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Original Article

Evaluating the Awareness, Perceptions, and Practices of Clinical Trial Sponsors Regarding the Utilization of Human Leftover Biospecimens in Future Research

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ABSTRACT

Background: Surplus human biospecimens serve as a valuable resource for advancing scientific discovery, and their ethical management is essential for maintaining integrity in biomedical research. Clinical Trial Sponsors hold a particularly important role in ensuring that these materials are handled in accordance with established ethical guidelines and regulatory frameworks. This study explores the level of awareness, perceptions, and practices among sponsors regarding the ethical use of leftover human biospecimens for future research purposes. **Materials and Methods:** A forward-looking interventional study was conducted using a validated questionnaire administered to Clinical Trial Sponsors. Participants completed surveys before and after an educational intervention addressing ethical principles, regulatory mandates, and best-practice procedures related to biospecimen use. A follow-up assessment was carried out 30 days after the intervention. Data were analyzed using appropriate statistical tools, including a paired *t*-test, to compare pre- and post-intervention scores. **Results:** A total of 52 participants took part in the study. Analysis revealed statistically significant improvements across all awareness, perceptions, and practices indicators following the intervention ($p<0.001$). Participants demonstrated greater clarity on essential ethical concepts, regulatory obligations, and correct biospecimen-handling procedures, indicating a strong positive effect of the educational program. **Conclusion:** Targeted educational initiatives markedly strengthen the ethical understanding and responsible conduct of Clinical Trial Sponsors in the management of surplus human biospecimens. These findings emphasize the need for ongoing training efforts and continued policy enhancement to reinforce ethical foundations and ensure sustained regulatory compliance within biospecimen-based research.

Keywords: Awareness, Perceptions, and Practices (APP), Bioethics, Ethical Compliance, Human Surplus Bio specimens (HSBs), Pharmaceutical Research, Regulatory Affairs.

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INTRODUCTION

Human biological materials, such as blood, serum, plasma and tissue biopsies, serve as critical resources in clinical research and disease management, facilitating the discovery of novel diagnostics and therapeutic interventions (Al-Hussaini *et al.*, 2014; Warner *et al.*, 2018). The secondary use of surplus human biospecimens These refer to unused biological samples collected during routine clinical procedures that weren't used at the time they were collected, has received increasing attention due to its potential to enhance translational research, optimise resource utilisation and reduce participant burden (Schäfer *et al.*, 2007; Meslin *et al.*, 2004).

Clinical Trial Sponsors occupy a pivotal position in the management and utilisation of such surplus biospecimens. Their awareness, perceptions, and practices regarding ethical use, data protection and consent significantly influence translational research outcomes and public trust. The reuse of surplus specimens can improve research efficiency and cost-effectiveness by minimising the need for additional sample collection, and by enabling advanced investigations into disease mechanisms, biomarker identification and variation in treatment response (Echeverri *et al.*, 2018; Matimba *et al.*, 2019). From an ethical standpoint, maximising the value of existing materials aligns with the principle of beneficence, minimising waste and acknowledging the contributions of participants to medical science while respecting autonomy (Kapp *et al.*, 2006; Lacaze *et al.*, 2017).

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Nevertheless, the secondary use of surplus biological samples introduces complex ethical, regulatory and logistical challenges. Issues surrounding informed consent, participant privacy, specimen traceability, governance of biobanks, and international material transfer agreements remain significant barriers (Baer *et al.*, 2010; Kapila *et al.*, 2016). Inconsistent storage, inadequate documentation and variation in organisational practices further compromise sample quality, reproducibility and regulatory compliance (Mathaiyan *et al.*, 2013; Chalmers *et al.*, 2014). In addition, heterogeneity in international regulatory frameworks complicates cross-border collaborations and standardised use of biospecimens (Barchi *et al.*, 2016; Singh *et al.*, 2021). In India, the "Indian Council of Medical Research (ICMR)" gives rules on how human samples should be collected, stored, and used for health and medical studies, as explained in its National Ethical Guidelines for research involving people (Mathur *et al.*, 2019). However, globally, there remains no single universally adopted framework that addresses broad consent for secondary use, international exchange of biospecimens and harmonised ethical governance (Moodley *et al.*, 2014; Peppercorn *et al.*, 2020). This situation underscores the need to assess how Clinical Trial Sponsors, major stakeholders in clinical trials understand and implement ethical practices for surplus biospecimens.

