

## FORM Applicable from April 2011

### PLEASE NOTE THE FOLLOWING;

- > **Incomplete and/or late** applications will not be processed and will be returned by post to the applicants.
- > Forms **without the following signatures** will not be processed: Applicant(s) signature, Research Supervisor signature (applicable in student application), **all researchers named on the form.**
- > Forms **without the checklist completed** will not be processed. (Please see checklist on next page)

<b>APPLICANT NAME:</b>	Dr Howard Boland
<b>APPLICANT EMAIL ADDRESS:</b> Please ensure this is correct. The decision will be sent to this email address	howard@c-lab.co.uk
<b>SUPERVISOR NAME:</b>	N/A
<b>SUPERVISOR EMAIL ADDRESS:</b> Please ensure this is correct. The decision will be sent to this email address	N/A
<b>STAFF MEMBER</b>	N/A
<b>STUDENT MEMBER</b>	N/A
<b>WHAT SCHOOL/DEPARTMENT ARE YOU AFFILIATED TO?</b>	C-LAB (UK) & University of Westminster (UK)
<b>WORKING TITLE OF PROPOSED STUDY:</b>	<i>Cellular Propeller</i>
<b>TO BE REVIEWED AT WHICH ETHICS COMMITTEE MEETING? PLEASE PROVIDE MONTH OF MEETING.</b>	'Trust Me, I'm an Artist' Transmediale, Berlin, Germany February 2016
<b>IS THIS A FASTTRACK APPLICATION?</b>	Yes

## FACULTY RESEARCH ETHICS GROUP – FACULTY OF HEALTH SCIENCES RESEARCH ETHICS APPLICATION FORM

### RESEARCH APPLICATION INDEX

#### Section 1: Applicants Details

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## **Section 7: Declaration of Approval and Signatures**

**Please complete the application form and return one signed hard copy to**

**Please also email your application in full**

**If you have any queries regarding the completion of this application form please email**

**To process your application form efficiently you are required to fill in the checklist below. Do not leave any blanks. If this checklist is not completed, your application will not be processed.**

**NOTE: The Faculty Ethics Committee does not process applications for approval of projects that assess the effect of a drug or therapeutic substance. Approval for such studies must be sought through the Irish Medicines Board and ethics clearance should be obtained from the JREC**

### **CHECKLIST BELOW MUST BE COMPLETED:**

<b>PLEASE TICK THE APPROPRIATE BOX</b>	<b>YES</b>	<b>NO</b>
Are you undertaking the proposed research study in your capacity as: (a) a student of the Faculty of Health Sciences? Or		X
(b) a staff member of the Faculty of Health Sciences?		X
1. Does the proposed research involve current students and / or staff of the Faculty of Health Sciences as research participants?	X	
2. If you are a student, has your supervisor endorsed the completed form?	N/A	
<b>IF APPROPRIATE TO THE STUDY YOU SHOULD ATTACH THE FOLLOWING:</b>		

<ul style="list-style-type: none"> <li>(a) the consent form you propose using</li> <li>(b) the letter(s) to prospective participants seeking their co-operation with the study</li> <li>(c) the participant information leaflet you propose using</li> <li>(d) for the purpose of your proposed study, if you require access to: (i) a site outside your home department/School, and/or (ii) the person who is responsible for the welfare of your proposed participants please attach the letter seeking access</li> <li>(e) If the study requires ethical approval by ethics committees of any other institutions, outside of the St. James's Hospital and Federated Dublin Voluntary Hospitals Joint Ethics Research Committee (J.R.E.C.), please attach a copy of the responses received from these committees</li> <li>(f) If relevant to this study please attach a copy of the tool(s) of data collection you propose using (Questionnaire / interview schedule / observation schedule/other)</li> </ul>	<ul style="list-style-type: none"> <li>(a) <a href="#">Consent form</a></li> <li>(b) Letter of cooperation</li> <li>(c) <a href="#">Information letter</a></li> <li>(d) TBC (Sample)</li> <li>(e) N/A</li> <li>(f) Material collection / overview</li> </ul>
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**TRINITY COLLEGE**  
**Faculty of Health Sciences**  
**RESEARCH ETHICS APPLICATION FORM**  
**CONFIDENTIAL**

