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OF MEDICINE
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SCIENCES

RCSI



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RCSI Intellectual Property Policy 2024

November 2024

RCSI UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

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1. Background

RCSI's focus on clinical and patient centred research leads to impactful discoveries, which address key Irish and international health challenges. We aim to improve human health through innovative translational medical research and to help achieved this we develop meaningful engagement through research commercialisation and collaboration with industry. Increasingly both National and International research funding agencies have prioritised the funding of research that can demonstrate high potential for achieving economic and societal impact. A strong culture of research commercialisation and industry engagement is critical for achieving such impact. These factors require RCSI to manage intellectual property arising from its research activities in a professional and transparent manner.

RCSI recognises the importance of delivering and disseminating impactful research. The main objectives of the *RCSI Strategy 2023-2027 Innovating for a Healthier Future* have been set to deliver on this goal and place an increased focus on research commercialisation and knowledge transfer. RCSI is committed to the professional management of intellectual property which arises from research carried out at RCSI and will use all reasonable endeavours to seek opportunities for the commercial exploitation of the results of this research.

2. Application and Implementation of Policy

This document sets out the policy, regulations and practice for management of intellectual property at RCSI. It also details the benefits accruing to, and responsibilities of, researchers under this policy. This document supersedes the original *RCSI Intellectual Property and Inventions Policy 2003* and minor updates thereto in 2008, the 2017 policy, which was developed with input from a cross-institutional working group. It also supersedes the 2019 version, which was updated following the launch of the latest National IP Protocol and the release of the KTI/HEA Review of Intellectual Property Management and Conflicts of Interest, and addresses recommendations therein. This 2024 version had been updated as required (every four years) under the National IP Management Requirements and incorporates recommendations of the KTI/HEA Review of Implementation of IP Policies within Higher Education Institutes. This policy is aligned with, and informed by national policy, specifically *Ireland's National IP Protocol 2019 - A Framework for Successful Research Commercialisation*. In line with this policy, RCSI will pursue research commercialisation, keeping in mind the objective to create economic and societal benefit for Ireland through the creation of sustainable jobs.

This policy has been approved by RCSI Academic Council and the RCSI Senior Management Team, is dated 23.9.2024 and is effective from 22.11.2024.

Version history

| Policy | Revision date | Approval date | Effective from |
|---|---------------|---------------|----------------|
| RCSI Intellectual Property and Inventions Policy 2003 | 2003 | N/A | 30.6.2003 |
| RCSI Intellectual Property and Inventions Policy 2008 | 2008 | N/A | N/A |
| RCSI Intellectual property Policy 2017 | 2017 | 30.5.2017 | 31.5.2017 |
| RCSI Intellectual Property Policy 2019 | 2019 | 12.12.2019 | 13.12.19 |
| RCSI Intellectual Property Policy 2024 | 2024 | 21.11.2024 | 22.11.2024 |

The most recent, approved policy shall apply to all distribution of revenue, irrespective of the date of invention or commercialisation of IP.

This policy shall be reviewed every four years with the next date of revision in August 2028 or within six month of publishing of a revision of the National IP Protocol. This Policy is the responsibility of the Deputy Vice Chancellor for Research and Innovation, questions relating to content should be addressed to the Head of Innovation.

This policy applies to the following cohorts:

- RCSI employees: full time, part time, permanent and contract while in the employment of RCSI (including, for the avoidance of doubt, joint appointees)
- Postgraduate students and undergraduate students who are in receipt of an RCSI administered stipend, scholarship, grant or salary which is intended to enable them to carry out research.
- Postgraduate or undergraduate students not in receipt of an RCSI administered stipend but using RCSI resources or RCSI Intellectual Property
- Postgraduate or undergraduate students performing research that is subject to an agreement between RCSI and a third party
- Visitors while at RCSI
- Individuals with honorary or associated positions while performing research using RCSI facilities, supports and/or using research funding that is subject to an agreement between RCSI and a third party

It is the responsibility of each person subject to this policy not to enter into arrangements with third parties that may conflict with this policy. If such a conflict arises (or exists already) it should be brought to the immediate attention of the RCSI Office of Research and Innovation.

This policy is implemented at RCSI through the RCSI Office of Research and Innovation (ORI). The RCSI ORI supports all research commercialisation and industry engagement activities at RCSI and is responsible for negotiation and execution of commercialisation and industry collaborative agreements with third parties.

This Policy does not confer any employment rights or entitlements on RCSI Personnel. This Policy supersedes all prior written and oral arrangements, understandings and agreements with respect to its subject matter, including all prior policies and practices of RCSI with respect to RCSI IP all of which are hereby terminated and no longer have any effect. No Inventor/Creator is entitled to rely on any right or entitlement under any such previous policy or practice.

RCSI reserves the right to amend, update or modify any of the terms of this Policy as it may determine from time to time, and procedures and documentation (e.g. guidelines) may also be developed and issued from time to time as necessary for implementing this Policy.

3. Definitions

Contributors: means individuals who contribute to the development of IP but who do not make an inventive contribution and are not considered Inventors under Irish patent law.

Equity Consideration: means exceptional cases where the sole or partial consideration for the licence or assignment of RCSI IP is the grant of equity to RCSI

Intellectual Property: means any and all patents, trademarks, service marks, materials, data, registered designs, drawings, utility models, design rights, business ideas, concepts, inventions, discoveries, copyright (including the copyright in software code or algorithm, and the copyright in all forms of digital materials created for educational and training purposes (for example recorded video content)), database rights, trade secrets and other confidential information, technical information, technology, know-how, business or trade names, goodwill and all other intellectual property and rights of a similar or corresponding nature in any part of the world, whether registered or not, or capable of registration or not, and including all applications and the right to apply for any of the foregoing rights.

