BioMod Interview schedule template: Induced pluripotent stem cells v1.2

Explanatory Note: The primary questions are indicated by a single, solid bullet point ‘•’. Prompts, which are only used when needed to stimulate further discussion or if the interviewee has not already discussed a particular topic of relevance, are indicated with a single clear bullet point ‘○’.

1) **Preliminary discussion**

* Brief introduction to aims and objectives of ESRC Biomodifying Technologies project
* Interviewee rights: confidentiality, anonymity and right to withdraw
* Data management plan – interview transcripts with identifying data removed will be deposited in UK Data Archive at end of project
* Opportunity to ask questions about project

2) **Interviewee and team overview**

* Can you tell me a bit about your professional background?
* Where did you train as a researcher and in what discipline?
* Roughly how long have you been working on induced pluripotent stem cells (hereafter IPS cells)?
* When did you first become interested in IPS cells?
* How many people work in your laboratory (on your research)?
* What sorts of backgrounds and training or skill sets do they have?
* Do you find that doing iPS cells research has required people in the team to develop new skills?

3) **Overview of the field**

* We are aware that iPS are currently being developed as tools for disease modelling, for small molecule drug discovery and for cell therapy. Are there any other areas of research or applications that you think are important or that we should be aware of?
  + - * Which of these areas do you think has attracted most academic interest to date?
      * Is that the same, do you think, for the commercial sector or do they have a different focus?
* Are some diseases, conditions or damaged tissues more suitable for IPS cells than others?
  + If so, which ones and why?
  + Which diseases/conditions, if any, should be priority targets? Why?
* How do you see the UK’s position in relation to the wider global work on IPS cells?
* Do you see the UK as a leader in any particular aspect of IPS cells research?
  + - * If so which?
      * Who are the UK’s main competitors?
* Which groups are shaping the evolution of work in this area? (What are the respective influences of policymakers, industry, regulators, patient groups, universities, etc?)

4) **Current scientific work**

* Can you discuss your current work with IPS cells in a bit more detail?
  + What are the key technologies and biomaterials that you use?
  + What are the main reasons for using this approach?
    - * Time?
      * Expense?
      * Available skill set in lab group?
      * Material properties?
      * Ethics?
  + How do you procure these materials?
  + Are there other groups addressing similar scientific/clinical problems using different techniques?
* What stage of development do you regard your work to be at (and in relation to the field)?
* What aspects of your (work/project etc) are established, what is ‘experimental’?
* What are the main challenges related to your work/projects etc. from your point of view?
* Who are the future users of your work/method/process/products?
  + How do you envisage this being applied as a therapy?
  + Have you started clinical trials?
  + What are the problems of doing clinical trials of IPS cells?
  + Have patient-related concerns been raised in discussion with colleagues?
  + How far off, in your view, is successful clinical translation?
  + Do you see IPS cells as something that could one day become a routine clinical procedure?
  + Who would deliver it? Would they need special training? In what?
  + Would hospitals/clinics need special facilities?
  + Would be able available across the NHS, or only in specialist centres?
* Do you use animal models in your everyday work?
  + What is your view regarding the ‘3Rs’ of replacement, reduction and refinement of animal use in research?
* Does your work involve any applications with gene editing or 3D bioprinting?

5) **Network and resources**

* What, if any, other groups or organisations do you collaborate with?
* Do you have collaborators in the NHS?
* Do you have (other) commercial collaborators?
* Do you provide services to any groups within your organisation or outside it?
* Do you outsource any tasks to other groups or draw on any external resources to carry out your research?
  + If so could you explain which tasks and why you outsource them?
    - * Bioinformatics?
      * Sequencing/Genotyping?
      * Cell lines?
      * Biobanks?
      * NHS patients?
      * Patient organisations?
      * Support for moving to clinical trials/commercialisation? [CGTC / BSGCT?]
  + What types of contractual arrangements do you need to enter into to pursue your aims?

For academic researchers:

* Who funds your current research?
  + - Who has funded it in the past?
    - Are you aware of possibilities for commercial funding?
    - If so which companies fund academic research on IPS cells?
    - Do you have or have you had any commercial funding?

For commercial researchers:

* (With due regard to confidentiality) what is your organisation’s funding model?

6) **Regulation and governance**

* Have there been any instances where regulations affect your research? For example where you have been prevented from doing something you wanted to do, or where you have had to do things a certain way to meet regulatory requirements?
* Do you think the existing regulatory frameworks work or are there things you would like to see changed?
  + - If so, why and which areas of law? (re medicinal regulation, ATMP, device regulation, liability, IP; equipment, software, personal data; etc).
    - Is data protection relevant?
    - If so what are the main data protection issues?
* What are the ‘chain of custody’ or accountability issues that arise, and what is the best arrangement?
* Have you had to licence any IP in order to do your research?
* Will there be any IP claims resulting from your work?
  + Who will own this IP?
  + Is there the possibility of commercialising your work? A spin-out company? [Have they been involved in start-ups etc. before?]

7) **Future** **Perspective:**

How do you see the iPS field in the near future, for example the next 5 years, and how do you see things going in 10-20 years time?