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Awareness and Perceptions Among the Medical Fraternity on Broad Informed Consent Involving Storage and Use of Biological Samples For Future Research At A Tertiary Medical College

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Broad informed consent process in clinical research is an additional consent to the main consent, taken by an Investigator at that point in time, to collect, store and re-use biological samples or data for future scientific research with no specific objectives planned at that given moment. As physicians counsel patients regarding the broad informed consent process, we decided to assess the medical fraternity's awareness and perceptions about the broad consent process. A questionnaire-based survey was conducted among medical professionals and post graduate and undergraduate students at a teaching hospital to evaluate their awareness & perceptions regarding the broad informed consent process for future clinical research. The study had a response rate of 66.77% with most responders aged between 21- 40 years. 271 participants supported broad informed consent for the storage of biological samples and their use in future research, whereas 163 felt that utilizing stored biological samples in future studies conflicted with research ethics principles. Among those who favoured broad consent, 162 approved the indefinite storage of their samples, while 248 were open to sharing their samples with other researchers, provided the research had Ethics Committee approval. On the other hand, among the 163 participants who opposed broad consent, 43 indicated they would agree if their samples were anonymized, 118 preferred re-consent for specific future studies, and 127 wanted the study findings to be shared with them. Thus, although many participants were in favour of broad consent for future research, they wanted transparency regarding the research for which these samples would be used, storage for a pre-defined period and reconsent when their samples were used. These findings underscore the critical need for evolving consent frameworks that balance scientific progress with individual autonomy, suggesting that future broad consent protocols must incorporate participant-centric safeguards to maintain ethical standards and public trust in medical research.

Keywords: Broad consent; Biological samples; Clinical research; Future research; Re-consent; Storage; Transport.

The CIOMS Guidelines 2016 defines 'Broad Consent' as consent given by an individual/ participant in the present time for an unspecified future use of his/her biological samples collected for research purposes or leftover after clinical diagnosis or treatment.[1] In 2017, the U.S. Department of Health and Human Services (HHS) revised the Common Rule [45 CFR§46.116(d)], introducing Broad Consent as a third option within Informed Consent for research. This approach

involves obtaining an individual's consent for the storage and secondary use of identifiable private information or biospecimens for research purposes.[2] Additionally, the concept of broad or blanket consent is outlined in the Indian Council of Medical Research's (ICMR) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017).[3]

Thus, Broad Consent is a one-time, open-ended consent provided by an individual permitting the collection, storage, and future use of his/her biological samples for research without requiring re-consent. This model of informed and voluntary consent enables both present and future access to biological samples or patient data for research purposes without specifying the exact objectives of future potential studies.[1,3] However, the participant is assured of safe and anonymous storage of his/her body sample, use of sample for future scientific research and destruction of his/her sample after the stipulated time. The main reason for such a provision is to prevent re-consenting and fresh enrolment of participants in a new study to obtain biological samples, saving on time and resources or spending time in tracing already enrolled study participants for collecting biological samples from same participants for future research. The participant however may be in a dilemma whether to consent now for unplanned additional research to be conducted in the future without knowing the purpose and consequences of that research. Research has shown that participants' willingness to provide broad consent for unspecified future use varies widely, ranging from 44% to 95%.[4-9]

No Indian studies have explored the ethical perspectives of broad informed consent concerning storage, transport, and future use of biological samples from either medical professionals or research participants, except one study that discusses data sharing and consent for the same.[10] Medical professionals conduct research studies while medical students, many a times are research participants in clinical studies and also future potential researchers who need to have knowledge of the various aspects of clinical research.

Aims and Objectives

To assess the level of awareness and perspectives regarding the broad informed consent process for the collection, storage, transport, and future use of biological samples in clinical research among medical faculty, post-graduate (PG) residents, Interns and under-graduate (UG) students at a tertiary care teaching hospital.