Inventor/Creator: means the RCSI Personnel who have made a material intellectual contribution to the generation of Intellectual Property.

IP Commercialisation Revenue: means revenue from commercialisation of Intellectual Property and shall include royalty, milestone payments and license fees from licence agreements, option payments, assignment payments, received by RCSI after the deduction of associated patent costs and vouched expenses, funding agency revenue share (where applicable), any revenue share with external parties and applicable taxes.

Lead PI Inventor: means the principal investigator named on an invention disclosure form that has made the largest contribution to an invention

Mediation Notice: means a notice given in writing to the other party requesting mediation of the dispute.

PI Research Account: means account of lead PI Inventor/Creator, or Head of School/Unit/Department if PI has left RCSI. If lead Inventor/Creator is a post-doctoral researcher, the funds will go to the research account of the PI named on the source of funding for the development of the Intellectual Property

RCSI Personnel: means individuals described in section 4.1

4. Ownership of Intellectual Property

4.1 RCSI claims ownership of all Intellectual Property created by RCSI Personnel in the course of their work. For the purpose of this policy, the following individuals shall be defined as RCSI Personnel:

- RCSI employees: full time, part time, permanent and contract in the course of their work, while in the employment of RCSI, in connection with, or in any way affecting or relating to the business of RCSI, or capable of being used or adapted for use therein or in connection therewith
- RCSI employees temporarily based elsewhere if there is no agreement to the contrary
- Postgraduate students and undergraduate students who are in receipt of an RCSI administered stipend, scholarship, grant or salary which is intended to enable them to carry out research.
- Postgraduate or undergraduate students not in receipt of an RCSI administered stipend but using RCSI resources or RCSI Intellectual Property
- Postgraduate or undergraduate students performing research that is subject to an agreement between RCSI and third party (eg funding agencies or industry partners)
- Visitors while at RCSI unless there is an agreement to the contrary
- Individuals with honorary, adjunct, emeritus or associated positions while performing research using RCSI facilities and/or using research funding that is subject to an agreement between RCSI and third party, subject to agreements to the contrary

RCSI shall have the exclusive right to commercialise Intellectual Property created by RCSI Personnel.

4.2 It is the responsibility of each person subject to policy:

- To facilitate agreements relating to Intellectual Property that may be necessary to allow RCSI to fulfil its obligations to third parties.
- Not to enter into arrangements with third parties that conflict with this policy. Any conflict or potential conflict that is likely to arise between a person's obligations under this policy and any third party arrangement should be brought to the attention of the ORI and other relevant parties.

RCSI does not claim ownership of Intellectual Property generated by:

- The unpaid work of students, except if such work is subject to the obligations of a contract between RCSI and a third party, uses RCSI Intellectual Property or resources.
- Personal consultancy work if performed in a manner consistent with RCSI's External Consultancy Guidelines.
- The creation of scholarly works (eg. books) by RCSI Personnel except where the creation of such scholarly works has been performed under a contracted work programme between RCSI and a third party.
- The creation of educational and training materials (with the exception of digital content created for these purposes). Copyright in course materials (e.g powerpoint presentations, lecture notes). This is owned by the academic who created the specific

material; however RCSI retains the non-exclusive royalty free perpetual right to use such course materials for educational and research purposes, including the right to sublicense (This does not convey a right to whole curricula, exam/assessment, module structure or other course materials which is owned by RCSI). For the avoidance of doubt, any copyright or other rights incorporated in software do not fall under this exception.

- Work performed by RCSI Personnel outside of the course of their employment and field of expertise.

5. Disclosure and Assignment of Intellectual Property

It is the responsibility of RCSI Personnel to promptly disclose to the ORI Intellectual Property that is potentially commercially valuable. Examples of such Intellectual Property include copyright, know how or patentable intellectual property generated during the course of research activities performed by RCSI Personnel. This requirement is necessary in order for RCSI to fulfil its contractual obligations to research funders and industry partners. Intellectual Property should be described in the template RCSI Intellectual Property Disclosure Form (IDF) available from the ORI on request. IDFs should be submitted to the ORI in a timely fashion before the submission of publications, abstracts or conference presentations to allow time for review, assessment of patentability, and patent filing (if required). To facilitate this process, completed IDFs should be submitted to the ORI at least 60 days (or longer if mandated in an agreement with a third party) prior to planned disclosure. Where an IDF arises from the efforts of multiple Inventor/Creators, such Inventors/Creators are required to agree the relative intellectual contribution of each Inventor/Creator in writing at the time of IDF submission in order to facilitate the distribution of any benefits arising from the commercialisation of such Intellectual Property. It is essential that good research records are prepared during the course of research projects. Such records will be of prime importance in allocating the intellectual contribution made by each Inventor/Creator. Relative intellectual contribution may be revised by inventor share agreement signed by all parties. Individuals who contribute to the development of IP but who do not make an inventive contribution and are not considered Inventors under Irish patent law (“Contributors”) may be included in an inventor share agreement and receive a share in IP Commercialisation Revenue subject to agreement by all Inventor/Creators and Contributors and approval by the Head of Innovation.

The Inventor/Creators of Intellectual Property deemed to be patentable or commercialisable shall be required to complete assignment and other documentation to facilitate patent filing and/or subsequent commercialisation. This obligation shall continue to apply in situations where the Inventor/Creator has left the employment of RCSI. In addition, Inventors/Creators shall be required to provide all reasonable assistance requested by the ORI to support the commercialisation of Intellectual Property, including engaging with potential industry partners and entrepreneurs.

Revenues received by RCSI from the commercialisation of such Intellectual Property shall be shared with the Inventor/Creators as set out in section 8.

6. Protection of Intellectual Property

The RCSI's ORI shall be responsible for determining the most appropriate form of intellectual property protection for any Intellectual Property created by RCSI Personnel.

