

# Consent for the use of human biological samples for biomedical research: a mixed methods study exploring the UK public's preferences

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## ABSTRACT

**Objective:** A mixed-methods study exploring the UK general public's views towards consent for the use of biosamples for biomedical research.

**Setting:** Cross-sectional population-based focus groups followed by an online survey.

**Participants:** 12 focus groups (81 participants) selectively sampled to reflect a range of demographic groups; 1110 survey responders recruited through a stratified sampling method with quotas set on sex, age, geographical location, socioeconomic group and ethnicity.

**Main outcome measures:** (1) Views on the importance of consent when donating residual biosamples for medical research; (2) preferences for opt-in or opt-out consent approaches and (3) preferences for different consent models.

**Results:** Participants believed obtaining consent for use of residual biosamples was important as it was 'morally correct' to ask, and enabled people to make an active choice and retain control over their biosamples. Survey responders preferred opt-in consent (55%); the strongest predictor was being from a low socioeconomic group (OR 2.22, 95% CI 1.41 to 3.57,  $p=0.001$ ) and having a religious affiliation (OR 1.36, 95% CI 1.01 to 1.81,  $p=0.04$ ). Focus group participants had a slight preference for opt-out consent because by using this approach more biosamples would be available and facilitate research. Concerning preferred models of consent for research use of biosamples, survey responders preferred specific consent with recontact for each study for which their biosamples are eligible. Focus group participants preferred generic consent as it provided 'flexibility for researchers' and reduced the likelihood that biosamples would be wasted. The strongest predictor for preferring specific consent was preferring opt-in consent (OR 4.58, 95% CI 3.30 to 6.35,  $p=0.015$ ) followed by non-'White' ethnicity (OR 2.94, 95% CI 1.23 to 7.14,  $p<0.001$ ).

**Conclusions:** There is a preference among the UK public for ongoing choice and control over donated biosamples; however, increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models for some people.

## ARTICLE SUMMARY

### Article focus

- To explore views of the UK public on the importance of consent being sought for the use of residual biosamples for medical research.
- The public's preferences for opt-in or opt-out approaches to consent.
- The public's preferences for generic, tiered or specific consent.

### Key messages

- Obtaining consent for the use of residual biosamples for biomedical research was perceived as important by members of the general public.
- Survey participants exhibited a desire to retain active choice and control when donating biosamples and over the uses to which their biosamples might be put, preferring an opt-in system and specific consent; however, these results differ from those reported during focus group discussions, where preference was for less restrictive consent models (an opt-out system and generic consent) that are likely to increase availability of biosamples.
- These differences might be accounted for by the fact that focus group participants were given more background information about the use of residual biosamples in research and had time to consider the benefits and disadvantages of the different approaches.

### Strengths and limitations of this study

- This study contributes further to our understanding of the UK public's views and preferences towards consent for the use of biosamples in medical research. Our study supports the premise that increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models.
- Owing to the hypothetical nature of the study, the findings may not necessarily correlate with actual behaviour.

## INTRODUCTION

Human biological samples (biosamples), including organs, tissues, biofluids such as blood, and their derivatives, are increasingly important resources for biomedical research.<sup>1 2</sup> For example, they can help us to understand how we diagnose, categorise and treat a whole variety of medical conditions including cancer<sup>1</sup> and are particularly important when studying rare diseases or conditions where biosamples are hard to obtain. Biosamples are donated by either healthy volunteers or patients, either through specific research studies or as residual tissues or biofluids surplus to diagnostic requirements, or postmortem. Biosamples can be used fresh or can be first stored in a biobank, a collection of biosamples often linked with the donors' clinical and demographic information, as biosample attributes. Here, the quality of the data linked to the biosample is as important as the quality of the biosamples themselves, providing essential context within which to design analyses and interpret results or carry our further experimental studies. Clinical data may also be enriched with lifestyle and environmental information.<sup>3</sup>

It is widely accepted that donor consent should be sought and obtained before biosamples can be used in research.<sup>4 5</sup> Consent in research ethics relates to ensuring respect for the autonomy and dignity of the donors (research participants) and protecting them from abuse<sup>5</sup> and in fact, in England, Wales and Northern Ireland, the Human Tissue Act establishes donor

consent as the baseline principle for the retention and use of organs and tissue for purposes beyond diagnosis and treatment, although further statutory consent exemptions do exist in certain circumstances, notably use of anonymised tissue from the living for research ethics committee (REC) approved research projects.<sup>6</sup> The value of biobanks, in supporting broad, long-term research purposes, means that the model of the consent process needs to be considered in order to ensure that it is valid and appropriate. A number of different consent frameworks which address consent scope and process have been proposed as a result.<sup>5</sup> However, there is continued debate as to which is the most appropriate in various situations.<sup>4 7 8</sup>