Evaluating the Awareness, Perceptions, and Practices regarding surplus human biospecimens offers critical insight into the gap between ethical intent and operational implementation. This study aims to evaluate the level of understanding, mindset and behaviour of Clinical Trial Sponsors toward surplus human biospecimen utilisation, with the purpose of supporting policy development and leading standardised practices for ethically responsible use of surplus biospecimens in clinical and translational research (Rivera *et al.*, 2015; Vaught *et al.*, 2011).

MATERIALS AND METHODS

Materials

This interventional study involved Clinical Trial Sponsors from the Belagavi district of Karnataka, including Clinical Research Associates (CRAs), Clinical Trial Assistants, and Project Managers. Data collection tools included a pre-validated questionnaire designed to assess awareness, perceptions, and practices related to clinical trial responsibilities, as well as specially developed learning materials to address identified gaps. The study also utilized structured interview guides for qualitative assessment. Microsoft Excel was employed for data organization, and SPSS software version 21 was used for statistical analysis.

Methods

A forward-looking interventional research design was adopted. Approval for the study was obtained from the Ethics Committee of KAHER, Belagavi, Karnataka, on July 29, 2021 (Ref. No: KAHER/EC21/22/021), followed by registration in the Clinical Trial Registry of India (CTRI/2021/11/038332) on November 30, 2021. Upon receiving ethical and institutional clearance, an initial survey was conducted using questionnaires to evaluate the baseline awareness, perceptions, and practices of Clinical Trial Sponsors. Observing gaps in knowledge, the researchers implemented educational interventions consisting of tailored learning materials and face-to-face discussions. After one month, a follow-up assessment was carried out to measure improvements. Structured interviews were used to collect additional insights. The pre- and post-intervention data were compared using the paired *t*-test in SPSS version 21 (Figure 1).

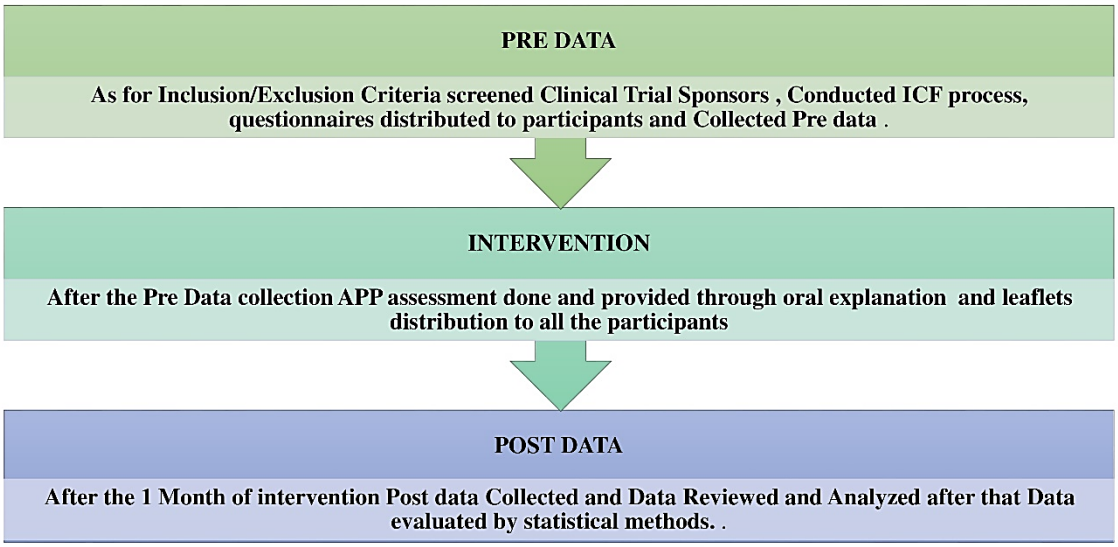

Figure 1: Study Procedure.

RESULTS

Table 1 presents the demographic profile of CRO and sponsor representatives, showing that the majority of participants were male (75%) and aged between 20-30 years (69.2%). Most respondents held roles such as Senior CRA (30.8%) and CRA (23.1%), with a smaller proportion serving as CTAs (15.4%), Project Managers (11.5%), QA Auditors/Managers (3.8%), Data Analysts (3.8%), or in other roles (11.5%). In terms of work experience, a large majority (82.7%) had 1-5 years of experience, while only a few had over 10 years (5.7%). Regarding educational background, most participants had a pharmaceutical qualification (73.1%), followed by life sciences or allied sciences (21.2%) and medicine (5.8%) (Table 1).

