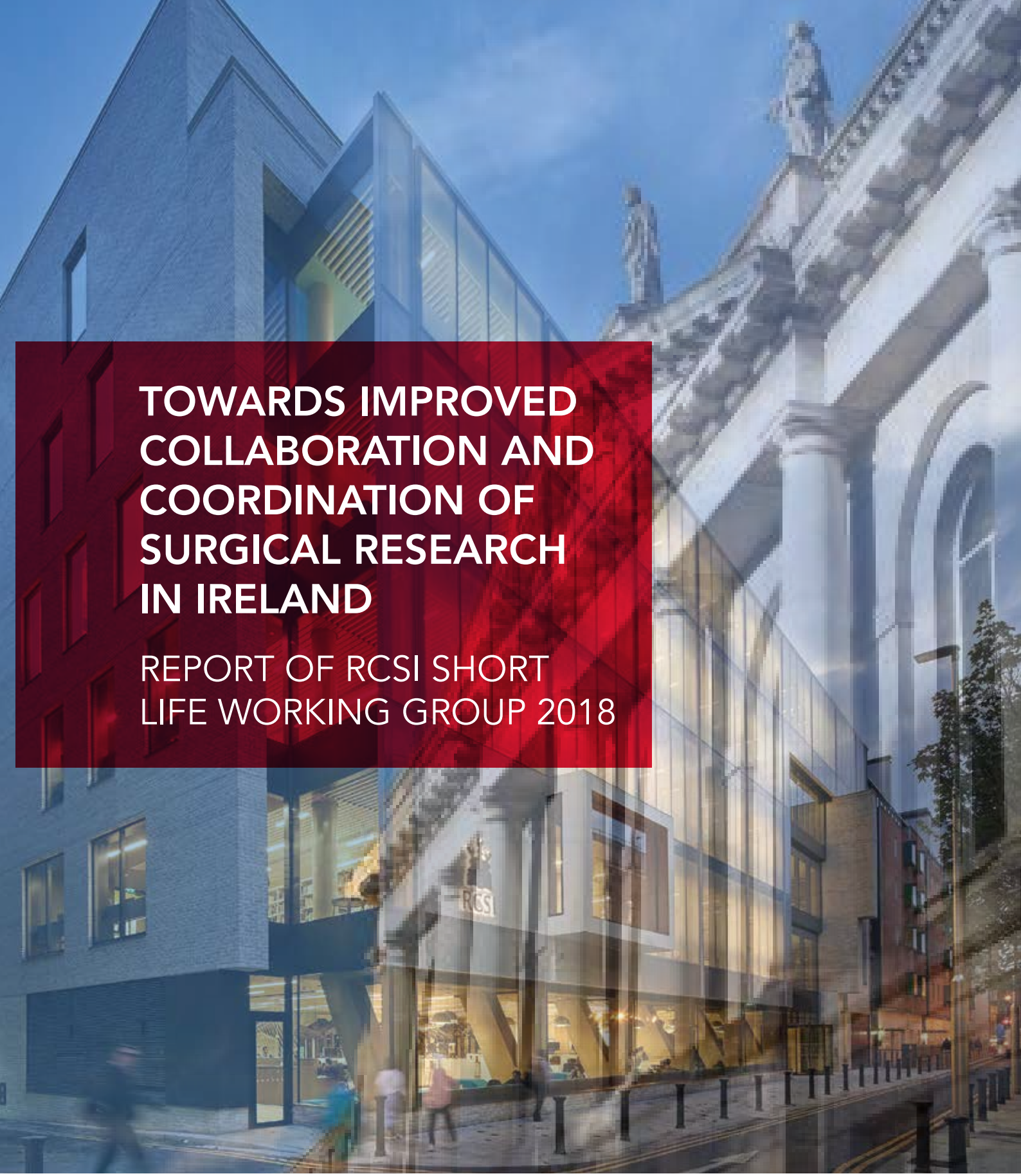
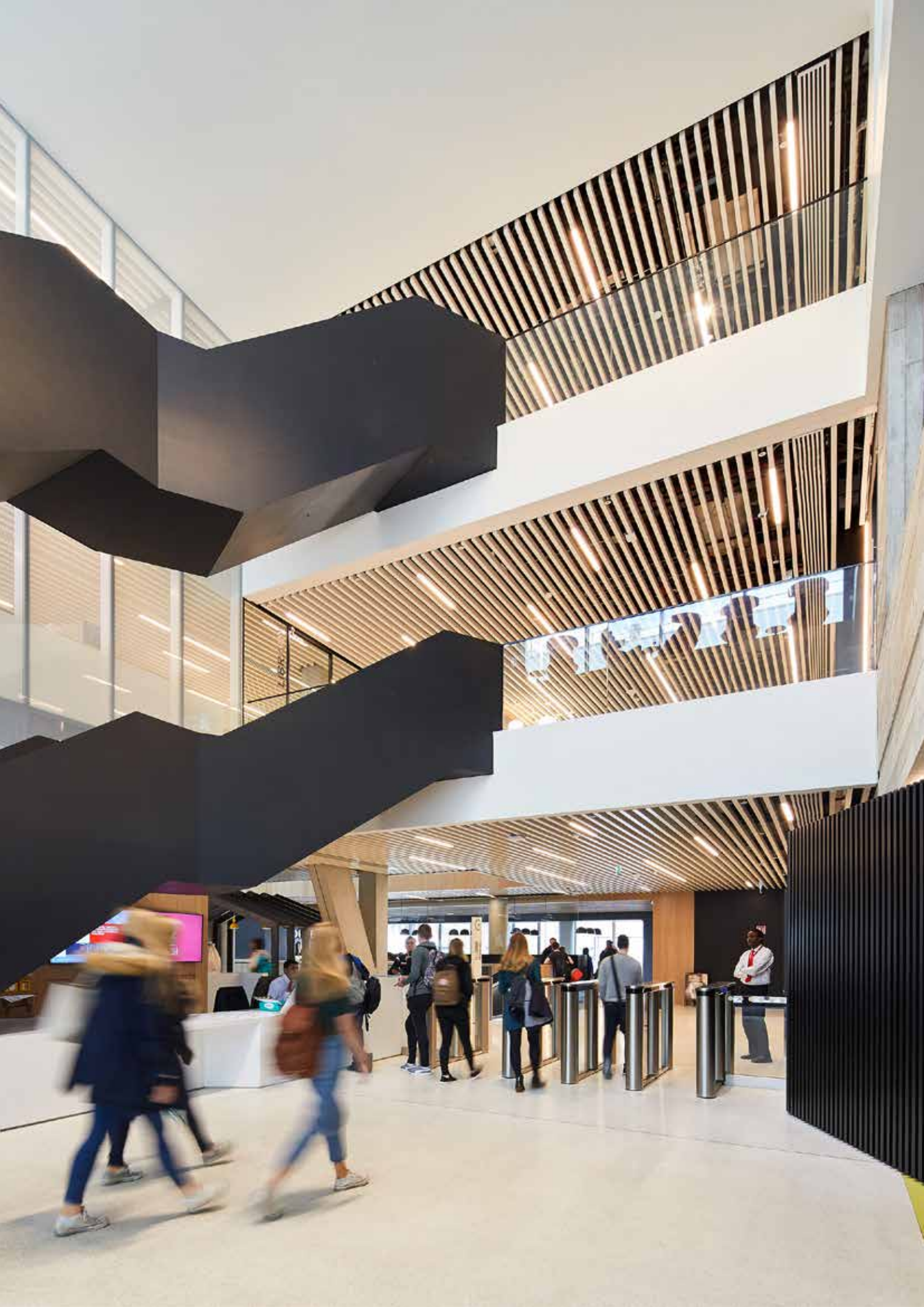
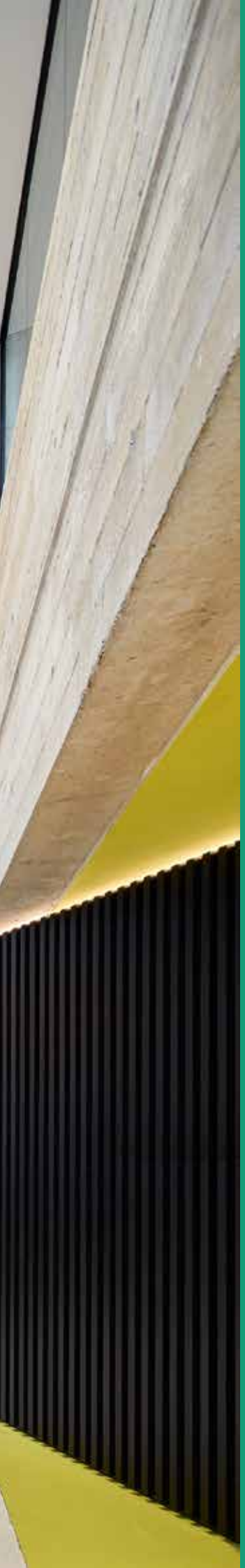


