip logic was employed within the demographics section of the form to end the survey if respondents selected "I am not involved with research".

Data collection took place between April 26 and July 12, 2021, using snowball sampling. The survey link was distributed via email to key stakeholders within the EFRS network (www.efrs.eu/members).

This organisation represents over 110,000 radiographers and over 8500 radiography students across 37 countries. Invited participants were requested to complete the questionnaire themselves and further distribute the survey link amongst their professional and social networks. While voluntary submission of the survey implied consent, an overview of the survey's aims, scope, estimated time to completion, and overarching data management procedures were presented within the introductory page of the questionnaire so individuals could make an informed decision about their participation. All responses were anonymous, and submissions were stored as encrypted, access-controlled electronic records in total and direct compliance with the General Data Protection Regulation (GDPR) and local legislation.[20,23,24] Participants could edit their responses at any point throughout the completion of the survey; however, upon final submission no further editing could occur.

Following the survey's closure, responses were statistically analysed using SPSS statistical software version 27 (IBM SPSS Inc., Chicago, USA). Response frequencies and corresponding percentages were tabulated for all survey items, and the central tendency was calculated for ordinal and continuous data. In some instances, respondents could select more than one answer, leading to cumulative frequencies above the reported sample size. Additionally, the Chi-square test of independence, and Fisher's exact test in cases of insufficient sample size, were employed to compare categorical response data across the various subgroups. Moreover, the Mann–Whitney U test and Kruskal Wallis test were used to compare ordinal and discrete response data across sub-groupings. Non-parametric tests were selected due to the skewed distribution and heterogeneity of variance across responses. The CHERRIES checklist for online survey reporting and the STROBE guidelines for observational studies have been used for the purpose of project reporting (see Supplemental Material).[25,26]

Results

Demographics

In total there were 285 partial (i.e. >15% of non-demographic questions answered; n = 58) and complete (i.e. 100% of questions answered; n = 227) submissions received across 56 countries (Fig. 1a and b). While the target population for this survey was European stakeholders involved in radiography research, snowball sampling resulted in 53 submissions from 23 non-European countries and 232 respondents across 33 European countries. To harness data from voluntary participants working outside of Europe, all submissions were included in the final analysis set; however, non-European responses were only analysed for the purposes of regional comparison against European radiography researchers. When asked to state their main area(s) of focus within radiography, the majority of respondents (n = 214; 75%) stated they work in medical imaging/diagnostic radiography, 69 (24%) individuals selected radiotherapy/radiation therapy, and 30 (11%) declared they work in nuclear medicine. Furthermore, there was good representation from education (n = 129; 45%), research (n = 111; 39%), and clinical (n = 110; 39%) sectors, as well as prominent student engagement (n = 89; 31%). Diversity in participants' level of seniority was also observed with representation from novice (n = 48; 17%), early-career (n = 89; 31%), mid-career (n = 80; 28%), and experienced (n = 60; 21%) researchers. A full breakdown of respondent demographics can be found in Table 1.

General survey findings (Europe)

When asked if research ethics approval is required before starting specific research projects within their country, most European respondents (n = 221; 95%) reported 'yes, approval is

