RESEARCH PAPER

Principal Investigators' Perspectives On Reuse of Leftover Bio Specimens in Future Research: A Prospective Interventional Assessment

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ABSTRACT

Background: Principal Investigators (PIs) are the main people responsible for conducting and supervising biomedical research. Their views are important because they directly handle research participants and biological samples. In many studies, some biological materials—like blood or tissue samples—remain unused after the main research. These leftover samples can be valuable for future studies, but reusing them raises ethical questions. Using these samples without the clear permission of participants can affect their rights, privacy, and trust. Therefore, it is important to understand what investigators know and believe about these ethical concerns.

Aim: This study aimed to understand the knowledge, attitude, and practice (KAP) of Principal Investigators toward reusing leftover human biological samples for future research and to see how educational intervention can improve their awareness and approach.

Methodology: A before-and-after study design was used. Principal Investigators were first surveyed using a structured questionnaire to assess their knowledge, attitude, and practices. After the first round, they received education and training through an intervention tool designed to increase awareness about ethical and legal aspects of biospecimen reuse. One month later, the same questionnaire was given again to measure any improvement in their responses.

Results: Most participants (80%) were male, coming from different medical departments and age groups. After the educational program, their understanding of ethical biospecimen use improved significantly ($p<0.001$). Their attitudes became more positive, and their practices showed better alignment with ethical and regulatory expectations. The study found that training and awareness programs help Principal Investigators handle leftover biological samples more responsibly and ethically.

Conclusion: This study highlights the importance of continuous education and well-defined ethical guidelines for the reuse of leftover human biological samples. Improved knowledge and attitudes among investigators can lead to more ethical and trustworthy research practices in the future.

Keywords: Human Surplus Bio Specimens (Hsbs), Knowledge, Attitude, Practice (Kap), Bioethics, Clinical Research, Biological Samples.

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Introduction

Ethical considerations in biomedical research have become increasingly complex with the growing use and storage of human bio specimens in clinical trials and translational studies. The collection, storage, and reuse of surplus or archived human samples raise pressing concerns regarding informed consent, participant autonomy, and responsible data governance[1,2,3]. These concerns are particularly relevant in the context of residual tissue use, where samples collected for diagnostic or therapeutic purposes may later be repurposed for secondary or future research without explicit participant re-consent[4,5,6].

Bio specimens play a pivotal role in clinical research, supporting biomarker discovery, therapeutic innovation, and evaluation of treatment outcomes[7,8]. However, the

increasing use of archived materials demands that researchers, clinicians, and regulatory bodies strengthen ethical awareness and transparency in bio specimen management[5,9]. The challenges encompass not only consent and confidentiality but also questions about commercialization, ownership, and long-term data stewardship[10,11].

This study assesses the knowledge, attitude, and practices (KAP) of Principal Investigators concerning the ethical use of leftover human bio specimens in clinical research. As key stakeholders, these professionals are directly involved in the convincing for participation, collection, storage, and utilization of bio specimens and therefore serve as critical informants in understanding ethical compliance and operational challenges[12,13]. Participants were surveyed to capture their perspectives on bio specimen handling, consent requirements, storage procedures, and ethical reuse in future studies.

Globally, gaps persist in the harmonization of bio specimen governance and consent frameworks, despite the increasing emphasis on ethical oversight by research ethics committees and institutional review boards[6,14]. In India, the Indian Council of Medical Research (ICMR) has issued guidelines emphasizing consent, confidentiality, and transparent use of biological materials in biomedical research. However, variability in institutional compliance and the lack of global standardization continue to challenge ethical implementation[9,15].

Therefore, this study aims to explore prevailing ethical challenges related to bio specimen management, including consent complexity, optional participation, secondary data use, and ethical storage of genetic materials. By focusing on Principal Investigators — professionals at the intersection of clinical care and research—the study seeks to assess their Knowledge, Attitude and practice scores in pre and post assessment and addresses their perspective on ethically sound practices in clinical research involving leftover bio specimens.

