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# *Use of Patients' Biological and Non-Biological Materials without Consent for Anonymous Research: A Cross-Sectional Ethical Study*

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## *Abstract*

**Background:** Using biological materials without consent is broadly unacceptable. To date there are many different types of consents that are needed to use human biological specimens for research. These variabilities have led to confusion regarding what type of research is permitted, and what is not. Consequently, this problem has unintentionally added constraints on all future research.

**Patients and methods:**

This study is a cross sectional survey that used an anonymous structured questionnaire which was designed and created to be disseminated in print and via Google online forms among participants.

**Results:**

A total sample of 296 participants was included in this study, males represented (40.2%) and females (59.8%). The majority (48.0%) were between 40 and 60 years old,about (52.0%) agreed to the publication of research results that used their samples or x-rays without their consent. Only (19.6%) considered bio-banks as important without any conditions and (66.9%) were willing to share their own samples for bio-banks. Sex, residence and education were statistically significant factors affecting approving the use of the remaining samples in future research**.**

**Conclusion and recommendations:**

Despite of the inadequate knowledge of bio-banks, there was a high willingness to participate in research, and to share their own samples for bio banks. Extensive research and experts' opinion studies should be executed to develop culturally, ethically, and legally appropriate flexible informed consent models. Public information, communication and education programs should be designed to increase public awareness, and to address public fears and concerns.

**Keywords:**

Ethical dilemma, biological material, unconsented samples, confidentiality, societal benefit.

## *Introduction*

In Order to conduct a sound scientific research, researchers should adhere to the ethical principles. These principles protect participants' right and dignity ***(WHO, 2024)***. Any social, biomedical, behavioral and epidemiological research that involves human subject exposure or identification should be reviewed by an ethical committee ***(WHO, 2024).*** Informed consent is a vital procedure both legally and ethically to ensure voluntary informed participation ***(Shah et al., 2024).***

To date there are many different types of consents that are needed to use human biological specimens for research. These variabilities have led to confusion regarding what type of research is permitted, and what is not. Consequently, this problem has unintentionally added constraints on all future research ***(Grady et al., 2015).***Moreover, collecting retrospective consents from people have been proven laborious, time consuming, and expensive (***Duque et al., 2010).***

Researches on using archived identifiable human biological materials are vital for the research community. There are strict requests for consent which are occasionally viewed as an obstacle. Consequently, certain conditions are specified in both international and national regulations that soften the consent in different types of research ***(Gefenas et al., 2011).***

From an ethical perspective, patients' autonomy and confidentiality are of utmost importance, however, the broader societal benefit should not be ignored. Moreover, Imposing consents and barring all data regardless of the types and/or grade of information, from low-risk to high-risk information, will only result in selection bias. Consequently, most of the population based studies will reflect an untrue information and in turn will harm the all the patients indirectly through the biased results ***(Porsdam et al., 2016).***

The current study was implemented in Egypt to know first hand patients and general population perspectives on which materials, samples, images, and/or results they are willing to waive the strict consent issues from and which they oppose.

## *Patients and Methods*

**Study Design**

This is a cross sectional survey that used an anonymous structured questionnaire which was designed and created to be disseminated physically in print form and also digitally via Google online forms among participants of different demographics to obtain the views of both educated and uneducated. The online form link was disseminated through Facebook and whatsApp groups.

**Study Population**

The questionnaire was distributed in Cairo university hospitals clinics, in addition to the online participants, during the period of the study. Both our online and off line participants were recruited and freely answered the anonymous questionnaire, designed by the authors. The recruitment criteria were: (I) Adults between 18 - 60 years old, males or females, (II) voluntary participation in this survey, (III) ability to complete the online survey or in print form, (IV) signing informed consent in paper form or by continuing the online questionnaire that was clearly stated to be an implied consent. The exclusion

criteria,participants who have severe neurological or psychiatric problems such as cerebral palsy, mental retardation, and schizophrenia.