The decision on whether to file a patent on any Intellectual Property created by RCSI Personnel will be made by the ORI in consultation with the Inventor/Creators following a detailed evaluation of the patentability and commercial potential of the Intellectual Property in question. The ORI will acknowledge receipt of an IDF as soon as practical and will endeavour to review and respond within eight weeks. Any decision regarding the continuation or discontinuation of a patent relating to RCSI Intellectual Property shall be made by the ORI in consultation with the Inventor/Creators and any third party that may have an interest in or has been granted commercial access rights to such Intellectual Property. Such decisions shall be influenced by a number of factors including any third party contractual requirements, the commercial opportunity, the technology development level and availability of further funding (if required) to develop the technology. More detailed information relating to the patent continuation/discontinuation decision making processes is available in ORI procedural documentation available on the RCSI staff portal.

Agreements with third parties may be necessary to protect intellectual property prior to patent filing. Examples of these are given below and advice on their implementation is available from the ORI. In all cases agreements must be signed by an authorised representative of RCSI and never by individual RCSI Personnel.

- Non Disclosure Agreements (NDAs) are required to provide protected disclosure of confidential information to third parties without compromising patentability.
- Material (and Data) Transfer Agreements (M(D)TAs) are required when sending or receiving materials (and data) to or from a third party.

RCSI Personnel must not submit an abstract, publication or present at a conference that would compromise patent protection prior to submitting an IDF to the ORI. Decisions about placing Intellectual Property in public domain should be made in consultation with the ORI and always subject to the terms of third party agreements.

7. Exploitation of Intellectual Property

The value of RCSI Intellectual Property is realised primarily by licensing such Intellectual Property to third parties for commercial exploitation. Licensing of Intellectual Property may be to an existing company or to a newly formed company (RCSI spin-out company) set up specifically for the exploitation of the Intellectual Property in question. In certain exceptional circumstances assignment of Intellectual Property may be considered.

An intellectual property licence agreement is a contract under which an owner, or licensee, of intellectual property rights (the licensor) permits another person (the licensee) to engage in activities that, in the absence of the licence agreement, would infringe the intellectual property rights. Intellectual property licences are sometimes granted to permit a licensee to use, make and/or sell products that use the licensed intellectual property, often in a specific field and/or

territory. In return for the grant of an intellectual property licence, the licensee will typically make payments to the licensor in respect of its use of their intellectual property – a fee bearing licence. In some situations a licence may be granted to a licensee with no such requirements.

An intellectual property option agreement grants a contractual right to the recipient to either negotiate a licence or to enter into a licence within a defined period. The recipient is not obliged to enter into negotiations or into the licence but it has the right to do so if it so decides. There may be a fee associated with the grant of an option.

An assignment of intellectual property rights transfers, or assigns to the buyer ownership and consequently the right to use the intellectual property. RCSI will not normally consider assignment of Intellectual Property, however it may do so in exceptional circumstances, once IP has been created and subject to conditions aligned with those in the National IP Protocol and EU State Aid Regulations.

Spin-out companies are commercially high risk ventures and, as RCSI has a duty to ensure that intellectual property is developed for economic and public good, RCSI shall ensure that the intellectual property can be recovered and recycled if things do not go to plan in the future. This is to ensure that there is the maximum opportunity to make economic and societal impact from funded research programmes at RCSI. RCSI shall therefore license intellectual property to spin-out companies on formation rather than assign. RCSI spin-out company formation is further described in section 13 below.

The ORI, as delegated by RCSI Senior Management Team (SMT), shall be solely responsible for managing the commercial exploitation of RCSI Intellectual Property and will negotiate and execute any agreements that are required. In the case of RCSI spin-out companies additional approval is required as described in section 13. Commercial terms, including royalty and upfront payments will vary depending on technology type, stage of development, state investment in its development, market opportunity and, in the case of Intellectual Property arising from industry funded programmes, the contribution of the industry partner. Intellectual Property commercialisation agreements shall be limited to fields that the commercialising partner can demonstrate their ability to exploit the RCSI Intellectual Property in and always provide for RCSI's retention of rights to use the Intellectual Property in question for internal non-commercial research and educational purposes. Subject to field and exclusivity, the commercialising partner shall be expected to cover future patent costs. In all cases, commercial exploitation shall be in line with Ireland's National IP Protocol 2019 or subsequent revisions.

RCSI is cognisant of the importance of careful management of its IP portfolio and associated costs; decisions relating to the filing and management of RCSI IP are made in accordance with the process outlined in Appendix IV and detailed in Innovation SOP. No 7 IDF Triage, No. 8 Market Research and TT Guideline 3, discontinuation of IP. In the event that the ORI decides not to commercialise or otherwise use or exploit RCSI Intellectual Property, it may, subject to any existing third party agreements, and at its sole discretion, assign such Intellectual Property, on request, to the lead PI Inventor/Creator who shall then become responsible for the management and commercialisation of such Intellectual Property and for the payment of associated Intellectual Property protection costs (if applicable). Such decision may happen prior to patent filing, if patent protection is appropriate, after patent filing or at any stage in the patent prosecution process. In return, the

lead PI Inventor/Creator shall share any revenue received in the future from the commercialisation of such Intellectual Property after the deduction of reasonable vouched costs with RCSI as described below:

- Up to €200,000 revenue[^] received by Inventor/Creators: 30% to RCSI which is split 50:50 between the RCSI Research Institute and the lead PI Research Account.
- In excess of €200,000 revenue[^] received by Inventor/Creators: 50% to RCSI which is split 50:50 between the RCSI Research Institute and the lead PI Research Account.

The Lead PI Inventor shall also be responsible for revenue distribution to other inventor/creators in accordance with their respective inventive contributions.