Both the Human Tissue Authority<sup>9</sup> and National Research Ethics Service<sup>10</sup> recommend generic consent (table 1), a view that has also been endorsed by the UK research funders<sup>11</sup> and the Nuffield Council on Bioethics.<sup>12</sup> One commonly cited criticism of generic consent is that it is not sufficiently 'informed' as future research uses are not known at the time of donation.<sup>13</sup> Empirical research examining public and patient preferences has highlighted that there is no clear consensus on the issue, with specific consent being identified as the most favoured form of consent in some studies,<sup>14 15</sup> and generic consent in others.<sup>16–18</sup>

The 2011 Nuffield Council report on donation of human material for medicine and research also recommends that research funders should work to increase

**Table 1** Approaches to consent of biosamples

Initial consent methods	
Opt-in consent	The storage and use of biosamples for research on the basis that the donor has actively agreed to do so
Opt-out consent	The storage and use of samples for research on the basis that the donor has not objected, after previously being given the opportunity to do so
Opt-in consent methods	
Consent once for life	Consent is provided once for life for use of any residual samples for research with the option of withdrawing permission at a later stage if the donor wishes to do so
Consent at certain points	Consent is provided at certain points for use of residual biosamples for research, eg, every 10 years or at the beginning of a particular episode of care
Consent every time	Consent is requested every time residual biosamples may become available for use in research
Consent for research use of biosamples	
Generic consent	Consent to the use of donated samples for a range of unknown uses, on the basis of general information about those possible uses and about the governance arrangements in place. Also referred to as 'broad' or 'blanket' consent
Tiered consent	A more restricted form of consent for use of samples, where the donor is invited to agree to the use of their samples in unknown projects, but given the option of specifying particular categories of research that they wish to exclude, eg, embryonic research. Also referred to as 'categorical' consent
Specific consent—once only	Consent to the use of donated samples for a specified study only, on the basis of information provided about that study. Any residual sample will be discarded at the end of that study
Specific consent—for every new study	Consent to the use of donated samples for a specified study, on the basis of information provided about that study. However, participants are recontacted and asked to consider participating in every new study for which their biosamples are eligible

Consent terms were selected based on common usage within the UK biobanking system (eg, generic consent is the term used by the Human Tissue Authority, National Research Ethics Service and National Cancer Research Institute) and definitions chosen in consultation with a team of representatives from universities, hospital biobank staff, pathologists and industry.

public awareness of the key role of donated tissue in scientific and clinical research.<sup>12</sup> Public trust and confidence in the consent process is of paramount importance to maintain and increase public support for donation and use of biosamples for biomedical research in the UK. For this reason, it is important to understand and inform public opinion to ensure that consent models are aligned to public expectations and preferences. While numerous international studies have been conducted which focus on consent preferences, research conducted in the UK has tended to focus on large-scale population biobanks, such as the UK Biobank<sup>19</sup> or Generation Scotland,<sup>20</sup> which require ongoing contact with donors, or on the views of patients on the donation of residual biosamples.<sup>21</sup> The current study was conducted to broaden our understanding of the UK public's views on biosample donation for biomedical research. Moreover, the findings are intended to inform a biobanking policy for Strategic Tissue Repository Alliance Through Unified Methods, a Technology Strategy Board<sup>1</sup> and pharmaceutical industry-funded project seeking to address the problem of insufficient numbers of biosamples and associated clinical data of adequate quality to fully support biomedical research in the UK.

The specific aims of this study were to (1) identify participants' views on the importance of consent when donating residual biosamples for medical research; (2) explore preferences for opt-in or opt-out approaches to consent and (3) explore preferences for different consent models (table 1). Public willingness to donate biosamples, views on donation of different biosample types and conditions of their use (by which organisations and for which types of research) are reported in the sister paper related to this study.<sup>22</sup>

## METHODS

This was a mixed methods study comprising qualitative focus groups and a quantitative on-line survey. Ethical approval for the study was granted by the University of Manchester Research Ethics Committee in April 2012.

### Focus groups

Twelve focus groups (including one pilot group) were conducted between May and July 2012 in six different geographic locations across the UK. Participants were recruited face-to-face in the street by a market research company, The Focus Group. Participants were purposively sampled; each group chosen to reflect a particular demographic (age, socioeconomic group (SEG), ethnicity) in order to gather a wide spectrum of views and enable comparisons across groups. Two 'patient' groups were also included, comprising people who had had an operation in the past 2 years requiring an overnight

hospital stay, and people who currently have, or have had, either a serious or chronic illness or disability. The latter group comprised people diagnosed with diabetes, cancer, heart disease, asthma and the genetic conditions, like Marfan syndrome. A further group consisted of generally healthy volunteers who had donated a biosample specifically for research purposes.

