BioMod Interview schedule template: Induced pluripotent stem cells v1.3

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?
* [name of organisation] has been involved with the [redacted- refers to a very specific, unique at the time of the project activity]. Can you tell me a bit about how [[name of organisation] came to be involved with stem cell work?
* How do you see [name of organisation] current and future role in the UK ecosystem for ATMPs?
* E.g. NHSBT has done deals with BeTheMatch therapeutics (US) to standardise collection and quality procedures for harvesting starting material for cell therapies. Is the type of activity you would undertake?
* Is there any sense of [name of organisation] strategically investing in GMP or near-patient manufacturing facilities, or biobanks or anything like that as a resource for the future?
* Can you tell me about your involvement with the [name of very specific, important for this research] project?
* [name of consortium] founded in [date]- can you tell me a bit more about the impetus for that founding?
* What is different from for example International Stem Cell Banking Initiative, which played such a prominent role in has been developing guidelines for research and clinical grade pluripotent stem cells (i.e. covering hESC and iPS)
  + Hope to engage more companies?
  + Avoid problems of ISSCR structure?
  + Why IPSC and not pluripotent SC more broadly?
  + What is different from other kinds of cells used in transplants e.g. haematopoietic stem cells?
* Importance of global harmonisation of criteria for clinical grade iPSC?
* What types of expertise do [name of consortium] members have –more than academic?
* Was intention to draw on experience / expertise from existing endeavours- hPSC REG? ([name of scientist) of [name of European university] present at database meeting) and Banking of research grade lines in NYSCF, EBiSC etc (name of scientist and name of scientist) of [name of European university] / [name of European FP7 project] also at meeting)
* Slide show [previously provided but not available to share beyond project members] talks about ‘tragedy of the commons’ – is the idea that if each national regulator develops criteria for iPSC-derived cell therapies this will fragment the market and add costs?
  + Can you explain ‘scores’ given to table of market risks in slide show (slide 4)
* What makes a critical quality attribute for an iPSC (or indeed any cell therapy)
  + Large number of research grade iPSC in banks like EBiSC,is data from these lines likely to be useful in identifying parameters of variability that affect critical performance attributes?
  + What about context- e.g. media, culture environment, bioreactor, biomaterials?
  + Role of Catapult clinical grade hiPSC line? Why make? What does it achieve?
* Is there a tension between inherent variability of iPSC given their source will always be an individual with a particular genetic background, and the desire for comparability across clinical grade lines as a ‘starting point’ for cell therapy manufacturing?
* In this context what are the possibilities or risks for using WEG / WES to characterise cell lines?
  + What about panel testing?
* Still some work- e.g. Ludovic Vallier at Cambridge or Peter Andrews at Sheffield still studying pluripotency – comparing naïve pluripotency in mice ES with human pluripotent cells, still learning about this so is there a danger of standardising too soon? Or at least of setting strict standards (difference between rigour and flexibility?)
* What stage of development do you regard your work to be at (and in relation to the field)?
* What are the main challenges related to the [name of consortium] from your point of view?
  + What are the challenges of getting different regulatory agencies on board?
  + CiRA may be unwilling to make their clinical grade hiPSC available outside Japan just yet. May be an issue of secrecy as a competitive advantage and/or fear of loss of control of publicly available information about product that may adversely affect its reputation?
  + Is standardisation best seen as a pre-competitive space
  + is this resisted in some quarters?
  + Challenge of establishing comparability of lines across contexts e.g. in large vol bioreactors, customised media?
* What aspects of your (work/project etc) are established, what is ‘experimental’?
* iPSC still need to be differentiated –do you see further rounds of standardisation in terms of defining clinical grade implantable materials?
* Do you envisage a later translational role for [name of consortium]?

Does the emphasis on HLA typing commit you to a particular vision of iPSC- i.e. in allogenic cell therapy? Even though some of the trials in Japan have looked at both?

What is value of international database- is it means of harmonisation? (authority by aggregation of expertise?)?

Database but not ‘catalogue’ like EBiSC or RIKEN BioResource centre in Japan (can order research grace hiSPC)?

5) **Network and resources**

* What, if any, types of groups or organisations does [name of organisation] collaborate with?
* Do you provide services to any groups within your organisation or outside it?
  + If so, where are these generally based –UK, EU, USA, elsewhere
  + Other banks, e.g. UK or Spanish national stem cell banks, Coriell, EBiSC etc?
* Does [name of organisation] or [name of consortium] link up with ventures that focus on PSC in particular disease areas e.g. G-FORCE PD?
* What is your perspective on the UK as an environment for translating and commercialising hiPSC ?

6) **Regulation and governance**

* 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? Recontact and incidental findings?
* IP issues? When companies own clinical grade hiPSC?
  + Had some issues with this in UK SCB-firms wanted strict limits on who could access hESC lines and data and when
  + Where does optimal balance lie between governing process and product with hiPSC

7) **Future** **Perspective:** How do you see the iPS field in the near future?

What are key translational areas (diseases) and why?