

Intellectual property and data sharing policy

1 Mission statement

- 1.1 Coeliac UK's core mission is to improve the lives of people living without gluten. By investing in research into the nature and effects of gluten, we hope one day to overcome coeliac disease.
- 1.2 As a charity, Coeliac UK is under an obligation to ensure that the useful results of research that it funds (whether in whole or in part) are applied for the public good. In some circumstances, this obligation may be best achieved through the protection of intellectual property (IP) and commercial exploitation.
- 1.3 Coeliac UK recognises that intellectual property protection (patenting in particular) is a valuable tool to provide incentives for the translation of research results into products that benefit public health. To achieve its aims, Coeliac UK believes that intellectual property issues must be approached carefully in light of individual circumstances.
- 1.4 This policy provides guidance on the ownership, disclosure, protection and exploitation of any form of IP generated during the course of Coeliac UK funded research so as to make this available for public benefit.

2 Definition of intellectual property

- 2.1 **'Intellectual Property'** means inventions, technologies, developments, improvements, materials, compounds, processes and all other research results and tangible research properties, including software and other copyrighted works, for example inventions, discoveries, materials, technologies, products, data (e.g. clinical trial data), algorithms, software.
- 2.2 **"Intellectual Property Rights" (IP Rights)** means entitlement, ownership and associated rights relating to intellectual property, including patents, rights in utility models, plant breeders rights, rights in designs, trademarks, topography rights, know-how, trade secrets and all other intellectual or industrial property rights as well as copyrights, either registered or unregistered and including applications or rights to apply for them and together with all extensions and renewals of them, and in each and every case all rights or forms of protection in the UK or having equivalent or similar effect anywhere in the world.

2.3 Ownership

Coeliac UK recognises that, in most cases, the recipients of Coeliac UK funding will be employees of an institution, and as a result, ownership of Coeliac UK funded IP and ensuing IPRs, will rest with the institution. However, as Coeliac UK funds research for the public good, Coeliac UK retains its right to ensure the Coeliac UK funded IP is managed appropriately, and is exploited for the public good. Coeliac UK will support the recipient institution to manage Coeliac UK funded IP, according to the terms of the funding agreement, on a case-by-case basis.

Coeliac UK requires that the institution must have procedures in place for the

identification, protection, management and exploitation of Coeliac UK funded IP. To this end, the institution must indicate at the time of application what provisions are in place for meeting Coeliac UK's IP and data sharing policy.

2.4 **Data sharing**

Coeliac UK wishes to ensure that data arising from the research that it funds should be managed and made available as widely and freely as possible to maximise public benefit. Such data must be shared in a timely and responsible manner and researchers who are providing and receiving data are required to adhere to any relevant regulatory requirements including those relating to the ethical use of data.

A limited period, defined in consultation with the lead applicant, of exclusive use of data for primary research is reasonable, according to the nature and value of the data and the way they are generated and used. Ongoing research contributing to the completion of datasets must not be compromised by premature or opportunistic sharing and analysis. Sharing should always take account of enhancing the long term value of the data.

Coeliac UK's data sharing policy is not intended to discourage filing of patent applications and recognises the need to safeguard intellectual property, to protect opportunities for commercialisation of research outputs and respect obligations of commercial confidentiality, and that it may be necessary on occasion to delay publication or restrict the release of data.

Coeliac UK believes that data generators and sharers should receive full and appropriate recognition (eg by acknowledged collaboration and/or citation) by funders, their academic institutions and new users for promoting secondary research. To acknowledge appropriate recognition of data generators and sharers, and allow appropriate citation of datasets, we encourage researchers to use persistent identifiers such as Digital Object Identifiers (DOIs) and ORCID identifiers.

For medical research involving personal data, the appropriate regulatory permissions - ethical, legal and institutional - must be in place before the data can be shared.

Data arising from Coeliac UK funded research should be properly curated throughout its life cycle and released with the appropriate high quality metadata. This is the responsibility of the data custodians, who are usually those individuals or institutes that received Coeliac UK funding to create or collect the data.

This data sharing and preservation policy applies to all Coeliac UK funded research while recognising that different fields of study will require different approaches. It does not prescribe when or how researchers should preserve and share data but requires them to make clear provision for doing so when planning and executing their research.