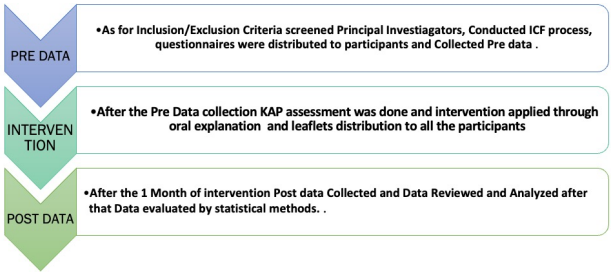
Materials and Methods

This study was a one-year prospective intervention carried out at a tertiary care hospital located in Belagavi, India. On July 29, 2021, the Ethical Committee of KAHER in Belagavi, Karnataka, approved the study (Ref. No: KAHER/EC21/22/021). After receiving this ethical clearance for research involving human subjects, the study was registered with the Clinical Trial Registry of India under the identifier CTRI/2021/11/038332 on November 30, 2021. The research included Principal Investigators as participants, and data collection was conducted using closed-ended questionnaires.

Study Participants Between December 1, 2021, and February 22, 2023, a survey was conducted involving Principal Investigators from a tertiary care hospital. The study successfully enlisted 50 Principal Investigators.

Stastical Analysis: The study included 50 participants whose responses were assessed using structured Knowledge, Attitude, and Practice (KAP) questionnaires. Data were compiled and organized in Microsoft Excel for statistical evaluation. Descriptive statistics were employed to summarize the demographic characteristics of the participants and the distribution of their KAP responses. To determine the significance of differences between pre-test and post-test scores, paired *t*-tests were performed. A *p*-value of less than 0.05 was considered statistically significant.

Figure 01: Flowchart showing the study design and participant Selection: This flow diagram outlines the sequential process of participant recruitment, application of inclusion criteria, and completion of pre- and post-intervention KAP assessments among Principal Investigators.



Results:

Figure 02: Demographic distribution of study participants by department and experience level: This figure illustrates the proportional distribution of participants across various clinical departments and professional experience categories. 50 participants were included in the study, predominantly male (80%), with the majority aged between 41–50 years (38%). Most respondents were from the Department of General Medicine (32%), followed by ENT (10%) and Urology (8%). Nearly half of the participants (48%) reported more than 16 years of professional experience. Regarding qualifications, 50% held MBBS–MD degrees, 22% MBBS–MS, and 16% MBBS–DM, reflecting a highly qualified cohort with extensive clinical exposure.

