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OpenPlant Fund Application

Name of Primary Applicant:

Dr Kathy Liddell – Director, Centre for Law, Medicine and Life Sciences, Faculty of Law Other positions held:

University Senior Lecturer in Law, University of Cambridge Deputy Director, Centre for Intellectual Property and Information Law, Law Faculty

Email address:

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Collaborators:

Dr Robert Doubleday - Director, Centre for Science and Policy (CSaP)

Dr Nicola Patron - Synthetic Biology Lead, The Sainsbury Laboratory Norwich.
Other positions held:
2015 SynBioLEAP Fellow

Additional Collaborator (to be confirmed):

Dr John Bradley – Director, NIHR Biomedical Research Centre
Other positions held:
Department of Medicine, Clinical School, University of Cambridge

Title:

RESPONSIBLE INNOVATION AND OPEN INNOVATION WITH LARGE BIORESOURCES: GOALS, CHALLENGES AND PROPOSALS

Secondary title:

Intellectual property issues for large-scale publicly-funded bioresources

The Idea:

This project will host a practical and highly-regarded Workshop in Winter/Spring 2016, that

- (1) elicits information, positions and ideas about IP licensing practices for large synbio and genomic bioresources including Biobricks and the 100,000 Genome Project;
- (2) identifies opportunities for policy impact.

The proposed Workshop would also help create a network and platform for on-going inter-disciplinary collaboration between the partner institutions (Faculty of Law, OpenPlant and TSL; CSaP and NIHR Biomedical Research Centre), and engagement with government and industry in the SynBio policy area.

Particular issues include:

- (i) current and emerging IP licensing practices for large genomic bioresources for example, BioBrick and 100,000 Genome Project
- (ii) the latest research findings about these licensing practices, and
- (iii) policy debates concerning whether and to what extent policies of "open science" and "open innovation" are appropriate for the bioresources in plant synthetic biology and genomic medicine.

An original aspect of this project is to bring together two areas of intellectual property expertise: synthetic biology and genomic medicine. These are two areas where responsible, effective innovation policy is crucial if cutting edge science is to have a real-world effect. An overarching question for both fields is how to promote fundamental scientific discoveries, and the development of knowledge resources alongside private investment in technological applications and commercialization? Both fields also share the common feature of extensive investment in large-scale publicly funded bioresources: for example BioBrick, the Structural Genome Project, and the 100,000 Genome Project.

Some of the specific questions that will be addressed by the workshop are:

- (1) What Terms and Conditions should be stipulated in the IP and access policies of large-scale public bioresources in order to realise their goals (e.g. extensive/appropriate utilisation of the resources; appropriate openness; public benefit)?
- (2) What does it mean for SynBio and genomic biobank technology platforms and resources to be 'open'?
 - a. How could that be implemented in a legal framework wherein some forms of IP protection can arise automatically without registration (eg copyright, database rights)?
 - b. How could/should the benefits of openness be integrated with policies to support upstream and downstream investment and commercialisation?
 - c. Could/should fees be levied to sustain the 'open' platforms (which otherwise often require upfront and ongoing public or charitable investment)?
 - d. Should access be restricted by contractual conditions of what kind? Should the conditions differentiate between research and non-research usages; commercial and public sector organisations; large and SME industry involvement?
- (3) What can prior experience with 'openness' and emerging technology teach us (eg software development (Linux); human genome sequencing; creative commons licensing)?
- (4) What policies are in place or needed to support an international platform of (relatively) opensource biotechnologies, which are readily available for research and commercial development without undue hindrances from IP protection and contractual limitations?

Who we are:

(1) Centre for Law, Medicine and Life Sciences (Dr Kathy Liddell)

The lead applicant, **Dr Kathy Liddell**, is the Herschel Smith Senior Lecturer for Intellectual Property in the Faculty of Law at the University of Cambridge. She is the Director of the recently established Centre for Law, Medicine and Life Sciences (LML) and Deputy Director for the Centre for Intellectual Property and Information Law. Kathy recently organized a workshop and Report on intellectual property issues surrounding the translation of basic genomic correlations into clinically-useful applications. It was attended and supported by senior individuals from the University, the Wellcome Trust Sanger Centre, Department of Health, and Genomics England amongst others.

Kathy will be joined by **John Liddicoat**, also from the Centre for Law, Medicine and Life Sciences. John is the recently appointed Philomathia Post Doctoral Fellow in Intellectual Property Law and Genomics, a position awarded by the School of Humanities and Social Science. John will take up his post in September 2015. This initiative would be an excellent opportunity for him to develop contacts at all levels, interdisciplinary expertise and policy-relevant lines of enquiry. It would likewise be an excellent institutional link between the Synthetic Biology SRI and the School of Humanities and Social Sciences.