All Coeliac UK grant awardees are expected to make every effort to ensure that new studies that result from data sharing should meet the high standards of all Coeliac UK funded research regarding scientific quality, ethical requirements and value for money; new studies should also add recognisable value to the original dataset. Such research is often most fruitful when it is a collaboration between the new user and the original data creators or curators, with the responsibilities

and rights of all parties agreed at the outset.

2.5 **Copyright**

Coeliac UK will, in general, refrain from claiming ownership of copyright in published academic works (not for profit), such as journal articles, theses, reports, conference papers, presentations and proceedings, posters, books, textbooks, and book chapters, provided that Coeliac UK has been suitably acknowledged in such works and subject to the right of Coeliac UK to have free, non exclusive use of such materials indefinitely within the limits of any publication restrictions.

3 Patents and applications for patents

3.1 **Coeliac UK's position on patents**

Coeliac UK believes that protecting IP by filing applications for patent protection, and maintaining granted patents, can be in the public interest.

Coeliac UK sees, for example, the following situations for pursuing patent protection:

- to prevent commercial organisations obtaining an unfair market position detrimental to people with coeliac disease.
- to underpin commercial activities to foster and support emerging therapies arising from Coeliac UK funded research
- to generate income from licensing, which income can be invested to fund further research

3.2 **Patent ownership**

As provided for above under "IP Ownership", Coeliac UK requires the recipient institution to have an IP management plan.

Prior to receiving Coeliac UK funds, it is required that the recipient institution has an agreement in place regarding inventorship rights. For example, the recipient institution should ensure all persons in receipt of Coeliac UK funding or working on a Coeliac UK funded activity (including employees, students, visiting staff and subcontractors) are employed or retained on terms that stipulate to whom the inventorship rights, and the right to file a patent application, are vested.

In many cases, it is foreseen that the Coeliac UK funded IP rights will primarily rest with the recipient institution. Coeliac UK has an interest in ensuring that the Coeliac UK funded IP, and ensuing rights, are managed in the interests of the goals and aims of Coeliac UK, and to this end Coeliac UK and the recipient institution will agree to terms for ownership, management and exploitation of patents and patent applications on a case-by-case.

In certain circumstances, Coeliac UK will itself act as sole- or co-owner of Coeliac UK funded IP rights. Cases will be evaluated individually, with Coeliac UK adopting an ownership position which best suits the goals and aims of Coeliac UK.

3.3 **Notification and monitoring**

Coeliac UK believes in actively monitoring Coeliac funded IP to ensure Coeliac UK meets its goals and aims.

Coeliac UK must be informed, at the earliest opportunity of any intended or possible publication, public dissemination, or invention disclosure relating to Coeliac UK funded IP so that Coeliac UK can be actively involved in the decision making process regarding whether or not to publish or patent the Coeliac UK funded IP.

Unless otherwise agreed, the recipient institution should notify Coeliac UK promptly in writing when IP arises from the funding and should take reasonable steps to ensure that such IP is "is maintained in a confidential condition and not published or otherwise disclosed publicly prior to protection (whilst at the same time ensuring that potential delays in publication are minimised).

3.4 **Permission to exploit**

If the institution decides not to protect, manage, or exploit any Coeliac UK funded IP arising out of the grant then Coeliac UK retains the right to protect, manage or exploit such IP, when this is in the best interest of the Coeliac UK and its members.

3.5 **Exploitation**

Coeliac UK recognises that the Coeliac UK funds will most often be one of several funding sources that leads to the creation of Coeliac funded IP. Accordingly, if Coeliac UK is not the sole funder it is the responsibility of the recipient institution to identify the inventive contribution of the inventors and the proportionate funding contributions of the funders. In the event that the recipient institution does not have the expertise to assess and assign inventorship, the recipient institution must ensure that an appropriately qualified individual or organisation is engaged to conduct such assessment. Revenues and royalties should be distributed accordingly.

It is also the responsibility of the recipient institution to reward inventors of IP from the revenue share according to its own policies and practice.

Similarly, the recipient institution and its technology transfer office or company should agree how to share between themselves any technology transfer fees or shares of net income and/or equity due to either or both of them.

As a condition of granting consent, Coeliac UK will require the institution to accept standard revenue and equity sharing terms of Coeliac UK, as provided for in the IP agreement to be signed on a case-by-case basis with the respective recipient institution.

The recipient institution, grant holders and co-applicants should inform Coeliac UK of any pre-existing arrangements of which they are aware and which could lead to a breach of the 'Coeliac UK' standard conditions.