TOWARDS IMPROVED COLLABORATION AND COORDINATION OF SURGICAL RESEARCH IN IRELAND

REPORT OF RCSI SHORT LIFE WORKING GROUP 2018

RCSI SURGICAL AFFAIRS





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Introduction

President's Introduction

Mr Ken Mealy

RCSI, as a leading international health science institution, commits itself to equipping its graduates and trainees with all the attributes to become healthcare leaders in education, research and service to communities not only here in Ireland but worldwide. Surgeons of the future also need to build on the heritage of surgical discovery and innovation which has contributed to the net pool of scientific and medical knowledge. Ample evidence suggests that patient care is best served in healthcare institutions committed to research and teaching. As part of the new surgical training programme, it is critical that we reaffirm the importance of research in the surgical curriculum so that surgical trainees and academic surgical departments have a clearer picture of the role research plays in developing young surgeons for practice in the coming years, in addition to promoting the viability and relevance of the profession in contributing to medical advances. We also need to encourage and support the academic surgical departments to strategically plan the infrastructure and research networks to foster discovery and support the career and research aspirations of current and future surgical trainees.

The purpose of this 'Towards Improved Collaboration and Coordination of Surgical Research in Ireland' document is twofold:

a. To advise surgeons in training where the opportunities for research exist during their training and how to compete in the research arena

b. To encourage academic units to develop research programmes that align with the research goals of their universities, RCSI and the ambitions of surgical trainees

Surgeons have made significant contributors to major research achievements in cancer biology, transplantation and immunology, materials sciences and biomechanical engineering to name just a few areas of surgical interest. However, in this genomic era, surgeons sometimes find it hard to establish programmes that compete successfully with other medical and scientific specialists that rely on molecular technologies. However, surgeons can contribute to research across a wide spectrum of disciplines which extend from surgical practice, healthcare economics, materials sciences, biomechanical, biomedical and basic sciences to clinical trials research. Within this wide spectrum of endeavour, clearly not all surgeons will require PhDs for satisfactory practice, in many cases Masters in Science, MCh and MD degrees will be adequate for the career needs of trainees. The important point however, is that all surgeons, as for all medical specialists require some understanding of research methodology and the ability to critically evaluate the medical literature, relevant to their field of practice. We would therefore encourage all surgical trainees embark on some form of structured research training to help prepare them for the dramatically changing medical and scientific landscapes of the future. This 'Research in Surgery' document aims to clarify for trainees when, where and how they may best compete for research positions and funding for a successful clinical career and which best suites their career aspirations.

I would like to commend Prof Michael Kerin for leading the 'short life working group' who prepared this document. I would also like to thank all members of the short life working group for their input to this report which outlines a clear research 'roadmap' for those embarking on a surgical career.

Chairperson's Foreword

Prof Michael Kerin

Surgery is an academic and clinical pursuit which is a science and a craft. No other single area of Medical endeavour yields equivalent value to human health and the heritage of Irish Surgery is full of pioneers who have kept us at the forefront of academic and clinical development. Recent innovations including the creation of University led Hospital Groups, Health Research Board funded Clinical Research facilities in major hospitals and the progress of research led academic surgery departments and surgeons with protected time for academic activities give hope for the future of Irish surgery.

The document has been crafted to create a roadmap for future surgical research productivity to harness our heritage, empower our current surgical faculty and especially our trainees to create a research rich surgical infrastructure for the betterment of human health and improve surgical care for our patients – knowing that best clinical outcomes come from a research rich environment.

I would like to thank the members of the group for their engagement and productivity especially our current President, Mr Ken Mealy and his Predecessor Professor John Hyland whose foresight was instrumental in establishing this group, Kieran Ryan, Ger Conroy and the Department of Surgical Affairs and especially the members of the Irish Surgical Trainees Group who were so engaged in the production of this document.