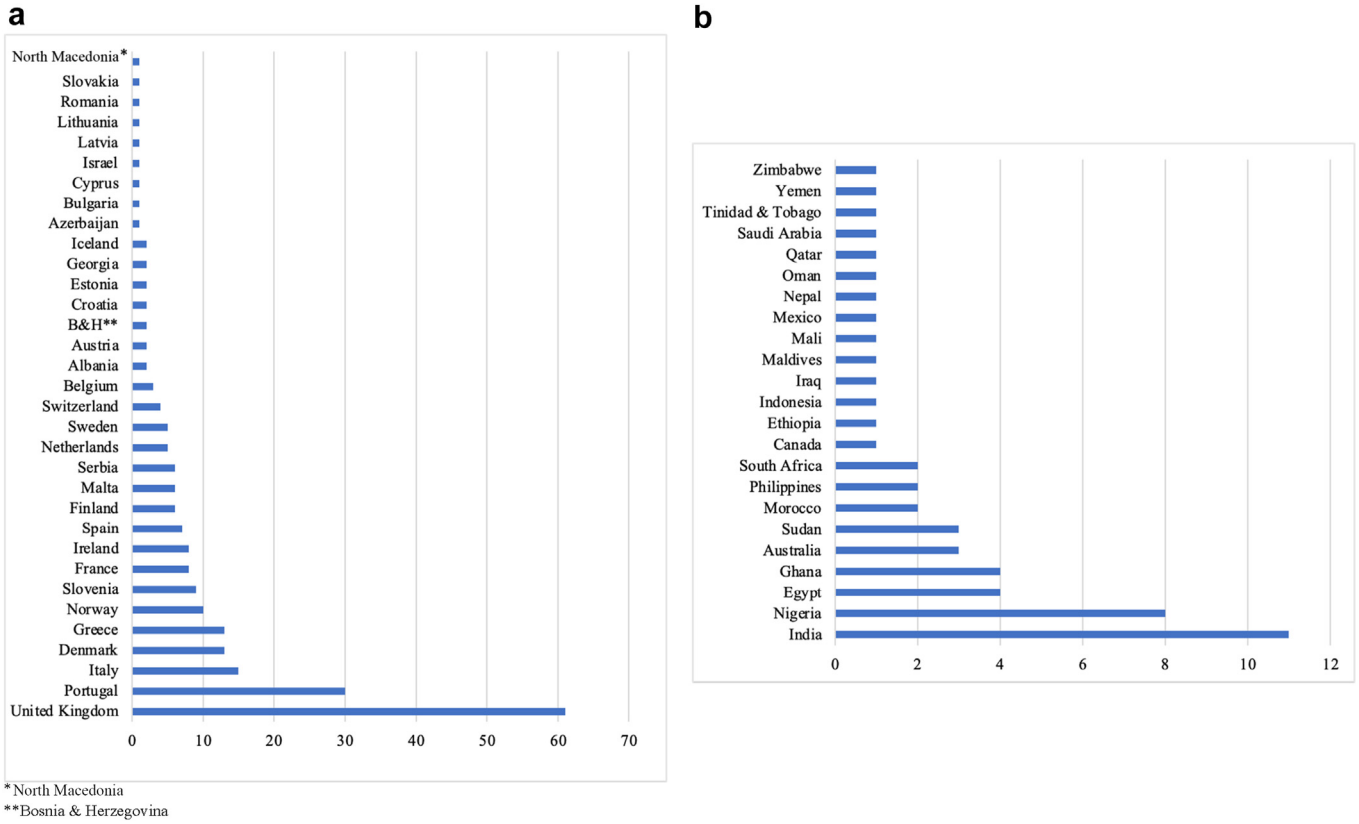

Figure 1. (a) Distribution of European responses by country. *North Macedonia. **Bosnia & Herzegovina. (b) Distribution of International responses by country.

Table 1
Respondent demographic characteristics.

Characteristic	Europe (n = 232) n (%)	International (n = 53) n (%)	Total (n = 285) n (%)
Main area(s) within radiography[a]			
Medical Imaging/Diagnostic	172 (74%)	42 (79%)	214 (75%)
Radiotherapy/Radiation Therapy	57 (25%)	12 (23%)	69 (24%)
Nuclear Medicine	25 (11%)	5 (9%)	30 (11%)
Role(s) in research[a]			
Radiography educator	110 (47%)	19 (36%)	129 (45%)
Radiographer researcher	96 (41%)	15 (28%)	111 (39%)
Doctoral student	37 (16%)	14 (26%)	51 (18%)
Master's student	27 (12%)	11 (21%)	38 (13%)
Clinical radiographer/practitioner	88 (38%)	21 (40%)	110 (39%)
Level of seniority in research			
Novice	37 (16%)	11 (21%)	48 (17%)
Early-career	67 (29%)	22 (42%)	89 (31%)
Mid-career	67 (29%)	13 (25%)	80 (28%)
Experienced/Established	55 (24%)	5 (9%)	60 (21%)
Other	6 (3%)	2 (4%)	8 (3%)

[a] Respondents could select more than one option.

required'. Similarly, 202 (87%) respondents reported a research ethics application process within their organisation and 179 (77%) respondents stated their organisation had its own research ethics committee (REC). Interestingly, 18 (8%) and 23 (10%) respondents were unsure if there is an application process and REC within their organisation, respectively. With regards to the specific types of research participants where ethics approval is required, 'patients' had the highest frequency of responses (n = 203; 88%), followed by 'healthcare staff and other professional staff' (n = 163; 70%), 'healthy volunteers' (n = 152; 66%), and the 'public' (n = 142; 61%) (Fig. 2). 'Student' participants in research received the lowest frequency of responses with only 125 (54%) participants indicating ethics approval must be sought before commencing research involving this population. Additionally, a considerable number (n = 20; 9%) of individuals were unsure of the research ethics requirements for at least one participant type. When asked how important it is to have research ethics approval before analysing patient data, even if the data is anonymised, the vast majority (n = 220; 95%) selected 'very important' or 'important'. Three percent (n = 6) indicated such ethics approval processes are 'unimportant' or 'not important at all'. The remaining six (3%) respondents noted they were 'unsure'. Additionally, many respondents (n = 158; 68%) noted it was a requirement in their country to report research ethics approval procedures/reference numbers in presentations, papers, and research funding applications. Conversely, 10% (n = 23) of participants stated such reporting 'is not necessary' and 19% (n = 43) noted they were 'unsure'. Of the remaining 8 (3%) respondents that selected 'other,' many explained that although ethics reporting is common it is often not a requirement.

Participants were then shown a list of 23 items often required within an ethics application and asked to state how confident they were. A sliding scale from 0 to 100, that each item must be produced for a REC submission regarding high-risk research (i.e. studies that include vulnerable groups, personal/identifiable information, pain or

