Informed Consent to Future Research on Stored Tissue Samples: the Views of Researchers, Ethics Review Committee Members and Policy Makers in Five Non-Western Countries[1]

Kenji Matsui, Alaa Abou Zeid, Zhang Xinqing, Benjamin Krohmal, Vasantha Muthuswamy, Young Mo Koo, David Wendler, Jesse Chao, Yoshikuni Kita and Reidar Lie

Introduction

Collections of large repositories of human tissue have become increasingly important for biomedical research. Amongst the most controversial is the question about the type of consent needed for the collection, storage, and future research use of tissue samples for yet to be specified research. Such biobanks raise a host of unique ethical and policy questions, many of which are quite controversial.[1] Typically, when investigators collect samples, either for a specific research project, or with the aim of establishing a biobank, they have only a vague idea of what future research might be conducted. Some have advocated that a one-time, general consent for any future research is ethically appropriate. In this model, tissue donors would be asked whether they agree to have their tissue samples stored for any future research. If they agree, the investigators are free to use the samples as they wish, subject to appropriate ethics review procedures. If they decline, the tissue samples would have to be destroyed after the specific purpose for the initial collection has been satisfied, or the tissue donors would have to be re-contacted for a new consent procedure for a future, specific project.[2] Others have, however, argued that tissue donors cannot give valid consent for

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unspecified, future research. Consent requires specific information about what one consents to, and this would mean, at a minimum, some indication of the type of research that is envisaged. Clayton *et al.*, summarising a discussion of a meeting called by the U.S. National Institutes of Health (NIH) and U.S. Centers for Disease Control and Prevention (CDC), advocated that prospective donors should be given specific choices, such as whether to limit research on their samples to certain types of research, or to allow their samples to be shared among other scientists.[3] The Tri-Council of Canada endorses specific consent, requiring disclosure of "potential uses for the tissue, including any commercial uses". For genetic studies, it specifically suggests either a comprehensive consent form, giving detailed options, or re-contact for new consent for future research.[4] Similarly, the Council of Europe recommendation requires that consent be "as specific as possible with regard to any foreseen research uses and the choices available in that respect".[5]

There are numerous studies of the attitudes of prospective research participants to issues of informed consent for future use of stored tissue samples.[6] In contrast, there has not been a systematic study of the attitudes of researchers and others involved in the research with regard to this same issue. Also, most of the scholarly discussion has taken place in North America and Europe, and little is known about the attitudes of non-Western researchers and policy makers to these issues. To provide such data, we have conducted a multi-country survey of attitudes and beliefs among researchers, ethics committee members, and people involved in policy making for research regarding several key ethical and policy issues on informed consent and ethics review in research on stored human biological samples. The presented data are one of two major sets of data obtained through a larger survey of ethical and policy issues on stored human biological samples.

Methods

Survey Countries and Populations

The target populations were enrolled from sites in China, Egypt, India, Japan, and Korea. The countries were chosen because of existing collaborative research projects in bioethics between the authors of this paper. The potential respondents were selected from the following four groups: 1) "researchers" who are conducting research on human biological samples, 2) "collectors" who are involved in the collection of human biological samples, 3) "ethics committee members" who are currently sitting as research ethics review board members, and 4) "policy-makers" who are involved in an institution's policy making process on the handling of human tissue samples. There is considerable overlap

between membership in these groups, and many respondents belong to more than one. “Researchers” is the broadest category, and can for example involve people who do research on existing sample collections, collect samples for new research (“collectors”), policy makers and ethics review committee members. The institutions identified for the survey were selected because they were known to be involved in human tissue research, but the specific individuals surveyed had not necessarily themselves been involved in such research. Local principal investigators (PIs) in each country determined the appropriate way of enrolling respondents; therefore, the respondents, other than the Japanese participants who were enrolled through cluster randomisation, were a sample of convenience.