The proof of the pudding is in the eating and I hope that over the next few years, we can create the environment to enact the recommendation which will help recruit, retain and develop the surgeons of the future and develop surgery as a science and an invigorated clinical pursuit. The adage of the trainees who want to "train for excellence not adequacy" reminds us of the necessity for action.

Introduction & Context

THE IMPORTANCE OF SURGICAL RESEARCH

Healthcare professionals who practice in a research active environment exhibit differences in delivery of care compared to peers in non-research active settings, a phenomenon attributed to a combination of personal characteristics, training and education, multi-disciplinary collaboration and specialization[1]. While the impact of an individual academic surgeon on surgical outcomes remains relatively unexplored, practice within an institution with an academic ethos translates into improved patient outcomes through adherence to evidence based guidelines and practice [1, 2]

Clinical research programmes promote retention of high calibre clinicians and scientists, promote collaborative interdisciplinary research and contribute to economic growth through interaction with pharmaceutical, engineering, biotechnology and medical device industries. Major international institutions pride themselves on creating a patient care environment based on the pillars of education, training and research. The key metrics of research income and outputs are regarded as a measure of the academic standing of academics and their associated institutions.

RCSI has a long tradition in training, educating and supporting Irish surgeons. Research exposure has until recently been a prerequisite to entry to higher surgical training. To that end, the majority of Irish trained surgeons have undertaken a period of research training either in Ireland or abroad, often at renowned institutions.

The recent restructuring of training pathways in surgery has diminished the imperative for research exposure during what is now 'run through' training. Unintended consequences of these changes include diminished participation by surgical trainees in research activities such that there is now increased reliance on non-clinical scientists within the national academic surgical units, loss of competitiveness of trainees for

international training fellowships towards the end of surgical training [3] and ultimately failure of the national training programme to produce the next generation of academic leaders in surgery.

The purpose of this document is to create a vision for the incorporation of research in the career of Irish surgeons, to highlight the opportunities that exist for those who wish to incorporate research into their training and to identify the infrastructure needed to support academic excellence in surgery.

QUALITIES OF A TRAINED SURGEON

The modern surgeon is required to be an accomplished clinician and technician who exhibits a commitment to life-long learning and professional development. He/she has a mandate to train, develop and mentor staff, be flexible and supportive in team development, have appropriate leadership skills, be an effective communicator capable of teamwork, adaptable and have the ability to incorporate new therapeutic and diagnostic skills into his/her repertoire. In addition he/she must advocate for patients and be capable of participating or leading a multidisciplinary team. Within this construct, academically active surgeons play an important role in advancing surgical science through translational research and innovation. The training required involves a varied skill set that is often best acquired within a research and academic training programme.

How best to train, develop, retain and structure surgical careers in the best interest of our population is an important and current issue. It requires a balanced, progressive approach that appeals to medical students, develops surgeons in training and engages the community of Irish surgeons in a progressive, stimulating and

broad based pursuit for the advancement of our profession and patient care.

CHALLENGES

Compared to 10 or 20 years ago, present day surgeons apply for and receive fewer grants, publish less and of most concern, an increasing number feel that research is not part of their role [4-7]. A survey of over 1000 academic surgeons found that while the majority saw basic science research as a priority, only one third felt that it was realistic to expect surgeons to succeed in this endeavour[6].

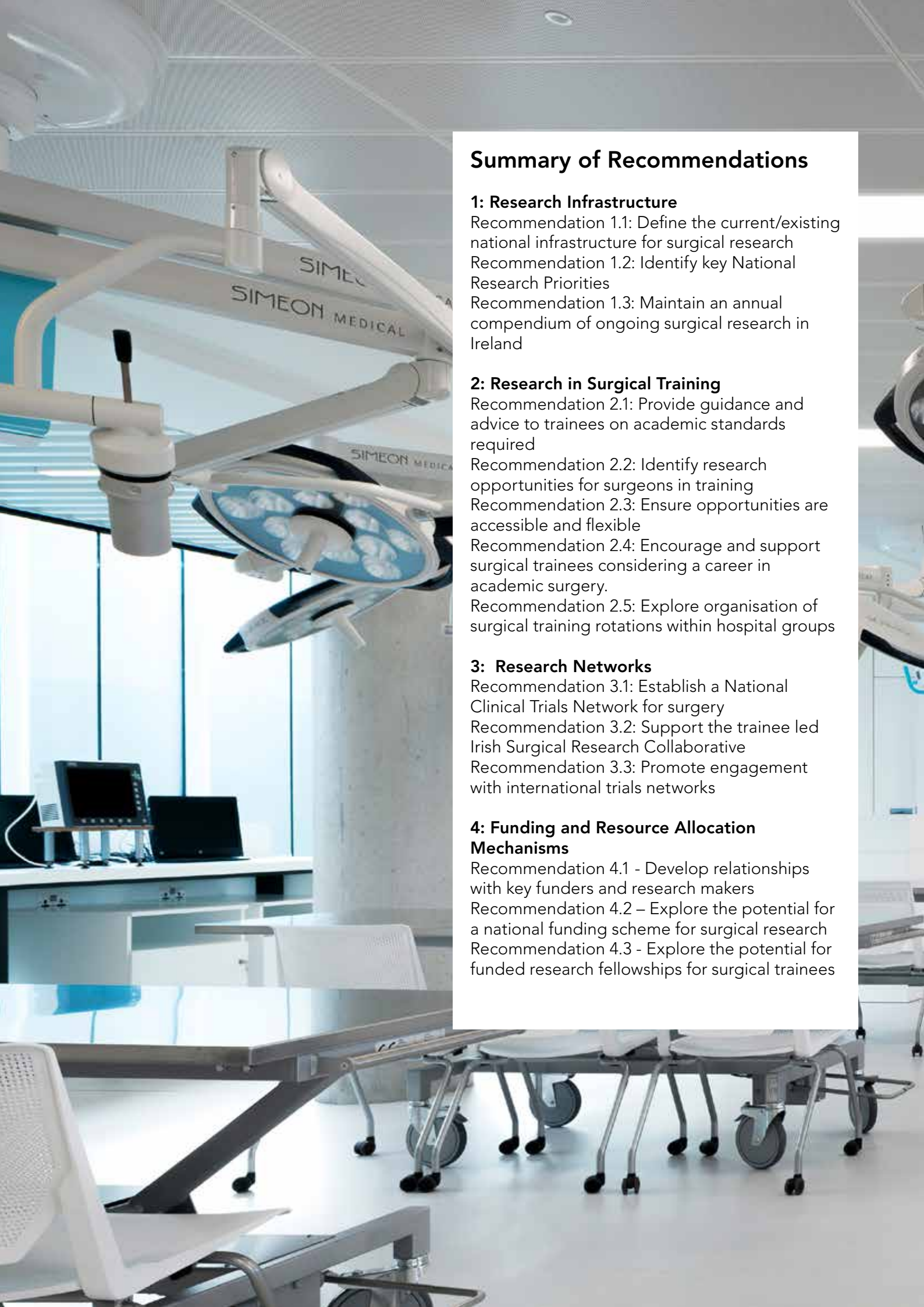
The practice of surgery provides a natural collaborative environment for research and surgeons have a unique appreciation of the translational opportunities stemming from scientific and clinical research. Some of the reasons for reduced engagement of surgeons in research are mainly summarised as follows:

- Competing clinical, educational and administrative demands
- Lack of a clear pathway to research or flexibility in training to facilitate research
- Lack of protected time for research activity
- Need to generate funding to support research

These factors combine to create an environment that does not encourage surgical research. Unless surgical leadership commits to support academic endeavour and ensures that this is prioritised within surgical training programmes, the trend away from research will be difficult to reverse. Thus, trainees should be encouraged in their research efforts and their progression facilitated by the development of training models and infrastructure that allow research in tandem with clinical productivity.

IRISH RESEARCH INFRASTRUCTURE AND ECOSYSTEM – CURRENT STATUS & FUTURE DIRECTIONS

Academic surgery in Ireland owes its development to a number of pioneering individuals whose research and innovation underpins surgical practice. Names such as Sylvester O Halloran, Abraham Colles, Peter Freyer, and Terence Millin have been replaced in more recent times by those of surgeon-scientists, such as Tom Hennessy, David Bouchier-Hayes, John Fitzpatrick and Gerry O Sullivan, who have contributed to the development of surgery as both a clinical and academic pursuit. Based on a strong tradition of basic and clinical surgical research, Ireland's contribution to the surgical literature compares favourably internationally with countries of larger size, population and GDP[8]. However clinical based research and in particular randomised controlled trials (RCTs) are under-represented in the Irish surgical literature (5) reflecting a relative lack of suitable infrastructure and poor inter-institutional collaboration, notwithstanding recent significant investment in CRFs (Clinical Research Facilities) within university led hospital groups.



Summary of Recommendations

1: Research Infrastructure
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Recommendation 1.2: Identify key National Research Priorities
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Focus area 1:
Research Infrastructure

RECOMMENDATION 1.1:
Define the current/existing national infrastructure for surgical research

Academic surgery in Ireland has developed principally around surgical professorial units associated with the six university medical schools. Little if any core funding is available to support research activity and research themes have, in general, focused on areas of clinical expertise of the incumbent leading academics, taking into account institutional research priories and local collaborative opportunities. While individual groups have been successful in attracting research funding, in the absence of a national surgical research infrastructure, research activity outside of the professorial units is modest and frequently confined to audit and outcomes assessment.

A notable gap in research output from Irish surgeons is the lack of clinically based research and in particular randomised controlled trials (RCTs) (5). Such trials are challenging to perform given the relative lack of suitable infrastructure, funding and poor inter-institutional collaboration, notwithstanding recent significant investment in CRCs (Clinical Research Centres) within university-led hospital groups.

Currently the academic surgical units in each of the universities has access to a CRC (also variously termed Clinical Research Facility (CRF) and Education and Research Centre (ERC)). However the location and partnerships involved in these research programmes varies across the universities.

- TCD : HRB-Welcome Trust CRF at St James's Hospital
- RCSI: CRC on the campus of Beaumont Hospital as part of Smurfit ERC
- There is The Lambe institute for Translational Research based on the University Campus
- UCD: CRCs at both Mater Misericordiae University and St Vincent's University Hospitals
- UL: HRI Clinical Research Support Unit (CRSU)
- UCC: Clinical Research Facility

Research performed through CRCs generally requires external funding to cover overhead and salary costs, and is generally funded through industry supported phase 3 trials. Little such funding is available for surgical trials. This shortfall that has been addressed in the UK by the National Institute for Health Research (NIHR) which supports trials infrastructure in clinically important surgical topics. The importance of developing a similar national surgical research platform and quality assurance infrastructure to support high quality surgical trials incorporating national and international collaborative networks cannot be overstated.

A lack of emphasis on research within the new surgical training programme has brought further difficulties, as fewer trainees are now prepared to spend time out of the clinical training pathways such that the majority of scientific research conducted in surgical professorial units is now performed by non-clinician scientists. Added to this are the higher salary costs of research when performed by surgical trainees compared to research performed by basic scientists undertaking PhD programmes. The reasons for this cost differential are several and reflect the seniority and clinical experience of medical graduates who usually undertake full time research 3 to 5 years following graduation from a 5 or 6 year undergraduate programme.

The number of full time academic contract holders in Irish surgery is small by international standards and by comparison with other disciplines in medicine in Ireland. All have major administrative, teaching and clinical commitments that leave little protected time for research. The most successful units rely on full time senior lecturers (usually with a basic science background) for day to day research activity. The problem of a low number of academic contract holders is compounded by split site units in UCD, TCD and RCSI that result

in sharing of scarce resources. Furthermore, the majority of surgeons with academic affiliation to one of the medical schools do not hold academic contracts and have either part-time (2 or 3 sessions), stipendiary or no formal commitment (honorary appointment). .

RECOMMENDATION 1.2: Identify key National Research Priorities

Little if any core funding is available to support research activity and research themes have, in general, focused on areas of clinical expertise of the incumbent leading academics, taking into account institutional research priories and local collaborative opportunities. While individual groups have been successful in attracting research funding, in the absence of a national surgical research infrastructure, research activity outside of the professorial units is modest and frequently confined to audit and outcomes assessment.

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The SLWG considers identification of national research priorities in surgical research as fundamental to successful integration of research into surgical practice. This will be challenging and require much engagement with stakeholders within the specialties of surgery, academic departments and funding agencies.

RECOMMENDATION 1.3: Maintain an annual compendium of ongoing surgical research in Ireland

The working group has been unable to accurately map current research activity in Irish surgery as there is no central registry of activity and data emanating from surgical professorial units do not capture activities out with the individual academic departments. This knowledge gap must be addressed as a prelude to developing a national strategy that would coordinate existing resources within formal research networks – be they hospital group, organ / disease based or sub-specialty based. The working group believes that such a strategy is an essential prerequisite to attracting the substantial core funding that will be required to support national surgical research networks. RCSI Council recognizes that as the national training body in surgery, RCSI Surgical Affairs is best placed to lead in developing the strategy.