*Please complete all information relevant to your application*

**SECTION 1 – APPLICANTS’ DETAILS**

**1.1 Name, qualification and position of each person associated with this research project.**

*List details of all personnel involved with the research (excluding participants)*

<b>Investigator Title / First name / Surname</b>	<b>Title of Study</b>	<b>Postal Address (Please note that approval will be posted to this address)</b>	<b>Email address</b>	<b>Tel No Work / Home</b>	<b>Role in research</b>	<b>Primary Employer (Hospital / University / Other)</b>	<b>Current Occupation</b>
Dr Howard Boland	<i>Cellular Propeller</i>	School of Life Science, University of Westminster, 115 New Cavendish Street, London W1W 6UW	howard@c-lab.co.uk	+44(0)75 95846441	Principal Investigator	C-LAB	Director
<b>Supervisor (if investigator is a student)</b>		<b>Postal Address (Please note that approval will be posted to this address)</b>	<b>Email address</b>	<b>Tel No Work / Home</b>	<b>Role in research</b>	<b>Primary Employer (Hospital / University / Other)</b>	<b>Current Occupation</b>

## **SECTION 2 – DETAILS OF RESEARCH STUDY & PARTICIPANT SELECTION**

### **2.1 Working title of proposed study**

*Cellular Propeller*

### **2.2 Dates & Duration of Study**

Proposed Start Date:  Proposed End Date:

### **2.3 What are the primary location(s) for data collection? (e.g. classroom, participant's home, hospital/clinic, laboratory, place of convenience for participant)**

Laboratory (Bioscience Department, University of Westminster, London)	
Exhibition Space (TBC)	

### **2.4 State research aim(s) and objective(s), research question or hypothesis (as appropriate)**

The aim of this research is to investigate the material and forces of biomatter by mobilising biomatter to perform novel behaviours. It makes use of sperm cells to spin a coin-size wheel made from synthetic material.

### **2.5 Provide brief outline of the project (maximum 400 words, must include background, research approach, design, data collection methods, sampling, indicate the method of sampling you intend to use and the sample size)**

*Cellular Propeller* makes use of synthetic biology that combines modern biology and engineering practices in a computational manner through modelling, prediction and implementation. Conceptualised as part of an awarded Art & Synthetic Biology residency at the German Cancer Research Center (DKFZ), it involves the fourth-domain of synthetic biology that hybridises synthetic and biological matter to form novel biological or biologically inspired systems stretching into the realm of *pseudo-organisms*.

To realise this idea, it involved experiments with heart cells from newborn rats to make motile scaffolds. Due to limited availability of such material and ethical issues, it also takes the significant leap of using sperm cells to spin a coin-size wheel made from synthetic material. Availability of sperm cells and its potential for circumventing ethical ownership makes it appropriate for the project.

*Cellular Propeller* brings together art, science, technology, ethics and humour.

Still today, with all advances of molecular biology, motion remains a key attribute used to characterise

something as living. *Cellular Propeller* partakes in rethinking *what is living* by producing a new hybrid living system or a bio-hybrid actuator. The project employs traditional quantitative engineering approaches to build a coin-size construct from living sperm cells and synthetic material that emulates a propeller motion. Morphologically, I am building a wheel or a functional propeller - genetically the propeller is human. Scientifically, the creation of *Cellular Propeller* is about understanding how sperm cells function in an artificial environment and the fundamental laws of forces and motion that govern this scale.

The scaffolds are moulded using PDMS (silicon/Polydimethylsiloxane). The sperms are bound to the scaffold and aligned so that the tail moves freely using a compound called Hyaluronic Acid (HA). To enable rotation, the compound is coated on opposite sites in a symmetrical manner. Once the sperm cells are bound and washed, the scaffold is submerged in a buffer solution to commence swimming. Given that an average male produces about 20 million sperms in a single ejaculation, a reserved estimation based on surface area and propulsion force of distributed sperms suggest that there is sufficient forces to spin the scaffold.