Questionnaire Development

The self-administered survey instrument has been developed by PIs in the Department of Bioethics at the United States (US) National Institutes of Health Clinical Center and in the department of Health Science at Shiga University of Medical Science, Japan, in collaboration with local PIs in each country. The survey instrument was pre-tested for possible misunderstandings and clarity in the US. After the instrument was finalised in English, it was translated by collaborating investigators to the languages appropriate for the target countries. The resulting first foreign language version was back-translated to English, and any discrepancies were resolved. The resulting foreign version was checked one final time by an independent person for clarity and language.

Questionnaire

The questionnaire was composed of four major sections: demographic characteristics, informed consent policy, rights of collaborating researchers, and dealing with international differences in regulatory frameworks. Only data from the first two sections are presented here. The instrument for the informed consent policy section contained the following four survey domains, which assessed participant attitudes towards:

1. Binary vs. multiple consent options to future research on samples
2. Possible consent options for future research on samples
3. Reasons for/against providing consent options to unspecified future research on samples
4. Mandatory limitations on consent to future research

Most questions used were in the form of a binary choice or a five-point Likert-like scale ranging from 1 (strongly disagree) to 5 (strongly agree). The survey was conducted between 2006 and early 2008.

Statistic Analysis

The chi-square test was applied for analysis. Two-sided p-values equal to or less than 0.05 were considered statistically significant. All analyses were done with the SPSS (ver. 14.0J) statistic software.

Results

The total number of valid responses obtained was 154 in China, 186 in Egypt, 127 in India, 864 in Japan, and 105 in Korea. The response rate for Japan, in which the questionnaires were sent out to the potential participants of randomly selected institutions, was approximately 33%. For the other four countries, where the potential participants were a sample of convenience, no detailed data about response rate were recorded.

Demographic Characteristics (Table 1)

The respondents in India and Japan were relatively older compared to those in the other three countries. Most of the respondents, except the Chinese, had doctoral degrees. Excluding China, only 18% of the respondents in the other countries were research ethics review committee members. About a quarter to half of the respondents in each country reported that they were currently involved in policy making processes concerning research. Other than in Japan, a majority of respondents in each country reported that they were conducting research on stored human biological samples and collecting them for future use in research.

Table 1. Demographic Characteristics of the Respondents in the Surveyed Countires

	China (N = 154)		Egypt (N = 186)		India (N = 127)		Japan (N = 864)		Korea (N = 105)	
	n (%)		n (%)		n (%)		n (%)		n (%)	
Sex (% of males)	93	(60.4)	89	(47.8)	87	(68.5)	722	(83.6)	62	(59.0)
Mean age (SD)	42.4	(9.1)	45.9	(10.0)	55.4	(12.1)	53.4	(10.1)	41.0	(8.1)
Current area of work[§]										
Law	1	(0.6)	1	(0.5)	2	(1.6)	57	(6.6)	2	(1.9)
Clinical medicine	80	(51.9)	139	(74.7)	59	(46.5)	343	(39.7)	67	(63.8)
Scientific research	63	(40.9)	178	(95.7)	95	(74.8)	434	(50.2)	28	(26.7)
Administration	30	(19.5)	9	(4.8)	41	(32.3)	138	(16.0)	13	(12.4)
Health policy	2	(1.3)	19	(10.2)	26	(20.5)	24	(2.8)	7	(6.7)
Social science	0	(0.0)	0	(0.0)	9	(7.1)	67	(7.8)	4	(3.8)
Philosophy	1	(0.6)	0	(0.0)	1	(0.8)	29	(3.4)	1	(1.0)
Others	2	(1.3)	14	(7.5)	30	(23.6)	134	(15.5)	11	(10.5)