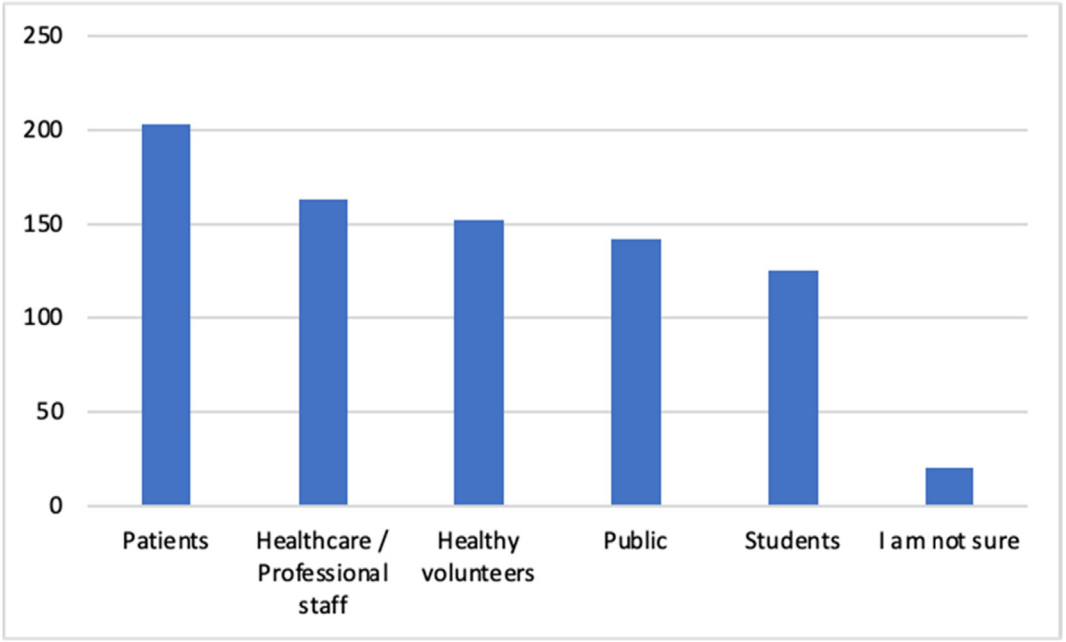

Figure 2. Frequency of respondents selecting that research ethics approval is required prior to commencing a research study involving each participant type.

stress to participants, or some type of intervention) was employed (Table 2). While there was overall a high degree of confidence that all items must be submitted to the REC, the median confidence across all 23 items was calculated to be 99 (interquartile range (IQR), 4), there was a notable level of uncertainty around the inclusion of 'strategies for incentives for research volunteers or participants' (83 (IQR, 48)). Subsequently, when given the opportunity to report on other necessary documentation for a REC application that was not already included in the provided list, staff training schedule/staff qualifications, case report forms, permission letters, insurance, and equipment guides were all put forth as essential items.

The proceeding section of the survey investigated the research ethics procedures for different study types. When comparing retrospective versus prospective and high-risk versus low-risk studies 30% (n = 57) and 36% (n = 69) of question respondents, respectively, reported a different application/approval process for each study type within their organisation. Prospective and high-risk studies were reported as requiring a more intensive approval process in such cases. Moreover, 44% (n = 83) of respondents noted varying approval processes for clinical audits/service evaluations/quality improvement studies compared to research studies. Approximately one-third of respondents to each of the questions above (64, 63, and 64 respondents respectively) were unsure if the ethics application/approval process differed for the various study types. The remaining 69 (36%), 58 (31%), and 43 (23%) respondents per question reported no difference in the ethics approval process for each of these paired study characteristics.

Regional comparisons

A series of regional analyses were conducted to explore the variability of research ethics systems, processes, and awareness across Europe. In the first of these sub-analyses, the investigated regions, based on geographical groupings with 10 or more responses, included Balkan countries (n = 24), Nordic countries (n = 36) and the United Kingdom and Republic of Ireland (n = 69). While there were many comparable findings across regions, a significant variation was observed. The proportion of respondents stating research ethics approval is a national requirement in their country (X^2 (2, n = 129) = 7.234, $p = 0.013$) varied as did the frequency of respondents reporting ethics application processes are present within their organisation (X^2 (4, n = 129) = 14.204, $p = 0.004$). The major contributor to the latter statistically significant result was the variable level of awareness regarding research ethics processes. When looking at the type of research participants requiring ethics approval, responses once again differed between regions (Table 3; Supplementary Table S1). Moreover, confidence levels in the documentation that must be produced for a REC submission also fluctuated significantly by region for 22 out of 23 listed items (Table 4).

A further regional analysis was conducted comparing European countries (n = 232) with non-European countries (n = 53). While the systems, processes, and awareness of research ethics were, once again, generally comparable between subgroups, a few notable differences were observed. Firstly, a comparative groupwise analysis via Mann–Whitney U test revealed that seniority in radiography research varied significantly, with European respondents self-reporting a higher level of seniority than their non-European counterparts (U(n = 277) = 4534.5, $p = 0.013$). Furthermore, respondents from European countries were significantly more likely to respond "Yes, research ethics approval is required before starting certain research projects in my country" (X^2 (1, n = 282) = 4.316, $p = 0.049$). Additionally, a significant difference was observed between groups for the proportion of respondents reporting different approval processes are in place for audits/service evaluation/quality improvement studies compared to research studies (X^2 (2, n = 227) = 6.857, $p = 0.031$).

Table 2
European participants' confidence level in the items (i.e., documentation) that must be produced for a research ethics committee (REC) submission regarding high-risk research. Confidence was submitted via a sliding scale from 0 to 100. Items are ranked by median value from highest to lowest overall confidence.

	Europe (n = 232)			
Item for REC submission	Mean	SD	Median	IQR
Participant information sheets	88.26	20.77	100.00	17.50
Participant consent forms	90.45	18.90	100.00	9.00
Strategies to request consent and/or assent	83.21	23.98	99.00	30.50
Strategies for data anonymisation and patient confidentiality	89.57	19.74	100.00	10.00
Strategies to report and document adverse events resulting from research	84.29	23.08	99.00	25.00
Research proposal (which includes aim or research question, methodology, data collection and data analysis, among other information)	89.53	19.74	100.00	10.00
Strategies to report and document incidental findings	78.97	24.64	90.00	42.00
Strategies for safe data management	88.32	20.66	100.00	17.00
Strategies for safe data storage	87.76	22.00	100.00	17.00
Strategies for safe data reuse, where applicable	81.04	24.34	95.00	36.50
Strategies on using data after participant withdrawal	80.57	27.18	97.00	35.00
Strategies for data transfer, if needed	80.84	25.28	98.00	40.00
Strategies for safe data disposal	83.33	25.49	100.00	27.00
Strategies to safeguard vulnerable people/groups	85.22	24.05	100.00	24.00
Strategies to support participants, if they become distressed due to the research project	77.90	27.50	90.00	42.00
Strategies for safe use of human tissue, where applicable	80.33	29.44	99.00	36.50
Strategies for safe use of chemical substances, where applicable	77.49	30.22	97.00	42.50
Strategies for safe use of ionising radiation or electromagnetic fields, where applicable	89.30	18.86	100.00	13.50
Strategies for safe use of experimental drugs for randomised control trials and reporting their side effects, where applicable	81.91	27.96	99.00	30.50
Strategies to explicitly confirm mental capacity to consent, if this applies to the study participants	79.96	27.65	97.00	36.00
Strategies for incentives for research volunteers or participants	74.24	28.31	83.00	48.00
Sample questionnaires/sample interview schedules	80.55	25.81	95.00	30.00
Strategies for assessing risks to researchers and participants, i.e. in a formal risk assessment document	78.87	26.76	90.00	41.00