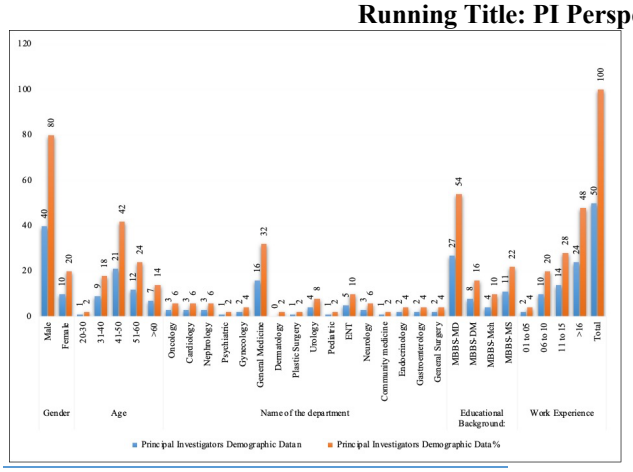


Table 1: Comparison of Pre- and Post-Test Knowledge Scores of Participants

This table presents a comparison of participants' knowledge before and after the intervention (n=50). Awareness about the correct handling of leftover bio specimens showed a major improvement. Initially, only 17 (34%) chose both discard and store/share options, but post-test 46 (92%) answered correctly ($p<0.001$). Understanding that consent is mandatory increased from 30 (60%) to 50 (100%). Awareness of study types (genetic and future research) rose sharply from 22 (44%) to 50 (100%). Knowledge regarding the need for permission improved from 31 (62%) to 50 (100%). Familiarity with consent requirements rose from 29 (58%) to 42 (84%) ($p=0.006$). Understanding of collection, storage, and sponsor procedures increased slightly from 37 (74%) to 42 (84%). Familiarity with optional consent procedures significantly increased from 3 (6%) to 38 (76%) ($p<0.001$). Meanwhile, awareness of Material Transfer Agreements (MTAs) remained steady at 42 (84%). Understanding the correct use of leftover specimens ("all of the above") improved markedly from 13 (26%) to 44 (88%) ($p<0.001$).Lastly, awareness that commercialization is unethical rose from 37 (74%) to 50 (100%). (Table 1).

Characteristics	**Pre-Test**	**Post-Test**	**P value**
	n=50	**n=50**	
1. What should be done with leftover bio specimens when conducting research?			
Discard	11(22)	1(2)	<0.001
Store/Share for secondary research	13(26)	1(2)	
Both A & B	17(34)	46(92)	
Don't Know	9(18)	2(4)	
2. Do you think consent is mandatory for using bio specimens in secondary research?			
Yes	30(60)	50(100)	-
No	6(12)	0	
Don't Know	14(28)	0	
3. Are you aware of the type of study being conducted when samples are used for secondary research?			
Genetic Research	6(12)	0	-
Future Research	12(24)	0	
Both A & B	22(44)	50(100)	
Don't Know	10(20)	0	
4. Does permission have to be obtained before using human leftover bio specimens for research?			
Yes	31(62)	50(100)	-
No	5(10)	0	
Don't Know	14(28)	0	
5. Do you know about the need for consent before the secondary or future use of bio specimens?			
Yes	29(58)	42(84)	0.006
No	10(20)	1(2)	
Don't Know	11(22)	7(14)	
6. Are you familiar with the collection methods, storage timelines, and use procedures specified by sponsors?			
Yes	37(74)	42(84)	-
No	2(4)	0	
Don't Know	11(22)	8(16)	
7. Have you reviewed any optional consent procedures related to biospecimen research?			

Yes	3(6)	38 (76)	<0.001
No	26(52)	6 (12)	
Don't Know	21(42)	6 (12)	
8. Do you know the importance of Material Transfer Agreements (MTAs) in biospecimen research?			
Yes	42(84)	42 (84)	0.804
No	0	0	
Don't Know	8(16)	8 (16)	
9. How are leftover bio specimens utilized in clinical research			
For Secondary/ Future research	5(10)	2 (4)	<0.001
For Academic/Teaching purposes	11(22)	1 (2)	
Preserving for further diagnostics	17(34)	2 (4)	
All of the above	13(26)	44 (88)	
Don't Know	4(8)	1 (2)	
10. Are you aware that commercialization of human biospecimens is unethical in research?			
Yes	37(74)	50 (100)	-
No	2(4)	0	
Don't Know	11(22)	0	

Table 2: Comparison of Pre- and Post-Test Attitude Scores of Participants

The pre- and post-test results show a marked shift in participants' attitudes. Agreement that the consent process is challenging increased from 20 (40%) strongly agreeing to 32 (64%) post-test. Belief that bio specimen research poses risks dropped, as "strongly agree" responses decreased from 6 (12%) to 1 (2%), indicating better understanding of low risk. Ethical confidence improved — those who strongly agreed that researchers use bio samples ethically rose from 13 (26%) to 29 (58%). Positive views on societal benefits increased, with strong agreement rising from 1 (2%) to 23 (46%). Belief that digital data storage supports bio specimen research grew from 1 (2%) to 24 (48%) strongly agreeing. Agreement that voluntary consent is mandatory rose from 2 (4%) to 26 (52%). Understanding of donor awareness remained constant at 6 (12%) strongly agreeing but neutral opinions dropped to zero (p=0.006). Agreement that abuse affects research outcomes changed significantly—strong disagreement increased, reflecting awareness (p<0.001). Support for IRB/IEC consideration rose from 7 (14%) strongly agreeing to 24 (48%). Concern about genetic data misuse increased, with strong agreement rising from 2 (4%) to 26 (52%). (Table 2).