continue

Table 1. continued

	China (N =		Egypt (N = 186)		India (N = 127)		Japan (N = 864)		Korea (N = 105)	
n (%)			n (%)		n (%)		n (%)		n (%)	
Mean years in current area	14.	(8.5)	20.8	(9.9)	24.9	(11.9)	24.5	(11.1)	11.9	(9.0)
Highest degree level (%)										
No degree or declined to answer	0	(0.0)	0	(0.0)	0	(0.0)	21	(2.4)	0	(0.0)
Masters or below		(52.6)	23	(12.4)	12	(9.4)	128	(14.8)	21	(20.0)
Doctoral degrees		(46.8)	162	(87.1)	109	(85.8)	705	(81.6)	82	(78.1)
Others	1	(0.6)	1	(0.5)	6	(4.7)	10	(1.2)	2	(1.9)
Current employer[§] (%)										
Private research institution		(7.8)	4	(2.2)	23	(18.1)	13	(1.5)	3	(2.9)
Public research institution		(90.9)	178	(95.7)	37	(29.1)	52	(6.0)	6	(5.7)
Hospital or clinic		(59.7)	171	(91.9)	35	(27.6)	133	(15.4)	70	(66.7)
Local government	1	(0.6)	1	(0.5)	5	(3.9)	42	(4.9)	1	(1.0)
National government	4	(2.6)	3	(1.6)	46	(36.2)	23	(2.7)	12	(11.4)
International organisation	2	(1.3)	1	(0.5)	7	(5.5)	3	(0.3)	5	(4.8)
University		(45.5)	159	(85.5)	26	(20.5)	705	(81.6)	49	(46.7)
Ethics committees		(71.4)	56	(30.1)	23	(18.1)	115	(13.3)	37	(35.2)
Others	3	(1.9)	1	(0.5)	20	(15.7)	48	(5.6)	2	(1.9)
Being involved in policy	5	(32.5)	70	(37.8)	61	(48.8)	203	(24.1)	28	(26.7)
Conducting research on	13 8	(89.6)	142	(76.8)	73	(57.9)	303	(35.7)	53	(50.5)
Collecting human biological	9 2	(59.7)	125	(67.9)	72	(56.7)	251	(29.7)	47	(44.8)
Experience of donating	6 8	(44.4)	43	(23.2)	54	(42.9)	319	(37.8)	39	(37.1)
Experience of research	6 9	(44.8)	92	(49.5)	91	(72.8)	551	(64.9)	27	(26.0)
People in only developing countries	2	(2.9)	4	(4.3)	4	(4.4)	26	(4.7)	1	(3.7)
People in only developed	5	(84.1)	49	(53.3)	30	(33.0)	232	(42.1)	18	(66.7)
Both	3	(4.3)	39	(42.4)	57	(62.6)	288	(52.3)	7	(25.9)
Answer missing	6	(8.7)	0	(0.0)	0	(0.0)	5	(0.9)	1	(3.7)
Working experience in a	5 8	(37.7)	91	(48.9)	75	(59.1)	531	(61.5)	45	(42.9)
Having worked in (%)										
Only developing countries		(51.3)	106	(57.0)	36	(28.3)	27	(3.1)	12	(11.4)
Only developed countries		(37.7)	22	(11.8)	33	(26.0)	595	(68.9)	41	(39.0)
Both	2	(1.3)	54	(29.0)	42	(33.1)	75	(8.7)	6	(5.7)
Answer missing	1	(9.7)	4	(2.2)	16	(12.6)	167	(19.3)	46	(43.8)

§: multiple choice.
SD: standard deviation.

Attitudes Towards Consent Options to Future Research on Samples (Table 2)

We asked the respondents whether or not consent forms for the storage of samples intended for future research should provide donors with the option to consent to future research. A large majority (range: 73.1% to 85.7%) accepted the idea of giving donors the option to give consent to future research, rather than prohibiting any such option.