Focus area 2: Research in Surgical Training

Optimising the potential and opportunities for surgical trainees to actively participate in research represents an investment in the future of Irish Surgery. The overarching aim is to train surgeons who will continue to be involved in academic pursuits which may cover a broad range of interests including clinical, translational and basic science research, administration, surgical education and training, healthcare policy development, innovation and technology.

Scholarly output is considered a core component of residency training by the Royal College of Physicians and Surgeons of Canada (http://www.royalcollege.ca/portal/page/portal/rc/canmeds/framework), the Accreditation Council for Graduate Medical Education (ACGME) in the United States (http://www.acgme.org/) and the European Union of Medical Specialists (EUMS) Board of Surgery (EBS) which strongly recommends a period of basic or clinical research within the surgical training program (https://www.uems.eu/__data/assets/pdf_file/0016/44431/UEMS-2013.21-European-Training-Requirements-General-Surgery.pdf). The Royal Australasian College of Surgeons introduced a thesis requirement in some surgical disciplines in 2008 which forms a mandatory part of the final examination (https://www.surgeons.org/surgical-specialties/cardiothoracic/thesis).

In 2013 academic achievement was embedded into the Joint surgical (Royal) Colleges' Surgical Training (JCST) curriculum in general surgery which mandates that all trainees must be in possession of three peer reviewed scientific publications and have delivered three communications to learned societies to qualify for a Certificate of Completion of Training (CCT) (http://www.jcst.org/quality-assurance/certification-guidelines). These requirements are endorsed by RCSI and are currently part of the minimum requirements for CCST in Ireland which is necessary for specialist registration by IMC.

The Association of Surgeons in Training (ASIT) and the National Research Collaborative (UK) have recently published a consensus statement supporting the requirement for acquisition of Good Clinical Practice (GCP) training and research methodology training as CCST requirements. They have proposed moving from using a specific number of publications as a minimum academic standard to a more flexible model that would allow trainees to demonstrate research involvement through GCP and research methodology training and a choice of two further requirements from a list of options that includes publication, presentation at national or international meeting, recruitment of patients to a multicentre study or completion of a higher degree [9]. This approach confirms the trainee recognition the benefits of research experience but provides flexibility for those with predominantly clinical practice interest and those with a greater focus on surgical and translational research as part of their career.

The JCST Strategy Update 2018 – 2023 (https://www.jcst.org/-/media/files/jcst/key.../jcst-strategy-201823_final.pdf?la=en) has highlighted the recommendations from the UK General Medical Council "Excellence by Design" publication which outlines new standards for postgraduate curricula (https://www.gmc-uk.org/education/postgraduate/excellence_by_design.asp). The Generic Professional Capabilities framework, which will be incorporated into the UK curriculum, identifies research and scholarship as essential professional skills and assessment of clinical research as a requisite capability in practice. This unequivocally confirms the importance of research as an integral component of surgical training to ensure a high standard of scholarship and continuous engagement in research activity throughout a surgical career.

RECOMMENDATION 2.1:
Provide guidance and advice to trainees on academic standards required

The SLWG recommends that RSCI provide guidance for trainees by acknowledge the need for wider recognition of what constitutes surgical research [9] while maintaining the minimum standards for CCST. The SLWG suggests that in addition to the existing surgical logbook, trainees should maintain a research portfolio and that this is reviewed at the annual Competence Assessment and Performance Appraisal (CAPA) and be given an appropriate weighting in relation to the other assessment variables.

RECOMMENDATION 2.2:
Identify research opportunities for surgeons in training

The SLWG recommends that consideration be given to the addition of trainee participation in the national meetings hosted by RCSI to include themed sessions on surgical issues which are of national priority/interest. This would engage predominantly clinical surgeons with those with a greater academic component to their practice and provide opportunities for research collaboration.

Formal research training opportunities such as the iCAT and the HSE Dr. Richard Steevens programme are offered on the existing training programme. A taught course in research methodology is provided, as is the option to complete a modular MCh or transfer credits from this course to pursue a PhD. Alternatively trainees have the option to take time out of clinical training between ST4 and ST5 to undertake full time research in the pursuit of a PhD. While the current training pathway does provide for these opportunities, there is insufficient flexibility in timing and structure to encourage trainee engagement.

Early mentoring and exposure to research methodology is predictive of future interest and success in an academic surgical career[10], thus some opportunities for research involvement should be included in the earlier years of the programme for trainees who wish to engage academically at an early stage in training. Taught modules which are incorporated into/mandated as part of the training programmes are currently provided by RCSI. There are, however similar taught research programmes and modular MCh courses provided at other academic institutions (https://www.nuigalway.ie/courses/taught-postgraduate-courses/masters-surgery.html; https://www.ucc.ie/en/ckx20/). These should be supported and recognised as being equivalent thereby broadening the choice for trainees in relation to where and when they engage with research opportunities. Information regarding training opportunities outside RCSI should be available on the RSCI Surgical Affairs website.

RECOMMENDATION 2.3:
Ensure opportunities are accessible and flexible

The SLWG recommends that consideration be given to development of a national registry of research opportunities and funding mechanisms for surgical trainees. The trainee induction session 'Bootcamp' delivered at RCSI prior to commencement of ST1 should include a lecture/ information session for trainees outlining research opportunities and requirements for progression in surgical training. Such a session would provide clarity relating to the role of research in surgical training and practice at an early stage so that trainees can make informed decisions relating to engagement with research opportunities throughout the surgical training pathway.

RECOMMENDATION 2.4:
Encourage and support surgical trainees considering a career in academic surgery

Trainees aspiring to a career in academic surgery require distinct training to enable them to develop as independent Principal Investigators (PIs) and go on lead research programmes. The promotion of clinician-scientist fellowship programmes, such as the Wellcome–HRB Irish Clinical Academic Training (ICAT) Programme (http://icatprogramme.org), should become a priotity within the training pathways to encourage surgical trainees aspiring to an academic career.

ICAT caters for postgraduate clinical training schemes in all disciplines in medicine. Entry to ICAT is determined by the proposed exit year such that ICAT Fellows complete full time PhD research

and return to to complete clinical training. A final two years of clinical training is usual, any longer is considered to negatively impact on fellows' ability to maintain sufficient research activity to subsequently compete for academic positions.