Obtaining biological material can be problematic due to legal restrictions and ethical frameworks especially critical in artistic scenarios. Using sperm cells opens debates about ownership of our body, its components and what we may harvest for art making. Beyond this, the cultural and biological condition of sperm cells involves a myriad of ideas including sex, pleasure, reproduction, IVF and health.

**2.6 If appropriate please identify how participants will be recruited and what steps you will take to access the sample, specifying details of people who will be contacted during this process:**

As part of the study will be shown publicly in the form of an art exhibition, and depending on exhibition space, interested participants may be recruited to take part of the performance on a voluntary basis.

Interested participants will be given a consent form to sign and a short information leaflet. Participation is restricted to adult male subjects. An appropriate room will be provided for sample collection.

**2.7 List your exclusion/inclusion criteria for participant selection:**

The nature of the material means that the participant selection is restricted to adult male subjects.

**SECTION 3 – CONSENT, CONFIDENTIALITY (INCLUDING DATA PROTECTION)**

**3.1 Will informed consent be obtained from the research participants?**

YES 

X

 NO 


If yes, please give details of **who** will take consent and **how** it will be done.

(Please attach a copy of letter, consent form (if required) and information leaflet. See guidelines on how to prepare these documents in Appendices and adapt examples accordingly to suit your study and participants)

Participant involvement is voluntary and subject to participants completing and signing a (1) Consent Form.

Participants will be provided an Information Sheet.

The (1) [Consent Form](#) and (2) [Information Leaflet](#) are included with this application.

### 3.2 What is the time interval between giving information and seeking consent?

*(It is recommended that a period of seven days be provided for reflection. If less than this, please justify).*

As the study is related to an exhibition and performance it depends on the length of the exhibition so anything from immediate and to a week.

### 3.3 Will the participants be from any of the following groups (tick as appropriate)

	INVOLVEMENT	
	YES	NO
Children under 18 years of age		X
Adults with learning disabilities		X
Adults with communication difficulties		X
Adults who are unconscious or very severely ill		X
Adults who have a terminal illness		X
Adults with mental illness		X
Adults suffering from dementia		X
Prisoners		X
Young Offenders		X
Those who could have been considered to have a particularly dependent relationship with the investigator, e.g. those in care homes, students		X
Other groups who may be considered vulnerable (Please specify below)		X

### 3.4 If participants are to be recruited from any of the potentially vulnerable groups listed above, please give details of:

N/A
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**3.5 Will participants include women of childbearing potential?**

The study will not specifically affect women of childbearing age, no agents that cause miscarriage will be used and safety precautions will be stringent.

YES	N O	IF NO, PLEASE EXPLAIN WHY NOTE: This information is required regardless of whether there are potential implications for the well-being of participants
	X	Study restricted to male subjects.

**3.6 If women of childbearing potential are to be involved, do the study design and the participant information sheet address the 9 essential points listed in the accompanying checklist (Appendix 3)?**

YES	N O	N/A	IF NO, PLEASE EXPLAIN WHY NOTE: This information is required regardless of whether there are potential implications for the well-being of participants
		X	

**3.7 During and after the study, what steps will you take to protect the confidentiality of:**

Any samples (used or otherwise) will be destroyed in accordance with biosafety procedures. (Eg. removal of samples in safe containers to laboratory facilities and incinerations.)
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**3.8 Is there any potential confidentiality issue through identification of the study location?**

No
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**3.9 If your data is to be held on computer, how will it be protected?**

N/A
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**3.10 What other person(s) other than the researcher/team as listed will have access to the data collected and what steps will be done to protect confidentiality?**

N/A

- 3.11 Accepted best practice recommends secure retention of data for 5 years. If there is any reason to apply for variation from these guidelines, please give details and justify;**

N/A

- 3.12 If identifiable data or material will be retained after the study is completed, is it stated on the informed consent form that this will be done and that material will not be used in future unrelated studies without further specific permission being obtained?**

YES	NO	IF NO, PLEASE EXPLAIN WHY
	X	Identifiable data and samples will not be retained after the study is complete.

