

UK Biobank Access and Intellectual Property procedures

At EGC16 it was agreed that the UK Biobank Ethics and Governance Council would compile a series of questions which it recommends that UK Biobank seeks to address during the further development of its access and intellectual property (AIP) policies and procedures. The questions are grouped into four part:

1. Access (subcategories: general, data, samples, re-contact)
2. IP (subcategories: general, in the resource, in the research findings)
3. Publication and return of research and results
4. Role of the EGC

Please note that, in asking these questions, the EGC is not advocating a particular process but is simply drawing on the processes that have been described but not fully elucidated in previous UK Biobank policies. The Council does not expect UK Biobank to respond directly to these questions but hopes that the questions will be addressed in a future draft of the access and intellectual property procedures.

1. Access

1.1. General

- 1.1.1. What are the core terms of UK Biobank's access agreement?
- 1.1.2. UK Biobank has previously indicated that it might put out an open call for access requests for certain diseases as the resource matures for each disease. Will access only be permitted within this framework or will *ad hoc* access requests also be considered?
- 1.1.3. Will UK Biobank publish the full tentative timetable as a means of describing when the different types of data will be 'mature' for use for particular conditions?
- 1.1.4. How and where will UK Biobank advertise the open calls?
- 1.1.5. By what process will applications for access be managed? Who has responsibility for what?
- 1.1.6. Access Committee (AC):
 - What is the remit and constitution of the AC?
 - Will all applications for access to data, samples and for re-contact be considered by the AC? If not, what will the exceptions be?
 - How are members to be appointed?
 - By what process will conflicts of interest be managed?
 - Will the Principal Investigator of UK Biobank serve on the AC and, if so, in what capacity (advisory only or part of the decision-making process)?
 - Are appeals against decisions possible? If so, to whom will appeals be addressed and by what process will they be managed?
- 1.1.7. What other committees are envisaged to be part of the access process (e.g. disease specific sub-groups). What will be the remit of such groups and how will they be constituted?
- 1.1.8. Against which criteria will applications be assessed? To what extent will applications be judged against each other, and how? How does UK Biobank define 'health-related and medical' research? How does UK Biobank define 'public good' and how will this criteria be applied to the access decision-making process?
- 1.1.9. Will there be scientific peer review of applications as part of the access process? If so, who or which parties will be responsible for this?
- 1.1.10. Will there be ethical review of applications as part of the access process? If so, who or which parties will be responsible for this?
- 1.1.11. How will the principles of optimal use of the resource and participant privacy operate together?
- 1.1.12. Will UK Biobank test certain technical competencies of the requesting researcher (e.g. procedures for ensuring anonymity is preserved, compliance with Human Tissue Act). If so, which competencies will be tested?
- 1.1.13. Will UK Biobank encourage researchers to collaborate in the event that similar research proposals are submitted?

- 1.1.14. Will access requests be considered prior to or after a researcher has secured funding? Will 'in principle' access be granted dependent on successful funding?
- 1.1.15. In what circumstances, if any, will a fee for access be charged? Will the fee be equivalent across all users or, as suggested in the EGF, weighted according to which organisations may/may not be expected to derive financial benefit?
- 1.1.16. By what process will the access decisions-making be audited?
- 1.1.17. Will data and sample requests be treated differently?
- 1.1.18. Who will monitor the access process and to whom should complaints be directed by aggrieved parties?
- 1.1.19. By what policy and monitoring techniques will UK Biobank ensure compliance with the terms of the Access Agreement and Material Transfer Agreement?
- 1.1.20. What methods will UK Biobank use for dealing with non-compliance?
- 1.1.21. Will UK Biobank permit exclusive use of the data sets? If so, what time restrictions will apply?
- 1.1.22. In what circumstance, if any, will researchers be permitted to transfer data or samples to further parties? (e.g. not at all; to collaborators known at the point of access approval, to collaborators not known at the point of access approval but since brought to the attention of UK Biobank etc.)

1.2. Data

- 1.2.1. How many categories of data has UK Biobank defined (e.g. 'open', 'controlled access')?
- 1.2.2. How are these categories defined and how will access to each be managed?
- 1.2.3. What types of agreement will be used? (e.g. full access agreements or other type of agreement e.g. 'clickwrap' agreement?)

1.3. Samples

- 1.3.1. By what strategy will UK Biobank manage the depletability of the resource? To what extent will samples be kept 'in case' for future research?
- 1.3.2. Under what circumstances, if any, will UK Biobank release sample to: third parties contracted by UK Biobank; independent researchers requesting access. In the latter case will it be up to the researcher to justify why the samples should be released?
- 1.3.3. Will UK Biobank retain copies of the results of sample analyses and incorporate them into the resource for general use after an exclusivity period?

1.4. Re-contact with participants

- 1.4.1. By what procedure will UK Biobank re-contact participants to (i) undertake further UK Biobank assessments; (ii) ask for consent for them to be contacted by researchers?
- 1.4.2. By what criteria will UK Biobank judge and prioritise requests from researchers to contact participants directly?
- 1.4.3. By what mechanism will levels of re-contact be monitored? Who will monitor these?
- 1.4.4. In what circumstances, if any, will researchers be provided with participants personal contact details or identifying information? Will this be for consented re-contact only?

