# PARTICIPANT INFORMATION SHEET

**Study title: Biomodifying technologies and experimental space: organisational and regulatory implications for the translation and valuation of health research**

**Ethics Approval Reference:**  **R55654/RE001**

**1. What is the purpose of this study?**

This project focuses on three case studies of innovative science in the UK: gene editing, induced pluripotent stem cells, and 3D bioprinting and biofabrication. The aim is to identify and compare the scientific, regulatory, ethical and economic factors shaping research trajectories across each case. Our approach combines documentary analysis with qualitative semi-structured interviews with key stakeholders in each of the fields being studied.

**2. Why have I been invited to take part?**

You have been approached as a participant in this project because of your involvement with one or more of our case studies, and your experience and expertise will make an invaluable contribution to advance our understanding of how and why this field is developing the way it is in the UK.

**3. Do I have to take part?**

No. It is entirely up to you whether you take part in this study or not. You are free to withdraw this consent at any point before, or during the interview, which will mean that any responses you have given will not be used during the data analysis. You may also withdraw your consent after the interview, until 1st December 2019 at which point anonymised data will be prepared for submission to the UK Research Data Service as described in point 7 below. Data, in the form of anonymised quotes which are used in a published paper cannot be withdrawn. You are free to refuse to answer any questions during the interview.

**4. What will happen if I do take part?**

I will arrange a qualitative interview with you to discuss your work on induced pluripotent stem cells and the current landscape of innovation in this field in the UK. The interview will last between 40 minutes and 1 hour. With your consent, an audio recording will be made of the interview. There are no physical risks involved but you will be sharing your time and information.

Interviews will be organised at a location that suits you or by telephone or online face-to face communication tools if no face-to-face meeting can be arranged.

**5. Who is organising this research?**

This research is being coordinated by the Centre for Health, Law and Emerging Technologies (HeLEX), which is part of the Nuffield Department of Population Health at the University of Oxford. The project also involves researchers from the University of Sussex and the University of York and is funded by the Economic and Social Research Council (ESRC). The Principal Investigator is Dr Michael Morrison. More information can be found on the project website: <https://www.biomodtech.com/>

**7. How will the information I provide be used?**

The audio recording of the interview will be transcribed for analysis. Findings will be written up and published in peer-reviewed journals. Audio recordings will be retained for at least the minimum three years required after the data is published. Anonymised transcripts will be retained and submitted for archiving to the UK Research Data Service. The lead researcher (M. Morrison) will be the data custodian and will be responsible for ensuring the secure storage and confidentiality of the data.

**8. What steps will be taken to protect my information?**

Audio recordings will only be accessed by members of the research team and will not be shared with anyone else without the prior explicit written permission of the participant. No identifiable data will be shared with third parties. Physical copies of the recordings (e.g. on SD cards) will be kept in a locked filing cabinet. Digital copies will be stored on secure, encrypted devices at all times. The recordings will be transcribed by an approved commercial transcription service with a non-disclosure agreement. Transcripts will be anonymised and assigned a code. A key linking the codes to the personal details of interviewees will be stored securely and kept separate from the transcripts.

Recordings and transcripts will be used for research purposes only. This will include submission to peer-reviewed publications of analysis of this data which can include selected quotes from the data set. Quotes in published works will be identified only by the code assigned to the transcript.

Anonymised transcripts will be reviewed by members of the project team for analysis and removal of any potentially identifying information before submission to the UK Research Data Service, a managed access repository of social science data funded by the Economic and Social Research Council.

**9. Who has reviewed this study?**

This project has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee. Ref No: **R55654/RE001**

**10. What if there is a problem?**

If you have a concern about any aspect of this project, please speak to the relevant researcher (M. Morrison) who will do his best to answer your query. The researcher will acknowledge your concern within 10 working days and give you an indication of how he intends to deal with it.

**Contact Details**

Lead Investigator: Dr Michael Morrison, Centre for Health, Law and Emerging Technologies (HeLEX), Nuffield Department of Population Health, Ewert House, Ewert Place, Banbury Road, Oxford, OX2 7DD

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Email: [michael.morrison@dph.ox.ac.uk](mailto:michael.morrison@dph.ox.ac.uk)

If you remain unhappy or wish to make a formal complaint, please contact the chair of the Research Ethics Committee at the University of Oxford (Chair, Social Sciences & Humanities Interdivisional Research Ethics Committee; Email: ethics@socsci.ox.ac.uk; Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD). The chair will seek to resolve the matter in a reasonably expeditious manner.

Thank you for reading this sheet and considering whether you would be willing to participate.