[^] Revenue shall include royalty, milestone payments and license fees and any other associated income on licence agreements, option payments, assignment payments and revenue from the sale of any equity provided in consideration for IP access.

8. Financial Reward to Inventor/Creators

To incentivise and reward RCSI Personnel to engage in research commercialisation, any revenue obtained through commercialisation of RCSI Intellectual Property shall be shared with the relevant Inventor/Creators. Revenue from commercialisation of Intellectual Property shall include royalty, milestone payments and license fees from licence agreements, option payments, assignment payments, received by RCSI after the deduction of associated patent costs and vouched expenses, funding agency revenue share (where applicable), any revenue share with external parties and applicable taxes (“IP Commercialisation Revenue”). IP Commercialisation Revenue only includes revenue received from licensing or assigning RCSI IP to a third party and does not include revenues earned by RCSI from equity in RCSI spin-out companies, save in exceptional cases where the sole or partial consideration for the licence or assignment of RCSI IP is the grant of equity to RCSI (“Equity Consideration”). In those cases, the RCSI may decide at its sole discretion, at the time of entering into the agreement, to allocate a portion of any proceeds realised by RCSI from the disposal of Equity Consideration for distribution as IP Commercialisation Revenue in accordance with this policy.

Revenue earned by RCSI from equity in spin-out companies shall be retained by the RCSI Research Institute.

For the avoidance of doubt income from industry sponsored programmes does not fall under the definition of IP Commercialisation Revenue and the cost of the time commitment by ORI staff to support for the IP commercialisation process shall not be considered a vouchable expense.

The distribution of IP Commercialisation Revenues shall be as follows:

- Up to €100,000 IP Commercialisation Revenue: 75% to Inventor/Creators; 15% to PI Research Account ; 10% to RCSI Research Institute
- Greater than €100,000 and up to €500,000 IP Commercialisation Revenue: 50% to Inventor/Creators; 25% to PI Research Account; 25% to RCSI Research Institute
- In excess of €500,000 IP Commercialisation Revenue: 33.3% to Inventor/Creators; 33.3% to PI Research Account; 33.3% to RCSI Research Institute

In the case of multiple Inventors/Creators, the disbursement of IP Commercialisation Revenue among individual Inventor/Creators shall be accordance with the inventive contribution noted in the IDF or inventor share agreement on record at the ORI. Any dispute between one or more of the Inventor/Creators or persons who claim to be Inventor/Creators shall be resolved in accordance with Section 14.

The IP Commercialisation Revenue sharing approach outlined above shall continue to apply after any Creator/Inventor leaves RCSI for other employment or due to retirement. In the case of a retired Creator/Inventor, they will be eligible to receive funds to a research account for spending at RCSI if they have an emeritus position with RCSI, if not it will be retained by the RCSI Research Institute.

Disbursement of IP Commercialisation Revenues to Inventors/Creators shall be subject to the following conditions:

- Payment of IP Commercialisation Revenues to Inventor/Creators will be through RCSI payroll and subject to income tax at source.
- Disbursement of IP Commercialisation Revenues shall be within 6 weeks of RCSI receiving such IP Commercialisation Revenue.
- If the Inventor/Creators concerned do not agree on a proportionate inventive contribution within a reasonable time period then RCSI will be entitled to allocate the IP Commercialisation Revenues in such proportions as it may, in its sole and absolute discretion, deem appropriate.
- It will be the responsibility of each Inventor/Creator (or their representative) to provide contact details to RCSI ORI from time to time so that RCSI can maintain contact with those who have left RCSI and, if necessary, make contact with the estate of any creator who has died. RCSI will make reasonable efforts to contact Inventor/Creators using the contact details on file. If RCSI cannot make contact over six months, RCSI will send notice to the last known address. If no contact details are received within one year after such notice has been sent, RCSI will retain that Inventor/Creator's share and any entitlements to distribution for that Inventor/Creator shall lapse.

9. Research Contracts with Industry

Engagement and collaboration with industry is a key focus of the RCSI Strategy. RCSI Personnel are encouraged to perform collaborative and fully funded research with industry partners. The ORI provides support to RCSI Personnel in the form of business development and contract negotiation expertise.

All research and consultancy agreements with industry must be reviewed by the ORI. **Agreements must be executed by an authorised signatory of RCSI; research and academic staff are not authorised to sign agreements of this kind.** The procedure governing research contracts with industry is described in TT guideline # 2 *Contract and Collaborative Research With Industry*, available on the RCSI staff portal and in the RCSI Researcher Handbook, which includes a list of authorised signatories.

All agreements entered into by RCSI will be aligned with the principles of *Ireland's National IP Protocol 2019 – A Framework for Successful Research Commercialisation* or subsequent version.

10. Personal Consultancy

RCSI Personnel wishing to engage in consultancy work with external parties are encouraged to do so in their capacity as an RCSI employee. Should RCSI staff wish to perform consultancy work in a personal capacity they should seek the approval of their Head of Department/Unit/School (and PI in the case of postdoctoral researchers) and must under no circumstances use RCSI's reputation and resources for personal financial gain.

The RCSI policy on consultancy is further described in TT Guideline # 1 *Consultancy*. Any potential conflict of interest must be disclosed in line with the RCSI Conflict of Interest Policy.

11. External Engagement and the RCSI Brand

RCSI values its brand and seeks to prevent its use by third parties in a way that may damage the reputation of the organisation. The RCSI corporate identity/logo and naming conventions are the property of Royal College of Surgeons in Ireland. Any individual or organisation seeking to use the RCSI corporate identity must first receive the written permission of RCSI. This permission must be sought through the Communications or Design departments and from the ORI. Where permission is granted to use the RCSI identity, the user will agree to adhere to the RCSI corporate brand identity guidelines and correct artwork files, both of which will be supplied by RCSI to the third party.