MATERIAL AND METHODS

This study protocol and related documents were approved by the Institutional Ethics Committee for Academic Research Projects [ECARP/2022/198 dt.27/01/2023]. A questionnaire, which was to be self-administered, was initially drafted and subjected to face and content validation before implementation. The validation process involved five faculty members (external to the institute) with a minimum of five years of teaching experience, achieving a content validity ratio of 0.8. Following validation, the questionnaire underwent pilot testing on a group of 30 medical students and faculty, including 12 postgraduate students, 12 undergraduate students, and 6 faculty members. Its reliability was established through Cronbach's alpha test, yielding an internal consistency score of 0.7. After validation, the structured questionnaire was randomly distributed to the study participants that included medical professionals (faculty) and students (medical residents, interns and undergraduate students) working at a teaching hospital in a metropolitan city of India who consented to participate in the study and complete the questionnaire after being explained to and understanding the reason for the study. The questionnaire gathered demographic information from participants along with their responses on the broad consent related to use of stored biological samples for research in the future.

Sample size

A cross-sectional survey conducted by Nansumba H *et al*[11] in Uganda assessed the acceptance of broad consent among 500 healthcare facility patients for the storage of biological samples and accompanying patient information for future use in research, reporting an overall acceptability rate of 86.2%. However, since no studies from India have examined the ethical perspectives of medical professionals on the topic of broad consent, we assumed a 50% response rate for the Indian population with a 5% margin of error (d) for our study. Using a 95% confidence level, the final sample size was calculated as N=400 based on the formula: $N = Z^2 \times p \times q / d^2$, where Z = 1.96

(for 95% confidence level), p = 0.5, q = 1 - p = 0.5, and d (precision) = 0.05.

Statistical analysis

The data collected from the respondents has been expressed in proportions and percentages and presented as descriptive statistics using Microsoft Excel.

RESULTS

The questionnaire was distributed to medical faculty, postgraduate medical residents and undergraduate medical students after explaining the reason for the study and obtaining their written informed consent. Only 2nd & 3rd MBBS students (n=300) were considered as they have some knowledge of clinical research; 100 Interns; 300 PG residents and 280 medical faculty, making it a total of 950 potential participants excluding 30 of those who participated in the questionnaire validation. About 650 of them agreed to participate in the study and fill the questionnaire. However, only 480 responses were received giving a response rate of 73.85%. Of these 46 were rejected due to incomplete responses with 434 completed filled questionnaires and a final response rate of 66.77%.

Majority of the responders belonged to the age groups between 21-40. There was equal distribution of men and women in the study and majority of the responders were Postgraduate residents (n=165; 38.02%) followed by Faculty (n=120; 27.65%). The details are listed in Table 1.

The questionnaire-based responses given by the participants are given below.

Awareness about Clinical Research & willingness to give broad consent

Participants were first asked about their knowledge and awareness of clinical research, informed consent, and broad informed consent. 85% (371) of the participants were familiar with clinical research, though 48.84% (212 participants) stated that they had never actively participated in a clinical research project. When asked if they would provide consent for the future use of their biological samples, 62.44% (271 participants) indicated their willingness, while 37.56% (163 participants) preferred not to give consent.

Reasons for unwillingness to give consent for future use of biological samples (n=163)

Participants who declined to provide consent were asked whether they believed that storing and use of biological samples in the future conflicted with fundamental research ethics principles, to which 150 (92.02%) participants responded in the affirmative while 13 (7.98%) participants were undecided. Reasons given for their response ranged from violation of the ethical principles of autonomy (freedom of right to change one's mind in the future on the decision taken regarding broad consent), beneficence (participants may get no benefits from the future research conducted on their biological samples and the researchers may get commercial gains), justice (no transparency about the type of research that would be conducted on their biological samples and if it would be used for commercial purposes), right to information regarding the planned future scientific research, issues of privacy and confidentiality and misuse of their personal information. The details are given in Table 2.