In its current structure ICAT year 1 is 70% clinical and 30% academic and is fully accredited for clinical training. ICAT years 2-4 are full-time PhD years with minimal clinical training (10-20% maximum); fellows can request accreditation for these years, equivalent to one year of clinical training. Therefore, of the four-year ICAT programme, two years are clinically accredited so generally specialist training takes two years longer than usual. There is recognition that surgical disciplines require trainees to develop and refine the manual dexterity and technical skills required to operate[11]. It is therefore likely that the duration of training for individuals choosing an academic pathway will be lengthened and that the proportion of academic time spent out of clinic may need to be reduced.

The SLWG have engaged with the ICAT programme directors to explore ways in which training for academic surgeons could be optimally facilitated on this programme. The most favourable approach would be for trainees to enter ICAT as early as possible in the training pathway and leave the maximum allowable time for clinical training post-PhD. The suggested framework in surgery is that trainees entering the current 8-year run-through surgical training scheme would complete two years of basic specialist training (BST) and then apply for ICAT during year one (ST 3) of higher specialist training (HST). If successful, ICAT year 1 would be combined with HST year 2; clinical training would be fully accredited for this year (ICAT year 1 is 70% clinical and 30% academic). During ICAT years 2-4, trainees would maintain a reduced clinical training component (perhaps 20%-30%), and one year of clinical training would be accredited towards these three years (equivalent to HST year 3). Trainees would re-enter full-time training (in HST year 4) to complete the final three years prior to CCST. Overall, the length of the training scheme would be extended to 10 years, but trainees would exit with CCST, PhD, peer reviewed publications and research experience.

This outline of integrated training for surgeons on the ICAT programme represents a proposal which is open to further discussion between ICAT and the RCSI and the Irish Surgical Postgraduate Training Committee (ISPTC). This should lead to awareness of ICAT among surgical trainees and the postgraduate surgical training body and facilitate development of a number of academic surgeons within the ICAT programme. In addition it must be ensured that academic internships and other academic programmes within training are promoted to trainees with an aspiration to a career in academic surgery.

RECOMMENDATION 2.5: Explore organisation of surgical training rotations within hospital groups

The restructuring of Irish hospital services into University Hospital Networks/ Health Care Groups presents an opportunity to develop a Hospital Network or Regional approach to surgical training. Trainees could be afforded longer periods of time within a specific network to develop mentor-mentee relationships with the regional trainers, to complete research projects and become involved in surgical education in a more immersive manner than is possible within a system of six-monthly or annual rotations. Such rotations would help address the negative impacts of short term rotations on trainee quality of life that trainees cite as major determinants in their career choice [12].

The academic linkages of each hospital group could support academic endeavour in each region where surgical trainees receive the majority of their education, research and surgical skills development. The SLWG recommends that RSCI Surgical Affairs review the current highly centralized model of training and consider providing local supports to trainees and trainers in the hospital networks in a manner that is being adopted by RCPI.

The Irish Surgical Training Group (ISTG) have been consulted on this proposal and have indicated that trainees would welcome this initiative. Flexibility and trainee inclusion in the allocation of training posts in this model would also be welcomed. The SLWG propose that this change to the current structure of training be trialled on a pilot basis with the provision of regionalised training in years 3 – 5 for a subset of trainees who are interested in engaging with this model of training.

The SLWG recommends that consideration be given to incorporation of temporary surgical lecturer positions within the six medical schools into higher surgical training programmes in order to enhance research and academic opportunities within higher surgical training. Such changes support development of local faculty to allow basic skills acquisition among surgical students and the development of regional academic networks.

Focus area 3: Surgical Research Networks

RECOMMENDATION 3.1: Establish a National Clinical Trials Network for surgery

Prospective and Randomised Clinical Trials provide the best evidence (Level I) for the evaluation of healthcare interventions. The complexity of trials involving surgical interventions has led to a paucity of high quality randomised controlled trials to inform evidence-based surgical practice, a fact that has left our specialty open to criticism [13, 14]. Undoubtedly, the very nature of surgical practice makes surgical trials difficult to design and conduct [15]. Factors that limit successful undertaking of surgical trials include suboptimal randomization or blinding techniques, inadequate recruitment accrual, lack of clinician engagement or rapid evolution of surgical technique during the time-frame required to conduct a trial[15-18].

Access to funding for surgical research is increasingly challenging; recent reports from the US have shown that National Institutes of Health (NIH) funding to surgical departments has dropped significantly in the last 20 years[6, 19, 20], and only 5% of funding in oncology goes to surgical trials [21]. Understanding the factors that limit successful undertaking of clinical trials in surgery is essential [15, 22, 23]. A common theme is the requirement for improved organization among surgical communities at both a national and international level, and particularly development of research networks and trial centres, led by surgeons to support prospective surgical studies [14, 15, 23]. There has been a concerted effort in a number of countries to develop national research networks which have both collated national disease-specific data [24-26] and produced successful surgical trials [19, 27-31].

A particularly successful example of this is the Surgical Trials Network initiative led by the Royal College of Surgeons in England aimed at developing an infrastructure for surgical research in the UK[30]. The incentive for this came from

recognition that surgical practice was lacking an evidence base and that well run multicentre RCTs had the potential to reduce disparities in patient care across the National Health Service[30]. With funding from the UK National Institute of Health Research (NIHR) and charitable partners, RCS Eng invested in Surgical Trials Centres and Surgical Specialty Leads at an initial 5 centres (subsequently expanded to 7) which are embedded in clinical trials units which are part of a UK network of units meeting specified criteria (UKCRC Registered Clinical Trials Units Network, http://www.ukcrc-ctu.org.uk/). The RCS Eng investment aimed to facilitate collaboration between surgeons and trial methodologists to develop surgical trials, mentoring of new surgical PIs and the provision of expertise to engage, educate and encourage teamwork [15]. RCS Eng Academic and Research Committee stated that "the College wants any surgical patient who wishes to join a trial to be able to do so, and every surgical trainee, by the time they become a consultant, to know that this is an essential part of consultant activity and not an optional extra"[30]. In this regard, the initiative has been hugely successful; in the first 3 years, 57 RCTS were initiated, producing 175 new principal investigators and the number of patients recruited to surgical RCTS more than doubled, from 11,000 in 2011-2012 to >25,000 in 2014-2015 (https://www.rcseng.ac.uk/standards-and-research/research/surgical-trials-initiative/)[15].