Before agreeing to take part, potential participants were given a participant information sheet telling them about the study (see online supplementary appendix I). Those who were interested were screened through a questionnaire containing demographic questions to assess their suitability for a particular focus group. These were held in 'neutral' locations such as hotel conference rooms or church halls and facilitated by an experienced facilitator (CL). Before each group discussion, participants were sent a short information leaflet about the use of biosamples in biomedical research to provide some background context for the discussion and to prompt them to think about the key issues (see online supplementary appendix II). This information was written by a core team of authors drawn from across academia and industry, including patient representation. It was reviewed by three members of the patient organisation Genetic Alliance UK as well as the science communication charity Sense about Science to ensure readability and non-bias. Before focus group discussions began, participants were asked to sign a consent form. Each participant received £50 for taking part to cover time and travel costs. Focus groups lasted 90 min and digital audio recordings were taken.

A detailed discussion guide was developed to explore participant views and preferences towards consent scope and process (see online supplementary appendix III). The main focus related to the use of biosamples surplus to diagnostic requirements following surgery or a medical procedure. Questions were informed by other empirical studies of consent in biobanking,<sup>16–23</sup> developed by the authors and addressed the topics described above. To enhance understanding around the different consent models, participants were given a sheet presenting three different scenarios, each of which elaborated on one of the three consent models chosen for discussion (see online supplementary appendix III, p.4). For each topic, discussions began by asking the group to consider the benefits and disadvantages of each particular approach. Once no new themes were emerging, each participant was asked to complete an accompanying anonymous questionnaire which asked them to select their preferred consent model. The discussion guide, scenario sheet and questionnaire were piloted at the first focus group which resulted in some minor amendments to wording.

Recordings were fully transcribed and transcriptions checked. The software package Nvivo V.9 (QSR International, Pty Ltd) was used to help organise the data for analysis. This comprised grouping responses to questions into broad thematic categories which were then refined through subcodes. Coding of all 12

<sup>1</sup>Under the Stratified Medicines Programme: Business Models Value Systems.

transcripts was conducted by CL. The first six transcripts to be coded were also independently coded by a second researcher (SR). Codes were then compared to assess consistency of coding and ensure inter-rater reliability. Any discrepancies were discussed until consensus was reached. The remainder of the transcripts were then coded according to the agreed coding framework.

### Survey

Once data analysis had been conducted on the focus group transcripts, the findings were used to inform development of a quantitative survey which was used to canvas public opinion on the issues of interest across a representative sample of the UK population (see online supplementary appendix IV). The survey was carried out by the market research company Research Now using their online panel community of the UK residents. A stratified sampling method was used: quotas were set on sex, age, geographical location, SEG and ethnicity, in line with data provided by the Office of National Statistics (ONS) to ensure the sample was as representative of the UK population as possible. Within each category, a random sample was selected from the Research Now database containing 451 185 active respondents. We aimed to recruit 1000 responders in total. The sample size required depends on the number of predictors, the expected effect size and the level of power. According to Miles and Shevlin,<sup>24</sup> if we are expecting a small effect size, a sample size of 600 is considered adequate to achieve a high level of power of 0.8 (a benchmark suggested by Cohen<sup>25</sup>) for four predictors. As highlighted in table 2 we can formulate at least four hypothesis, for example, people from a higher SEG are more likely to donate biosamples than those from a lower SEG. With a sample size of 1000, this study would provide highly reliable results. In order to reduce any on-line bias in our sample, 100 face-to-face interviews with non-internet users were conducted. An additional 'boost' sample of 100 people (not included in the main sample analysis) was also conducted with people from three minority ethnic groups ('Black', 'Chinese', 'S Asian') so that we could conduct subgroup analysis between the groups.

The survey questions were developed by the authors and piloted with 60 members of Research Now's online panel community who were from low SEG's. Members of the pilot group were then invited to take part in a subsequent telephone interview asking about the survey. Interviews were conducted with 25 pilot survey responders. Questions focused on question clarity, survey length and whether responders felt the survey to be neutral. Some minor amendments to wording were made in light of the responses. The main survey was then conducted in September 2012. Surveys recorded online took, on average, 17 min to complete and each responder received a small payment (around £2) from Research Now.

Survey data were organised and analysed using SPSS statistical software V.20 (SPSS Inc; 2011; Chicago, Illinois,

USA). Initial univariate descriptive statistics were obtained for the entire study. Pearson  $\chi^2$  test was used to examine demographic factors associated with willingness to donate and preference for different consent models. Those associations that were found to be significant ( $p \leq 0.05$ ) were then entered into a multiple logistic regression to explore the predictivity of these variables. Before running the model, we tested for multicollinearity among the independent variables. No multicollinearity issues were found.

## RESULTS

### Study populations

Participant characteristics are detailed in table 2.

### Focus groups

One hundred and eighty-two members of the public who were approached were eligible to participate (ie, they fitted the criteria for a particular focus group) and 81 people agreed to participate (45% participation rate; 48 women, 33 men). There were seven participants in each focus group apart from the 18–25 age group and high SEG group (eight participants in each); serious/chronic illness group and healthy volunteers group (six participants in each) and the pilot group (five participants).