A comparison of the sponsors' awareness levels before and after the intervention was done using a paired *t*-test. The analysis included statistical measures such as the average difference, *t*-value and *p*-value to assess the significance of the change. Initially, during the pre-test phase, 7 participants (13.5%) had no awareness 35 participants (67.3%) had low level awareness (<50%), and 10 participants (19.2%) had average level awareness (50-75%). Conversely, in the post-test phase, there were no participants with low level awareness, 1 participant (1.9%) had average level awareness and a significant increase was noted with 51 participants (98.1%) achieving high level awareness (>=76-100%). The analysis revealed a mean difference of 5.73, accompanied by a *t*-statistic of 15.13 and a p-value below 0.001, demonstrating a highly significant enhancement from pre-test to post-test scores. The findings suggest a notable improvement in awareness levels following the intervention, with all participants demonstrating progress and the majority transitioning to high-level awareness (Table 2).

A comparison of sponsors' perceptions levels before and after the intervention was carried out using a paired *t*-test. perceptions were grouped into three categories: low, average, and high. In the pre-test, none of the sponsors showed a low perceptions level (<50%), 53.8% had an average level (50-75%), and 46.2% showed A higher category (≥76-100%). Post-intervention, considerable progress was noted - the share of participants in the average category dropped to 23.1%, whereas those reaching the higher category rose substantially to 76.9%. This change was statistically significant, as indicated by a mean difference of 4.71, a *t*-value of 5.75, and a *p*-value below 0.001. These findings indicate a notable improvement in perceptions among Clinical Trial Sponsors after the intervention. This improvement is evident in both the shift in proportions across perceptions levels and the increase in mean attitude scores from 67.37 to 72.08, along with the corresponding standard deviations (Table 3).

A paired *t*-test analysis was performed to determine the statistical differences between pre- and post-practice levels of Clinical Trial Sponsors. Initially, the majority of participants displayed practices at average levels (55.8%), followed by low levels (32.7%), and a smaller proportion at high levels (11.5%).

Table 1: Demographic Details of Clinical Trial Sponsors and Their representatives.

Demographic Data	Variables	n	%
Gender	Male	39	75
	Female	13	25
Age	20-30	36	69.2
	31-40	13	25
	41-50	3	5.8
Role	CTA	8	15.4
	CRA	12	23.1
	Senior CRA	16	30.8
	QA Auditor/Manager	2	3.8
	Project Manager	6	11.5
	Data Analyst	2	3.8
	Others	6	11.5
Work Experience	1 to 5 Years	43	82.7
	6 to 10 Years	6	11.5
	11 to 15 Years	2	3.8
	>16 Years	1	1.9
Qualification	Medicine	3	5.8
	Pharma	38	73.1
	Life Sciences/Allied Sciences	11	21.2

Table 2: Pre And Post Intervention Awareness Scores Among Clinical Trials Sponsors Using Paired *t*-Test.

Levels of Perception	Pre-Test			Post-Test			Mean Diff	*t*-Value	*p* Value
	No	%	Mean±SD	No	%	Mean±SD	5.73	15.13	<0.001
Low level (<50%)	7	13.5	16.79±2.88	0	0	22.52±1.66			
Average level (50-75%)	35	67.3		1	1.9				
High level (>=76-100%)	10	19.2		51	98.1				
Total	52	100		52	100				

Table 3: Pre And Post Intervention Perception Scores Among Clinical Trials Sponsors Using Paired *t*-Test.

Levels of Perception	Pre-Test			Post-Test			Mean Diff	*t*-Value	*p* Value
	No	%	Mean±SD	No	%	Mean±SD	4.71	5.75	<0.001
Low level (<50%)	0	0	67.37±4.88	0	0	72.08±5.71			
Average level (50-75%)	28	53.8		12	23.1				
High level (>=76-100%)	24	46.2		40	76.9				
Total	52	100		52	100				

Table 4: Pre And Post Intervention Practice Scores Among Clinical Trials Sponsors Using Paired *t*-Test:

Levels of Perception	Pre-Test			Post-Test			Mean Diff	*t*-Value	*p* Value
	No	%	Mean±SD	No	%	**Mean ±SD**	6.46	8.75	<0.001
Low level (<50%)	17	32.7	11.81±2.47	0	0	18.27±1.47			
Average level (50-75%)	29	55.8		2	3.8				
High level (>=76-100%)	6	11.5		50	96.2				
Total	52	100		52	100				

However, after the intervention, there was a significant shift in practices. The majority now exhibited high levels (96.2%), with a minor percentage at average levels (3.8%), and none at low levels (0%). This drastic change is evident in the mean difference, which increased from 6.46 to 8.75, indicating a substantial improvement post-intervention (*t*-value=8.75, $p<0.001$). Moreover, the mean value improved substantially, rising from 11.81 during the pre-test phase to 18.27 in the post-test, with a concurrent decline in the standard deviation. This suggests a more consistent and elevated level of practices among Clinical Trial Sponsors following the intervention (Table 4).