In Ireland the development of national disease-specific registries through the National Office of Clinical Audit (NOCA), operationally supported by RCSI, now provides for the first time robust data on surgical activity. Through Irish Audit of Surgical Mortality (IASM), Irish Audit of Critical Care, Irish National Orthopaedics Register (INOR) and the Trauma Audit Research Network (TARN) (https://www.noca.ie/wp-content/uploads/2015/04/NOCA-Strategy-2017-2020.pdf) reliable data on outcomes are beginning to be available. Unfortunately, the situation less favourable in relation to surgical trial capability.

In 2014, the HRB made a €10M investment in the development of HRB Funded Clinical Trials Networks to support thematic groups of clinician investigators and health researchers to deliver national multi-centre clinical trials in selected health themes. HRB Clinical Research Co-Ordination Ireland (HRB CRCI) was established and funded by extramural grants from the HRB, Enterprise Ireland (EI) and is supported by five Irish Universities.This initiative resulted in the establishment and support of 4 networks: HRB Stroke Clinical Trial Network Ireland, HRB Critical Care Clinical Trials Network Ireland, HRB Mother & Baby Clinical Trials Network Ireland and HRB Primary Care Clinical Trial Network Ireland – these networks were selected for funding based on a competitive application process and their potential for undertaking research with outstanding health, scientific, societal and economic impact.

These developments in clinical trials infrastructure, methodological support and funding for thematic clinical trials networks have significantly enhanced the clinical research environment in Ireland and optimised the potential to undertake high quality clinical trials. Irish surgery has yet to establish itself within this infrastructure.

The SLWG proposes that RCSI would co-ordinate the development of a National Surgical Research Programme, encompassing a Surgical Trials Network harnessing key stakeholders including academic departments, hospital groups, CRFs and potential funders. The objective would be to achieve similar success to that of the RCS Eng initiative in UK. Once established, the Network would provide the leadership and expertise in surgical trials through recruitment of appropriate academic surgeons and development of training supports for research interested clinicians, thereby fostering a "research culture" in Irish surgery.

It will be important to facilitate varying levels of participation for surgeons, ranging from PIs co-ordinating multicentre trials, local investigators wishing to lead institutional trials, to active clinicians recruiting patients and contributing samples and/or data for multicentre studies co-ordinated by the network. It is envisaged that the provision of options and flexibility in addition to appropriate training and support will motivate the Irish surgical community and change the view held by some clinicians that research activity is too onerous in the context of competing clinical, administrative and service demands within the healthcare system.

Consultation with the clinical surgical community to identify research priorities will generate further interest generating patient focused clinical questions and developing a pipeline of prioritised

national trials. This approach should foster a high level of engagement from the broader surgical community.
A key area where RCSI may provide leadership will be in exploring and establishing funding models to support a National Surgical Trials Network. The SLWG envisages that leadership for these projects will come from Principal Investigators across the networks of academic hospital groups and surgical departments and specialties.

RECOMMENDATION 3.2: Support the trainee led Irish Surgical Research Collaborative

In order to overcome the competing demands of clinical training requirements and service provision, research collaboratives have been established by surgical trainees. These provide a framework within which surgical trainees across a network/ region can work together to deliver patient-focused, multicentre observational and prospective projects. Collaboratives exist in the UK [32], Europe[33], and are emerging in low-middle income environments to investigate global surgery issues[34, 35]. These networks have proven highly successful, resulting in several observational studies and high quality randomised trials [36-38].

The development of trainee led research collaboratives in the UK occurred in parallel with investment in surgical research by RCS Eng that established regional surgical trials networks[30]. The UK trainee networks have proceeded to undertake large scale observational studies which have generated research questions and informed the design of future RCTs [39]. By virtue of their participation in multi-centre studies, trainees are gaining invaluable experience in teamwork/ collaboration, peer review, research methodology and good clinical practice training. Ultimately this exposure will result in a surgical workforce with an understanding and interest in surgical research, trial design and multicentre collaboration.

In Ireland, the surgical trainees through the Irish Surgical Training Group (ISTG) have emerged as pioneers of collaborative surgical research through their motivation and development of the trainee led "Irish Surgical Research Collaborative". Modelled on the networks led by counterparts in the UK, this network has recently completed data collection for their first observational study the PERioperative Fluid in Elective ColecTomy (PERFECT) multicentre study which collated data from 17 Irish hospitals. The collaborative is now accepting proposals from trainees for further multicentre studies which will be selected on a competitive basis. This is a very positive development and highlights the enthusiasm and motivation on the part of the trainees to participate in surgical research. The SLWG recommends that RCSI actively support this initiative through providing training in research methodology and Good Clinical Practice (GCP) through engagement with the HRB CRCI https://www.hrb-crci.ie/training-conferences/.

The Irish Surgical Research Collaborative has identified attainment of ethical approval as a significant challenge in undertaking multi-institutional research. There is currently no accepted mechanism for single location ethical approval for multicentre surgical studies, thus separate approval from all participating centres is required [40]. The SLWG propose that the system for research ethical committee (REC) approval for national multicentre surgical studies/ trials be reviewed with the aim of developing a more efficient/streamlined process. Potential improvements to the current situation may include provision of administrative support for the preparation of REC applications when multiple applications are required. More importantly, consideration should be given to the development of RECs tailored to specific research themes, for example surgical trials and to the development of National Guidelines relating to the operation of these RECs. The provision of National Guidelines for themed/tailored RECs may provide a framework for mutual acceptance of approval across centres in multicentre studies[40]. The SLWG recommends that RCSI take a leadership role in exploring the potential for National Guidelines relating to REC approval for surgical research.

RCSI should seek sustainable funding models for the provision of support and resources for the trainee led surgical research network as a priority. This will promote a generational change in surgical activity nationally to a culture where participation in clinical research and surgical trials becomes embedded in routine clinical activity, leading to inevitable improvements in surgical care.

The culture of innovation is strong in surgery and development of increasingly sophisticated medical devices allows surgeons play a major role in the translation to clinical practice, leading to opportunity for valuable interdisciplinary collaboration with bioengineers and other medical/surgical device developers. These collaborations are an opportunity for the surgical community to play a central role in driving scientific advances within our specialty.