Table 2. Attitudes Towards Consent Options to Future Research on Stored Samples

	China (N = 154)		Egypt (N = 186)		India (N = 127)		Japan (N = 864)		Korea (N = 105)		*P* value
(% agree)	n (%)		n (%)		n (%)		n (%)		n (%)		
Consent forms for the storage of samples intended for future											
Never provide donors with the option to consent to future research	15	(9.7)	34	(18.3)	14	(11.0)	102	(11.8)	14	(13.3)	0.061
Sometimes provide donors with the options to consent to future research	127	(82.5)	136	(73.1)	101	(79.5)	693	(80.2)	90	(85.7)	
Don't know/no opinion	12	(7.8)	12	(6.5)	4	(3.1)	51	(5.9)	1	(1.0)	
Answer missing	0	(0.0)	4	(2.2)	8	(6.3)	18	(2.1)	0	(0.0)	
Consent forms that give donors the option to consent to future research should include:											
Multiple options regarding the types and conditions of future research for which the	87	(56.5)	87	(46.8)	57	(44.9)	486	(56.3)	62	(59.0)	0.002
Binary options, to either consent or not consent to all future research on the	60	(39.0)	78	(41.9)	67	(52.8)	313	(36.2)	40	(38.1)	
Don't know/no opinion	7	(4.5)	14	(7.5)	0	(0.0)	51	(5.9)	3	(2.9)	
Answer missing	0	(0.0)	7	(3.8)	3	(2.4)	14	(1.6)	0	(0.0)	

We then asked them whether consent forms that give consent to future research should include a multiple-type consent option in which the types and conditions of research for which the samples may be used are explicitly specified, or merely a binary-type of consent option to either consent or not consent to all future research on samples. Although the opinions varied from country to country, they were more or less evenly divided between the two options, with a high of 59% in Korea, and a low of 44.9% in India preferring multiple consent options.

There was a difference in the answers to this question among those who conduct research on stored tissue samples and those who do not; 47.8% of respondents who conduct research on stored tissue samples favoured multiple options, compared to 60.9% of non-researchers. Policy makers did not answer this question differently from other groups, nor was there any difference among the group in their attitude towards allowing consent to future research in general.

Opinions on Possible Options Provided in the Consent Form (Table 3)

We asked the respondents to imagine that they were writing a consent form where they had to provide specific options, and asked them which specific options they might want to include. There were significant differences in the answers from different countries, indicating a wide disagreement regarding what specific options to include in a consent form. While there was a general agreement that the option "for any ethics committee approved research" (varying from 70.1% in China to 91.3% in India) should be included, there was less agreement on providing an option to require researchers to re-contact donors before proceeding with any new research (varying from 26% in Japan to 51.9% in China).

Table 3. Opinions on Possible Options Provided in the Consent Form for Future Use of Samples

Option	China (N = 154)	Egypt (N = 186)	India (N = 127)	Japan (N = 864)	Korea (N = 105)	*P* value
(% yes)	n (%)	n (%)	n (%)	n (%)	n (%)	
For any ethics committee approved research	108 (70.1)	156 (83.9)	116 (91.3)	750 (86.8)	92 (87.6)	< 0.001
Only after re-contact by researchers	80 (51.9)	62 (33.3)	31 (24.4)	225 (26.0)	44 (41.9)	< 0.001
If the samples do not retain personal identifiers	115 (74.7)	99 (53.2)	86 (67.7)	491 (56.8)	65 (61.9)	< 0.001

continue

Table 3. continued

Option (% yes)	China (N = 154) n (%)	Egypt (N = 186) n (%)	India (N = 127) n (%)	Japan (N = 864) n (%)	Korea (N = 105) n (%)	*P* value
If donors will be notified of research findings that may be relevant to the donor's health	76 (49.4)	138 (74.2)	105 (82.7)	265 (30.7)	81 (77.1)	< 0.001
If the donor can later withdraw his/her samples from use in research	66 (42.9)	101 (54.3)	89 (70.1)	551 (63.8)	83 (79.0)	< 0.001
If it is sponsored by non-for-profit organisations	85 (55.2)	129 (69.4)	76 (59.8)	62 (7.2)	56 (53.3)	< 0.001
If the research pertains to a particular disease	97 (63.0)	93 (50.0)	77 (60.6)	271 (31.4)	68 (64.8)	< 0.001
If the samples will remain in a specified country or region	67 (43.5)	103 (55.4)	70 (55.1)	111 (12.8)	56 (53.3)	< 0.001
If the research will be performed by specified researchers or institutions	88 (57.1)	112 (60.2)	66 (52.0)	225 (26.0)	60 (57.1)	< 0.001

