BioMod Interview schedule template: iPSC technology [Companies template]

11) **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?
  + What qualifications do you hold?
  + Do you have any scientific training?
  + If so in what discipline(s)?
  + Have you previously held any academic positions?
  + Or worked for other RM firms?
* What is your current role in the company?

3) **Company and products**

* Can you say a bit about your therapy/product/technique? How novel is it compared to existing therapies/tools/products?
  + What are the key techniques and biomaterials that you use?
  + What are the main reasons for using this approach?
    - Time?
    - Expense?
    - Available skill set in house?
    - Material properties?
    - Ethics?
    - Advantages over hESC and/or directed differentiation?
  + How do you procure these materials? (NB we do **not** need names of specific suppliers, but are interested to know if materials are sourced from other companies, hospitals, biobanks etc).
  + Are you aware of similar products/therapies/techniques being developed elsewhere?
* (With due regard to confidentiality) what is your organisation’s funding model?
* 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’?
* Do you envisage your technology eventually being used as a routine product or service in a clinical or industrial context?
  + What are the obstacles to translation?
  + 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?
  + 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?
* Are suitable animal models available for preclinical testing of your product(s)
* Does your work involve any applications with gene editing or 3D bioprinting? (our other project case studies)
* If so can you say a bit more about this work
  + What is the rationale?
  + Exploratory, precompetitive research, new product development?
  + Is gene editing / 3DP integrated into your main R&D ?

4) **Network and resources**

* What, if any, types of groups or organisations do you collaborate with?
  + UK Advanced Therapy Treatment Centres?
  + Cell and Gene Therapy catapult?
  + collaborative activities with other institutions (universities, other firms, Contract Research Organisations, big pharma, NHS or private hospitals)?
* If so could you provide some detail on how this relationship works?
  + What do they bring to the work?
  + What do they expect from you?
* Do you provide services to any groups within your organisation or outside it?
  + If so could you explain which tasks and why you outsource them?
* Do you draw on any external resources to conduct your research e.g.
  + Bioinformatics?
  + Sequencing/Genotyping?
  + Cell lines?
  + Biobanks?
  + NHS patients?
  + Patient organisations?
  + Support for moving to clinical trials/commercialisation? [CGTC / BSGCT?]
* If so, where are these generally based –UK, EU, USA, elsewhere?

5) **Regulation and translation**

* (How) does regulation impact your work?
  + MHRA/ FDA / EMA etc
  + IP issues
  + Chain of custody of biological materials
  + Manufacturing liability
  + Data protection
  + NICE and HTA (reimbursement)
* Do you find the regulatory climate difficult to navigate? How does it compare to that of more conventional therapies/products/techniques.
* Are hospital ‘specials’ or compassionate use exemptions a useful potential option for cell therapies?

7) **Perspective and future of the field**

* How do you see the UK’s position in relation to the wider global work on iPSC technology (and other pluripotent cell therapies if relevant)?
* How do you see iPSC technology being used in the short term?
* How do you see things developing in the longer term, over the next few decades?