**Sampling**

This study followed a previous similar study ***(Duque et al., 2010)*** and by considering the agreement on informed consent and research with stored biological samples on a retrospective study conducted at the Brazilian National Cancer Institute as a primary outcome. The following formula was used to calculate the sample size of this cross-sectional survey.

n = [DEFF*Np(1-p)]/ [(d2/Z21-α/2*(N-1) +p*(1-p)] . Open epi program was used to calculate the sample size. Assuming 90% Confidence level, 5% level of significance, an estimated similar proportion of 71%, design effect of 1. The minimum required sample size for this study was 223 participants, then 10% (n = 22) was added to accommodate for possible missing data, so 245 participants were necessary.

**Data Collection Tool**

A questionnaire was developed by the authors; the questionnaire was translated into Arabic followed by a back-translation into English performed by two additional translators. The back translators compared their translations with the previous English version. Any discrepancies that were identified were resolved by discussions between the researchers and the translators.

The questionnaire included the following sections:

(I) socio-demographic data (4 questions) including; gender, age, residence, and education level. (II) The main body of the questionnaire focused on participants opinion on whether they would accept that the scientific community could use of the remainder of their samples and/or results of their diagnostic/therapeutic workup for the sake of societal benefits through publishing the assessment of these results in periodical journals nationally or internationally (7 questions). (III) questions about their knowledge about bio banking, their purpose, then a short brief about biobanks to those who weren't aware of biobanks, this was followed by questions about necessity of biobanks and the possibility that they would be willing to share their samples to build such bio-banks for the sake of the overall societal health benefits (4 questions). (IV) and finally questions on human medical research importance (2 questions).

**Questionnaire validity**

Content validity: the questionnaire was assessed for content validity with an expert panel of 3 researchers from Forensic Medicine and Public health departments with knowledge and expertise in medical and research ethics and research methods. The experts were asked to individually review the relevancy of the items, and the questionnaire was adjusted accordingly.

Face validity: authors conducted face validity for the questionnaire by consulting laypersons. Their feedback ensured that the questions were clear, relevant, and appropriate to the study objectives.

**Pilot testing**

The questionnaire was piloted on 10 patients who were excluded from the analysis. No modification to the questionnaire was needed based on the pilot testing.

**Data management and statistical analysis**

All data were an onymous, handled and treated with confidentiality and only the authors had access to the results. Final data were reviewed for completeness and consistency. Microsoft excel 2013 was used for data entry and the statistical package for social science (SPSS) version 23 (SPSS, Armonk, New York: International Business Machines Corporation) was used for data analysis. Simple

descriptive statistics (arithmetic mean and standard deviation) used for summary of quantitative data, while frequencies and percentages were used for qualitative data. Bivariate relationship was displayed in cross tabulations and Comparison of proportions was performed using the chi-square test or fisher exact whenever appropriate. The level of significance was set at (P) value <0.05.

**Ethical consideration**

The research protocol and consent procedures were approved before hand by the Central Research Ethics committee at the University hospitals Supreme Council, Egypt (Approval number: NO-0327), the committee acts in accordance with the Declaration of Helsinki.

## *Results*

A total sample of 296 participants were included in this study, males represented (40.2%) and females (59.8%). The majority (48.0%) were between 40 and 60 years old, (82.8%) of them resided in urban areas. The educational background of the participants varied (16.9%) were uneducated and (53.7%) had university education (Table 1). More than (50%) of the participants agreed to use their remaining laboratory analysis samples, remaining tissue analysis, diagnostic scans, therapeutic radiology results, genetic analysis samples, and x-ray results for scientific research. About (52.0%) agreed to the publication of research results without their consent. More than half (53%) of the participant didn't know what is bio-banks. Only (19.6%) considered bio-banks as important without any condition and (66.9%) were willing to share their own samples for biobanks. About (74.0%) of the participants accept human medical research implementation if it would lead to the development of a useful treatment method or better treatments **(Table 2)**. Regarding age, none of the variables were found significant with it (**Table 3).** There was a statistically significant difference between males (65.5%) compared to females (49.7%) who agreed to use their remaining laboratory samples for scientific research (P-value= 0.023). Also (64.7%) of males agreed to use their remaining tissue analysis samples for scientific research, while (48.0%) of females agreed with a statistically significant difference (P-value= 0.014). Regarding the importance of medical research, (88.7%) of females were aware of it compared to (79.8%) of males with a statistically significant difference (P-value= 0.035) **(Table4).**