Reasons for Opinions Regarding the "Re-contact" Requirement and Consent (Table 4)

We asked the respondents about the reasons for their opinions on the appropriateness of requiring researchers to re-contact donors before using samples in a new research project. A majority in each country, except China, agreed that such a requirement would be too burdensome on researchers. Not surprisingly, a larger proportion among those who do research on stored tissue samples agreed with this assessment compared with those who do not (64% versus 43.3%). There was less agreement that a "re-contact" requirement would be an inconvenience for the donors, ranging from 31.2% in China to 52.2% in Egypt.

We also asked respondents about reasons for their opinions on the appropriateness of obtaining consent to future research from donors. They were mostly evenly divided between agreeing and disagreeing with various reasons that have been advanced in the literature against allowing consent to future research.

Table 4. Attitudes Towards Possible Reasons for Not Requiring Re-contact or Allowing Future Research

		China (N = 154)		Egypt (N = 186)		India (N = 127)		Japan (N = 864)		Korea (N = 105)	
Statement	Attitudes †	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Requiring researchers to re-contact donors before using the											
Place an unacceptable burden on researchers	agree	61	(39.6)	125	(67.2)	83	(65.4)	430	(49.8)	69	(65.7)
	neutral	33	(21.4)	4	(2.2)	9	(7.1)	191	(22.1)	18	(17.1)
	disagree	60	(39.0)	54	(29.0)	31	(24.4)	228	(26.4)	18	(17.1)
Be prohibitively costly for researchers	agree	64	(41.6)	114	(61.3)	80	(63.0)	302	(35.0)	54	(51.4)
	neutral	38	(24.7)	13	(7.0)	13	(10.2)	298	(34.5)	20	(19.0)
	disagree	52	(33.8)	55	(29.6)	29	(22.8)	245	(28.4)	31	(29.5)
Be an inconvenience to donors	agree	48	(31.2)	97	(52.2)	48	(37.8)	278	(32.2)	44	(41.9)
	neutral	50	(32.5)	23	(12.4)	34	(26.8)	301	(34.8)	31	(29.5)
	disagree	56	(36.4)	62	(33.3)	40	(31.5)	260	(30.1)	30	(28.6)
Donors' consent to future research on their											
Doesn't provide donors with enough to give meaningful consent	agree	101	(65.6)	66	(35.5)	44	(34.6)	371	(42.9)	36	(34.3)
	neutral	30	(19.5)	27	(14.5)	32	(25.2)	258	(29.9)	33	(31.4)
	disagree	23	(14.9)	88	(47.3)	47	(37.0)	210	(24.3)	35	(33.3)
Doesn't show enough respect for donors	agree	59	(38.3)	40	(21.5)	22	(17.3)	170	(19.7)	17	(16.2)
	neutral	53	(34.4)	17	(9.1)	24	(18.9)	325	(37.6)	24	(22.9)
	disagree	42	(27.3)	124	(66.7)	75	(59.1)	345	(39.9)	64	(61.0)
Doesn't provide enough protection for donors	agree	70	(45.5)	47	(25.3)	35	(27.6)	301	(34.8)	20	(19.0)
	neutral	46	(29.9)	18	(9.7)	22	(17.3)	264	(30.6)	28	(26.7)
	disagree	38	(24.7)	116	(62.4)	64	(50.4)	275	(31.8)	56	(53.3)
Doesn't provide donors with enough control the future use of their samples	agree	85	(55.2)	78	(41.9)	47	(37.0)	386	(44.7)	38	(36.2)
	neutral	47	(30.5)	22	(11.8)	30	(23.6)	250	(28.9)	27	(25.7)
	disagree	22	(14.3)	79	(42.5)	41	(32.3)	204	(23.6)	40	(38.1)

Note: Cases without any answer were excluded from the table and the analysis. Therefore, the total percentage for some items may not reach a hundred per cent.