Successful development of a surgical trials infrastructure will facilitate partnership with other well established National Trials Networks to identify common research priorities and undertake collaborative research with common themes, goals and shared research infrastructure within the HRB-CRF framework. Examples of established research networks nationally with clear potential for collaboration from a thematic and disease specific perspective include Cancer Trials Ireland, Investigator Network for Inflammatory Bowel Disease Therapy in Ireland (INITIative), HRB Critical Care Trials Network Ireland, and HRB Stroke Clinical Trials Network Ireland. It is envisaged that the Irish Surgical Trials Network will engage with these networks to identify common areas for investigation and through these collaborations deliver surgery-led research to improve outcomes nationally. Close collaboration and engagement with national registries including NOCA will serve to identify areas of clinical need warranting prospective evaluation through clinical trials.

RECOMMENDATION 3.3: Promote engagement with international trials networks

International collaboration in research provides many benefits, including greater ease in the recruitment of large patient numbers, improved methodological quality and increased generalisability/broader applicability of results [18]. The highest impact science comes from international collaboration [41]. RCSI as an international health sciences institution is focused on education and research to drive improvements in human health worldwide, with a global campus and an international presence across 3 continents. Furthermore, the clinical collaboration of RCSI and the College of Surgeons of East, Central and Southern Africa (COSECSA), and the strong international collaborative links of RCSI based research programmes, highlight the capacity of RCSI to overcome these cited barriers to international collaboration, and the potential to take a leadership role in international surgical trials/research collaboratives.

The recognition that international collaboration is essential to further surgical research and practice was the subject of an open letter to the surgical community published in the Annals of Surgery in 2016[14]. This communication announced the formation of the SURCARE platform, a collaborative initiative by the European Society of Surgical Oncology (ESSO), the Japan Clinical Oncology Group (JCOG), and the European Organization for Research and Treatment of Cancer (EORTC) which is described as a comprehensive platform with the necessary competencies and facilities to organise and undertake pragmatic clinical research in surgical oncology. This collaborative have committed to focusing on quality assurance in surgical trials and surgical practice and have called for the support of the surgical and scientific communities as being crucial to the success of this initiative.

As part of the Royal College of Surgeons (UK) surgical trials initiative, the RCSEng have also moved to develop an international surgical trials platform and hosted researchers from the UK, US and Europe for discussion on how best to co-ordinate and launch such a network https://www.rcseng.ac.uk/standards-and-research/research/surgical-trials-initiative/international-network/. The surgical trainee networks, having also recognised the importance of international research collaboration have fostered collaborative links with trainees across Europe to deliver multi-centre, international surgical studies [42] and launched the student driven EuroSurg Collaborative Network (http://eurosurg.org/)[43] It is imperative that incentives for international collaboration, including research funding, training fellowships and exchange of data and expertise is supported by the RCSI for the benefit of surgical research to advance our specialty and shape the future practice of surgery both nationally and internationally.

Focus area 4: Funding and Resource Allocation Mechanisms

RECOMMENDATION 4.1
Develop relationships with key funders and research makers

RECOMMENDATION 4.2
Explore the potential for a national funding scheme for surgical research

Successful implementation of the recommendations of this report will require engagement and commitment by the College, the university academic leads in surgery, surgical specialties and trainee representatives. While RCSI may provide leadership, through Surgical Affairs, the strategy will only be successful if sustainable business models can be developed to provide the funding necessary to support the infrastructure required to establish a National Surgical Trials Network. A small implementation group should be established to engage with HRB – Clinical Research Co-ordination Ireland such that RCSI – Surgical Affairs will be in a position to bid for funding in the next competitive call for funding. The group should also explore funding opportunities though with potential charitable partners e.g. Wellcome Trust and Irish Cancer Society.

RECOMMENDATION 4.3
Explore the potential for funded research fellowships for surgical trainees

The College, through the Irish Surgical Postgraduate Surgical Training Committee, should explore changes to the training pathways designed to encourage and support surgeons in training who wish to follow an academic pathway. This will require engagement with HSE-NDTP, as training duration will be lengthened (requiring additional approved and funded posts) and out of programme research years will need to be supported. The SLWG recommends the College explore means of supporting a number of ICAT type posts – initially one or two per year – to establish the pathway. The SLWG suggest that sources for such funding might include a levy on Fellows and Members subscriptions, philanthropic funding of named fellowships (e.g. the UCD Newman Scholarship programme) or allocation of a percentage of revenue from postgraduate examinations. To be successful and to gain the support of the surgical community as a whole, such fellowship would be open to all surgical trainees in all specialties and in all training institutions.

The SLWG strongly recommends that the Irish Surgical Research Collaborative be supported by RCSI –Surgical Affairs and that such support would in time be incorporated into the larger National Clinical Trials Network envisaged in this report.

Membership

Chair:	Professor Michael Kerin	
Council:	Mr Ken Mealy	President RCSI
	Professor Ronan O'Connell	Vice President RCSI
	Professor Kevin Conlon	Council Member & Chair of the Professors in Surgery Group
	Ms Bridget Egan	Council Member, Chair of Finance Committee (Formerly Chair of ISPTC)
Surgery:	Professor John O'Byrne	President of IITOS and Lead
	Ms Ruth Prichard	Consultant Surgeon and Chair of Society of Irish Breast Surgeons
	Professor Aoife Lowery	Consultant Surgeon and Associate Professor of Translational Research NUIG
	Professor Des Winter	Counsultant Surgeon and Associate Professor UCD, Editor of BJS.
RCSI:	Professor Hannah McGee	Dean of Medicine and Health Sciences
	Prof Ray Stallings	Director of RCSI Research Institute
	Mr Kieran Ryan	Managing Director of Surgical Affairs
	Professor Jan Sorenson	RCSI Health Outcomes Research Centre
	Mr Dara Kavanagh	Consultant Surgeon, Research lead, RCSI Surgical Affairs
Trainees:	Mr Peter O'Leary	
	Mr Jarlath Bolger	
	Ms Helen Mohan	
	Ms Deirdre Nally	

Appendix 1

TERMS OF REFERENCE

To create a network of Irish Surgical Research harnessing the key stakeholders including Academic Departments, Hospital Groups, Clinical and Translational Research Facilities and Funders.

To explore, establish and co-ordinate infrastructure for a National surgical research programme and to address the means of creating National Networks in key areas, such as Biobanking, surgical outcomes and clinical trials across Surgical Specialties.

Ensure that we optimise the potential and opportunities for all Surgeons and trainees to take part in research, acquiring necessary skills and methodology throughout their careers

Develop a supportive and collaborative research environment to enhance academic productivity across Irish Surgery.

Develop relationships with key funders and research policy makers to provide support for surgical research in the interest of public health

Provide necessary leadership, opportunity and structures to facilitate development of new RCSI led and supported surgical research framework.

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