### Survey

In total, 4607 people were invited to take part in the survey; 2014 did not respond, 860 began completing the survey but did not finish, 102 did not qualify to continue (eg, they were under 18 years old), 521 qualified for the survey but the quota was full and 1110 completed the questionnaire (28% response rate excluding those who did not qualify and where the quota was full). This response rate is comparable with similar studies on this topic.<sup>16</sup> Our participant quotas closely, though not exactly, matched our targets based on the UK population data as provided by the ONS. For this reason we carried out both weighted and unweighted analyses. There was no difference in the conclusions we reached by either method. In this paper we present the unweighted results (weighted results can be found at online supplementary appendix V).

### Importance of asking for consent

The majority of survey participants believed that obtaining consent for the use of residual biosamples was either extremely important (55%) or important (25%). Only 4% selected 'not at all important'. Focus group participants also saw the consent process as important and cited reasons including: that it was 'polite', 'respectful' and 'morally correct' to ask permission; that it enabled people to feel they had made a contribution and an active choice; that it provided control, in particular for those people that might not want their biosamples to be used, for example, for religious reasons; that taking without asking was akin to theft; and that it was

**Table 2** Participant characteristics

Characteristic	Focus group N=81	Survey N=1110
Gender		
Male	33; 41%	504; 45%
Female	48; 59%	606; 55%
Age		
18–24	13; 16%	135; 12%
25–34	18; 22%	184; 17%
35–44	19; 23%	198; 18%
45–54	10; 12%	184; 17%
55–64	16; 20%	176; 16%
65+	5; 6%	233; 21%
Socioeconomic group		
A	9; 11%	41; 4%
B	22; 27%	215; 19%
C1	24; 30%	311; 28%
C2	14; 17%	233; 21%
D	6; 7%	145; 13%
E	6; 7%	165; 15%
Region		
East of England	7; 7%	92; 8%
East Midlands	–	57; 5%
London	18; 22%	213; 19%
North East	–	40; 4%
North West	–	121; 11%
Northern Ireland	–	30; 3%
Scotland	14; 17%	76; 7%
South East	14; 17%	165; 15%
South West	–	81; 7%
Wales	–	51; 5%
West Midlands	14; 17%	94; 8%
Yorkshire/Humberlands	14; 17%	90; 8%
Ethnicity		
White or White British	54; 67%	1057; 95%
Mixed race	1; 1%	7; 1%
Asian or Asian British	10; 12%	18; 2%
Black or Black British	9; 11%	19; 2%
Chinese or Chinese British	7; 9%	2; 0%
Other ethnic group	0; 0%	4; 0%
Prefer not to say	0; 0%	3; 0%
Religion		
Christianity		677; 61%
Islam		13; 1%
Hinduism		6; 1%
Sikhism		0; 0%
Judaism		6; 1%
Buddhism		11; 1%
Other religion		15; 1%
No religion		370; 33%
Prefer not to say		12; 1%
Religiosity		
Not at all religious		234; 32%
Moderately religious		422; 58%
Very religious		64; 9%
Prefer not to say		8; 1%
Education		
No formal qualification	15; 19%	70; 6%
GCSE, O level, Scottish Standard Grade or equivalent	19; 23%	264; 24%
GCE, A-level, Scottish Higher or similar	17; 21%	214; 19%

Continued

Table 2 Continued

Characteristic	Focus group N=81	Survey N=1110
Vocational (BTEC/NVQ/diploma)	–	230; 21%
Degree level or above	30; 37%	317; 29%
Prefer not to say	–	15; 1%
Self-reported knowledge of medical research process		
No knowledge		463; 42%
Some knowledge		603; 54%
Good knowledge		44; 4%
Have you been affected by a disability or illness?		
Yes		399; 36%
No		711; 64%
Has a close family member been affected by a disability or illness?		
Yes		767; 69%
No		343; 31%
Have you had blood or tissue removed during a medical procedure?		
Yes		446; 40%
No		553; 50%
Don't know		111; 10%
Have you ever been asked to donate blood or tissue for medical research?		
Yes		182; 16%
No		904; 81%
Don't know		24; 2%
If so, did you agree to donate?		
Yes		155; 85%
No		23; 13%
Don't know		4; 2%

Percentages may not add up to 100 due to rounding.

important in order to maintain trust between patients and doctors.

It then doesn't allow them to take liberties or advantage of the fact that you're out cold having an operation and someone says 'Oh we need a bit of that'. Male, patient—had operation in past 2 years

A small minority did not feel that consent was important, the main reasons being that they did not want the tissue back, that once it was removed it no longer 'belonged to them', and that the tissue would just go to waste otherwise.

Survey participants were asked what would be their preferred method of consenting to donate leftover bio-samples for research use. The majority (65%) wanted to do so face-to-face with a health professional; 15% wanted to complete a form and return it by post. This issue was not specifically addressed with focus group participants due to time constraints.

