

Soren Holm – 22<sup>nd</sup> September 2015

	So I'd like to introduce to you Soren Holm who works for UK... who is a representative on UK Biobank Ethics and Governance Council.
_00:00:10_	Thank you for the invite to speak today, I apologise I have a cold which my son has brought home from school. I'm a medical doctor and philosopher and in my day job I am Professor of Medical Ethics at the University of Manchester.
_00:00:29_	So I will talk a little about what the UK Biobank Ethics and Governance Council does, why it was set up and sort of what it has been doing.
_00:00:39_	So first I'll talk about the Ethics Governance Framework, the EGF and the EGC, the Ethics Governance Council. Then I'll talk about sort of how it actually works, some reflections on 10 years of work. As an academic I've followed the Ethics and Governance Council and then for the last four years I've been a member of it myself and then I'll say something in conclusion.
_00:01:07_	And essentially when UK Biobank was set up it was recognised that this is a very important project which over its lifetime is going to raise a lot of ethical, legal and regulatory questions and that it's very important to get this right. It is as Andrew has already said in many ways a model for what other Biobanks do, other Biobanks which have been set up later.
_00:01:41_	So a very detailed document was drawn up I, the two main funders, Medical Research Council and the Wellcome Trust which is the UK Biobank Ethics and Governance Framework and it lays out the principals on which UK Biobank should function and how it should be governed sort of ethically and regulatory. So it's in the Ethics and Governance Framework you can find the description of the consents that you've already been through when you were recruited, a description of your unconditional right to withdraw if you should become unhappy with UK Biobank and also the commitment which Andrew has already mentioned that UK Biobank will keep both your samples and data absolutely confidential. Researches will only get access to non-identifiable data and samples.
_00:02:49_	It confirms that UK Biobank is the legal owner of the database and then it describes the principals which govern access to a resource by researchers. And you have to think about that this was written before anyone had actually collected any data. So for instance with regards to access so that principals could be laid down at that time but no one could really predict "well how would researchers get access in 2014". So UK Biobank in collaboration with the Ethics and Governance Council have had to sort of implement a set of principals described in the Ethics and Governance Framework. It also describes the benefit sharing requirements that all researchers have access and that they have to give back their results so as to enhance the resource.
_00:04:03_	Part of this governance is the Ethics and Governance Council which is set up independently so it's not sort of owned by UK Biobank, if it's owned by anyone it is the Wellcome Trust and the Medical Research Council as the two major funders of the project.
_00:04:25_	So our task is to monitor whether UK Biobank works in conformance with the Ethics and Governance Framework, does it keep within the principals laid out, the principals that you initially consented to and it's also recognised that this framework needs revisions now and again so we're going to start a revision cycle this year looking at sort of what has happened since 2006 and what needs to be changed and the Ethics and Governance Council is involved in this and also more regularly in advising UK Biobank on the interests of the participants and the ethics in relation to the project.
_00:05:14_	Now the Chairs and Members are all appointed by the Medical Research Council and the Wellcome Trust. There's an announcement, an advert in The Guardian and other

	reputable newspapers and you have to apply and say “well I would like to become a member” and then you may be shortlisted and then if you’re shortlisted they’ll be an interview with a quite scary interview panel. When I was interviewed by a very famous philosopher was on the panel and she is quite scary!
_00:06:00_	So essentially the whole purpose is to ensure that you have a council of independent people who can give both advice to UK Biobank but also look at sort of is UK Biobank doing what it should do? Why was it felt and is still felt that you need this? Well, because this is an extraordinary broad project. It involves health research and you have consented to health research but health research and what falls under that umbrella term is continually developing. Researchers can do things today that no one could imagine 10 years ago was possible and of course this is going on for a long time. When Andrew is talking about the results becoming more valuable, he is really talking about some of you becoming ill and dying!
_00:07:03_	Because of course then the researchers can compare you who have become ill and dying with some other people who share all your characteristics but are not ill and try to figure out “well why did one person become ill and another one not”. So this has a very long timeframe and already from the beginning it was quite clear that... well they would need ongoing advice and the mechanisms that we have in the UK for sort of more... and shorter term resource projects, the research Ethics Committee’s really don’t do that kind of thing.
_00:07:55_	So essentially sort of the UK Biobank Ethics Governance Council adds as a critical friend to UK Biobank. So it was established in 2004. It’s multi-discipline area, there are people like me who are experts in ethics, there are lawyers, experts in biomedical science, social science, information governance, public communication and so on and at the moment it had 10 members, 4 meetings per year and then we also have sub-groups on specific topics that meet as required. So for instance we have in relation to developing the protocol for the imaging there has been a sub-group which has worked with UK Biobank on the ethics and legal aspects of the whole imaging scenario.
_00:08:50_	So essentially we advise, review and report on UK Biobank. Does the Council have a stick? Well it does have a stick, the stick is that if it feels necessary it can make a public statement that’s certain actions should or should not be taken by UK Biobank but our relationship with UK Biobank is good and we have never had to use this particular stick.
_00:09:24_	Recent issues, well the EGC was quite involved in developing the access process and in developing ways in which that process could later be ordered to be monitored and also for instance in relation to imaging, engaging with Biobank about issues concerning so called incidental findings “well what if in one of these scans something is seen that may be significant or may not be significant what procedure should UK Biobank use”? And one of the things that come out of this is that a very important social science study has been included in the pilot of the imaging which will give us much more knowledge about what actually happens when you tell people that something was seen in their scan. So that’s very important.
_00:10:31_	And what have we been doing these 10 years? Well, at the beginning the EGC was very much involved in drafting the participant materials, drafting the consent forms, later we have been more monitoring and reactive and I think over time the EGC has also realised that well its role is sort of to discuss with Biobank and come up with a range of reasonable approaches. There are many ethical and regulatory issues around UK Biobank which does not have one unique right answer and it’s not up to the EGC to tell Biobank “well this is what you must do and this is the only right thing in the world”. It’s up to us in communication with Biobank and dialogue to come up

	with a set of reasonable approaches and then Biobank should adopt that one that is possible for instance within its funding envelope for a particular issue.
_00:11:46_	So in conclusion well the council was established in direct response to the broad model of consent. We have the Ethics and Governance Council which sort of overlooks the framework and that UK Biobanks keeps within that and it's important to have partly because the traditional research says it to not do this. By acting as a critical friend, by engaging in constructive dialogue with Biobank the Council can promote and facilitate good governance and good science in the public interest.
_00:12:29_	So what we have been doing over time has changed and it will no doubt continue to evolve as Biobank evolves. Andrew has already talked about the genetic analysis that's being done on all participants and that will undoubtedly raise new issues that will need discussion and a reasoned solution.
_00:13:03_	Thank you very much Mr Holm.
	<b>ENDS _00:13:10_</b>