2. IP

2.1. IP general

- 2.1.1. Who will have the authority to vary the approach of UK Biobank towards IP in any of the sets of circumstances listed below? What will inform such decisions?

2.2. IP in resource

- 2.2.1. If a partner organisation (e.g. a Regional Collaborating Centre) has developed IP to support the project (e.g. IT systems) where will that IP vest? How - or will - UK Biobank seek to promote that the IP is available to it and to other organisations?
- 2.2.2. What arrangements are in place for assigning/managing IP in studies that involve the collection of additional information or biological samples or otherwise expand the scope of the resource.
- 2.2.3. Early drafts of the IPA policy stated that 'in cases where UK Biobank collaborates with users or otherwise provides additional input over and above the compilation or

curation of the Resource, it may negotiate suitable arrangements to recognise its additional input (for example, revenue-sharing arrangements). These arrangements will take due account of the contributions of the parties involved (e.g. intellectual or financial input, responsibility assumed for legal risks), as well as the need to ensure that exploitation of the IP for the public good is not unnecessarily impeded. Any royalty income will be used by UK Biobank to implement its purpose for public benefit.' In drafting its procedures and policies, will UK Biobank retain the possibility of negotiating suitable arrangements to recognise its additional input?

2.3. IP in research findings

- 2.3.1.** Will UK Biobank seek to prevent parties who access the resource from pursuing intellectual property rights on certain data types? If yes, in what circumstances?
- 2.3.2.** Will UK Biobank prevent the licensee using any future patents based on the licensed material to restrict research use of such material by UK Biobank or its users?
- 2.3.3.** In what circumstances, if any, will UK Biobank claim reach through royalties on the results of research conducted on data and/or samples?
- 2.3.4.** Will UK Biobank contain material that is proprietary? If so, how will UK Biobank promote the availability of this material to a wide research community while respecting the rights of the proprietor?

3. Publication and return of research and results

3.1. Will UK Biobank publish information about applications for access which have been successful and have been unsuccessful? If yes:

- Where access has been granted, what information will be published and where? (E.g. Title, a lay summary, a scientific abstract, type of samples/data to be released, name of researcher(s)? Published on the UK Biobank website?)
- Where access has been denied, what information will be published and where?
- How soon after granting/denying access would publication take place?

3.2. Will researchers be required to publish the results of their research? If yes:

- By what process will this occur? How will UK Biobank monitor and police such a process?
- Will UK Biobank stipulate the methods of publication? (peer review journal, open access etc)
- Within what timetable will publication be expected to occur (is there a permitted time delay and if so, how long will this duration be)?
- Will this include the publication of negative findings?

3.3. Will all researchers be required to feedback their research findings to UK Biobank?

If yes:

- By what process will this occur? How will UK Biobank monitor and police such a process?
- Within what timetable will feedback of results be expected to occur (is there a permitted time delay and if so, how long will this duration be)?
- Will this include negative findings?
- Will this include raw data or published results only?
- In the event that researchers contact participants directly and go on to generate new information about these participants, will this data be fed back to UK Biobank?
- Will larger research projects be required to feedback findings incrementally or only at the conclusion of the research?
- Will UK Biobank require that users copy their data to UK Biobank on terms that permit them to be used for research by users of the resource without charge (other than standard UK Biobank access charges where applicable) generally and even if the data concerned are the subject matter of a patent.
- What sanctions will be imposed in cases of non-compliance?

If no:

- In what circumstances will researchers not be required to feedback their research findings to UK Biobank?

4. Role of the EGC

Previous drafts of the AIP policy have described various roles for the EGC as detailed below. The EGC welcomes further discussion with UK Biobank regarding these and other responsibilities and their implementation.

- SoPs to describe processes for anonymisation will be developed by UK Biobank in consultation with the EGC.
- The Board of UK Biobank will develop detailed processes for assessment of proposals based on advice from its Steering Committee and an Access Committee, and in consultation with the Ethics & Governance Council.
- Requests for access to samples and participants will be considered according to criteria set by the Board of Directors in consultation with the EGC.
- UK Biobank's decisions on whether to re-contact participants will be taken after prior consultation with the EGC¹.
- UK Biobank and the EGC will monitor the level of re-contact to ensure that participants are not overburdened.
- EGC will monitor applications for access to the resource and in particular will receive the Access Committee's recommendations regarding sensitive requests (including access to samples and re-contact) prior to each meeting of the Board of Directors so that the EGC may then raise any concerns it may have.
Question: Does UK Biobank still intend to define and identify the sensitivity of requests which it receives? If so how will these be defined and judged, and by whom?
- Both the EGC and the International Scientific Advisory Board will have oversight roles with respect to the timetable for proposals, the review process, the access recommendations, and the outcomes of approved research.

¹ It would be useful if UK Biobank could supply the EGC with information about the erosion rates and causes of erosion in other longitudinal epidemiological studies so the Council can start to judge when re-contacting becomes a burden and what sorts of re-contacting might be deemed burdensome.