Table 3
Comparison of research ethics approval requirements for the various participant types across regional, programme duration, postgraduate training, EQF Level 6 subgroups.

Participant type	Regional comparison[a]				Comparison by duration of programme[a]				Comparison by availability of postgraduate training				Comparison by EQF level 6 establishment[a]			
	n	df	X^2	*P*-value	n	df	X^2	*P*-value	n	df	X^2	*P*-value	n	df	X^2	*P*-value
Patients	129	4	17.889	**<0.001**	232	8	31.092	**<0.001**	232	2	15.938	**<0.001**	232	4	24.071	**<0.001**
Healthcare/ Professional staff	129	4	17.055	**<0.001**	232	8	35.362	**<0.001**	232	2	13.292	**<0.001**	232	4	12.022	**0.010**
Public	129	4	54.568	**<0.001**	232	8	60.027	**<0.001**	232	2	37.023	**<0.001**	232	4	13.813	**0.004**
Healthy volunteers	129	4	49.309	**<0.001**	232	8	43.809	**<0.001**	232	2	18.069	**<0.001**	232	4	17.538	**0.001**
Students	129	4	43.838	**<0.001**	232	8	44.989	**<0.001**	232	2	24.928	**<0.001**	232	4	9.16	**0.039**

[a] Results of the post-hoc comparison are available in the supplementary material.

Comparison by duration of radiography programme

Given the variability in radiography education reported across Europe through previous EFRS surveys, further ancillary analyses were conducted to compare survey responses across countries with different educational models; the first of these sub-analyses was a comparison by undergraduate radiography programme duration. Submissions were organised into five programme subgroups: 2-year (n = 13), 3-year (n = 71), 3.5-year (n = 21), 4-year (n = 57), and those countries with multiple undergraduate radiography programme durations offered (n = 70). Interestingly, 2-year and 3-year programmes were associated with a higher frequency of individuals stating ethics approval is not required before commencing research projects (X^2 (4, n = 231) = 10.075, $p = 0.016$). The presence of ethics application processes within respondents' organisations also varied by degree length (X^2 (8, n = 232) = 19.134, $p = 0.005$), with notably fewer ethics processes reported from countries with 2-year programmes. Regarding the sub-populations where ethics approval is required before commencing research, responses varied significantly for all participant types (Table 3; Supplementary Table S2), with longer programme durations and availability of multiple programme lengths generally associated with less uncertainty and more comprehensive research ethics requirements. When asked if there is a different application/approval process in respondents' organisations for clinical audits/service evaluation/quality improvement studies versus research studies, responses also varied significantly across programme duration (X^2 (8, n = 190) = 28.898, $p = <0.001$). Countries with multiple programme durations were observed implementing different processes for these study types more often than their 2, 3, 3.5, and 4-year programme counterparts.

Comparison by availability of postgraduate training

To further explore educational programming's association with survey findings, submissions were organised into two subgroups based on the availability of postgraduate training: training available within respondents' country (n = 170) versus training not available within their country (n = 61). The frequency of responses affirming ethics committee approval is required before starting specific research projects was significantly higher for the postgraduate training available subgroup (X^2 (1, n = 231) = 15.448, $p = <0.001$). Additionally, countries with no postgraduate training were associated with greater uncertainty around the research ethics application processes (X^2 (1, n = 232) = 8.284, $p = 0.007$). This subgroup also reported greater uncertainty and a notably lower proportion of responses affirming ethics approval is required for the various participant types compared to countries where postgraduate training is available (Table 3). Analysis via Mann–Whitney U test also revealed an association between availability of postgraduate training and higher perceived importance of obtaining research ethics committee approval (U = 4226.00, $p = 0.025$). When looking at the ethics approval processes for various study types, differing approval processes for prospective versus retrospective research, along with a greater level of uncertainty around such processes, was more commonly reported by respondents working in countries with no postgraduate training (X^2 (2, n = 190) = 6.415, $p = 0.040$).

Comparison by EQF level 6 establishment

Lastly, a sub-analysis of survey responses based on the status of the implementation of the European Qualifications Framework (EQF) Level 6 (Bachelors) for radiography was conducted. Submissions were organised into three subgroups: EQF Level 6 established in the respondent's country (n = 208), EQF Level 6 not established in respondent's country (n = 15), and both EQF Level 5 and 6 established in respondent's country (n = 9). From this analysis, it was observed that the presence of an application process within respondents' organisations varied across subgroups; countries where EQF Level 6 has not been established was associated with fewer respondents noting an ethics application process within their own organisation (X^2 (2, n = 214) = 7.671, $p = 0.024$). Once again, ethics approval processes were also found to vary by participant type (Table 3; Supplementary Table S3); respondents from EQF Level 6 countries stated that ethics approval is required for all participant types more often than their non-EQF Level 6 counterparts. When respondents were asked if an REC is present within their organisation, responses also varied across subgroups with respondents in the EQF Level 6 established subgroup more often reporting the presence of RECs (X^2 (6, n = 232) = 12.033, $p = 0.032$).