### Preference for 'opt-in' or 'opt-out' consent

Participants were asked whether they preferred an opt-in or opt-out model of consent for donating residual bio-samples. The results of the survey showed that opt-in consent was preferred by over half of the participants (55%), 28% preferred opt-out, 14% had no preference and 4% selected 'don't know'. Participants who were

significantly more likely to prefer opt-in consent were: from a low SEG (E) (79.8% vs 64.1%,  $\chi^2=11.13(1)$ ,  $p=0.001$ ); over 65 years (75.1% vs 64%,  $\chi^2=7.68(1)$ ,  $p=0.006$ ); had a religious affiliation (68.8% vs 61.2%,  $\chi^2=4.84(1)$ ,  $p=0.028$ ); and had an education level of GCSE or lower (71.1% vs 63.9%,  $\chi^2=3.89(1)$ ,  $p=0.048$ ). The strongest significant predictor for preferring opt-in consent was being from a low SEG (E) (OR=2.22, 95% CI 1.41 to 3.57,  $p=0.001$ ) followed by having a religious affiliation (OR=1.36, 95% CI 1.01 to 1.81,  $p=0.04$ ; table 3).

Focus group participants preferred opt-out consent ( $n=46$ ; 57%) over opt-in consent ( $n=29$ ; 36%), with six participants (7%) unsure, after in-depth discussion around the benefits and disadvantages of each approach. The main benefit of opt-out consent cited by participants was that more biosamples would be available and consequently spur research. Other reasons included: that it would be less costly administratively; that it maximised the value of left over biosamples; that patients would not have to consider it every time they were having an operation or blood test; that those that did not want to donate still had the opportunity to opt-out and that it would 'normalise' donating leftover biosamples which would be a positive step.

It would be an incentive for society if everyone knew that this is what happens routinely, but you can choose not to

**Table 3** Multiple logistic regression of participant preferences for consent models

Participant characteristic	Coefficient	95% CI	OR	p Value
Preference for opt-in consent				
Socioeconomic group	0.806	1.41 to 3.57	2.22	0.001
Religion	0.304	1.01 to 1.81	1.36	0.04
Preference for consent every time				
Religion	0.72	1.05 to 4.00	2.04	0.036
Age	0.47	1.07 to 2.41	1.60	0.023
Preference for specific consent				
Opt-in	1.52	3.30 to 6.35	4.58	<0.001
Ethnicity	1.08	1.23 to 7.14	2.94	0.015
Preference for generic consent				
Opt-out	1.52	3.13 to 6.67	4.55	<0.001
Religion	0.04	1.08 to 2.72	1.56	0.021
Knowledge of medical research process	0.44	1.06 to 2.28	1.56	0.024

Demographic items were excluded from this table if none was statistically significant. All variables were entered into the models as categorical variables.

be involved. It would be more like 'that's normal'. Male, aged 18–24 group

Those that preferred the opt-in approach cited the following reasons as to why: an active choice whereby participants had to act on a decision to take part was preferable to a passive choice whereby consent was assumed; it enabled people to have more control over their biosamples; it was truly 'informed consent' in the context of donating surplus samples for research (rather than as part of a clinical trial; clinical trials were outside the scope of the study) and hence more ethically acceptable; it enabled people to feel that they were making a positive contribution and would prevent the problem of vulnerable groups not being aware they were automatically 'opted-in'.

There are going to be members of the public who are not going to always be able to consider rationally themselves what it actually means. Female, healthy volunteer

While the majority of focus group participants overall preferred opt-out consent, the results were different for the three minority ethnic groups ('Black', 'S. Asian' and 'Chinese'), where opt-in consent was favoured by the majority.

### Consent once for life or consent every time

The most prevalent system in current use for donating new biosamples that are surplus to clinical requirements in the UK is the opt-in approach, with potential donors being asked for consent every time a procedure is performed that may result in a biosample becoming available for research. (The law allows for the use of diagnostic archives for research without consent as long as certain criteria are met.) Participants were therefore asked to consider variations on this model and state whether they preferred: (1) consent once for life, covering all subsequent biosamples, until or unless the donor

decides to withdraw consent; (2) consent every time samples surplus to diagnostic requirements may become available or (3) consent at certain points in life. Consent every time (43%) was preferred by the majority of survey participants, followed by consent at certain points (27%) and consent once for life, for example, at age 18 (21%). Seven per cent had no preference and 2% did not know. Groups who were significantly more likely to prefer consent every time compared with consent once for life were: under 55 years (70.3% vs 60.9%;  $\chi^2=5.88$  (1),  $p=0.015$ ); had no knowledge of the research process (72.3% vs 63.4%;  $\chi^2=5.77$  (1),  $p=0.016$ ) or were either not at all or moderately religious (70.2% vs 51.3%;  $\chi^2=5.1$  (1),  $p=0.024$ ). When entered into the regression analysis, the strongest significant predictor for preferring consent every time was being not at all or moderately religious (OR=2.04; 95% CI 1.05 to 4.00,  $p=0.036$ ) followed by being under 55 years (OR=1.60; 95% CI 1.07 to 2.41,  $p=0.023$ ; table 3).

