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I'd like to try to draw some conclusions or tie some loose ends together. You might be thinking or at least thought at one point, what do these diverse topics have to do with DNA forensic data banks? We've talked about genetics research, we've talked about behavioral genetics and we've talked about biobanks in general, but the forensic repository is really a subset of the biobanks in general. Also, one of the great concerns certainly of scholars and commentators in expanding the scope of DNA forensics is that somehow researchers will gain access to these samples and perform behavioral genetics research without consent, without any of the protections that we normally associate with ethical research, and draw all sorts of wild and crazy conclusions because the sample is so unrepresentative of the population. It's skewed by race and ethnicity. It's skewed by income. It's skewed by education. It's skewed by all sorts of variables.

I want to try and avoid most of the things that Hank Greely talked about but I'm trying to paint a picture for you of why it is so difficult to ethically and legally regulate biobanks. The first thing that I want to try to impress upon you is that it reflects a model that we're not used to seeing. The common rule was not created for biobanks, it was created for a much narrower model where the risks and benefits were largely to individuals. It was designed for a single known researcher, or a group of known researchers, who would use samples in known ways and each of the subjects would give their informed consent. With bio bank research, the situation is more commonly a third party soliciting the consent to participate in the research repository that is not personally doing the research or even involved directly with the institution doing the research.

We have all different levels of bio banks: government bio banks, university bio banks, commercial for-profit bio banks, etc. And in some of them, these are only collecting the specimens to be brokers, to sell it, or to loan it to a third party who may be using it. The repository is to be used for many research protocols, often in widely diverse areas. The whole notion of the bio bank is that it's for future research; you collect samples, but you don't know what they're going to be used for in five or ten or fifteen years from now. Therefore, how can you ask people to consent to protocols done by researchers who are asking research questions that you don't know yet.

For biobanks to work, they need to move beyond the 'one-study-one consent' model to a broader type of consent that I'm going to talk about in a minute.

Now, the third class is a subheading under biobanks of DNA forensic repositories. For traditional ethics purposes, keep in mind, these samples were not collected for research. They were collected for other purposes and not collected voluntarily. They involve a population that is different in many ways from the population as a whole. It's also a vulnerable population for which there are special research ethics rules, because of the abuses in the past and the great possibility of coercion in obtaining informed consent. Here is a population who've done something society deems criminal and requires imprisonment, which automatically lends itself to research about crime and the elements of crime. Those are automatically controversial or can be highly stigmatizing.

What should we fear or be concerned about protecting in this kind of research? Considering the ethical framework for both identifiable and unidentifiable research, I think there's a fairly widespread understanding and acceptance that even research with de-identified, anonymized, unlinked, and so on may be ethically unproblematic. It may involve research of which the donor does not approve. You can do anonymous research on, for example, conditions that would, if identified and are identifiable through a genetic test, arguably lead to an increase in the number of abortions. There are many people who would be opposed to having their samples, anonymous or otherwise, used for that research. It may involve using a sample donor's tissue when they feel for religious or moral reasons that it is improper to do research.

Plus you also get the prospect of group-based harms. If you identify the gender, ethnicity or other characteristics of the individual, even if you don't identify the individual, then your findings can have adverse consequences for any member of that group.

There are also consequential harms but those are limited to identifiable research and discrimination after disclosure of the records to third parties. Often, by going from the research record to the clinical record can disclose identity to compelled authority, which raises a very interesting question of what do you do? Do you keep records separate in the research? By doing that you may prevent this but you've now destroyed, largely, all the clinical value to the individual that the treating physician may gain from getting access to the results? Identifiable research can also lead to stigmatization and group harms.

What about the harms associated with research using law-enforcement specimens? I think there are several that were touched on before so I just want to go through them quickly. First of all, I think it would undermine the law enforcement uses of the databases. I think the public support for aggressive use of law-enforcement databases would be undermined if those samples were indiscriminately available for research. Law-enforcement uses are valuable in catching lots of serial murderers and rapists and all sorts of bad guys and I think its integrity would be compromised.

I also think it would undermine research ethics by allowing research to be conducted on a vulnerable population with no informed consent and all the other principals that we've talked about. To be valuable you would have to turn over to researchers often sensitive information surrounding the crimes that these individuals committed. Information in police investigatory files are not considered open to the public, unlike conviction records and so very sensitive information about victims as well as the perpetrators of the crimes could be disclosed. You may want to link this to clinical data of a health nature so you're also going to get health information and health histories about the individuals in the data banks.

Then you've got the potential for-- and I use this term advisedly - subpopulation harms which I mean to say are even greater than group harms, which is a whole class of people who are defined as being a particular ethnic or racial group.

There are a number of very complicated legal issues surrounding bio bank research, and here I am speaking of biobanks in general, not just limited to research on law enforcement samples. Under the common rule, an IRB is permitted to approve prospective consent for unspecified research. If they couldn't do that then biobanks would be out of business because you'd have to get consent for each individual, from each individual donor, for each individual protocol. It would be a mess. It would completely undermine all of the advantages that we've gained scientifically by collecting these repositories.