Discussion

Over the past century, extensive efforts have been made to develop, implement, and enforce universal ethical principles that safeguard the health, well-being, and rights of human subjects involved in medical research.[16,27–29] Thus, it is not surprising that 95% of surveyed radiography researchers acknowledged the importance of ethics approval and reported at least some form of research ethics requirement at the national level within their country. Nevertheless, there is still room for improvement with regard to the implementation of, and adherence to, a relevant research ethics framework. The scope of research ethics requirements represents one such area for advancement as demonstrated by the current survey findings. The present work showed that 46% of respondents understood that they were not required to seek full ethics committee review or were unsure of the review process for projects where students are participants. A further 39% and 34% of respondents, respectively, could not confirm ethics approval processes were in place for research involving the public and healthy volunteers. Even research involving patient

Table 4
Regional comparison of European participants' confidence level in the items (i.e., documentation) that must be produced for a research ethics committee (REC) submission regarding high-risk research. Confidence was submitted via a sliding scale from 0 to 100.

	Regional comparison within Europe (n = 114)				Post-hoc pairwise comparisons of regions	
Item for REC submission	Region	n	Mean rank	P-value	Comparator groups	P-value
Participant information sheets	Balkan	18	31.31	**<0.001**	Balkan - Nordic	**<0.001**
	Nordic	32	61.02		Balkan - UK & Ireland	**<0.001**
	UK & Ireland	64	63.11		Nordic - UK & Ireland	0.715
Participant consent forms	Balkan	18	29.39	**<0.001**	Balkan - Nordic	**<0.001**
	Nordic	32	59.88		Balkan - UK & Ireland	**<0.001**
	UK & Ireland	64	64.22		Nordic - UK & Ireland	0.448
Strategies to request consent and/or assent	Balkan	18	32.97	**<0.001**	Balkan - Nordic	**0.005**
	Nordic	32	57.27		Balkan - UK & Ireland	**<0.001**
	UK & Ireland	64	64.52		Nordic - UK & Ireland	0.254
Strategies for data anonymisation and patient confidentiality	Balkan	18	44.03	**0.046**	Balkan - Nordic	0.107
	Nordic	32	56.72		Balkan - UK & Ireland	**0.013**
	UK & Ireland	64	61.68		Nordic - UK & Ireland	0.391
Strategies to report and document adverse events resulting from research	Balkan	18	40.67	**0.006**	Balkan - Nordic	0.182
	Nordic	32	52.52		Balkan - UK & Ireland	**0.003**
	UK & Ireland	64	64.73		Nordic - UK & Ireland	0.061
Research proposal (which includes aim or research question, methodology, data collection and data analysis, among other information)	Balkan	18	36.14	**0.002**	Balkan - Nordic	**0.007**
	Nordic	32	58.88		Balkan - UK & Ireland	**<0.001**
	UK & Ireland	64	62.82		Nordic - UK & Ireland	0.527
	Total	114				
Strategies to report and document incidental findings	Balkan	18	48.61	0.433	Balkan - Nordic	N/A
	Nordic	32	59.28		Balkan - UK & Ireland	
	UK & Ireland	64	59.11		Nordic - UK & Ireland	
Strategies for safe data management	Balkan	18	34.72	**<0.001**	Balkan - Nordic	**<0.001**
	Nordic	32	62.31		Balkan - UK & Ireland	**<0.001**
	UK & Ireland	64	61.5		Nordic - UK & Ireland	0.891
Strategies for safe data storage	Balkan	18	38.14	**0.003**	Balkan - Nordic	**0.015**
	Nordic	32	57.42		Balkan - UK & Ireland	**<0.001**
	UK & Ireland	64	62.98		Nordic - UK & Ireland	0.341
Strategies for safe data reuse, where applicable	Balkan	18	44.61	**0.015**	Balkan - Nordic	0.536
	Nordic	32	50.27		Balkan - UK & Ireland	**0.015**
	UK & Ireland	64	64.74		Nordic - UK & Ireland	0.310
Strategies on using data after participant withdrawal	Balkan	18	35.36	**<0.001**	Balkan - Nordic	**0.019**
	Nordic	32	55.8		Balkan - UK & Ireland	**<0.001**
	UK & Ireland	64	64.58		Nordic - UK & Ireland	0.169
Strategies for data transfer, if needed	Balkan	18	43.69	**0.031**	Balkan - Nordic	0.288
	Nordic	32	53.17		Balkan - UK & Ireland	**0.014**
	UK & Ireland	64	63.55		Nordic - UK & Ireland	0.113
Strategies for safe data disposal	Balkan	18	38.39	**0.005**	Balkan - Nordic	**0.029**
	Nordic	32	56.89		Balkan - UK & Ireland	**0.001**
	UK & Ireland	64	63.18		Nordic - UK & Ireland	0.313
Strategies to safeguard vulnerable people/ groups	Balkan	18	29.42	**<0.001**	Balkan - Nordic	**0.002**
	Nordic	32	55.67		Balkan - UK & Ireland	**<0.001**
	UK & Ireland	64	66.31		Nordic - UK & Ireland	0.081
Strategies to support participants, if they become distressed due to the research project	Balkan	18	45.33	**0.007**	Balkan - Nordic	0.763
	Nordic	32	48.09		Balkan - UK & Ireland	**0.015**
	UK & Ireland	64	65.63		Nordic - UK & Ireland	**0.009**
Strategies for safe use of human tissue, where applicable	Balkan	18	50.08	**0.017**	Balkan - Nordic	0.788
	Nordic	32	47.73		Balkan - UK & Ireland	**0.009**
	UK & Ireland	64	64.47		Nordic - UK & Ireland	0.069
Strategies for safe use of chemical substances, where applicable	Balkan	18	49.17	**0.017**	Balkan - Nordic	0.984
	Nordic	32	47.98		Balkan - UK & Ireland	**0.010**
	UK & Ireland	64	64.6		Nordic - UK & Ireland	0.054
Strategies for safe use of ionising radiation or electromagnetic fields, where applicable	Balkan	18	48.75	**0.030**	Balkan - Nordic	0.850
	Nordic	32	50.3		Balkan - UK & Ireland	**0.045**
	UK & Ireland	64	63.56		Nordic - UK & Ireland	**0.027**
Strategies for safe use of experimental drugs for RCTs and reporting their side effects, where applicable	Balkan	18	44.47	**0.006**	Balkan - Nordic	0.553
	Nordic	32	49.56		Balkan - UK & Ireland	**0.008**
	UK & Ireland	64	65.13		Nordic - UK & Ireland	**0.014**
Strategies to explicitly confirm mental capacity to consent, if this applies to the study participants	Balkan	18	33.14	**<0.001**	Balkan - Nordic	0.073
	Nordic	32	48.95		Balkan - UK & Ireland	**<0.001**
	UK & Ireland	64	68.63		Nordic - UK & Ireland	**0.002**
	Balkan	18	43.56	**0.032**	Balkan - Nordic	0.335