Unlike survey responders, focus group participants favoured consent once for life ( $n=35$ ; 43%) followed by consent every time samples surplus to diagnostic requirements may become available ( $n=27$ ; 33%) and consent at certain points ( $n=16$ ; 20%) with three choosing do not know (4%). Like opt-out consent, consent once for life was seen to be better as it was 'quicker' and 'easier' administratively and prevented researchers from 'losing out'. Consent provided most control for participants as you would 'know the specific purpose of it', particularly if the sample was considered to be sensitive, for example, eggs; allowed 'no room for error'; and enabled people to change their mind easily.

You may feel differently [depending on] what tissue is being donated and for what purpose the research is being carried out. Female, aged 18–24 group

Some participants had concerns about how consent preferences (eg, what types of research they were willing

to donate a biosample for), would follow them across the healthcare system if a 'consent once for life' model was adopted. Consent at certain points was seen by some as a good middle ground as patients would still have some control, but would not have to go through the consent process every time they had a medical procedure. Examples of consent at certain points included every '5 or 10 years', or at the beginning of particular episodes of care such as pregnancy or cancer treatment.

### Models of consent for research use of biosamples

Survey participants were presented with four consent models (table 1), and asked whether they would consider consenting residual biosamples to each of them, providing the research had been approved by a REC (described as a committee usually made up of doctors, scientist, patients and the general public which ensure any research allowed to be carried out is for the benefit of patients). Eighty per cent would agree to specific consent—once only; 77% would consent to specific consent—for every new study; 71% would agree to tiered consent and 67% of participants would agree to generic consent. When asked which model they preferred, specific consent—for every new study, was the first choice among those who had a preference (30% of participants overall), followed by generic consent and specific consent—once only, jointly second (both 18%) and lastly tiered consent (14%). Sixteen per cent had no preference and 6% did not know.

After collapsing the two specific consent models together (specific consent—for every new study and specific consent—once only), those participants who preferred specific consent were significantly more likely to: have a religious affiliation (63.9% vs 48.9%,  $\chi^2=16.88(1)$ ;  $p<0.001$ ); live in the North East or Scotland (60.9% vs 42.7%,  $\chi^2=10.23(1)$ ,  $p=0.001$ ); be over 65 years (67.1% vs 57.1%,  $\chi^2=5.31(1)$ ,  $p=0.021$ ) and be of a non-'White' ethnicity (68.9% vs 58%,  $\chi^2=4.17(1)$ ,  $p=0.041$ ). Using the boost sample we found that 'Black' participants were significantly more likely to prefer specific consent models compared with 'White' participants (75.6% vs 58%,  $\chi^2=4.31(1)$ ,  $p=0.038$ ). Those people who preferred opt-in consent were also more likely to prefer specific consent models (71.1% vs 35.3%,  $\chi^2=91.72(1)$ ,  $p<0.001$ ). The strongest significant predictor for preferring specific consent was preferring opt-in consent (OR=4.58, 95% CI 3.30 to 6.35,  $p<0.001$ ) followed by being of non-'White' ethnicity (OR=2.94, 95% CI 1.23 to 7.14,  $p=0.015$ ; table 3).

We also looked at who was most likely to prefer generic consent, the least restrictive of the proposed consent models. Those who preferred generic consent were significantly more likely to: have no religious affiliation (51.1% vs 36.1%,  $\chi^2=15.97(1)$ ,  $p<0.001$ ); have some or good knowledge of the medical research process (26.1% vs 18.3%,  $\chi^2=6.79(1)$ ,  $p=0.009$ ); be male (26.8% vs 19.9%,  $\chi^2=5.40(1)$ ,  $p=0.02$ ) and be from a higher SEG group (A–D) (24.3% vs 15.1%,  $\chi^2=4.66(1)$ ,  $p=0.031$ ). They were also

significantly more likely to prefer opt-out consent (64.7% vs 28.9%,  $\chi^2=91.72(1)$ ,  $p<0.001$ ). The strongest significant predictor for preferring generic consent was preferring opt-out consent (OR=4.55, 95% CI 3.13 to 6.67,  $p<0.001$ ) followed by having no religious affiliation (OR=1.56, 95% CI 1.08 to 2.72,  $p=0.021$ ) and some or good knowledge of the medical research process (OR=1.56, 95% CI 1.06 to 2.28,  $p=0.024$ ; table 3).

Focus group preferences differed from those of survey responders with generic and tiered consent being equally popular ( $n=36$ ; 44% and  $n=35$ ; 43%, respectively). Specific consent—once only, was least popular ( $n=6$ ; 7%) (this was the only specific consent model given to participants). Four participants (5%) did not know. Generic consent was valued as it provides most 'flexibility for researchers'; reduces the likelihood residual biosamples will go to waste; is more straightforward to put in place; is 'simpler to understand' and enables biosamples to be used for more than 'one specific thing'.