- 3.13 If the study involves audio taping interviews, you must allow the participant access to the transcript, if they so wish. This must be included in the Informed Consent Form and Information Leaflet (if these forms are being used). Will the participant be given access to a transcript of the audio tape interview?**

YES	NO	N/A	IF NO, PLEASE EXPLAIN WHY
		X	

## **4 - RISK, BENEFIT AND HARM**

- 4.1 Are there ethical issues or problems which may arise with the proposed study, and what steps will be taken to address these?**

The experiment involves the use of researcher's own sperms cells (i.e. self-experimentation) in laboratory settings to validate the study's hypothesis and in a public art exhibition. In such scenario, the ethical issues of concern are therefore (a) the use of human biological material and (b) the use of researchers own material.

As a subject in my own research, this type of research (investigator self-experimentation) is regarded as research with human participants and procedures will therefore follow the same safety precautions as with other subjects.

Handling of sperms follows conventional method when dealing with biological material (e.g. gloves and protective clothing) and following standard protocols for cleaning spillage that may accidentally occur.

Appropriate disposal of sperm cells will be carried out in accordance with institution guidelines. Transport of the material to the facility will be carried out in a biohazard bag.

In addition, the experiment may be extended to include interested voluntary participants to take part. There may be an issue if participants find minimal mobilisation as this could indicate issues with the sperm quality. The information sheet seeks to highlight that given the artistic experimental nature of this could be a result of the conditions the experiment is undertaken and should not be taken as a *de facto* clinical test for sperm quality (although the project could at some stage become such a product).

**4.2 What is the potential for an adverse outcome (for example, illness, pain, discomfort, distress, inconvenience) for research participants? NOTE: for the protection of both the investigator and the participant, this list must be comprehensive and must also appear in full in the participant information leaflet.**

There might be psychological distress in containing samples from some participants either by failing to provide the samples or provide samples that do not perform as intended. The information leaflet outlines that this is an art experiment and therefore should not be considered a clinical analysis.

**4.3 If there is potential for an adverse outcome, please indicate what steps you will take in the case of an adverse outcome/results for participants.**

N/A

**4.4 Will individual or group interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could take place during the study (e.g. during interviews/group discussions, or use of screening tests for drugs)?**

*If Yes, give details of procedures in place to deal with these issues*

No

**4.5 If participants are to undergo a clinical assessment, what is the nature and extent of this assessment?**

N/A

**4.6 If applicable will there be ongoing clinical supervision of the participants by a duly insured clinical practitioner during the study?**

N/A

**4.7 Will the research participant's General Practitioner be informed that they are taking part in the study?**

YES	NO	NOT APPLICABLE
		X

**4.8 Will permission be sought from the research participants to disclose information (for example, information about adverse outcomes) to their GP?**

YES	NO	NOT APPLICABLE
		X

**4.9 What is the potential for benefit for research participants?**

Seeing one's own cells perform in an unusual setting outside his body.

**4.10 Are there elements of genetic testing involved in the proposed project? If Yes please explain.**

No

## **SECTION 5 - FUNDING & PAYMENT**

**5.1 Outline sources of funding for the study if applicable and how you will manage any possible conflict between the funders of the study and the aims and results of the study if applicable?**

To be confirmed

**5.2 Will payment be made to research participants?**

<b>YES</b>	<b>NONE OTHER THAN MINIMAL EXPENSES TO COVER TRAVEL COSTS ETC</b>	<b>NO</b>
		X

**5.3 If you answered YES to question 5.2, please specify for what purpose the payment will be made and the amount per participant.**

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## **SECTION 6 – ETHICAL APPROVAL FROM OTHER COMMITTEES**

**Ethical approval from the Faculty Research Ethics Committee, if granted, does not supersede any requirements that outside bodies may have that similar applications be made to local ethical approval bodies in advance of the study commencing.**

**6.1 Has ethical approval been sought from any other organisation(s) in which the study will take place?**

YES ☐ (If you answer YES go to question 6.2)  
S  
NO ☒ (If you answer NO go to question 6.3)  
N/A ☐ (If N/A please explain why below)

**6.2 If you have answered YES to question 6.1, where has approval been sought from and has ethical approval been given?**

