BioMod Interview schedule template: gene editing v1.1

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 sorts of backgrounds and training or skill sets do they have?
  + Do you find that engaging with gene editing research has required people in the team to develop new skills?

4) **Current scientific work**

* Can you discuss your current work with high throughput sequencing for gene editing in a bit more detail?
  + What are the key technologies and biomaterials that you use?
  + Which sequencing approach / technology
  + Does this work build on your prior work on adapting Chromosome conformation capture techniques for low volume cells?
  + If so, without giving away details of work in progress, can you say how?
  + Are you looking for specific things, and does your technique require whole genome or whole exome sequence data or does it only return relevant findings?
* What existing methods are available for predicting off-target effects?
* What are their limitations?
* Does it work with non-homologous end joining and homologous repair with inserted DNA sequences?
* With Cas9 variants for base editing, cas12 etc?
* What are the main reasons for using this approach?
  + Time?
  + Expense?
  + Available skill set in lab group?
  + Material properties?
  + Ethics?
* 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?
* Have you thought about possible clinical translations of this work?
* Do you envisage any difference between autologous and allogenic cell transplants?
* If none, who are the future users of your work/method/process/products?
* If so:
  + How do you envisage this being applied? How might findings be used?
  + What are the obstacles to translation?
  + Do you have any plans for a clinical test?
  + 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?
* 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?
* 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?]

6) **Regulation and governance**

* Does regulation impact your work?
  + If so, how and which areas of law? (re medicinal regulation, ATMP, device regulation, liability, IP; equipment, software, personal data; etc).
  + Is data protection relevant –now or further down the line?
  + Are the relevant regulatory environments clear to you?
* Do you envisage that your work might be of interest to regulatory agencies in future, for example with regards to establishing safety standards for human gene editing in vivo or in vitro?
* 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?]