The common rule has been interpreted to allow consent for unspecified future uses, but IRB's are allergic to the idea of signing away all of your rights forever and ever. So instead of blanket consent, many IRB's have gone to a sort-of checklist, called "layered" or "tiered" consent. You give people an option and you say, "Do you consent to research on AIDS, on psychiatric disorders, on cancer, on epilepsy, on diabetes, etc. and they give you consent by category. And once you have that it seems quite acceptable that you don't have to go back and describe -- and get rule consent for every diabetes study that you want to do in the future. I think, ethically, that would be fine.

Unfortunately, HIPPA throws a monkey wrench into all of that. Towards the end of the *JOD* issue that you all have is an article that I wrote in which I identify several areas in which the common rule and the HIPPA privacy rule are out of synch with recommendations for harmonizing those rules to make life easier for researchers, especially in cases where the more stringent rule adds nothing to the privacy protections of individuals.

The HIPPA privacy rule does not permit authorization for future uses. In theory, if you're a researcher and you want to use information -- any protected health information, not just samples -- individually identifiable information about somebody's health has to have separate authorization for each study which, as you can see, defeats the purpose of the bio bank.

I am familiar with several institutions that have told me of cases like this. They build a repository from excise tissue from cancer patients and the cancer patient, when they gave their consent, said, "My surgeon told me I am going to be fine. They've got it all. I'm happy to give you the tissue. Do whatever the hell you want with it on one condition, that you don't ever, ever, ever contact me again. Because psychologically, I think I'm going to be fine. I don't want to think about this. I'm moving on. I don't want a call from a cancer center for permission to do anything. Just leave me alone; do whatever you want with my specimen."

You can't do that because under HIPPA they have to keep calling them. They call them up and now this person says, "What about my instruction was vague to you," and now they can't use the samples anymore.

That strikes me as absolutely, totally idiotic, indefensible, and not furthering anybody's interest. There is a provision now in the HIPPA privacy rule that allows an IRB or privacy board to waive the necessity of the researcher going back and getting authorization from each individual but you still have to get a separate waiver for each new study that you do from the IRB or privacy board, again adding a layer of unnecessary bureaucracy and paperwork. Last year, the National Committee on Vital Health and Statistics sent a letter to the Secretary of HHS urging that these discrepancies between the privacy rule and common rule be eliminated, but there has been no action taken on this.

Another interesting issue is the question of authorization for future uses of future health information, but HIPPA's privacy rule does not address this and it's going to have to be addressed at some point. I can give my authorization to give you my health records as they exist today. What authorization can I give you as a researcher to use my health records that I may generate a year, five years or ten years down the road? I think, at minimum, this authorization for future health information should make clear that the researcher will have access to a growing and changing health record over time, that future records may contain more sensitive information than they do today, and that disclosure to entities not covered by HIPPA will no longer be protected. Once the researcher, who is a non-covered identity, gets these records, HIPPA doesn't apply. They could sell them, trade them or do all sorts of other things with them.

Then the question is raised as to whether there should be a time limit for future authorizations. One proposal would be to limit it to five years, so every five years you would have to go back and get authorizations. That's an issue that is still unresolved.

I want to conclude by listing some options for research ethics bringing us back to the issue of DNA forensic databases. There are four of them.

First, we could enact legislation to exempt research on law enforcement repositories from the common rule and to preempt state research laws from

applying. I'm at a public university, and we are covered by the common rule. Researchers at my university signed an agreement saying we'd abide by the common rule. Suppose we wanted to do research on the prisoners at some prison in Kentucky. By using the forensic information, we would be subject to the common rule, unless we were exempt from it somehow. We can enact legislation to exempt research on these repositories, though I would not advocate doing so

Another option is to do nothing. If we do nothing, then we would in essence permit by not completely prohibiting this research. Most of the states' DNA forensic databank laws do not specifically address the issue of research. If we enacted no laws, then the research would be subject to IRB review. Given what I know about the IRB, there is no chance in hell that the IRB would approve research on the involuntarily submitted DNA specimens of people who were in prison.

The third option is to somehow, perhaps legislatively, federal or state, prohibit all research with these samples. The practical effect of option three versus option two is zero, but I think three is preferable to two because it has the advantage of reassuring the public that the research will not go forward in an on-the-record legislative statement that there will be no research instead of relying on local IRB's. On the other hand, if you destroyed all the DNA samples and their analysis so that there would only be a list of numbers, then this moots the whole issue because you couldn't do any research. There would be nothing to do the research on. You wouldn't have raw DNA; you'd have a bunch of numbers.

Well, I apologize for revisiting an issue that the first two of our meetings here sponsored by ASLME debated at length. However, as someone who feels strongly on this issue, I don't apologize too heartily about sneaking in this sort of extra plug for the benefits of destroying the DNA samples after you've analyzed them. I feel that legally, if there's a match, that would establish probable cause to go get another sample from the alleged perpetrator and if there's something wrong with the records, it would clearly be indicated by the retyping of the individual. If the individual thinks that they've been wrongly apprehended they can obviously have their own DNA tests performed and see if it matches with the crime scene evidence.

The only argument that I think has any weight in terms of law enforcement's side of this is that the technology may change and you may be able to do more things in the future and so on and so forth.

I'm willing to stipulate to that but I think the scientific benefits do not outweigh all the other considerations that I've laid out. Therefore, I think in the interest of getting acceptability to the use of the samples from the data banks, I would favor destroying them.