12. Publication and Confidentiality

Subject to contractual obligations in agreements with third parties and in compliance with relevant funding agency terms and conditions, RCSI Personnel have the freedom to publish the results of their research as they see fit. Compliance with confidentiality and publication clauses in agreements with third parties is of the utmost importance and RCSI Personnel shall be responsible of ensuring that any proposed publication is not in breach of agreements entered into relating to their research. In the case where the grant agreement with a research sponsor (funding agency, charity or other third party) requires that intellectual property with commercial potential be protected prior to publication, RCSI Personnel shall work with the ORI to evaluate and, where appropriate, protect such intellectual property prior to publication. Notwithstanding the above, RCSI Personnel shall ensure that inventions with commercial potential are not disclosed in such a way as to affect their patentability, e.g. by premature disclosure to third parties.

13. RCSI Spin-Out Company Formation

RCSI seeks to encourage the formation of new companies in order to promote new, technology-based, job-creating enterprises in Ireland (where possible) in order to ensure that RCSI research may be transferred to the community for socio-economic benefit.

RCSI may provide support, including provision of access to laboratories and other infrastructure, to RCSI spin-out companies and may allow RCSI Personnel to organise and assist in the running of such companies in accordance with their contracts of employment. Any additional allocation of normal working time to RCSI spin-out companies should be under an appropriate services, consultancy or secondment agreement. Access to space, if required, will require approval and involve entering into a space licence agreement.

Personal equity may be allocated to RCSI academic founders by an RCSI spin-out and relates to what an individual has done to support company formation and will do for the company in the future.

In accordance with the National IP Protocol, RCSI shall take equity in the spin-out company, recognising the environment it has created in which the original idea was developed and supported.

As stated above, spin-outs are commercially high risk ventures and, as RCSI has a duty to ensure that intellectual property is developed for economic and public good, RCSI shall ensure that the intellectual property can be recovered and recycled if things do not go to plan in the future. This is to ensure that there is the maximum opportunity to make economic and societal impact from funded research programmes at RCSI. RCSI shall therefore license intellectual property to RCSI spin-out companies on formation, rather than assign.

The procedure and guidelines for setting up an RCSI spin-out company are outlined in Appendix 1 along with the following associated documents:

1. Procedures to apply for approval as an RCSI spin-out company and apply to use RCSI laboratories
2. Application form for approval as an RCSI spin-out company
3. RCSI spin-out company space request application form

Applicant companies must:

- Apply for approval by RCSI Senior Management Team (SMT) using the process described in Appendix 1. SMT approval will take into account advice given by the ORI and the RCSI Innovation Advisory Committee upon review of business plan and founders
- Issue a minimum of 10% equity in the form of ordinary share capital to RCSI. Such equity shall be dilutable at first bona fide, arm's length, investment
- Clarify the role of any RCSI Personnel in the company along with allocation of working time under consultancy, services or secondment agreement
- Negotiate a license agreement for access to RCSI Intellectual Property
- Incorporate at Companies Registration Office (the timing of company incorporation may vary, however in all cases it shall be subject to approval from the ORI)

- Apply for access to space, if required, as described in Appendix 1 and enter into a licence agreement to facilitate access to such space.

RCSI Personnel involved in RCSI spin-out Companies must:

- Declare perceived or actual conflict of interest and comply with all relevant RCSI policies including the Conflict of Interest Policy.
- Obtain prior written approval of their line manager to be a director in the company and ensure that they have appropriate insurance to cover any potential liability

The time scale for RCSI spin-out company approval is eight weeks from the submission of a completed application form.

Social enterprises, for example not for profit companies limited by guarantee, while not for profit in nature and structured differently, are subject to the RCSI spin-out company approval process, which will be tailored to suit the nature of the enterprise.

Existing opportunities/entities may wish to engage with RCSI to access RCSI facilities to support intellectual property development (RCSI spin-in opportunities) RCSI spin-in opportunities shall be governed by the RCSI Spin-In Guidelines and disbursement of IP Commercialisation Revenue shall be as outlined in this policy.

Equity management is performed by ORI in conjunction with the Director of Finance and the Deputy Vice Chancellor for Research and Innovation. RCSI will have absolute discretion in the disposal of any shares or equity interest held in a company or any income derived therefrom. On an annual basis a review of RCSI's equity holding in spin-out companies will be performed with RCSI Finance, aligned with the preparation of annual financial statements. Management of equity, including decision making on the sale of RCSI equity will take into account feedback from RCSI Finance, the ORI and the RCSI Innovation Advisory Committee.

14. Derogation and Dispute Resolution

Implementation of this policy is the responsibility of the ORI headed by the Deputy Vice Chancellor for Research and Innovation. Day to day activity under the policy is managed by the Head of Innovation. Requests for specific derogation from this policy shall be addressed to the Head of Innovation in the first instance and subsequently to the Deputy Vice Chancellor for Research and Innovation. The Deputy Vice Chancellor for Research and Innovation may at their discretion consult the RCSI Innovation Advisory Committee and /or the Research Strategy Committee and RCSI SMT in relation to any derogation request.

Disputes under the policy shall be addressed to the Deputy Vice Chancellor for Research and Innovation and shall be brought to the RCSI Innovation Advisory Committee for input (terms of Reference described in Appendix III).

This Committee will seek in good faith, through the Deputy Vice Chancellor for Research and Innovation, to amicably and promptly resolve the dispute within Thirty (30) days of the dispute being referred to them or such other later date as may be agreed between the Parties in writing.