Scenarios that were likely to positively influence participants refusing broad consent

Anonymization of biological samples

On further inquiring with these 163 participants if they had ethical issues regarding future use of stored biological samples even if the samples were anonymized wherein the participant's identity would not be revealed, 65.64% (107) participants still had reservations while 26.38% (43) said that they would permit the future use of their stored anonymised biological samples while 7.98% (13) participants were undecided. Main reasons given by the participants for their reservations was their right to know what would be the future research for which their samples would be used and only then take a decision. Some participants felt that the samples, especially those stored for prolonged periods, may be used for research purposes other than that informed to the participants without disclosing the same to them for example, for commercial gains.

Options offered in the Broad Consent form regarding future use of biological samples

On being asked if they would be willing to participate in a research study requiring broad consent, provided specific options were included in the informed Consent Document, *viz.* (1)) re-consent would be taken when the future research is planned on the stored biological samples, information of which will be given to the participant

at that point in time; (2) re-consent would be taken and collection of new biological samples would be done when the future research is planned OR (3) broad consent would be taken only for the specific type of future research planned on the stored biological samples. Majority of the participants wanted the option of 'Re-consent will be taken only for a specific type of future research planned on the stored biological samples, to which I agree' (n=67) followed by the option of 'Re-consent will be taken again and new biological samples to be collected for any extended future research at that point in time' (n=51), with 'Re-consent would be taken when future research is planned on the stored biological samples, information of which will be given to me at that point in time' option ticked by 45 participants. The responses received from the participants regarding their willingness to participate in the research depending on their selected choice of the option in the Broad Consent Document are enumerated in Table 3.

Table 1. Demographic information of the study participants [n=434]

Demographic information	Category	Number of participants (%)
Age	21-30	179 (41.24)
	31-40	180 (41.48)
	41-50	055 (12.67)
	51-60	020 (4.61)
Gender	Male	211 (48.62)
	Female	223 (51.38)
	Others	0
Educational qualifications	Undergraduate &	112 (25.81)
	Interns	37 (8.53)
	Postgraduate	165 (38.02)
	Faculty	120 (27.65)

Table 2. Responses received regarding the violation of ethical principles for storing samples (n=150 participants)

S. No	Response regarding ethical principle violated for storing samples	Number of study participants (%)
1	Right to information regarding the planned future research	31 (20.67)
2	Autonomy	29 (16.67)
3	Privacy and confidentiality & misuse of personal information	25 (16.67)
4	Justice	20 (13.33)
5	Beneficence	19 (12.67)
6	More than one option selected	30 (20)

Table 3. Responses received regarding consenting if following options were present in the Broad Informed Consent Document (n=163 participants)

Options	Options regarding addition of clauses in ICD	Responses (%)
1	Re-consent would be taken when future research is planned on the stored biological samples, information of which will be given to me at that point in time.	45 (27.61)
2	Re-Consent and re-sampling of fresh biological samples to be collected for any extended future research at that point in time.	51 (31.29)
3	Broad Consent would be taken only for a specific type of future research planned on the stored biological samples	67 (41.10)

Sharing of results and right to revoke consent in the future

Participants were asked whether sharing the results of research conducted using their biological samples, along with the option to revoke consent at any time, ensuring that their samples would no longer be used, would positively influence their decision to provide broad consent. Among them, 127 (77.91%) agreed to give consent if research results were shared, 17 (10.43%) remained unwilling, and 19 (11.66%) were undecided. Regarding the right to revoke consent later, 126 (77.30%) participants agreed to provide broad consent, while 18 (11.04%) remained hesitant, and 19 (11.66%) were uncertain.

Additionally, questions were posed to the 271 participants who were willing to provide broad consent for the future of their biological samples.