Regarding agreement of the use of remaining samples of laboratory analyses, tissue analysis samples, diagnostic scans, therapeutic radiology results and x-ray results for research there was a statistically significant difference (P-value < 0.05) between those who resides in the countryside and urban residences in favor of urban residence. Also, about (52.9%) of countryside residents agreed to share their samples for use in biobanks compared to (69.8%) of urban residents (P-value= 0.020) and (87.3%) of urban residents were aware of the importance of medical research, while only (74.5%) of countryside residents were aware (P-value= 0.019) **(Table 5)**. Finally, as regards the association between participants' educational level and their agreement to use the remaining samples of the various laboratory analyses tissue analysis samples, diagnostic scans, therapeutic radiology results, genetic analysis samples and x-ray results for research, a statistically significant difference (P-value < 0.05) was found between uneducated and those with university education in favor of the university educated are less likely to refuse **(Table 6).**

**Table (1)**

Demographic Characteristics of the Enrolled Participants (N=296)

| Variables | Categories | No. | % |
|---|---|---|---|
| Gender | Male | 119 | 40.2 |
| | Female | 177 | 59.8 |
| Age | <40 years | 124 | 41.9 |
| | 40-60 years | 142 | 48.0 |
| | >60 years | 30 | 10.1 |
| Residence | Countryside | 51 | 17.2 |
| | Urban | 245 | 82.8 |
| Education | Uneducated | 50 | 16.9 |
| | School education (primary and/or preparatory) | 36 | 12.2 |
| | Intermediate education | 51 | 17.2 |
| | University education | 159 | 53.7 |

**Table (2)**

Percent Distribution of the Enrolled Participants by Their Views on Sample Reuse in Scientific Research and Biobanks (N=296)

| Variables | Response | No. | % |
|---|---|---|---|
| Reuse of lab samples | Yes | 166 | 56.1 |
| | No | 33 | 11.1 |
| | Yes but after consent | 97 | 32.8 |
| Reuse of tissue samples | Yes | 162 | 54.7 |
| | No | 31 | 10.5 |
| | Yes but after consent | 103 | 34.8 |
| Reuse of diagnostic scans | Yes | 166 | 56.1 |
| | No | 30 | 10.1 |
| | Yes but after consent | 100 | 33.8 |
| Reuse of therapeutic radiology results | Yes | 161 | 54.4 |
| | No | 40 | 13.5 |
| | Yes but after consent | 95 | 32.1 |
| Reuse of genetic samples | Yes | 151 | 51.0 |
| | No | 51 | 17.2 |
| | Yes but after consent | 94 | 31.8 |
| Reuse of samples results and x-rays | Yes | 155 | 52.4 |
| | No | 42 | 14.2 |
| | Yes but after consent | 99 | 33.4 |
| Publish research that has used your samples or x-rays without your consent | Yes | 154 | 52.0 |
| | No | 63 | 21.3 |
| | Yes but after consent | 79 | 26.7 |
| Awareness of biobanks | Yes | 139 | 47.0 |
| | No | 157 | 53.0 |
| Knowledge of biobank purpose (n=139) | Yes | 123 | 88.5 |
| | No | 16 | 11.5 |
| Perceived necessity of biobanks | Important | 58 | 19.6 |
| | Important with conditions | 238 | 80.4 |
| Willingness to share samples to biobanks | Yes | 198 | 66.9 |
| | No | 98 | 33.1 |
| Perceived value of medical research | Yes | 252 | 85.1 |
| | No | 44 | 14.9 |
| Support human medical research implementation if beneficial | Yes | 219 | 74.0 |
| | No | 77 | 26.0 |