† : Cases with 'strongly agree' and 'agree' and with 'strongly disagree' and 'disagree' were respectively categorised into either a category of 'agree' or 'disagree' in the table.

Opinions on Conditions to Allow Consent to Future Research (Table 5)

We asked the respondents their opinions regarding the conditions under which donors should be able to provide consent to future research on samples. Across countries, a majority agreed that donors should be able to do so if the samples

would be anonymous and unlinked to identifying information and if donors would have the opportunity to withdraw their consent later on, although this places two contradictory requirements on the condition for consent to future research.

Table 5. Attitudes Towards Conditions to Allow Advance Consent in Research

		China (N = 154)	Egypt (N = 186)	India (N = 127)	Japan (N = 864)	Korea (N = 105)
Condition	Attitudes †	n (%)	n (%)	n (%)	n (%)	n (%)
Donors should ONLY be able to provide consent to future research on their						
If their samples will be anonymous and unlinked to identifying information	agree	98 (63.6)	124 (66.7)	87 (68.5)	514 (59.5)	78 (74.3)
	neutral	29 (18.8)	12 (6.5)	9 (7.1)	179 (20.7)	9 (8.6)
	disagree	27 (17.5)	43 (23.1)	26 (20.5)	144 (16.7)	17 (16.2)
If donors will have the opportunity to withdraw consent later on	agree	67 (43.5)	102 (54.8)	77 (60.6)	513 (59.4)	66 (62.9)
	neutral	48 (31.2)	11 (5.9)	17 (13.4)	222 (25.7)	17 (16.2)
	disagree	39 (25.3)	67 (36.0)	28 (22.0)	101 (11.7)	19 (18.1)
If the donors will be notified if any information relevant to the donor's health is discovered	agree	56 (36.4)	135 (72.6)	95 (74.8)	160 (18.5)	62 (59.0)
	neutral	63 (40.9)	19 (10.2)	14 (11.0)	411 (47.6)	24 (22.9)
	disagree	35 (22.7)	26 (14.0)	15 (11.8)	266 (30.8)	19 (18.1)
There should be no limitation on the consent that donors may provide, so long as future research on their samples is approved by an ethics committee	agree	63 (40.9)	131 (70.4)	75 (59.1)	208 (24.1)	48 (45.7)
	neutral	40 (26.0)	13 (7.0)	15 (11.8)	268 (31.0)	21 (20.0)
	disagree	51 (33.1)	35 (18.8)	33 (26.0)	358 (41.4)	35 (33.3)

Note: Cases without any answer were excluded from the table and the analysis. Therefore, the total percentage for some items may not reach a hundred per cent.

† : Cases with 'strongly agree' and 'agree' and with 'strongly disagree' and 'disagree' were respectively categorised into either a category of 'agree' or 'disagree' in the table.

Discussion

This study is novel in that it demonstrates, for the first time, the attitudes and choices of researchers, ethics review members and policy makers in multiple non-Western countries, including both developing and developed countries, towards informed consent options to future research on stored samples. Similar to what has been demonstrated in position papers in Western countries, there

is no agreement among our respondents regarding which type of consent for future research is preferable.[7] Most respondents agree that consent to future research is permissible, but a substantial portion of the respondents think that tissue donors should be provided with a list of options restricting the use of their samples in future research, rather than a binary option to consent or not to any future research. There is, however, no agreement on what kind of restrictions should be included in the options provided.