If this interaction does not successfully resolve the dispute then the parties agree to refer the matter to mediation. To initiate mediation a party will give notice in writing (a “**Mediation Notice**”) to the other party requesting mediation of the dispute. Unless otherwise agreed in writing between the parties:

- a. The mediator shall be nominated at the request of either party by the International Centre for Dispute Resolution in accordance with the rules of ICDR and the mediation shall be conducted in accordance with the Model Mediation Procedure of the ICDR, in each case being the relevant rules for the time being and from time to time in force ;
- b. The costs of the mediator shall be borne and discharged equally between the parties but the costs of all experts and any other third parties who, at the request of any party, shall have been instructed in the mediation, shall be for the sole account of, and shall be discharged by, that Party;
- c. The mediation shall be conducted in Dublin, Ireland, at a venue agreed upon by the Parties and the mediator or, failing such agreement, at a venue selected by the mediator in his/her discretion;
- d. The mediation shall commence not later than twenty (20) working days following a request for mediation being made in accordance with the provisions above;
- e. The Parties will co-operate with any person appointed as mediator providing him/her with such information and other assistance as he/she shall require.

15. Intellectual Property of Others

The use of any third party Intellectual Property, including the copying and reproduction of such third party Intellectual Property, must be lawful or within the terms of any applicable licence. If any RCSI Personnel is unsure as to what use can be made of any particular Intellectual Property, then they should seek advice from the ORI.

RCSI recognises that Intellectual Property may be created using Open Source materials and in particular using Open Source Software (OSS). Open Source materials are those materials which may be used without payment of a fee and may be distributed and reproduced without a fee. OSS is defined according to the definition used by the Open Source Initiative and found at <https://opensource.org/osd>. Open Source materials and OSS are usually subject to licensing arrangements. RCSI respects the need to ensure compliance with legal obligations in licence agreements when using Open Source materials or OSS. When considering commercialisation of research generated using OSS, RCSI Personnel should consult with the ORI. Specifically, inclusion of OSS in industry funded research should be considered in advance of doing so.

16. Conflict of Interest

RCSI grants the right to exploit its Intellectual Property to commercial entities and receives income and/or equity as a result of these activities thus raising the possibility of conflict of interest for RCSI Personnel. It is the responsibility of RCSI Personnel to identify and declare any potential, perceived or actual conflicts of interest, whether financial, personal, ethical, legal, or other, so that this does not become a complicating or actionable issue, and to comply with RCSI's policies on intellectual property, conflict of interest, consultancy and external work.

Specifically relevant to this policy, such conflicts may arise relating to research or research funding, Intellectual Property, industry engagement or spin-out creation and should be disclosed in accordance with the RCSI Conflict of Interest Policy. [available [here](#)]

Conflicts of interest that may arise in connection with intellectual property commercialisation include, but are not limited to, the following:

- An individual using their position to:
 - influence a contract or other favourable terms for a company in which they, or a relative or friend, had a financial interest
 - obtain financial or non-financial benefits for themselves or for a relative or friend in return for providing advantage, or potential advantage.
 - use RCSI resources or confidential information for personal financial or nonfinancial benefit or benefit to a relative or friend.
- Conducting business, employment or activity outside of RCSI, which adversely affects the individual's ability to perform their duties.
- An individual compromising research objectivity or independence in return for financial or non-financial benefit for them or for a relative or friend.

Examples of these kinds of conflicts include:

- A researcher having a financial interest in the company sponsoring research, this being exacerbated if the value of the researcher's interest may be affected by the outcome of the research.
- An individual is an inventor of patents or creator of other IP whose value may be affected by the outcome of research in which they are involved.
- An individual holds a position in an enterprise (e.g. as director) that may wish to restrict (or otherwise manage) adverse research findings for commercial reasons or not wish to publish the results of the research.
- An individual having a financial interest or other personal interest in a spin-out or may have personal IP with which they are intending to create a start-up company.
- An individual having a financial interest in the licensee (or proposed licensee) of RCSI intellectual property.
- An individual taking part in the negotiation of a contract between RCSI and a company, where the individual or their family or a close personal friend has a financial or non-financial interest (e.g. a directorship) in that company.

17.Data Protection

ORI use of Personal Data

- The ORI may process Personal Data (as defined in the General Data Protection Regulation EU 2016/679, Article 4 (1) from time to time from Staff, Students and/or Visitors in order to implement the regulations set out in this IP Policy.
- Any Personal Data is processed by the ORI in accordance with the General Data Protection Regulation (GDPR) (EU) and the Data Protection Acts, 1988-2018. Personal data may be required for the following purposes, which are non-exhaustive:
 - filing patent applications or other such intellectual property filings;
 - disbursing future revenue to Inventors/Contributors;
 - carrying out commercial and patentability due diligence on disclosed inventions;
 - abiding by RCSI Policies

Use of Personal Data for RCSI Research

- RCSI Personnel should at all times ensure compliance data protection legislation. The relevant legislation is set out in Appendix 1 to this Policy.

RCSI Personnel should also ensure compliance with the RCSI Researcher Handbook and RCSI's Data Protection Policy when processing any Personal Data during their employment or studies.

Appendix I Legislation and National Policy.

Irish Statute Law relating to Intellectual Property

The Patents Act 1992

The act states that if an Inventor/Creator is an employee, the right to the patent shall be determined in accordance with the law of the state in which the employee is wholly or mainly employed.

Note: However, in Ireland, the Common Law principle is that the employer will own the product of the work of an employee in the course of employment.

Copyright and Related Rights Act 2000

The act provides that the employer will be the first owner of any copyright in work made by an employee in the course of employment, subject to any agreement to the contrary.

The act provides that the employer shall be regarded as the maker of any database made by an employee in the course of employment, subject to any agreement to the contrary.

Software is defined as Literary Work for the purposes of this act.