**Table (3)**

Age-Based Distribution of Participants' Responses on Sample Reuse in Scientific Research and Biobanks(N= 296)

| Variables | Response | <40 Years (n=124) | | 40-60 Years (n=142) | | >60 Years (n=30) | | p-value |
|---|---|---|---|---|---|---|---|---|
| | | No. | % | No. | % | No. | % | |
| Reuse of lab samples | Yes | 64 | 51.6 | 86 | 60.6 | 16 | 53.3 | 0.100 |
| | No | 11 | 8.9 | 20 | 14.1 | 2 | 6.7 | |
| | Yes but after consent | 49 | 39.5 | 36 | 25.4 | 12 | 40.0 | |
| Reuse of tissue samples | Yes | 63 | 50.8 | 82 | 57.7 | 17 | 56.7 | 0.092 |
| | No | 10 | 8.1 | 20 | 14.1 | 1 | 3.3 | |
| | Yes but after consent | 51 | 41.1 | 40 | 28.2 | 12 | 40.0 | |
| Reuse of diagnostic scans | Yes | 68 | 54.8 | 82 | 57.7 | 16 | 53.3 | 0.477 |
| | No | 9 | 7.3 | 18 | 12.7 | 3 | 10.0 | |
| | Yes but after consent | 47 | 37.9 | 42 | 29.6 | 11 | 36.7 | |
| Reuse of therapeutic radiology results | Yes | 63 | 50.8 | 84 | 59.2 | 14 | 46.7 | 0.316 |
| | No | 15 | 12.1 | 21 | 14.8 | 4 | 13.3 | |
| | Yes but after consent | 46 | 37.1 | 37 | 26.1 | 12 | 40.0 | |
| Reuse of genetic samples | Yes | 56 | 45.2 | 81 | 57.0 | 14 | 46.7 | 0.256 |
| | No | 21 | 16.9 | 23 | 16.2 | 7 | 23.3 | |
| | Yes but after consent | 47 | 37.9 | 38 | 26.8 | 9 | 30.0 | |
| Reuse of samples results and x-rays | Yes | 59 | 47.6 | 81 | 57.0 | 15 | 50.0 | 0.324 |
| | No | 17 | 13.7 | 22 | 15.5 | 3 | 10.0 | |
| | Yes but after consent | 48 | 38.7 | 39 | 27.5 | 12 | 40.0 | |
| Publish research that has used your samples or x-rays without your consent | Yes | 61 | 49.2 | 78 | 54.9 | 15 | 50.0 | 0.421 |
| | No | 23 | 18.5 | 33 | 23.2 | 7 | 23.3 | |
| | Yes but after consent | 40 | 32.3 | 31 | 21.8 | 8 | 26.7 | |
| Willingness to share samples to biobanks | Yes | 85 | 68.5 | 95 | 66.9 | 18 | 60.0 | 0.671 |
| | No | 39 | 31.5 | 47 | 33.1 | 12 | 40.0 | |
| Perceived value of medical research | Yes | 106 | 85.5 | 119 | 83.8 | 27 | 90.0 | 0.680 |
| | No | 18 | 14.5 | 23 | 16.2 | 3 | 10.0 | |
| Support human medical research implementation if beneficial | Yes | 96 | 77.4 | 101 | 71.1 | 22 | 73.3 | 0.504 |
| | No | 28 | 22.6 | 41 | 28.9 | 8 | 26.7 | |