Limited support for a simple binary consent option for future research is somewhat surprising. A large proportion of the respondents in our sample are currently engaged in research on stored tissue samples. One would expect that this group would favour as few restrictions as possible on future research. While we did find that the respondents involved in research were generally more favourably inclined towards fewer restrictions than those who were not, about half of them were still in favour of requiring multiple options for future research.

In a previous review of studies of donor attitudes from mainly Western countries to consent options for future research on samples, it was noted that "most people prefer one-time general consent, on the understanding that an ethics committee will review and approve future projects".[8] In contrast, in the present study, the majority (44.9–59%) of the respondents favoured the multiple-type of consent option to be given to the donors, rather than the binary-type of option. There may be several explanations for this apparent discrepancy in the data.

First, our respondents were asked which consent option they preferred, one with two options, or one with multiple options regarding the types and conditions of future research for which the samples may be used. This question was given after an introductory explanation of the two alternatives with a brief indication of the main reason for choosing one over the other. When presented with this choice, the respondents seemed more or less evenly divided between which option was preferable. In contrast, in none of the studies examined by Wendler is the choice presented to the respondents in this way. For example, in a study of the actual choices of research subjects, 87.1% chose the option of allowing unlimited future research on their samples, if they were given this option.[8] The examined consent forms, however, include a whole range of different types of choices, some with multiple options and some with only two options. A figure more comparable to the data obtained in our study would be how many would choose allowing unlimited future research when confronted with an informed consent form with multiple options. Interestingly, when presented with three choices, to be re-contacted for new consent, authorising all

future research, or refusing all future research, 26.2% of the research participants in Chen's study chose the option to be re-contacted,[9] a figure more closely in line with the views expressed by our respondents. This figure is similar to what is reported in another study from Sweden, where 22.3% of respondents who donated samples for genetic research wanted to be informed about, and given new consent for, each new genetic project.[10] Similarly, another study from Japan reported that when given these three choices, 19.5% of actual genetic tissue donors chose the option to be re-contacted.[11] Another recent study found that although 88.4% of donors were willing to provide samples for research on any condition, there were significant differences between ethnic and socioeconomic groups in their attitudes to this issue,[12] indicating that there may not be a consensus about this issue across different socioeconomic groups after all.

Other studies have reported that research participants did not seem to care much about whether their samples were used for research on their own disease (cancer) versus other health problems such as diabetes or heart disease when presented with these two choices: 93.7% would allow research on cancer, and 86.9% would also allow research on other diseases.[13] This result is, however, not directly relevant to whether one should present potential participants with several choices. It only demonstrates that they do not think the type of disease is relevant, not that they would prefer a binary option to multiple options if given a choice between these two alternatives, in the way we presented the choice to our respondents.

Second, our respondents may have preferred to give donors the option to be re-contacted before future research even if the respondents themselves would have overwhelmingly chosen to permit any approved future use of their samples. They may think that allowing any future research is not a prudent choice by potential participants, or that current guidelines on research ethics require specific consent for future research, and that, even if they disagree personally with that position, this is what they would recommend. Or one might simply assume that our respondents wanted potential participants to have as many options as possible. The answers given in our questionnaire may, therefore, not directly correspond with the choices made by actual participants in research studies.

Third, our questionnaire differed from previous surveys of research participants by providing explanatory information about the different choices. We also asked the respondents to provide reasons for their choices. This feature of the questionnaire together with the fact that most of the respondents have some experience with research on stored tissue samples, might have the effect of inducing the respondents to provide more reflective answers about what informed consent procedure is preferable. It is, however, also evident that our respondents had some difficulty resolving apparent conflicts between various

concerns they thought relevant (Table 5). Most respondents answered that donors should only be able to provide consent to future research on their samples if their samples would be anonymous and unlinked to identifying information, yet the same respondents also agree that donors should be able to withdraw their consent later on, and be notified of any information relevant to their health if discovered, as conditions for allowing future research on their samples. Those two conditions are of course incompatible with the first condition of requiring anonymous samples. The likely explanation for this apparent inconsistency is that respondents think that all of the items they are asked about seem in general to be reasonable conditions for research on samples. They therefore tend to agree with all of them, without recognising that they are mutually exclusive as conditions for future research on samples.