Table 4 (*continued*)

Item for REC submission	Regional comparison within Europe (n = 114)				Post-hoc pairwise comparisons of regions	
	Region	n	Mean rank	P-value	Comparator groups	P-value
Strategies for incentives for research volunteers or participants	Nordic	32	52.56		Balkan - UK & Ireland	**0.016**
	UK & Ireland	64	63.89		Nordic - UK & Ireland	0.099
Sample questionnaires/sample interview schedules	Balkan	18	47.94	**0.020**	Balkan - Nordic	0.942
	Nordic	32	48.61		Balkan - UK & Ireland	**0.042**
	UK & Ireland	64	64.63		Nordic - UK & Ireland	**0.016**
Strategies for assessing risks to researchers and participants, i.e. in a formal risk assessment document	Balkan	18	37.14	**0.005**	Balkan - Nordic	**0.037**
	Nordic	32	56.03		Balkan - UK & Ireland	**0.001**
	UK & Ireland	64	63.96		Nordic - UK & Ireland	0.234

populations, although shown to have the most comprehensive ethical requirements, was only confirmed to require ethics approval by 88% of survey respondents. Unfortunately, this lack of thorough adherence to established ethical practices leaves room for misinterpretations, mishandling, abuse of the research ethics frameworks and may lead to both researcher and research participant distrust and harm.[28–30] To assure the highest standard of ethical research, which prioritises the health and well-being of every participant, ethics review and approval must be required for all high-risk projects involving human subjects, regardless of participant type. Article 55 of the EU Basic Safety Standards Directive and the Good Clinical Practice Directive and General Data Protection Regulation (GDPR) have laid the groundwork for a comprehensive regulatory framework.[16,31,32] Though many of the current regulations and standards emphasise the 'patient' as the research participant, without explicit mention of non-patient participants. Additionally, more must be done across Europe, at the national level, and within individual organisations, to uphold these standards and ensure adherence to the relevant ethics framework across all research activities.

We must also go beyond regulations and standards to create an ethical culture ensuring research relies on all key stakeholders, from the students to academics, researchers, academic institutions, professional bodies, patient organisations, and the public.[30,33] A lack of clarity surrounding research ethics requirements was noted among several survey respondents. Notably, one-third of participants could not confirm whether the ethics approval process differed for prospective versus retrospective research, high-risk versus low-risk studies, or clinical audits versus research projects. The findings from a recent Nordic survey conducted by Bolejko and colleagues suggest this uncertainty may be due to the absence of a research culture within the workplace.[34] These findings, together with various commentaries throughout the literature, advocate for the further development of a robust ethical research culture within the radiographic community which begins with integrating evidence-based research within radiography education and training programmes.[35–37] The EFRS and the federation's contributing professional bodies have taken a leading role in fostering this ethos. The importance of radiographer-led research and evidenced-based practice acknowledged in the 2016 *EFRS Statement on Radiography Research in Europe*.[7]

Harmonisation is another area for improvement within the research ethics framework. Analysis of survey results revealed that research ethics systems and processes vary significantly by region. A finding aligned with the literature where inter-country variation in research ethics procedures has been repeatedly reported.[38,39] Standardised implementation and adherence to a central research ethics framework at the European level is thus needed. In this way, multi-site/multi-country research projects can be executed with greater ease, the transferability of research findings can be improved, and the free movement of radiographers throughout Europe is better enabled. The International Harmonisation Committee's (ICH) Good Clinical Practice (GCP) Guidelines and the associated EC Directive have made great strides towards harmonised ethical standards for pharmacological clinical trials; however, adherence to this directive is not yet universal.[32,40,41] Moreover, there exists no comparable directive for non-interventional observational studies, which presents a gap in the current research framework. This gap may help explain the variability in survey responses when participants were asked if there is a different application/approval process in their organisation for various study designs.[38,39] Hence, it is recommended that additional international guidelines be developed for the ethical conduct of low-risk studies (e.g. projects involving the imaging of healthy volunteers and educational research projects) involving human subjects. These guidelines can then be translated into European level directives, national legislation, and local operating procedures.

