

### Andrew Russell - ECG

	<p>The Ethics and Governance Council of UK Biobank. UK Biobank as we've heard is a world leading project and it does spend quite a lot of money, public money and it's important that that is spent properly and that the public interest is served and that's what really lies behind the Ethics and Governance Council which is not the body managing UK Biobank it's a body one removed from that which scrutinises how things are going and gives advice and so on.</p>
_00:00:24_	<p>Now research participants and I think that probably almost everybody here is a participant in UK Biobank, in the normal run of things give an informed consent to the research that they're participating in. So they will know the area of research, sometimes what specific tests will be done on their samples and their data and which particular research questions will be asked. But, Biobanks are different because they are about the future and indeed some of the areas of research which will be undertaken through UK Biobank data and samples in the future aren't known about yet and indeed the technologies might not even exist yet. So the kind of consent that you have given is not informed consent because you can't be informed about the detail of all that which is to come. It's more of a general consent or broad consent whereby you are expressing trust in UK Biobank to behave properly and to act in the public interest and to bear in mind the interest of participants and there is a reciprocal duty on the party of UK Biobank to behave properly, to protect your data and to undertake the kind of research activities that in general the public and the participants would approve of.</p>
_00:01:51_	<p>So the EGC was set up, the Ethics and Governance Council was set up in 2004 to ensure that standards were upheld. So this was a one removed scrutiny of UK Biobank and its management to make sure that the standards which were set out in a document called The Ethics and Governance Framework are complied with. So this Ethics and Governance Framework, the EGF sets out principals along which UK Biobank will conduct itself. It establishes UK Biobank as the legal owner of the data and samples that you have given. It lists the principals governing access by researches to all this data including, it describes benefit sharing requirements so that the resource is used in the public interest and that would include that research results are published and that results are archived in an accessible way so that other researches can follow through on that and grey enterprise of improving medical research and health research can go on into the future.</p>
_00:03:15_	<p>The EGF says that participants may be re-contacted at certain times in the future. So it's not a once off thing, you may well be and many of you have been re-contacted for example to wear the Accelerometer's or for other tests like the cognitive tests which some of you have undertaken.</p>
_00:03:35_	<p>The EGF also affirms participant's right to withdraw from the study at any time so you're not nailed in if for some reason you wish to withdraw and that is laid down in the Ethics and Governance Framework.</p>
_00:03:54_	<p>It also commits to do everything possible to protect confidentiality of the data and samples that you have given. And it also says that UK Biobank will communicate with you and listen to your views which is partly what this evening is about and a number of</p>

	other ongoing meetings around the country to listen to and to put across information for participants.
_00:04:19_	So the EGC, the Ethics and Governance Council was established to scrutinise UK Biobank activity including the provisions... that the provisions of the EGF are stuck to and also to advise how that framework might be enhanced and developed and grown over time to reflect progress in medicine and in technology which is of course very rapid.
_00:04:47_	So the EGC is an independent council formally appointed by the funders, which is the Medical Research Council in Wellcome Trust. It is not there to manage UK Biobank, that's the job of the management board and the Chief Executive of UK Biobank. But it is there to exercise oversight at one remove. It can advise on the participants interests on the basis of the broad consent that I've referred to that you have given and it can advise on ethical aspects of new developments for example, the MRI scans which are being done or maybe have been done... they haven't been completed, but obviously a great deal more diagnostic information is going to be found out through those scans and so there may be other ethical issues that come about.
_00:05:41_	So the UK Biobank and its management team have an enormous management challenge. You've heard of some of the incredible progress that has been made over the last 10 years or more making UK Biobank really a world leading project in its field. And to do that the management team have to be highly focussed on strategic and operational management for example, setting up the physical resources, the coordinating centre, the recruitment centres which are the medical assessment units which were set up in major cities throughout the country when the recruitment was going on. The specialised warehousing facilities that Andrew has shown us a photograph of with its robot. Many IT systems which have to be fall proof and failsafe. So all of these things are a tremendous management challenge to the UK Biobank management and they need to be focussed on achieving progress in that field.
_00:06:45_	We at the EGC bring a totally different mind-set and we are not involved in that management challenge. We are there to focus on the interests of participants and the interests of the public, to advise and draw attention to things in terms of the conduct of UK Biobank that can be made better. Who is on the Ethics and Governance Council? Well I have nine other colleagues, there are ten of us at the moment, there has been as many as twelve in the past. I'm coming to the end of my period of office which is strictly limited so you have a turnover of people and we're all appointed by a transparent process of application, interview and sending a curriculum vitae and all that. So it's a transparent process and there are ten members and normally there are equal numbers of men and women on the council. It's multi-disciplinary so that the kind of backgrounds which members of the council bring to the work are law and international law, ethics also with an international viewpoint on ethics, the biomedical sciences, the social sciences, consumer issues and so on. So each member brings something to the party. We have four meetings a year and then we have other meetings in between on specific topics as necessary.
_00:08:22_	How we work is we receive reports from UK Biobank on key aspects of their activities and progress. For example, progress on linkage to health records which Andrew mentioned, the various hospital incidents, death registries, cancer registries, and GP

	and primary care records. That's a very complex piece of work to carry out and it can't all be done overnight so we have, for example, ongoing updates on the progress in that way.
_00:08:57_	We have reports on data security so that we're aware of what audits are going on and how well the massive data which is being collected is protected including the commissioning of penetration tests so that the hackers with the right hats can try and get into the Biobank information and in that way it can be checked up whether there are any possible gateways which might illicitly get out the information and I can tell you, we are keen on following up those reports and so far there has been no such leakage of information.
_00:09:42_	We receive reports on re-contact as I've said people/participants can be re-contacted [_00:09:47_]. So that we can try and ensure that there is sufficient re-contact going on but not so that everybody is badgered too much and gets a sort of re-contact fatigue which could happen if it was overdone.
_00:10:04_	Another thing which we take an interest in is the potential deprecation of the samples so that we receive reports on what research is being undertaken and which of those pieces of research needs the use of the physical samples that are re-connected because obviously in theory those could be depleted completely over time and so it's important that they are used for key and important research.
_00:10:32_	And another thing we receive reports on from Andrew is communication. So we know we can see it for ourselves what the website is doing but we hear about other aspects of communications between UK Biobank and participants.
_00:10:50_	Things that we've pushed for, there have been quite a few things over the years, the Ethics and Governance Council has advised more could be done for example, some relaxation of the strict no feedback of health results policy what they call Potentially Significant Incidental Findings. We have pushed for revision and expansion of the Ethics and Governance Framework which is underway at the moment and there will be some padded version... extra aspects to that in due course.
_00:11:27_	We've also pressed to find out how best we can scrutinise the access process, that is access by researchers to the data and the samples because we are not managing the access process, we're merely looking on so we need enough information without being there doing some sort of parallel review and leaning in too much to management. So there are these relationships which are important which we have to get right.
_00:11:58_	What are the powers of the Ethics and Governance Council? Well, it's more influence though informal discussion than actual powers. Sometimes we can send a written communication to the Board of UK Biobank. We can approach the funders with whom we have a very good and very communicative relationship and as a last resort, although this has never happened yet, the EGC could make a public statement drawing attention to some anomaly or something where we feel the UK Biobank has gone wrong. As I say that has yet to happen and I hope it never will but that's the reason for this council, the Ethics and Governance Council, being one removed and independent of UK Biobank.

_00:12:56_	So I would say in conclusion that we have a mutually respectful relationship with the EGC acting as a critical friend to the UK Biobank and we do see it as our job to look after the public interest and the interests of participants. Thank you.
	<b>ENDS 13:20</b>