Types of clinical studies which the participants were likely to participate and agree to broad consent (n=271)

When asked about the types of clinical research studies they would be willing to participate in and provide broad consent, most respondents (154) expressed willingness to take part in research that focused on medical conditions that would contribute to the advancement of human well-being, 47 said that they would participate in studies related to treatment and/or prevention of cancer, 29 in genetic research involving gene therapy

Table 4. Responses received regarding type of clinical research studies participants would be interested to participate (n=271 participants)

S. No.	Types of Clinical Research studies	Responses (%)
1	Research regarding any medical illness	154 (56.83)
2	Treatment and/or prevention of Cancer	47 (17.34)
3	Gene therapy or genetic intervention studies	29 (10.70)
4	Treatment and/or prevention of degenerative neurological disorders like Parkinson's and Alzheimer's disorders	14 (5.17)
5	Cancer + Genetic studies + Neurological disorders	12 (4.43)
6	Cancer + Genetic studies	10 (3.69)
7	Genetic studies + Neurological disorders	3 (1.11)
8	Cancer + Neurological disorders	2 (0.74)

Table 5. Responses received regarding clinical research scenarios wherein the participants were likely to give broad consent for sharing of their biological samples

S. No.	Clinical research Scenarios	Responses (%)
1	Academic research studies	138 (50.92)
2	Research being done by Government organizations	72 (26.57)
3	Research being done by Pharmaceutical companies	37 (13.65)
4	Research being done by any Organisation – academia, Government or Pharmaceutical organizations	24 (8.86)

Table 6. Responses received for the transport of biological samples (n=271 participants)

Options regarding the transport of biological samples	Responses regarding transport of samples	
	Agree (%)	Disagree (%)
Transport of biological samples to another Institution within the city	159 (58.67)	9 (3.32)
Transport of biological samples to other Institutes within the country	52 (20.66)	18 (5.17)
Transport of biological samples to other Institutes outside the country	12 (4.43)	21 (7.75)

or genetic intervention studies, 14 in research involving prevention or treatment of degenerative neurological disorders while 27 participants gave more than 1 response (refer Table 4).

Storage, sharing and transport of biological samples (n=271)

Participants who consented to broad consent were asked about their willingness to allow the storage, sharing, and transport of their biological samples for research in the future. Their responses are detailed below.

Participants who agreed to give broad consent were asked whether they would agree to the storage, sharing and transport of their biological samples and use of their samples for future research, and their responses are documented below.

Storage of human biological samples

59.78% (162) participants agreed for indefinite storage of their biological samples whereas 40.22% (109) said that their biological samples should be stored only for a stipulated time duration with the provisions for destruction of their samples to be pre-specified in the study informed consent document.

Sharing of biological samples with other researchers and Institutes

When asked whether they would be willing to permit the sharing of their samples with other researchers and Institutes for research purposes, 57.14% (248) participants said that they would agree to the sharing of their samples with other interested researchers working on similar medical research as long as the research had the Institutional Ethics Committee approval, while 22.58% (98) refused the sharing of their samples and 20.28% (88) participants were undecided.

However, 50.92% (138) participants preferred their samples to be shared with Investigators/researchers from academic Institutes, either from the same Institute or from other academic hospitals/universities, 26.57% (72) if the research was being carried out by Government agencies whereas 13.65% (37) were fine with their samples being shared for research being carried out by Pharmaceutical companies. 8.86% (24) gave multiple responses (refer Table 5).

Transport of biological samples

When asked whether they would agree for the transport of their biological samples for research purposes outside the hospital to (1) another Institute within the city, (2) to an Institute in another city or (3) to an Institute outside the country, most participants had no issues with the transport of their samples to Institutes within the city and country, however they were not comfortable with their samples being shipped out of the country. The detailed responses are listed in Table 6.