It's better not to restrict the possible use of the sample because by restricting it you're increasing the chance that it'll go to waste. You want the highest probability that something good will come from it. Male, patient—affected by a condition

It was also the consent model favoured by all participants who were affected by an illness or disability.

Tiered consent was valued because it provided more control over donated biosamples than generic consent, allowing people to opt-out of certain types of research, and therefore provided 'clarity and peace of mind'. All but one participant in the 'Black' focus group and all participants who had donated biosamples as healthy volunteers preferred tiered consent. While specific consent was seen to provide the most control and enabled participants to have 'some understanding of what it might be used for', concerns raised were that it 'can't be used for anything else', 'could be wasted' and would require a time-consuming explanation from health professionals.

In both the survey and focus groups, the donation of potentially sensitive biosamples produced a preference for specific consent. In the survey, a quarter (25%) preferred specific consent—for every new study, 22% preferred specific consent—once only, 12% preferred generic consent and 9% preferred tiered consent. Nineteen per cent had no preference and 13% did not know. When discussing donation of eggs, one woman commented:

People could reproduce a child or whatever and it's about the personal-ness of what's been taken from you. So if it's a bit of blood, yeah take it, I mean you just cut yourself and blood is gone, but if it's something that's quite personal you only have every now and again, that needs to be guarded. Female, 'Black' ethnicity group

We asked survey participants whether they would like to be kept up-to-date with research going on at a particular



hospital or biobank to which they had donated a biosample. Eighty-five per cent said they would be interested; the most popular methods to receive updates were via a website (27%), email (27%) or letter (22%).

## DISCUSSION

This study contributes further to our understanding of the UK public's views and preferences towards consent for the use of biosamples in medical research. In summary, we have found that: (1) the consenting process was perceived as important in order to maintain trust between patients and health professionals and respect patient autonomy; (2) survey participants exhibited a desire to retain active choice and control when donating biosamples and over the uses to which their biosamples might be put and (3) these results differ from those reported during focus group discussions, where preference was for less restrictive consent models that are likely to increase availability of biosamples. These differences might be accounted for by the fact that focus group participants were given more background information about the use of residual biosamples in research and had time to consider the benefits and disadvantages of the different approaches. These interventions may have allayed any anxieties participants had about relinquishing control of their biosamples and seem to have encouraged participants to choose approaches that maximised biosample access to researchers, highlighting the importance and potential impact of education on influencing public perception in this area.

The preference for opt-in consent identified in the survey is consistent with the results of other studies in this area.<sup>3 15 16</sup> One reason for this preference may be that it matches the current system for organ donation for transplant in the UK. It was also perceived as being truly informed consent by some participants (although it is worth noting that it is the information provided to potential donors that guarantees consent is informed rather than the consent mechanism). Nevertheless, the sizeable number of survey responders who preferred opt-out consent (27%) coupled with the preference for opt-out among focus group participants (57%) does suggest that there may be broader support than previously believed for this approach. This point is also supported by the finding that fewer than half of survey participants wanted to be consented every time a sample was taken and nearly 30% preferred consent at certain points. Alternate, more streamlined approaches to consenting should therefore be considered and evaluated. Interestingly, our results showed that preference for opt-out consent was associated with being younger (under 65 years), from a higher SEG and a higher education level. These demographic groups may be more trusting of medical institutions to use residual biosamples appropriately, or perhaps feel empowered to be able to opt-out if so desired, for example, online. Similar

findings have been reported in relation to organ donation; a study by Gimbel *et al*<sup>26</sup> found an association between cadaveric donation rate and percentage of the population enrolled in third-tier education. Internet access has also been found to correlate with increased organ donation.<sup>27</sup>

Concerning consent models for research use of biosamples, the majority of people (69%) were willing to donate biosamples via the least restrictive model, generic consent. A study conducted in Sweden found a similar percentage of the general public were happy to agree to generic consent (67%), whereby surrogate decisions were performed by a REC.<sup>28</sup> Other national studies have found the acceptability of generic consent among the general public and in particular patients to be higher, between 79% and 95%.<sup>4 29–32</sup> Nevertheless, our survey findings suggest that willingness to donate increased where greater choice and control over research participation is retained, although the difference between those who were willing to agree to generic compared with specific was only 13%. Similarly, when survey responders were asked about their preferred approach, their preference was also for specific consent for every new study that might be conducted using their biosample. This may indicate a general interest in how samples are being used. This notion is supported by the high number of people who wanted ongoing contact about the research leading from their donation. Moreover, they may have not considered the practicalities of being asked to consent every time their sample is used, and the high level of recontact they might receive from research teams. Nevertheless, it is important to take note of the fact that more tailored forms of consent represent an attractive approach to many people. While specific consent may be practical for individual research projects, this restriction would make biobanking challenging, as biobanks exist to facilitate access to samples for a wide variety of approved research projects without the need for additional consent. It may be that as more sophisticated biosample tracking and management systems are adopted, resources could become available to support more interactive forms of consent, and more biobanks could offer tiered consent, for example. Further public dialogue and information about the use of the samples may also provide the same assurances for people that arise from specific consent, as highlighted by the preference for less restrictive consent models among focus group participants.