**Table (4)**

Relationship between Gender and Participants' Responses on Sample Reuse in Scientific Research and Biobanks (N=296)

| Variables | Response | Male (n=119) N(%) | Female (n=177) N(%) | P-value |
|---|---|---|---|---|
| Reuse of lab samples | Yes | 78 (65.5) | 88 (49.7) | 0.023* |
| | No | 9 (7.6) | 24 (13.6) | |
| | Yes but after consent | 32 (26.9) | 65 (36.7) | |
| Reuse of tissue samples | Yes | 77 (64.7) | 85 (48.0) | 0.014* |
| | No | 8 (6.7) | 23 (13.0) | |
| | Yes but after consent | 34 (28.6) | 69 (39.0) | |
| Reuse of diagnostic scans | Yes | 75 (63.0) | 91 (51.4) | 0.094 |
| | No | 8 (6.7) | 22 (12.4) | |
| | Yes but after consent | 36 (30.3) | 64 (36.2) | |
| Reuse of therapeutic radiology results | Yes | 70 (58.8) | 91 (51.4) | 0.289 |
| | No | 17 (14.3) | 23 (13.0) | |
| | Yes but after consent | 32 (26.9) | 63 (35.6) | |
| Reuse of genetic samples | Yes | 68 (57.1) | 83 (46.9) | 0.209 |
| | No | 19 (16.0) | 32 (18.1) | |
| | Yes but after consent | 32 (26.9) | 62 (35.0) | |
| Reuse of samples results and x-rays | Yes | 69 (58.0) | 86 (48.6) | 0.144 |
| | No | 18 (15.1) | 24 (13.6) | |
| | Yes but after consent | 32 (26.9) | 67 (37.9) | |
| Publish research that has used your samples or x-rays without your consent | Yes | 68 (57.1) | 86 (48.6) | 0.349 |
| | No | 23 (19.3) | 40 (22.6) | |
| | Yes but after consent | 28 (23.5) | 51 (28.8) | |
| Willingness to share samples to biobanks | Yes | 75 (63.0) | 123 (69.5) | 0.246 |
| | No | 44 (37.0) | 54 (30.5) | |
| Perceived value of medical research | Yes | 95 (79.8) | 157 (88.7) | 0.035* |
| | No | 24 (20.2) | 20 (11.3) | |
| Support human medical research implementation if beneficial | Yes | 87 (73.1) | 132 (74.6) | 0.778 |
| | No | 32 (26.9) | 45 (25.4) | |

***Significant difference**

**Table (5)**

Relationship between Residence and Participants' Responses on Sample Reuse in Scientific Research and Biobanks (N=296)

| Variables | Response | Countryside (n=51) N (%) | Urban (n=245) N (%) | P-value |
|---|---|---|---|---|
| Reuse of lab samples | Yes | 26 (51.0) | 140 (57.1) | 0.001* |
| | No | 13 (25.5) | 20 (8.2) | |
| | Yes but after consent | 12 (23.5) | 85 (34.7) | |
| Reuse of tissue samples | Yes | 27 (52.9) | 135 (55.1) | 0.002* |
| | No | 12 (23.5) | 19 (7.8) | |
| | Yes but after consent | 12 (23.5) | 91 (37.1) | |
| Reuse of diagnostic scans | Yes | 23 (45.1) | 143 (58.4) | <0.001* |
| | No | 13 (25.5) | 17 (6.9) | |
| | Yes but after consent | 15 (29.4) | 85 (34.7) | |
| Reuse of therapeutic radiology results | Yes | 27 (52.9) | 134 (54.7) | 0.013* |
| | No | 13 (25.5) | 27 (11.0) | |
| | Yes but after consent | 11 (21.6) | 84 (34.3) | |
| Reuse of genetic samples | Yes | 28 (54.9) | 123 (50.2) | 0.064 |
| | No | 13 (25.5) | 38 (15.5) | |
| | Yes but after consent | 10 (19.6) | 84 (34.3) | |
| Reuse of samples results and x-rays | Yes | 27 (52.9) | 128 (52.2) | 0.017* |
| | No | 13 (25.5) | 29 (11.8) | |
| | Yes but after consent | 11 (21.6) | 88 (35.9) | |
| Publish research that has used your samples or x-rays without your consent | Yes | 24 (47.1) | 130 (53.1) | 0.296 |
| | No | 15 (29.4) | 48 (19.6) | |
| | Yes but after consent | 12 (23.5) | 67 (27.3) | |
| Willingness to share samples to biobanks | Yes | 27 (52.9) | 171 (69.8) | 0.020* |
| | No | 24 (47.1) | 74 (30.2) | |
| Perceived value of medical research | Yes | 38 (74.5) | 214 (87.3) | 0.019* |
| | No | 13 (25.5) | 31 (12.7) | |
| Support human medical research implementation if beneficial | Yes | 35 (68.6) | 184 (75.1) | 0.338 |
| | No | 16 (31.4) | 61 (24.9) | |