YES	Awaiting Reply	NO	IF NO, PLEASE EXPLAIN WHY

**6.3 If you have answered NO to question 6.1, is it your intention to seek ethical approval from the organisation(s) in which the study will take place?**

YES	NO	IF NO, PLEASE EXPLAIN WHY
S	O	
X *		

\* Ethical Review by University's Research Ethics Committee (REC)

## **SECTION 7 - DECLARATION OF APPROVAL AND SIGNATURES**

### **LEAD INVESTIGATOR**


The lead investigator must provide all data below and sign:

- 7.1** If applicable please state briefly what preparatory work you will need to undertake to become competent in your chosen method of data collection (e.g. training in the use of a standardised schedule/test, clinical procedures, or practice in conducting an interview)

N/A

### **LEAD INVESTIGATOR DECLARATION:**

- 7.2** I confirm that the information provided in this protocol is correct, that I am not aware of any other ethical issue not addressed within this form and that I understand the obligations to and the rights of participants (particularly concerning their safety and welfare, the obligation to provide information sufficient to give informed consent, the obligation to respect confidentiality and all the obligations as set out in the **Declaration of Helsinki** (appendix attached) governing the conduct of research involving human participants) and/or other relevant guidelines (please refer to your Head of Department/School)
- I undertake to provide an annual report **within twelve months of the date of approval** to the Faculty Research Ethics Group with details of the number of participants who have been recruited, the number who have completed the study and details of any adverse effects. Any serious adverse effects will be reported immediately to the Faculty Research Ethics Group, and, if involving medication this will also be reported to the Irish Medicines Board.

<b>NAME:</b> (BLOCK CAPITALS)	DR HOWARD BOLAND		
<b>STAFF / STUDENT I.D. No.</b>	124607621		
<b>SCHOOL / DEPARTMENT:</b>	University of Westminster		
<b>COURSE OF STUDY:</b> (if appropriate)	N/A	<b>YEAR</b>	2016
<b>SIGNATURE:</b>		<b>DATE:</b>	3/2/2016

**PLEASE NOTE THAT IF THERE IS MORE THEN ONE APPLICANT, ALL APPLICANTS MUST SIGN THE APPLICATION FORM.**

<b>NAME:</b> (BLOCK CAPITALS)			
<b>STAFF / STUDENT I.D. No.</b>			
<b>SCHOOL / DEPARTMENT:</b>			
<b>COURSE OF STUDY:</b> (if appropriate)		<b>YEAR</b>	
<b>SIGNATURE:</b>		<b>DATE:</b>	

<b>NAME:</b> (BLOCK CAPITALS)			
<b>STAFF / STUDENT I.D. No.</b>			
<b>SCHOOL / DEPARTMENT:</b>			
<b>COURSE OF STUDY:</b> (if appropriate)		<b>YEAR</b>	
<b>SIGNATURE:</b>		<b>DATE:</b>	

<b>NAME:</b> (BLOCK CAPITALS)			
<b>STAFF / STUDENT I.D. No.</b>			
<b>SCHOOL / DEPARTMENT:</b>			
<b>COURSE OF STUDY:</b> (if appropriate)		<b>YEAR</b>	
<b>SIGNATURE:</b>		<b>DATE:</b>	

<b>NAME:</b> (BLOCK CAPITALS)			
<b>STAFF / STUDENT I.D. No.</b>			
<b>SCHOOL / DEPARTMENT:</b>			
<b>COURSE OF STUDY:</b> (if appropriate)		<b>YEAR</b>	
<b>SIGNATURE:</b>		<b>DATE:</b>	

**RESEARCH SUPERVISOR**

Student applicants are required to have their Research Supervisor complete this section.

Name of Supervisor: \_\_\_\_\_  
(BLOCK CAPITALS)

Position: \_\_\_\_\_

State the educational value of this research:

As the student's supervisor, I accept responsibility for the ethical conduct of this project:

Signature of the Supervisor: \_\_\_\_\_

Date: \_\_\_\_\_

**Office Use Only:**

<i>Reference Number</i>	
<i>Faculty Research Ethics Committee Meeting Date</i>	
<i>Approved</i>	
<i>To be resubmitted</i>	

<i>Date</i>	
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