Data Protection

The main Irish law dealing with data protection is the Data Protection Act 1988 and Data Protection Act, 2018. The 1988 Act was amended by the Data Protection (Amendment) Act 2003, bringing Irish law into line with the EU Data Protection Directive 95/46/EC. The General Data Protection Regulation (GDPR) enforced on 25 May 2018, replaced the existing data protection framework under the EU Data Protection Directive. The Data Protection Act, 2018 gives further effect to Directive (EU) 2016/680.

State Aid Legislation

State Aid refers to forms of public assistance, using taxpayer-funded resources, given to undertakings on a discretionary basis, with the potential to distort competition and affect trade between member states of the European Union. State aid is banned because of its anti-competitive effects. However, various schemes are approved as their positive effects are considered to outweigh their negative impact, for example to promote regional development or Research, Development and Innovation (RDI) in Industry.

National IP Protocol

Ireland's National IP Protocol 2019 – A Framework for Successful Research Commercialisation
Policies and resources to help industry and entrepreneurs make good use of public research in Ireland

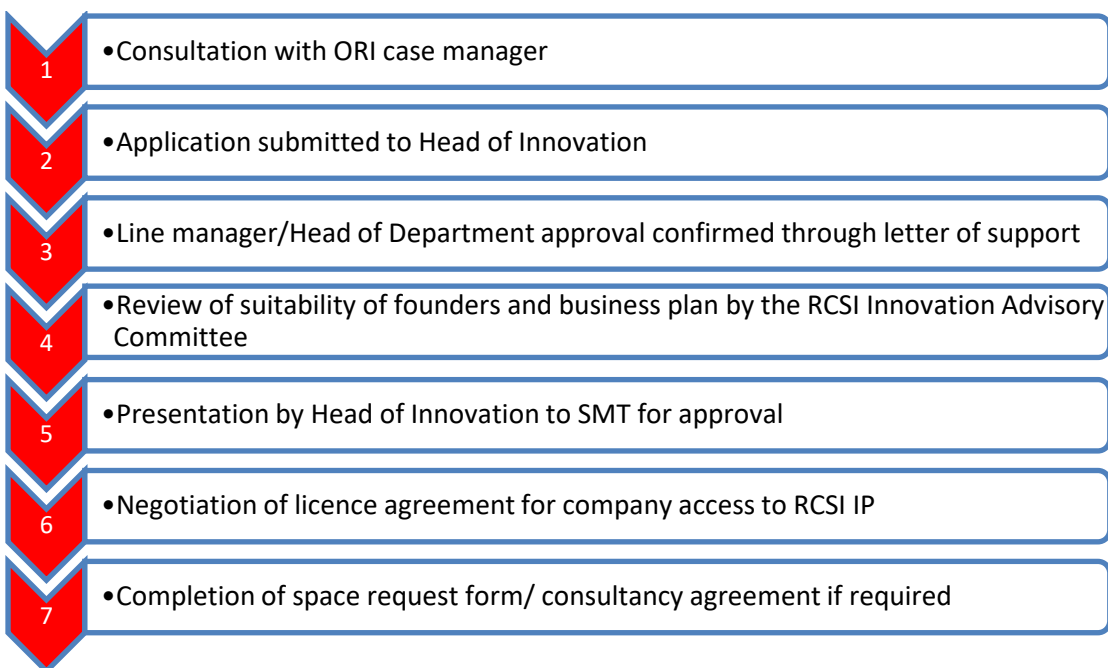
<https://www.knowledgetransferireland.com/ManagingIP/National-IP-Protocol/>

Appendix II RCSI Spin-Out Company Approval Process and Application Forms.

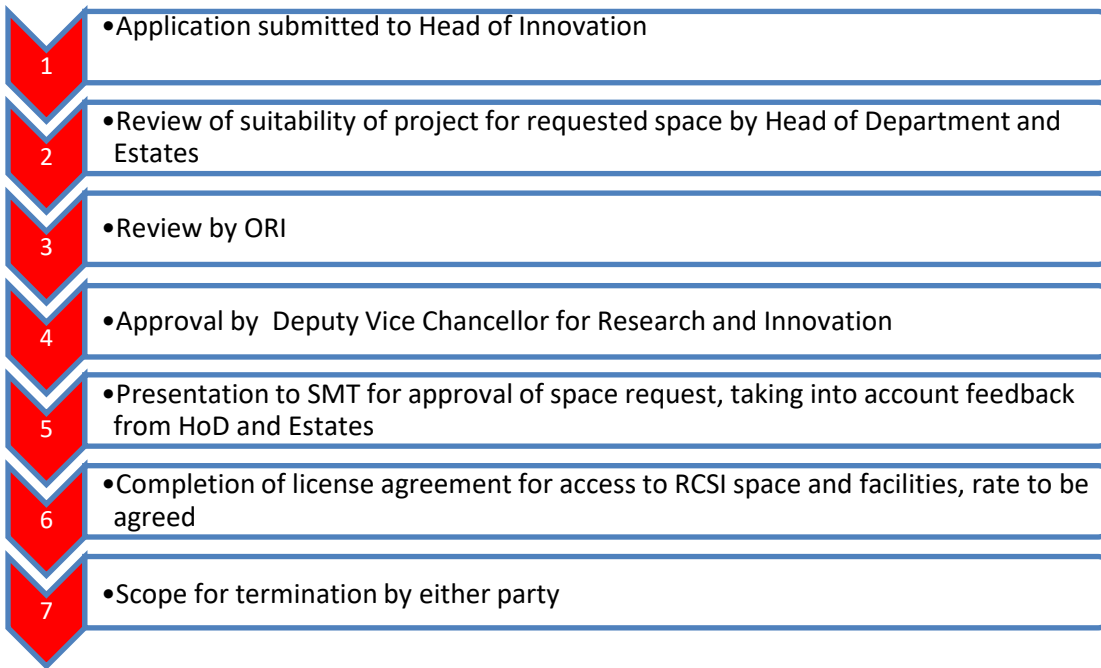
The aim of this procedure is to:

- Set guidelines in establishing an RCSI spin-out company
- Establish the rules governing the conduct of business between any RCSI spin-out company and RCSI
- Prevent activities or practices that may be prejudicial to both RCSI, and its reputation as an academic institution, and to the employee(s).
- Ensure compliance with research funding terms and conditions

RCSI Spin-Out Company Approval Process:



RCSI Spin-Out Company Space Approval Process



RCSI Spin-Out Company Application Form

1. Promoters names and contact details:

Please copy as required

| | |
|--|--|
| Name: | |
| Address: | |
| Contact Phone number: | |
| Email address: | |
| A CV must be included, please indicate if attached | |

2. Shareholding

| Name of Share Holder | Existing Shareholding | Proposed Shareholding |
|----------------------|-----------------------|-----------------------|
| | | |
| | | |

3. Management team and contact details:

Please copy as required

| | |
|--|--|
| Name: | |
| Address: | |
| Contact Phone number: | |
| Email address: | |
| A CV must be included, please indicate if attached | |

4. RCSI Spin-Out Company name and objectives

| |
|---|
| Proposed Name: Address if available: Key objectives: |
|---|

5. Business plan

| |
|--|
| A business plan must be appended to this application including initial funding sources for the company |
|--|

6. Intellectual Property

Outline intellectual property owned by RCSI to be licensed by the company, and how it will be used:

7. Role of RCSI Promoters

Please outline the role of the RCSI promoters in the company (if any), and how this will be managed

8. Other RCSI Assets

Please outline other RCSI assets that may be required, eg expertise, space, equipment, services

9. Head of Department/line manager support

A letter of support must be provided by the relevant head of department/line manager indicating:

- The role of the company
- Description of and support for the role of the RCSI promoter if any
- Proposed time to be spent working in the company

Please append

10. Government agency support

Please give details of any government agency support sought or provided

Declaration

I declare that the information provided by me in this application is accurate and true to the best of my knowledge and belief.

I agree that I will promptly declare to RCSI any potential conflict of interest which may arise as a result of my involvement with the RCSI spin-out company.

I agree to abide by all relevant RCSI policy including but not limited to the Conflict of Interest policy, Good Research Practice policy and Intellectual Property policy and the RCSI Consultancy Guidelines

Signed on behalf of **RCSI promoter**:

Name:

Title:

Date:

I declare that the information provided by me in this application is accurate and true to the best of my knowledge and belief.

Signed on behalf of **External promoter**:

Name:

Title:

Date:

Please return a completed electronic copy to:

Dr. Aoife Gallagher

RCSI Office of Research and Innovation

111 St Stephen's Green

Dublin 2.

Aoife.gallagher@rcsi.ie

For internal use only

RCSI Head of Department/line manager comments

| |
|--|
| |
|--|

RCSI Spin-Out Company Space Request Form

1. Company name and contact details:

2. Research focus/planned activity (detailed description required)

3. Resources required eg space, facilities, equipment

4. Duration of space request

5. Value of proposed engagement to RCSI

6. Known health and safety issues and mitigation strategy

7. Company insurance status

8. Project funding

Is the source of funding for the project compliant with RCSI's policy on good research practice?
Yes/No

Declaration

I declare that the information provided by me in this application is accurate and true to the best of my knowledge and belief.

Signed on behalf of **Company** Ltd:

Name:

Title:

Date:

Please return a completed electronic copy to:

Dr. Aoife Gallagher

RCSI Office of Research and Innovation

111 St Stephen's Green

Dublin 2.

Aoife.gallagher@rcsi.ie

For internal use only

RCSI Head of Department comments

Please consider the following in your response:

- Is suitable space available?
- Are there other implications for the department?
- Are there any health and safety concerns?

RCSI Estates comments

Please consider the following in your response:

- Is suitable space available?
- Are there other implications?
- Are there any health and safety concerns?

Appendix III RCSI Innovation Advisory Committee Terms of Reference.

The terms of reference for the committee are as follows:

- Review proposed commercialisation deals for conflict of interest and market rates
- Advise on and approve changes in the RCSI IP policy
- Provide escalation path for disputes relating to implementation of the IP policy
- Review and guide the development of formal process procedures
- Support decision making on the IP portfolio
- Advise on value creation for commercialisation of research
- Advise on how best to support RCSI spin-out company formation
- Provide oversight on the patent budget
- Provide awareness on external trends and challenges in industry academic collaborations
- Assist in the identification of opportunities for strategic partnership with Industry
- Act as external champions for RCSI industry engagement activities
- Provide access to valuable networks and act a door openers
- Ensure continuous improvement of innovation activities

Provision is made for recusal in the case of perceived or actual conflict of interest.

Appendix IV Decision Making Fora.

| Implementation Forum | Attendees | Frequency | Terms of Reference |
|------------------------------------|---|-------------|---|
| Commercialisation Meeting | Innovation Team | Bi-Weekly | <ul style="list-style-type: none"> • IDF Triage • Opportunity Pipeline review • Patent Portfolio and budget Review • Patent Go/No Go decisions • Industry Collaborations • Spin-out Pipeline review |
| Innovation Meeting | Innovation Team + Deputy Vice Chancellor for Research and Innovation | Monthly | <ul style="list-style-type: none"> • Review of progress against KPIs • Spin-out approval |
| RCSI Senior Management Team | Deputy Vice Chancellor for + Head of Innovation | As required | <ul style="list-style-type: none"> • Spin-out approval |
| RCSI Innovation Advisory Committee | Innovation Team + Deputy Vice Chancellor for Research and Innovation Advisory Board | Bi-annually | <ul style="list-style-type: none"> • See appendix III above |