Fourth, the difference between the results in our survey in non-Western countries and the previous review of studies from mainly Western countries may be explained by this difference in the surveyed populations. Given the other major difference between the two surveyed populations, actual or prospective tissue donors on the one hand and researchers and policy makers on the other hand, it is not possible to say anything definite about which one of these two differences is a plausible explanation for the different results.

Results such as these raise questions about the role of empirical studies of attitudes towards research on human tissue samples when one attempts to determine what an appropriate informed consent policy should be. Clearly, the finding from numerous studies that prospective participants overwhelmingly choose the option of allowing future research on their samples when confronted with a binary choice of not allowing any research or allowing all research on their samples, shows that having this option would be a practical solution. Since relatively few people would refuse any research, one would not have to worry too much about whether the sample continues to be representative. However, it would be a mistake to conclude from this data alone that such a policy is ethically justifiable. Prospective research participants may prefer allowing all future research to prohibiting all future research, yet at the same time they might prefer a larger degree of control over their own samples. The fact that a substantial number of people seem to prefer to be re-contacted when this option is included strengthens this view.[14] Including such an option in the informed consent form with around a quarter of the respondents choosing it, would of course increase the burden on researchers. This has to be weighed against the right of prospective subjects to be informed about and give consent to any use of their tissue samples. Given the substantial variability in the data about both donor and researcher attitudes, the empirical data gives little direct guidance on how to resolve this dilemma.

On the other hand, it is interesting to note that prospective donors of tissue have less restrictive views than one would expect, and stored tissue researchers more restrictive views than expected. Prospective donors seem to be willing to give consent to any future research, whereas at least the researchers in our samples favour some restrictions on future use during the initial informed consent process. Since donors favour, but do not require, less restrictive views than researchers, it would indicate that it is feasible to develop an ethically defensible position satisfying the diverse group of stakeholders in the debate.

During the past couple of decades there has been a heated debate about the appropriate role of informed consent for research on stored tissue samples.[15] A number of policy bodies have recommended that consent for future use should be as specific as possible.[16] Generally, this recommendation is based on a presumption that all research requires specific consent and that valid consent implies having an understanding of what one consents to.

It is commonly claimed that strict requirements for informed consent are based on culture specific norms arising out of a Western philosophical tradition. It is indeed the case that the vast majority of policy recommendations and academic commentaries on this issue have been authored in the West. However, a closer look at policy documents in the West and in Asia reveals similarities. The Bioethics Advisory Committee of Singapore issued a recommendation in 2002 — allowing consent to future unspecified research, which is similar to what is allowed in the newly adopted Research Act in Norway.[17] The data from our study do not support the notion that the requirement of specific, informed consent to future research is culture specific. Our results show a wide variability in the attitudes of our respondents to the various options both within and between countries. We also found a general agreement with the statement that donor consent to future research does not provide them with enough information to give meaningful consent, and an agreement indicating a fairly strong belief in the right of individuals to control the use of their samples, commonly associated with Western philosophical traditions.

This study has several limitations. First, we assessed the choices of survey respondents, most of whom were a sample of convenience. As a result, our findings may be biased towards particular groups of samples and may not be generalisable to other populations. Second, because our study was conducted in multiple countries whose cultural and economical backgrounds widely varied, some of the results may reflect only such socioeconomic differences between countries.

In conclusion, this study demonstrates that researchers, members of research ethics review committees and policy makers in several non-Western countries generally agree that prospective donors of tissue samples for research should be

able to provide specific conditions under which their tissue is used for future research. A substantial portion of them believe that one should allow tissue donors the option to be re-contacted for consent for any future research on their samples.

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