The recipient institution should make reasonable endeavours to ensure that no consultancies, third party restrictions or arrangements which might impact on a Coeliac UK funded grant are entered into in relation to any Coeliac UK funded person or activity without prior agreement of the charity. Coeliac UK funded investigators or individuals involved in a Coeliac UK funded project should not use materials or compounds (other than those obtained commercially), on terms which would place restrictions on the publication of the results. Recipient institutions should make reasonable endeavours to ensure that 'reach through rights' have not been granted on any Coeliac UK funded IP in favour of

commercial organisations providing materials or compounds to charity funded individuals for research purposes.

However, Coeliac UK recognises that companies providing materials may often require exclusive rights to any intellectual property arising from use of that material, and that this requirement is often non negotiable. Where intellectual property arises from research linked indirectly to the use of material provided under such agreement, the provider should be offered a time limited opportunity to take out a revenue generating licence.

Glossary

“Assignment” means an assignment where one party transfers its ownership of the IP to another. The benefit of using an assignment is that the charity can seek a payment there and then and will not be responsible for the future costs of registering, protecting, developing and commercialising the IP. Further payments can be agreed for the future.

“Background IP” means information, techniques, know how, software and materials (regardless of the form or medium in which they are disclosed or stored) that was in existence before the research project began, and on which the research project was based.

“Charity” means Coeliac UK, a Charity registered in England and Wales 1048167 and in Scotland SC039804 and a company limited by guarantee in England and Wales, details of which are set out above.

“Charity funded IP” or “Coeliac UK funded IP” means any and all intellectual property which is or has been created, exemplified or developed (whether in whole or in part) using the grant, whether such grant funds are used before or after an invention disclosure or patent filing, and whether or not any person in receipt of Charity funding or working on a Charity funded activity is named in invention disclosure records.

“Collaborative venture” means, the formation of a spin out company but it could also cover, for example, a joint venture or a new charitable organisation focused on a particular aspect of the IP. Whatever form the collaborative venture takes, the assumption is that it will involve the charity in working closely with another party and that it is likely to be built around an independent legal entity that is owned and run by the charity and the collaborating party.

“Copyright” Copyright protects written, theatrical, musical and artistic works as well as film, book layouts, sound recordings, and broadcasts. Copyright is an automatic right and does not require a formal application or registration.

“Data sharing” means the dissemination of research results arising from Coeliac UK funding.

‘Intellectual Property’ means inventions, technologies, developments, improvements, materials, compounds, processes and all other research results and tangible research properties, including software and other copyrighted works, for example inventions, discoveries, materials, technologies, products, data (e.g. clinical trial data), algorithms, software.

“Intellectual Property Rights” (IP Rights) means entitlement, ownership and associated rights relating to intellectual property, including patents, rights in utility

models, plant breeders rights, rights in designs, trademarks, topography rights, know how, trade secrets and all other intellectual or industrial property rights as well as copyrights, either registered or unregistered and including applications or rights to apply for them and together with all extensions and renewals of them, and in each and every case all rights or forms of protection in the UK or having equivalent or similar effect anywhere in the world.

“Licence, licensing agreement” means the agreement that one party retains ownership of the IP and authorises another party to make use of the IP on defined terms.

“Material transfer agreement (MTA)” means an agreement that governs the transfer of one or more materials from the owner (or authorised licensee) (‘the provider’) to a third party (‘the recipient’) who may wish to use the material for research purposes. Materials may include cultures, cell lines, plasmids, nucleotides, proteins, bacteria, transgenic animals, pharmaceuticals, other chemicals, alloys and other materials with scientific or commercial value.

“Patent” means an intellectual property right for an invention that is granted by government to the inventor/owner, giving the owner the right to stop others, for a limited period, from making, using or selling the invention without their permission. A patent is an object of property, which like any other form of property or business asset can be bought, sold, rented or hired. Patents are territorial rights: a UK patent will only give the holder rights in the UK and rights to stop others from importing the patented products into the UK.

“Recipient institution” means the institution, for example university, hospital or research body, or company that receives Coeliac UK funding.

“Revenue share” means an agreement regarding a contractual obligation to divide any revenue arising in a pre-arranged manner.

“Technology transfer” means the taking of fundamental scientific discoveries and turning them into marketable products so that the general public at large can benefit from the research as quickly and efficiently as possible.