***Significant difference**

**Table (6)**

Relationship between the Educational Level and Participants' Responses on Sample Reuse in Scientific Research and Biobanks(N=296)

| Variables | Response | Uneducated (n=50) N(%) | School Education (n=36) N(%) | Intermediate Education (n=51) N(%) | University Education (n=159) N(%) | P-value |
|---|---|---|---|---|---|---|
| Reuse of lab samples | Yes | 32 (64.0) | 20 (55.6) | 28 (54.9) | 86 (54.1) | <0.001* |
| | No | 11 (22.0) | 5 (13.9) | 10 (19.6) | 7 (4.4) | |
| | Yes but after consent | 7 (14.0) | 11 (30.6) | 13 (25.5) | 66 (41.5) | |
| Reuse of tissue samples | Yes | 31 (62.0) | 19 (52.8) | 30 (58.8) | 82 (51.6) | 0.018* |
| | No | 8 (16.0) | 6 (16.7) | 8 (15.7) | 9 (5.7) | |
| | Yes but after consent | 11 (22.0) | 11 (30.6) | 13 (25.5) | 68 (42.8) | |
| Reuse of diagnostic scans | Yes | 31 (62.0) | 19 (52.8) | 26 (51.0) | 90 (56.6) | 0.004* |
| | No | 9 (18.0) | 6 (16.7) | 9 (17.6) | 6 (3.8) | |
| | Yes but after consent | 10 (20.0) | 11 (30.6) | 16 (31.4) | 63 (39.6) | |
| Reuse of therapeutic radiology results | Yes | 31 (62.0) | 20 (55.6) | 26 (51.0) | 84 (52.8) | <0.001* |
| | No | 12 (24.0) | 7 (19.4) | 11 (21.6) | 10 (6.3) | |
| | Yes but after consent | 7 (14.0) | 9 (25.0) | 14 (27.5) | 65 (40.9) | |
| Reuse of genetic samples | Yes | 31 (62.0) | 21 (58.3) | 25 (49.0) | 74 (46.5) | 0.001* |
| | No | 13 (26.0) | 6 (16.7) | 14 (27.5) | 18 (11.3) | |
| | Yes but after consent | 6 (12.0) | 9 (25.0) | 12 (23.5) | 67 (42.1) | |
| Reuse of samples results and x-rays | Yes | 30 (60.0) | 19 (52.8) | 25 (49.0) | 81 (50.9) | <0.001* |
| | No | 11 (22.0) | 7 (19.4) | 14 (27.5) | 10 (6.3) | |
| | Yes but after consent | 9 (18.0) | 10 (27.8) | 12 (23.5) | 68 (42.8) | |
| Publish research that has used your samples or x-rays without your consent | Yes | 29 (58.0) | 18 (50.0) | 24 (47.1) | 83 (52.2) | 0.316 |
| | No | 13 (26.0) | 7 (19.4) | 15 (29.4) | 28 (17.6) | |
| | Yes but after consent | 8 (16.0) | 11 (30.6) | 12 (23.5) | 48 (30.2) | |
| Willingness to share samples to biobanks | Yes | 26 (52.0) | 24 (66.7) | 22 (43.1) | 126 (79.2) | <0.001* |
| | No | 24 (48.0) | 12 (33.3) | 29 (56.9) | 33 (20.8) | |
| Perceived value of medical research | Yes | 40 (80.0) | 29 (80.6) | 35 (68.6) | 148 (93.1) | <0.001* |
| | No | 10 (20.0) | 7 (19.4) | 16 (31.4) | 11 (6.9) | |
| Support human medical research implementation if beneficial | Yes | 34 (68.0) | 29 (80.6) | 34 (66.7) | 122 (76.7) | 0.286 |
| | No | 16 (32.0) | 7 (19.4) | 17 (33.3) | 37 (23.3) | |