1. Is the consent process challenging while using archived bio specimens for future research?			
Strongly Agree	20(40)	32 (64)	-
Agree	24(48)	18 (36)	
Neutral	6(12)	0	
Disagree	0	0	
Strongly Disagree	0	0	
2. Do you think human biospecimen research poses any risk or harm to participants?			
Strongly Agree	6(12)	1 (2)	-
Agree	9(18)	0	
Neutral	26(52)	0	
Disagree	8(16)	6 (12)	
Strongly Disagree	1(2)	43 (86)	
3. Do you believe researchers commonly use biosamples for secondary/future research ethically?			
Strongly Agree	13(26)	29 (58)	-
Agree	27(54)	21 (42)	
Neutral	10(20)	0	
Disagree	0	0	
Strongly Disagree	0	0	
4. Do you think human biospecimen research benefits society or the public?			
Strongly Agree	1(2)	23 (46)	-
Agree	9(18)	23 (46)	
Neutral	21(42)	0	
Disagree	14(28)	3 (6)	
Strongly Disagree	5(10)	1 (2)	
5. Do you think digital data storage of donor information supports biospecimen research?			
Strongly Agree	1(2)	24 (48)	-
Agree	10(20)	10 (20)	
Neutral	23(46)	0	
Disagree	12(24)	12 (24)	
Strongly Disagree	4(8)	4 (8)	
6. Do you agree that voluntary consent is mandatory and applicable to secondary research?			

Strongly Agree	2(4)	26 (52)	
Agree	10(20)	19 (38)	
Neutral	25(50)	0	-
Disagree	13(26)	5 (10)	
Strongly Disagree	0	0	
7. Do you believe tissue donors fully understand the purpose of biospecimen archiving and use?			
Strongly Agree	6(12)	6 (12)	
Agree	22(44)	22 (44)	
Neutral	20(40)	0	0.006
Disagree	2(4)	2 (4)	
Strongly Disagree	0	20 4 0)	
8. Does abuse of human biospecimens affect the quality of research outcomes?			
Strongly agree	6(12)	1 (2)	
Agree	22(44)	8 (16)	
Neutral	0	0	<0.001
Disagree	2(4)	17 (34)	
Strongly Disagree	20(40)	24 4 8)	
9. Should IRB/IEC provide special considerations while approving biospecimen collection and consent tools?			
Strongly agree	7(14)	24 (48)	
Agree	28(56)	21 (42)	
Neutral	14(28)	0	-
Disagree	1(2)	5 (10)	
Strongly Disagree	0	0	
10. Do you think genetic data within human tissues increases the risk of misuse?			
Strongly agree	2(4)	26 (52)	
Agree	8(16)	16 (32)	
Neutral	26(52)	0	0.186
Disagree	14(28)	7 (14)	
Strongly Disagree	0	1 (2)	

Table 3: Comparison of Pre- and Post-Test Practice Scores of Participants

Practice-related responses show substantial improvement. Approaching sponsors for leftover tissue information increased from 29 (58%) to 45 (90%) (p=0.002). Identification of leftover tissue samples rose from 23 (46%) to 47 (94%) (p<0.001). Taking comprehensive action ("all of the above") jumped from 18 (36%) to 42 (84%) (p=0.001). Following all bio specimen guidelines increased from **27** (54%) to 43 (86%) (p<0.001). Anti-commercialization practice rose from 29 (58%) to 42 (84%) (p=0.049). Adherence to bio specimen collection and storage regulations improved from 27 (54%) to 39 (78%) (p=0.014). Following SOPs increased from 28 (56%) to 40 (80%), and use of electronic tracking systems rose from 36 (72%) to 45 (90%). Compliance with MTAs improved from 33 (66%) to 44 (88%), and assigning unique IDs to bio specimens rose from 33 (66%) to 47 (94%), showing more standardized practices (Table 3).