Confirmed Collaborators:

(2) Centre for Science and Policy (Dr Robert Doubleday) <rvld2@cam.ac.uk>

Dr Rob Doubleday, is the Director of the Centre for Science and Policy. The Centre for Science and Policy promotes engagement between the University, policy professionals, experts in the sciences and engineering, business leaders, early career researchers and others who have an interest in the relationship between science and policy. Rob (CSaP) and Kathy (LML) both have extensive experience working on interdisciplinary projects, integrating academic and policy-related knowledge, and have worked on many past occasions with each other. For instance, the Workshop mentioned above was a joint enterprise. CSaP also organized a very successful policy Fellowship for Dr Linda Kahl, a lawyer from the Biobricks Foundation. Discussions during that Fellowship contributed to the current proposal.

(3) The Sainsbury Laboratory (Dr Nicola Patron) <Nicola.Patron@sainsbury-laboratory.ac.uk>

Dr Nicola Patron is a molecular and synthetic biologist at The Sainsbury Laboratory (TSL), a world-leading research institute working on the science of plant-microbe interactions. At TSL Nicola designs and develops molecular tools to engineer plant genomes and produce novel functions in plant cells and supervises the Norwich Research Park's iGEM team. As a bioengineer, Nicola is interested the societal impacts of synthetic biology and the complex intellectual property issues that surround genetic sequences, DNA and natural products. She is a member of the OpenPlant working group on Intellectual Property and, with collaborators in OpenPlant, is aiming to create a suite of Open-Source tools and parts for plant synthetic biology and establish an Open Registry of parts for plants. The workshop described in this proposal will help to describe and inform these activities.

We also hope to be joined by:

(4) Department of Medicine, Clinical School, University of Cambridge (Dr John Bradley)

(5) Cambridge NIHR Biomedical Research Centre (Dr John Bradley) <jab52@cam.ac.uk>

Dr John Bradley, from the Department of Medicine (University of Cambridge), is Consultant Renal Physician, and Director of Research and Development at Cambridge University Hospitals, where he is also Director of the NIHR Biomedical Research Centre. The NIHR Cambridge Biomedical Research Centre (http://www.cambridge-brc.org.uk/about) is a partnership between Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge, creating an environment where internationally outstanding biomedical and clinical scientists work alongside clinical practitioners to achieve translation of research for the benefit of patients. It represents the UK's biggest-ever investment in early-stage health research. Dr Bradley also leads the NIHR Bioresource - a panel of thousands of volunteers (currently 20,000; aiming to grow to 100,000), both with and without health problems, who are willing to be approached to participate in research studies investigating the links between genes, the environment, health and disease.

Implementation

Funds are requested to support a Workshop jointly organized by CSaP and the Centre for Law, Medicine and Life Sciences. These workshops represent a tried and tested formula for bringing policy makers from across relevant governmental organisations together with researchers, the third sector, and industry, allowing highly effective knowledge exchange and network building. The event will focus on the issues described above, and bring together academic and policy expertise.

Dr Kathy Liddell (LML) has extensive contacts in the field of intellectual property law and policy, and human genomics. Dr Rob Doubleday (CSaP) has an extensive list of contacts in science and the humanities in the University of Cambridge, fellows Whitehall and the third sector, and an express commitment to developing pathways to impact to help University experts communicate their research with wider society. Dr Nicola Patron (TSL) brings scientific expertise and contacts in the field of synbio and open-resource tools. We also propose working closely with the University's Strategic Research Initiative in Synthetic Biology. Dr John Bradley brings scientific expertise and contacts in the field of genomics and biomedical resources.

The collaborating partners will utilise their network and skills to arrange relevant participants for the Policy Workshop. This workshop will play an important role in ensuring that research addresses the needs of policy makers and delivers the conclusions of research to decision makers in an effective way

We propose to invite 25 well-informed, well-connected individuals drawn from scientific, government, industry and public sectors, providing depth and breadth on relevant policy issues. For example, we envisage invitees from University of Cambridge, LSE, TSL, EBI-EMBL, the Wellcome Trust Sanger Centre, Marks & Clerk, Biobricks, Cambridge IP, Cambridge Enterprise, University of Edinburgh, Kings College London, SPRU, Genomics England and Whitehall (Department of Health, DEFRA, BIS). With sufficient funding, we could also invite a representative of Synberc (a consortium of synthetic biology leaders at UC Berkeley, UC San Francisco, Stanford, Harvard, and MIT).