***Significant difference**

## *Discussion*

The Current study revealed several important findings regarding public awareness, attitudes and willingness to participate in biobanks. It was found that more than half of the participants didn't know what the bio-banks are, however majority acknowledged medical research importance and more than two thirds were willing to share their own samples for bio-banks.

A Chinese study exploring public awareness and attitude reported that bio-bank is a vital resource for research progress ***(Gao et al., 2022)***. Community participation in bio-banks, required for their expansion, is inadequate due to insufficient awareness of bio-banking and fears regarding donation of samples ***(Gao et al., 2022).***

This was conformed to a previous survey conducted during 2007 among Finns, the study found that majority of the participants, had slight or no awareness about bio-banks. However nearly, three quarters accredited the national bio-bank ***(Tupasela et al., 2010).***

Researches published to study patient view regarding clinical data and sample sharing is scarce. Also there are many debates regarding legal, ethical and social implication of sharing clinical data and samples ***(Broes et al., 2020).***

Using patient data is vital to improve health care and research, so people support this use. However they feel that this should happen after their permission. A differentiation between informed consent, opt in and opt out is important. Informed consent is detailed information with discussion to allow a clear action for data collection. Opt in individual or patient has to actively sign for data to be collected and used. Opt out data will be collected and used by default unless individual actively refuse ***(UK Org, 2018)***. Regarding National Health System United Kingdom ***(NHS-UK, 2024),*** it supports mechanisms for both individuals and organization to opt out. This includes either their data should be or should not be shared in certain research ***(NHS UK, 2024).*** Also this was articulated in a study conducted among cancer patients, where the participants were willing to share their data and samples for future researches but their opinion varied in the need of re-consent before the use ***(Broes et al., 2020).***

More than half of the participants in the current study agreed to use their remaining laboratory analysis samples, remaining tissue analysis, diagnostic scans, therapeutic radiology results, genetic analysis samples and x-ray results for scientific research. However nearly one third agreed using their remaining samples but after taking their consent.

Similarly another study reported that one third of the participants required consent to be recaptured with each new research, whereas 44% wanted to select the research type where their samples would be used for ***(Tupasela et al., 2010).***

Informed consent and institutional oversight may be required before the secondary use of samples however concerns are present to discuss that informed consent could be exempted when the risks are appropriately small. Though debate have proposed that, small risk is not satisfactory to tolerate the secondary use of samples without consent ***(Lenicov and Fink, 2023).***

A review study about the attitudes towards the reuse of health data conducted among people in the European Union, reported that, people have positive attitude towards the use of data for research.However specific types of sensitive and stigmatizing data are mentioned to be sensitive to share. Many studies reported that participants' would allow the use of health data for research purposes without consent, providing that data were anonymous; on the other hand minority appears to accept the use of identifiable health data also with no consent ***(Skovgaard et al., 2019).***

Also an on line survey found that mostly there was positive attitude for data sharing, predominantly anonymous data, with the highest levels of support for sharing information for NHS purposes ***(Caldicott, 2016).***

Socio demographic characteristics are important factors for individual perception and attitudes. The current study found that residing in urban area and being university graduate affect your

knowledge and attitudes. Also a previous study mentioned that participants with more education had more awareness of bio-bank, though there were no differences among participants in respect of level of education in their willingness to participate or share their data and samples. While those living in small cities were more aware of bio-banks, less willing to participate or share data and samples ***(Mezinska et al., 2020)***.