Evidence from other empirical studies looking at preferences for consent models is mixed. The UK studies focusing on donations purely for research by 'healthy volunteers' to biobanks (ie, not donating residual biosamples) have identified a preference for specific consent,<sup>19 33</sup> as did a study conducted in the USA that also focused on healthy volunteers.<sup>15</sup> In a pan-European survey, the majority of the UK public also preferred specific consent for every new study, although the percentage that did was slightly lower than the overall European

average (65% compared with 67%).<sup>34</sup> It was, however, higher than in Denmark and Finland, where the percentage of people who wanted to be recontacted for every new study was lower at 51% and 54%, respectively. These countries were also found to have very few concerns about the collection of personal information by biobanks and had high levels of trust in ethics committees. Other empirical work conducted in the USA, Canada, Sweden and Spain has shown that public preference is for generic consent.<sup>3 16 18 35 36</sup> These findings highlight the divergence of opinion on this issue, in particular in different contexts and with different information provision, although the difficulty of comparing across studies with different methodologies and backgrounds must also be taken into account. Notably, where participants had some or good knowledge of the research process and where there was in-depth discussion (ie, during focus groups), participants were more likely to prefer generic consent, a finding that has also been identified elsewhere in the literature<sup>37</sup> and supports the need for information and education if increasing the acceptability of generic consent is deemed desirable. Focus group participants affected by an illness or disability were also found to prefer generic consent, and is likely to reflect the fact that they have greater interests at stake.<sup>38</sup> Preference for specific consent was found to be associated with being over 65 years and from a non-‘White’ ethnicity, findings which resonate with other studies.<sup>3 39 40</sup> Consent documentation and written information targeted specifically at these particular groups may also help alleviate any specific concerns these groups may have.

This research into current public attitudes regarding biosample donation in the UK provides valuable guidance for biobanking governance. While generic consent is the model largely endorsed by regulators and funders in the UK,<sup>9 11</sup> the evidence from this study suggests that there is a need to address the potential concerns that some people may have about the minimal information and lack of control provided through this model. Education and opportunity for discussion may be one way to allay concerns, as demonstrated through focus groups. Keeping donors informed of current research taking place at the hospital or research institutions to which they donated also appears to be desirable and is likely to be both motivating and promote public trust and confidence in the research process, a finding reported elsewhere.<sup>41</sup> The opportunity for face-to-face discussion with an appropriately trained healthcare professional at the time of donation may also allay any potential concerns, and is indeed the approach usually taken in the UK at present. This approach has been found to yield high acceptance rates among patients of well over 90%.<sup>42–44</sup>

### Strengths and limitations

This was a mixed-methods study to explore public views and preferences towards consent for biosample donation.

Integrating quantitative and qualitative approaches is valuable in exploratory research as it can strengthen the inferences made through triangulation and allow for a more nuanced understanding of the topic.<sup>45</sup> This study presented participants with a series of hypothetical questions about their preferences and willingness to donate residual biosamples for medical research. By presenting questions as ‘real life’ scenarios, we hoped to make the questions as realistic as possible. However, as with any hypothetical scenario, the findings may not necessarily correlate with actual behaviour.

The questions for both the focus groups and the survey were piloted to ensure they were clear and understandable and were not biased towards any particular viewpoint. Nevertheless, many of the issues covered were complex, particularly around the meaning of the different consent models which may have contributed to the dropout rate. Focus groups participants were not presented with the option of ‘specific consent—for every new study’ (they were only given ‘specific consent—once only’). This may have been an attractive option for some given that a concern raised was biosamples being wasted. However, given that the key reasons participants’ valued generic consent were because it provided most flexibility to researchers and was most straightforward to administer, this seems unlikely. In addition, given time and resource constraints we were unable to explore whether ‘stronger’ consent models would have been preferable for organisations that donors trusted less. This is an area that would be worth exploring further in future research. Some participants did complete the survey possibly because of strong feelings about the issues raised and this may have skewed the results; however, every effort was made to ensure that the results were as representative of the UK population as possible. The focus groups and survey were conducted in English and so the findings may not be representative of non-English speaking members of the general public. Future research might target these particular groups.

### CONCLUSION

There is a general willingness among the UK population to donate biosamples for medical research. Our research suggests that there is a preference among the UK public for more information on the uses and outcomes of research, and ongoing choice and control over donated biosamples. Our study also supports the premise that increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models.

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