A Report will follow the Workshop, which will be minuted according to Chatham House Rules. This will create a permanent, accessible record of the event; capturing information, positions, and ideas that emerge at the Workshop.

Benefits and Outcomes

This proposal accords closely with the aims of the OpenPlant Fund. It will:

- ✓ Produce a tangible outcome that can be readily shared:
 - > A Report will follow the Workshop, creating a permanent, accessible record of the event; capturing information, positions, and ideas that emerge at the Workshop.
- ✓ Promote interdisciplinary working and exchange:
 - > the Workshop is strongly interdisciplinary, involving law, synthethic biology, genomics, science and technology studies, industry. Furthermore it will facilitate a new interdisciplinary interaction between Cambridge and Norwich (The Sainsbury Laboratory)
- ✓ Focus on issues relevant to synthetic biology and provide a valuable contribution to the current field:
 - the Workshop will inform, explore and develop ideas about open innovation, intellectual property frameworks in the fields of synthetic biology and genomics, promoting shared learning and a valuable contribution to the field.
- ✓ Address focus areas of the OpenPlant initiative:
 - > as mentioned above, the Workshop will address open technologies and responsible innovation which are key issues for the OpenPlant initiative.
- ✓ Involve realistic timing and costing:
 - > the Workshop is anticipated to be held in Winter 2015 or Spring 2016. The proposed budget is attached.
- ✓ Involve external collaborations:
 - > the Workshop will be attended by representatives from industry, policy, and Cambridge-based research organisations (eg the Wellcome Trust Sanger Centre; the Public Health Genomics Foundation).
- ✓ Secure matched funding:
 - this project will seek matching funding from the Cambridge Wellcome Trust ISS Fund, and the Cambridge NIHR Biomedical Research Centre.

Sponsor for the research and cost centre

Dr Rosie Šnajdr Research Grants Administrator Faculty of Law, University of Cambridge, Rosie Snajdr <u>rs364@cam.ac.uk</u>

Cost code: [tbc]

I confirm that I have the full support of the sponsor listed above and that they can be added to the OpenPlant Fund mailing list to receive project updates (to which they can unsubscribe at any time).

[Budget on next page]

£5700

A+B+C-D

Budget

Conference organisation: CsaP – Workshop logistics and administrative assistance Law Faculty – Workshop facilitator, and preparation including research	£2000
assistance for literature review, Chair's and participants' briefings, rapporteur duties, and final report Sub-Total A:	£4700 £6700
Venue and meals: Venue hire Refreshments for 25 (two coffee breaks @£4/person) Briefing Lunch for 10 (presenters, Chair, organisers, rapporteur) (lunch @£15/person). Dinner for 25 participants (£50/person) Sub-Total B:	£500 £200 £150 £1250 £2100
Travel and accommodation: Return taxi travel for 5 participants travelling within Cambridge surrounds, £20 per person. Return train and local travel for 10 participants from London/Norwich, £60 per person. Return train and local travel for 3 participants from other parts of UK, £200 per person. Accommodation for 3 UK-based participants @ £100/person Sub-Total C:	£100 £600 £600 £600 £1900
Sub-total A+B+C	£10,700
Match-funding TBC - Match-funding from the Cambridge- Wellcome Trust Institutional Strategic Support Fund £4000	
TBC - Match-funding from the Cambridge NIHR Biomedical Research Centre	
Sub- total D	£1000 £5000*

* To be confirmed.

**Additional funding - at the discretion of Open Plant -

Return flight, local travel and two nights accommodation for 2 US-based participants £2400

Total Requested from OpenPlant Fund

The Workshop would be significantly advantaged by US participation. For example with additional funding we could invite (1) a representative from Synberc, a consortium of synthetic biology leaders at UC Berkeley, UC San Francisco, Stanford, Harvard, and MIT, and (2) a senior US-based technology manager with US industry expertise in synthetic biology and genomics.

It might be possible to co-ordinate the visitor's stay with another speaking event drawing together the wider Synthetic Biology community in Cambridge and Norwich, and raising the Workshop's profile.

Linda Mahl is also a key invitee. Linda is the Legal Program Director for the BioBricks Foundation, where her work focuses on developing policy initiatives, legal tools, and educational materials to promote the open and ethical use of biotechnologies. Prior to joining the BioBricks Foundation, Linda led the Ownership, Access, Sharing, and Innovation Systems (OASIS) project for Synberc. It may be possible to co-ordinate the timing of the workshop with the second stage of Linda's CSaP Policy Fellowship; otherwise her travel costs would need to be covered by the terms of the grant.