**Conclusion**

Despite of the inadequate knowledge of bio-banks, there was a high willingness to participate in research, and to share their own samples for bio banks if this will bring societal benefit and scientific development. Yet it is very complex and complicated as it is governed by many factors as type of data, sensitivity, patient or public awareness, perception and attitude, legal and ethical frame work.

**Recommendation**

Extensive research and experts' opinion studies should be executed to develop culturally, ethically, and legally appropriate flexible informed consent models. Public information, communication and education programs should be designed to increase public awareness, and to address public fears and concerns.

**Abbreviations**

NHS-UK: National Health Service, United Kingdom
SPSS: Statistical Package for Social Science
UK: United Kingdom
WHO: World Health Organization

## *References*

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# استخدام المواد البيولوجية وغير البيولوجية للمرضى دون موافقتهم لأغراض بحثية غير مسماه: دراسة أخلاقية مقطعية

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## الملخص العربى

**الخلفية:**

يُعد استخدام المواد البيولوجية دون موافقة أمرًا غير مقبول على نطاق واسع. حتى الآن، هناك العديد من أنواع الموافقة المختلفة اللازمة لاستخدام العينات البيولوجية البشرية في الأبحاث. وقد أدت هذه الاختلافات إلى حدوث ارتباك بشأن نوع البحث المسموح به وما هو غير مسموح به. ونتيجة لذلك، أضافت هذه المشكلة قيودًا غير مقصودة على جميع الأبحاث المستقبلية.

**المرضى والطرق:**

هذه الدراسة عبارة عن مسح مقطعي استخدم استبيانًا منظمًا لا يطلب الاسماء تم تصميمه وإنشاؤه لنشره في شكل مطبوع وعبر نماذج جوجل عبر الإنترنت بين المشاركين.

**النتائج:**

تم تضمين عينة إجمالية من 296 مشاركًا في هذه الدراسة، ومثل الذكور (40.2٪) والإناث (59.8٪). كانت الأغلبية (48.0٪) تتراوح أعمارهم بين 40 و 60 عامًا، ووافق حوالي (52.0٪) على نشر نتائج الأبحاث التي استخدمت عيناتهم أو الأشعة السينية دون موافقتهم. اعتبر (19.6٪) فقط البنوك الحيوية مهمة دون أي شروط وكان (66.9٪) على استعداد لمشاركة عيناتهم الخاصة للبنوك الحيوية. كان الجنس والإقامة والتعليم عوامل ذات دلالة إحصائية تؤثر على الموافقة على استخدام العينات المتبقية في الأبحاث المستقبلية.

**الاستنتاج والتوصيات:**

على الرغم من عدم كفاية المعرفة بالبنوك الحيوية، كان هناك استعداد كبير للمشاركة في البحث ومشاركة عيناتهم الخاصة للبنوك الحيوية. يجب إجراء أبحاث مكثفة ودراسة رأي الخبراء لتطوير نماذج موافقة مستنيرة مرنة مناسبة ثقافيًا وأخلاقيًا وقانونيًا. يجب تصميم برامج معلومات وتواصل وتثقيف لزيادة الوعي العام ومعالجة مخاوف الجمهور واهتماماته.

**الكلمات المفتاحية:**

معضلة أخلاقية، المواد البيولوجية، العينات بدون موافقة، السرية، المنفعة المجتمعية.