DISCUSSION

The term "Broad consent" is used when consent is taken for future unspecified research. It is commonly used with reference to data repositories and biobanks where consent is taken for the use of stored data and biological samples, in future research (whose objectives have not been specified yet).[1]

The use of broad consent in research has been a topic of ongoing debate. Critics argue that it can be misleading, as it restricts donors from exercising their fundamental right to know how their biological samples will be used in the future, thereby limiting their ability to make fully informed decisions.[12-15] On the other hand, supporters contend that broad consent is an ethically valid model aligned with current research practices and does not necessarily compromise participant autonomy.[16-23] In many secondary studies, the risks to participants are considered minimal, while broad consent facilitates the meaningful reuse of samples without the need for costly and time-consuming recruitment processes. Additionally, repurposing stored samples enhances scientific efficiency, reduces expenses, and eliminates the logistical challenges associated with obtaining reconsent for each new study utilizing the same samples and data.

Several studies have examined the perspectives of various stakeholders on broad consent across different countries, such as those in Africa, the Middle East, and parts of Asia,[23] with only one Indian study discussing data sharing and consent for the same.[10] A literature review on public perspective regarding biobanks for biological samples for potential research in the future, found a higher willingness to donate samples in countries where the awareness of biobanks is greater; for example, 86% in Sweden, 83% in Finland, 81% in Saudi Arabia, 75% in UK, 69% in USA, 65%

in China and 64% in Jordan; as compared to only 4% in Greece.[24]

Hence, our study was conducted to evaluate the awareness and perceptions regarding the broad informed consent process among medical students and physicians.

Our results show that: 1] 62.44% (271) of the study participants were favourably inclined towards broad consent; and 2] 37.56% (163) felt that biobanking violated the principles of research ethics (these participants wanted the option to know the type of research for which the broad consent was being taken, and reconsent when this research is planned).

Our results showed that 62.44% (271) of the study participants were inclined towards broad consent while 37.56% (163) felt that biobanking violated the principles of research ethics and their right to know details of the planned future research studies. These participants wanted the option of knowing the type of research for which the broad consent was being taken and also reconsent when this research is planned. This study aligns with findings from a study by Abou-Zeid et al.,[25] where 54% of participants agreed to broad consent; however, 44.3% believed that informed consent forms should also provide an option for participants to decide on storing blood samples specifically for future research. Among them, 39.9% felt that consent forms should include an option to restrict the future research to the specific illness being studied. Similar studies from Poland have shown that participants, including students studying at a medical University (who tend to have greater awareness of biobanking and research involving biological materials), were more likely to prefer specific consent over broad consent. This preference was primarily driven by a strong sense of autonomy and a desire for greater control over their data and donated biological samples.[26]

Another reason for the reluctance by our study participants to give broad consent was the fear of lack of privacy and confidentiality, and likely misuse of personal information. Similar concerns have been observed in studies from Australia, Egypt, Saudi Arabia, and Colombia, where both medical students and physicians expressed apprehensions about the confidentiality of their data, potential exploitation of their biological samples, and the risk of discrimination. Additionally, there were fears that biospecimens could be exploited for unethical research, such as human cloning, or commercial purposes.[27-29]

Our study also indicated that 77.91% of participants agreed to give consent if the research results were shared with them, and 77.30% agreed to give broad consent if their right to revoke their consent in the future was offered. Research has indicated that the inclination to donate biological samples is influenced by the information provided to participants about the intended future research, whether access to the research findings would be restricted, and the methods used for sample storage. Anonymizing of the samples and the option that the participants could withdraw from the research at a later date also encouraged the donation of samples.[27]

We observed the following metrics regarding the sharing of biological samples with different entities: 1] 57.14% participants willing to share with other researchers and Institutes (provided the research was approved by the Institutional Ethics Committee); 2] 50.92% willing to share with researchers from academic Institutes; 3] 26.57% willing to share with researchers from Government agencies; and 4] 13.65% willing to share with Pharmaceutical companies. Further, most participants were not comfortable with their samples being shipped out of the country. In the study by Abdelhafiz et al[30] too, less than one-third participants were willing to share their samples with either researchers abroad (32.4%) or with pharmaceutical companies (27.8%). Other studies have also found that trust towards researchers depended on where they worked. There were concerns raised towards sharing samples and data with researchers working for commercial organisations in many studies.[24,31] Similarly, a study from the USA reported a high degree of distrust toward academic researchers, while research from Australia indicated a greater degree of trust in them.[32,33]