1. Do you approach sponsors or representatives for leftover tissue sample information in research?			
Yes	29(58)	45(90)	
No	16 (32)	2(4)	0.0 02
Don't know	5(1 0)	3(6)	
2. Have you identified leftover tissue samples in sponsor or pathology laboratories?			
Yes	23(46)	47(94)	<0.
No	23(46)	1(2)	001
Don't know	4(8)	2(4)	
3. What action do you take when you become aware of leftover tissue samples?			
Suggesting to discard/ Requesting to return	12(24)	2(4)	
Agreeing to secondary use/ future use	12(24)	4(8)	0.0
All the above	18 (36)	42(84)	01
Dont know	8(1 6)	2 4)	
4. Do you follow any specific guidelines for using archived or retrieved biospecimens?			
ICMR Guidelines -2017	1(2)	1(2)	
NABH-Laboratory Guidelines	4(8)	2(4)	
Regulations of Bio Banking research	3(6)	2(4)	<0.
GLP-GCP Guidelines	15(30)	2(4)	001
All of the above	27(54)	43(86)	
5. Are you practicing anti-commercialization regulations in your laboratory?			
Yes	29(58)	42(84)	
No	15(30)	4(8)	0.0 49
Don't know	6(1 2)	4(8)	
6. Are specific regulations followed for the collection, tracking, and storage of biospecimens?			

Yes	27(54)	39(78)	0.014
No	16(32)	3(6)	
Don't know	7(14)	8(16)	
7. Is practicing SOPs mandatory for biospecimen management and research use?			
Yes	28(56)	40(80)	-
No	17(34)	2(4)	
Don't know	5 (10)	8(16)	
8. Is an electronic tracking system for biospecimen handling being implemented or considered?			
Yes	36(72)	45(90)	-
No	11(22)	2(4)	
Don't know	3(6)	3(6)	
9. Do you ensure compliance with Material Transfer Agreement (MTA) requirements for biospecimen transport?			
Yes	33(66)	44(88)	-
No	14(28)	2(4)	
Don't know	3(6)	4(8)	
10. Is a unique identification number assigned to each surplus biospecimen in your research?			
Yes	33(66)	47(94)	-
No	14(28)	2(4)	
Don't know	3(6)	1(2)	

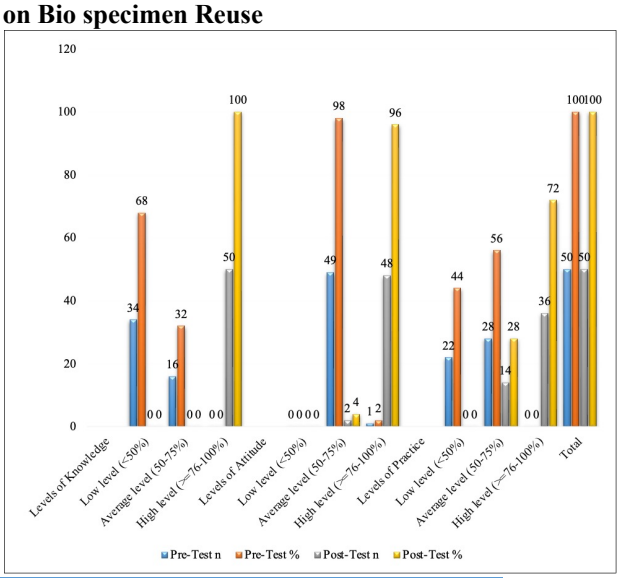


Figure 3. Comparison of Pre- and Post-Test Knowledge, Attitude, and Practice (KAP) Scores among Principal Investigators: This bar chart illustrates the changes in mean KAP scores before and after the educational intervention. A statistically significant improvement was observed across all three domains ($p < 0.001$). The figure demonstrates that the intervention effectively enhanced participants' knowledge, attitude, and practice regarding the ethical utilization of surplus biospecimens for future research. The visual representation underscores the positive impact of targeted awareness and training sessions on promoting ethical research practices.