Both policy and education are critical determinants of a robust research culture, one that cannot be abused or manipulated and does not leave space for misinterpretations. Europe's lack of harmonised regulation for the radiography profession and variability of radiography curricula, in duration and content, present likely barriers to successfully implementing a central and integrated research ethics system.[42–44] The EFRS has taken a leading role in this issue by developing the EQF Level 6 (Bachelors) and EQF Level 7 (Masters) benchmarking documents.[9,10] As emphasised by these documents, it is critical that all radiographers have a working knowledge of how to conduct and evaluate research studies, implement findings, and adhere to the relevant ethical framework. Our data for radiography researchers in Europe demonstrates the importance and relevance of dedicated education and training on research methods at both undergraduate and postgraduate levels, as vital to establishing and sustaining a strong research culture.

While this study has provided valuable insight into the research ethics systems, processes and associated level of awareness across Europe, it is not without its limitations. Principally, the current survey is limited by its small sample size and self-selection study design. Moreover, the temporal confines of the cross-sectional survey may limit the relevance of study findings. The presence and variable adherence to ethical requirements reported herein will likely become less indicative of broader practice as the radiography profession continues to undergo harmonisation and as EQF Level 6 and Level 7 are more broadly implemented. Nevertheless, the survey results inform the current status of research ethics within evidence-based radiography and serve as a benchmark for future audits and research of the radiography research ethics landscape.

Conclusion

The survey findings indicate there has been widespread implementation of research ethics systems and processes throughout

Europe. However, there remains work to be done regarding research ethics requirements, standardisation of and adherence to ethical practices, including auditing, and radiographers' knowledge, awareness, and training on the relevant research ethics frameworks. Current regulations and standards must be amended to encompass all research participants, not just patient populations, explicitly. Frameworks must be expanded to include clear guidelines for observational, non-interventional, and similar so-called low-risk research projects. Future surveys are recommended to investigate the radiography research ethics landscape and monitor and enhance practice in this area.

Declaration of interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Authors JMcN, PB, AE, RK, MMcE, NM, HP, LR, VS, CB, and CM hold, or have held, voluntary roles linked to research activity within the European Federation of Radiographer Societies. All authors hold, or have held, research roles within their organisation. Authors JMcN, PB, AE, DF, RK, MMcE, NM, HP, AS, VS, CB, RH, TOR, and CM hold, or have held, roles within their national professional societies. JMcN (Editor in Chief, *Radiography*), AE (Associate Editor, *Radiography*), and MMcE (Deputy Editor, *Journal of Medical Imaging and Radiation Sciences*) hold editorial roles within the identified professional journals. NM, HP, LR, and CM hold journal advisory roles.

Acknowledgements

The authors would like to acknowledge all of the individuals who engaged with this work and who took the time to respond to the online survey. We would also like to recognise the non-financial support of the European Federation of Radiographer Societies.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.radi.2022.07.002.

