BioMod Interview schedule template: gene editing

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 gene editing?
* When did you first become interested in gene editing?
* How many people work in your laboratory (on your research)?
* What do they do [i.e. what are their roles]?
* What sorts of backgrounds and training or skill sets do they have?
* What are the main scientific and engineering disciplines required to develop gene editing and its applications in your field?
* Do you find that doing gene editing research has required people in the team to develop new skills?

3) **Overview of the field**

* How would you define the field or sector you are working in?
* What are the biggest areas in which gene editing is developing?
* What is of greatest academic interest?
  + - * What is of greatest interest to the commercial sector?
      * Which areas receive most funding?
      * Which areas have the highest public profile?
* Which areas of gene editing research do you think are the most important to take forward – which applications deserve the most support?
* Are some diseases, conditions or damaged tissues more suitable for gene editing than others?
* If so, which ones and why?
* Which diseases/conditions, if any, should be priority targets? Why?
* Who are the leaders in the field?
* What makes their team/work distinct?
* How do you see the UK’s position in relation to the wider global work on gene editing?
* Do you see the UK as a leader in any particular aspect of gene editing research?
  + - * If so which?
      * Who are the UK’s main competitors?
* Which are the key policy actors in bioprinting in the UK?
* Which groups are shaping the evolution of bioprinting? (What are the respective influences of policymakers, industry, regulators, patient groups, universities, etc?)

4) **Current scientific work**

* Can you discuss your current work with gene editing 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 any approaches that you do not use?
* If so why not?
* 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 advantages/disadvantages of your approach?
* What are the main ‘risks’ related to your work/projects etc. from your point of view?
* What are the possible clinical translations of this work?
* If none, who are the future users of your work/method/process/products?
* If so:
  + How do you envisage this being applied as a therapy?
  + What are the obstacles to translation?
  + Have you started clinical trials?
  + What are the problems of doing clinical trials of gene editing?
  + Have patient-related concerns been raised in discussion with colleagues?
  + How far off, in your view, is successful clinical translation?
  + Do you see gene editing 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 induced pluripotent stem cells 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?
* What do they bring to the work?
* What do they expect from you?
* How many people are authors on your research papers?
* What are their contributions?
* How is authorship and order decided?
* How long does it take to get from beginning work in the lab to a submitted research paper?
* Do you provide services to any groups within your organisation or outside it?
* Do you outsource any tasks to other groups?
* If so could you explain which tasks and why you outsource them?
* What types of contractual arrangements do you need to enter into to pursue your aims?
* 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 based –UK, EU, USA, elsewhere?
* In what outside forums do you discuss your work, and why? – meetings, conferences, workshops etc.

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 gene editing?
* 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**

* How does regulation impact your work?
  + Probe - Respective influence of MHRA/FDA/EMA, others?
* Are the relevant regulatory environments clear to you?
* How do they affect your strategy?
* Does the gene editing require new regulations or official guidance, given the existing measures?
* 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?
* What’s your/your organisation’s position on seeking patent protection?
* 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 gene editing being used in the short term?
* How do you see things developing in the longer term, over the next few decades?
* What will be the obstacles to these applications?
  + Scientific?
  + Cultural/Social?
  + Economic?
  + Legal/Regulatory?