Table 4: Comparison of Pre- and Post-Test KAP Scores Using Paired t-Test

This table presents the mean differences in knowledge, attitude, and practice (KAP) scores using the paired t-test. The mean knowledge score increased from 12.38 ± 2.36 to 23.10 ± 1.69 (mean diff = -10.72; t = -30.84; p<0.001). The attitude score rose from 58.04 ± 3.43 to 74.88 ± 4.37 (mean diff = -16.84; t = -26.14; p<0.001). The practice score improved from 10.26 ± 2.33 to 16.24 ± 1.42 (mean diff = -5.98; t = -16.89; p<0.001). These results indicate a statistically significant enhancement in participants' knowledge, attitude, and practice after the intervention. (Table 4).

Parameters	**Time points**	**Mean**	**SD**	**Mean Diff**	**t-value**	**P value**
Knowledge	Pre-test	12.38	2.36	-10.72	-30.84	<0.001
	Post-test	23.10	1.69			
Attitude	Pre-test	58.04	3.43	-16.84	-26.14	<0.001
	Post-test	74.88	4.37			
Practice	Pre-test	10.26	2.33	-5.98	-16.89	<0.001
	Post-test	16.24	1.42			

Discussion

This study demonstrated a significant enhancement in knowledge, attitude, and practice (KAP) regarding ethical utilization of human leftover bio specimens following an educational intervention. The results emphasize the importance of targeted awareness programs for clinicians

and researchers involved in biomedical and translational studies.

Before the intervention, knowledge gaps were evident—particularly concerning consent requirements, bio specimen storage, and ethical guidelines. These findings align with prior literature indicating limited awareness among clinical professionals about bio specimen governance and ICMR ethical frameworks. Post-intervention improvements highlight that structured educational sessions effectively strengthen comprehension of ethical, legal, and procedural standards. Attitudinal shifts reflected a greater acknowledgment of participants' rights and institutional ethical oversight. Increased agreement toward the necessity of informed consent and IRB/IEC involvement suggests improved ethical sensitivity. Furthermore, improved perceptions regarding societal benefits of biospecimen research indicate growing trust in ethically governed translational research systems.

Enhanced practices—including adherence to guidelines, use of MTAs, and implementation of biospecimen tracking—demonstrate translation of knowledge into behavior. The significant gain across all KAP domains ($p<0.001$) supports that continued training and policy reinforcement are essential for sustainable ethical compliance in research settings.

Conclusion: The educational intervention markedly enhanced clinicians' knowledge, attitudes, and practices concerning the ethical use of human leftover bio specimens. These results highlight the importance of ongoing training programs that focus on consent procedures, governance frameworks, and the prevention of commercialization. Ethical management of bio specimens should remain a key priority for institutional review boards and research sponsors to ensure transparency and uphold integrity in biomedical studies. Incorporating bio specimen ethics modules into clinical and research curricula can further strengthen compliance and foster trust in translational research. Analysis of all four data tables revealed substantial post-intervention improvements in ethical awareness, particularly regarding consent, regulatory adherence, and professional conduct. The statistically significant findings ($p < 0.001$) across most measures confirm the intervention's strong effectiveness in enhancing participants' ethical competence.

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CONFLICT OF INTREST:

The authors declare that there is no conflict of interest.

ABBREVIATIONS: KAP: Knowledge, Attitude, and practice, HSBs: Human Surplus Bio specimens, ICMR: Indian council of medical research, IEC: Institutional ethics Committee.

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