References

1. Munn Z. Why isn't there an evidence-based radiography? Reflections and a call to action. *Radiography* 2020;**26**:S14–6.
2. McEntee MF, Hogg P. Translating radiography research into practice. *Radiography* 2020;**26**:S1–2.
3. England A, McNulty JP. Inclusion of evidence and research in European radiography curricula. *Radiography* 2020;**26**:S45–8.
4. Nightingale J, McNulty J. Valedictory editorial – new horizons. *Radiography* 2021;**27**(4):991–3.
5. Hogg P, Alrehily F, Sá dos Reis C, Buissink C, Erenstein H, Voet M. Inspiring radiographers to engage in research. *Radiography* 2020;**26**:S69–70.
6. World Health Organization. *Transforming and scaling up health professionals' education and training* [internet]. Geneva: World Health Organization; 2013 [cited February 21, 2022]. Available from: https://www.who.int/publications/i/item/transforming-and-scaling-up-health-professionals%E2%80%99-education-and-training.
7. European Federation of Radiographer Societies (EFRS). *EFRS statement on radiography research in Europe* [internet]. Utrecht: European Federation of Radiographer Societies; 2016 [cited February 1, 2022]. Available from: www.efrs.eu.
8. European Federation of Radiographer Societies (EFRS). *EFRS Statement on evidence-based practice in the undergraduate Curriculum* [internet]. Utrecht: European Federation of Radiographer Societies; 2015 [cited February 1, 2022]. Available from: www.efrs.eu.
9. European Federation of Radiographer Societies (EFRS). *European qualifications framework (EQF) level 6 benchmarking document: radiographers* [internet]. 2nd ed. Utrecht: European Federation of Radiographer Societies; 2018 [cited February 1, 2022]. Available from: www.efrs.eu.
10. European Federation of Radiographer Societies (EFRS). *European qualifications framework (EQF) level 7 benchmarking document: radiography* [internet]. Utrecht: European Federation of Radiographer Societies; 2017 [cited February 1, 2022]. Available from: www.efrs.eu.
11. Pettigrew A. Ethical issues in health care research. *Radiography* 2002;**8**(1):21–5. https://doi.org/10.1053/radi.2001.0352.
12. European Congress of Radiology. ESR press releases [Internet]. Vienna; European Society of Radiology [cited February 2, 2022]. Available from: https://www.myesr.org/press.
13. Dyer O. GP struck off for fraud in drug trials. *BMJ* 1996;**312**:798. https://www.bmj.com/content/312/7034/798.2.
14. Rothman KJ, Michels KB. The continuing unethical use of Placebo controls. *N Engl J Med* 1994;**331**(6):394–8. https://doi.org/10.1056/NEJM199408113310611.
15. Ritchie SJ. *Science fictions*. London (UK): Vintage Publishers; 2021.
16. World Medical Association. *World medical association declaration of Helsinki: ethical principles for medical research involving human subjects*. Brazil: 64th WMA General Assembly; 2013.
17. International Committee of Medical Journal Editors (ICMJE). *Recommendations for the conduct, reporting, editing and publication of scholarly work in medical journals* [internet]. International Committee of Medical Journal Editors; 2021 [cited February 2, 2022]. Available from: http://www.icmje.org/recommendations/.
18. Radiography. Guide for Authors [internet]. Amsterdam: Elsevier [cited February 2, 2022]. Available from: https://www.elsevier.com/journals/radiography/1078-8174/guide-for-authors.
19. Pettigrew A. Ethical issues in health care research. *Radiography* 2002;**8**:21–5.
20. European Union. *European Parliament and the Council of the European Union of April 27, 2016 Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)*. European Union; 2016.
21. Scally A. Ethical issues in research involving children and young people. *Radiography* 2014;**20**:202–5.
22. Jonker L, Cox D, Gill M. Considerations, clues and challenges: gaining Ethical and Trust research approval when using the NHS as a research setting. *Radiography* 2011;**17**:260–4.
23. City, University of London. Research Integrity and Ethics [internet]. London: City, University of London [cited February 1, 2022]. Available from: https://www.city.ac.uk/research/support/integrity-and-ethics.
24. UCD Research Ethics. Research ethics & data management [internet]. Dublin: University College Dublin [cited February 1, 2022]. Available from: https://www.ucd.ie/researchethics/informationforresearchers/researchethicsdatamanagement/.
25. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Lancet* 2007;**370**(9596):1453–7.
26. Eysenbach G. Improving the quality of web surveys: the checklist for reporting results of Internet E-surveys (CHERRIES). *J Med Internet Res* 2004;**6**(3):e34–.
27. Annas GJ, Gordin MA, editors. *The Nazi doctors and the nuremberg code: human rights in human experimentation*. New York: Oxford University Press, Inc.; 1992.
28. European Federation of Radiographer Societies (EFRS). *EFRS code of ethics* [online]. Utrecht: European Federation of Radiographer Societies; 2010 [cited February 2, 2022]. Available from: https://api.efrs.eu/api/assets/posts/209.
29. World Medical Association. *Medical ethics manual. Ferney-voltaire cedex*. World Medical Association, Inc.; 2015.
30. Muller SHA, Kalkman S, van Thiel GJMW, Mostert M, van Delden JJM. The social licence for data-intensive health research: towards co-creation, public value and trust. *BMC Med Ethics* 2021;**22**(1):110.
31. The Council of the European Union. *Council Directive 2013/59/EURATOM laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directive 89/618/Euratom, 90/641/Euratom, 97/43/Euratom and 2003/122/Euratom*. Official Journal of the European Communities; 2013.
32. European Commission. *Commission Directive 2005/28/EC of April 8, 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products*. Official Journal of the European Union; 2005.
33. The Society of Radiographers. Patient public and practitioner partnerships within imaging and radiotherapy: guiding principles [internet]. London: The Society and College of Radiographers [cited February 21, 2022]. Available from: https://www.sor.org/learning-advice/professional-body-guidance-and-publications/documents-and-publications/policy-guidance-document-library/patient-public-and-practitioner-partnerships-withi.
34. Bolejko A, Andersson BT, Debess J, Fridell K, Henner A, Sanderud A, et al. Facilitators for and barriers to radiography research in public healthcare in Nordic countries. *Radiography* 2022;**28**(1):88–94.
35. McNulty J. Fostering clinical research in imaging departments. *Health-Managememetorg* 2018;**18**(3).
36. Higgins R, Robinson L, Hogg P. Unlocking student research potential: toward a research culture in radiography undergraduate learning curricular. *J Med Imaging Radiat Sci* 2015;**46**(3s):S6–9.
37. Malamateniou C. Radiography and research: a United Kingdom perspective. *Eur J Radiol* 2009;**1**:2–6.
38. de Lange DW, Guidet B, Andersen FH, Artigas A, Bertolini G, Moreno R, et al. Huge variation in obtaining ethical permission for a non-interventional observational study in Europe. *BMC Med Ethics* 2019;**20**(1):39.
39. Claudot F, Alla F, Fresson J, Calvez T, Coudane H, Bonaïti-Pellié C. Ethics and observational studies in medical research: various rules in a common framework. *Int J Epidemiol* 2009;**38**(4):1104–8.

40. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). ICH E6(R2) guideline for good clinical practice [online]. Amsterdam: European Medicines Agency [cited February 22, 2022]. Available from: https://www.ema.europa.eu/en/ich-e6-r2-good-clinical-practice.
41. Bernabe R, van Thiel G, Breekveldt NS, Gispen-de Wied CC, van Delden Jjm. Ethics in clinical trial regulation: ethically relevant issues from EMA inspection reports. *Curr Med Res Opin* 2019;**35**(4):637–45.
42. Couto JG, McFadden S, Bezzina P, McClure P, Hughes C. An evaluation of the educational requirements to practise radiography in the European Union. *Radiography* 2018;**24**(1):64–71.
43. England A, McNulty JP. Inclusion of evidence and research in European radiography curricula. *Radiography* 2020;**26**(Suppl 2):S45–8.
44. McNulty JP, Rainford L, Bezzina P, Henner A, Kukkes T, Pronk-Larive D, et al. A picture of radiography education across Europe. *Radiography* 2016;**22**(1):5–11.