Cook *et al* [34] examined perceptions of broad consent among a subset of Young Sexual Minority Men (YSMM) and found that participants were most willing to provide broad consent to researchers from the study they were enrolled in (85.3%), followed by researchers within the same university (82.4%) and those at other universities (74.5%). However, willingness

declined for government organizations (64.4%) and pharmaceutical companies (53.8%). Additionally, the study highlighted that distrust towards medical research, influenced by racial/ethnic identity and sexual orientation, played a role in shaping the participants' attitudes toward broad consent.

A semi-qualitative study by Tindana *et al*[35] in Ghana and Kenya explored the ethical perspectives on broad consent for the storage, transport, and reuse of biological samples through in-depth interviews and focus group discussions. The findings indicated that while participants were in favor of broad consent, they emphasized that this consent was conditional to local issues, such as community engagement and respect for local cultural values. Maintaining trust and transparency between stakeholders was also identified as a crucial factor. Similar conclusions were drawn in qualitative studies conducted by Warner *et al,*[36] Cheah *et al,*[37] and Matandika *et al.*[38]

Study limitations

Our study is not without its limitations *viz.* (1) the study was carried out in students and faculty of a single tertiary care hospital which may affect the extrapolation and generalisability of the study results to encompass the entire medical population of the city or even the country. Future studies need to be conducted to include medical fraternity from other medical colleges; (2) the study participants were students and faculty and not research participants which offers a one-sided view of the research question; the reason being that we wished to assess the level of knowledge and awareness among the medical fraternity as only then will they be able to explain to the research participants the meaning of broad consent. We understand that some of the study participants, especially undergraduate students, may not have been exposed or were not aware of the details of clinical research and the informed consent process that may have influenced their opinion about the broad consent process; (3) this was a descriptive study to understand the level of knowledge among the medical students and faculty; however more in-depth qualitative studies are needed to probe the reasons for their responses, their expectations, motivations and fears regarding broad consent for the future use of their biological samples. Thus, there is a need for training and discussion among medical fraternity to encourage better understanding of the various nuances of clinical research like biobanking and storing samples for potential research in the future with proper ethical processes.

CONCLUSION

Most participants were in favour of broad consent storing, transporting and use of their biological samples in the future, however they wanted more transparency in terms of the research for which these samples would be used, storage for a pre-specified period of time and reconsent prior to re-using the samples. Another important issue raised was the importance of privacy and confidentiality of their personal data and efforts taken to prevent misuse of this information. These findings underscore the critical need for evolving consent frameworks that balance scientific progress with individual autonomy, suggesting that future broad consent protocols must incorporate participant-centric safeguards to maintain ethical standards and public trust in medical research.

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Conflict of Interest

The author(s) do not have any conflict of interest.

Data Availability Statement

This statement does not apply to this article.

Ethics Statement

The study received approval from Ethics Committee for Academic Research Projects [ECARP/2022/198].

Informed Consent Statement

Informed consent was obtained from all the study participants before experimentation and the study conforms to the standards currently

applied in India. The protection of human subjects' privacy rights has been maintained.

Clinical Trial Registration

This research does not involve any clinical trial.

Permission to reproduce material from other sources

Not Applicable.

Author contributions

Dr. Renuka Munshi: Conceptualization, data analysis, drafting and reviewing the manuscript; Dr Pallavi Dhupe: protocol drafting, data collection and analysis, drafting the manuscript; Ms Nikita Yadav: data collection, data entry, drafting the manuscript.

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