DISCUSSION

The demographic data indicated that the majority of respondents were young professionals (69.2% aged 20-30 years) with limited work experience (82.7% having 1-5 years). This demographic trend suggests that while many professionals are actively engaged in clinical research, they may lack extensive exposure to complex ethical frameworks governing biospecimen use. The predominance of individuals from pharmaceutical and life science backgrounds (94.3%) highlights a technically skilled workforce that nonetheless requires enhanced ethical orientation to align with international research standards.

The results of the awareness assessment revealed a significant improvement post-intervention, with 98.1% of participants achieving high-level awareness compared to only 19.2% pre-intervention. Similar outcomes have been reported in previous studies indicating that structured educational programs within clinical and research institutions substantially improve awareness about the ethical use of biospecimens (Al-Hussaini *et al.*, 2014). The marked increase in awareness also supports evidence suggesting that clear communication and appropriate guidance on broad consent and specimen governance enhance understanding and acceptance among research stakeholders (Warner *et al.*, 2018).

In terms of perceptions the shift toward a high-level category (from 46.2% to 76.9%) after the intervention demonstrates growing ethical sensitivity and a positive perception of biospecimen reuse. Previous studies have shown that improved literacy and awareness are directly associated with a greater willingness to participate in and support ethical biospecimen-based research (Echeverri *et al.*, 2018). This transformation in perceptions highlights the vital role of ethics education in promoting responsibility and respect for donor autonomy, in line with earlier discussions on beneficence, justice, and informed consent in biomedical research (Meslin *et al.*, 2004; Kapp *et al.*, 2006).The ethical complexities surrounding consent, privacy, and governance-particularly in low- and

middle-income contexts such as India-underscore the ongoing need for dialogue to balance scientific progress with human rights considerations (Mathur *et al.*, 2019; Moodley *et al.*, 2014).

The practice component also demonstrated a significant post-intervention improvement, with 96.2% of participants adopting high-level practices compared to only 11.5% pre-intervention. This reinforces the concept that ethical training and structured institutional frameworks can effectively translate knowledge into practice. Earlier findings have emphasized that improved policies and consistent ethical education contribute to greater compliance and standardization in biospecimen management (Baer *et al.*, 2010; Rivera *et al.*, 2015). Moreover, the positive shift in practice reflects stronger adherence to ethical principles such as beneficence and justice, reducing wastage of valuable biological materials while ensuring respect for participant rights.

The present study findings suggest that Clinical Trial Sponsors are receptive to ethical training and capable of implementing best practices when appropriate guidance and institutional support are available. However, ethical and legal inconsistencies across regions continue to pose challenges to global harmonization of biospecimen governance (Matimba *et al.*, 2019; Barchi *et al.*, 2016). The development of standardized international frameworks and transparent material transfer agreements remains essential for ensuring the responsible and equitable use of human bio specimens in research (Chalmers *et al.*, 2014).

CONCLUSION

This study demonstrates that targeted educational interventions can significantly enhance pharmaceutical sponsors' awareness, perceptions, and practices regarding the ethical use of human surplus bio specimens. The post-intervention improvements indicate that awareness and structured training foster a stronger ethical foundation, aligning research practices with international standards of autonomy, beneficence, and justice. Nonetheless, continued efforts are essential to address global variations in ethical governance, informed consent mechanisms, and biospecimen sharing policies. The findings advocate for institutional capacity-building initiatives, policy reforms, and collaborative international frameworks to ensure the responsible, transparent, and equitable use of human biological materials in research. Strengthening ethical literacy among sponsors and clinical research professionals will ultimately contribute to advancing translational science while preserving public trust and participant dignity.

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ABBREVIATIONS

CRA: Clinical Research Associate; **CTA:** Clinical Trial Assistant; **CRO:** Contract Research Organization; **CTRI:** Clinical Trials Registry-India; **ICMR:** Indian Council of Medical Research; **KAHER:** KLE Academy of Higher Education and Research; **QA:** Quality Assurance; **SPSS:** Statistical Package for the Social Sciences; **SD:** Standard Deviation.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ETHICAL APPROVAL

The study received approval from the KAHER Ethics Committee, Belagavi, Karnataka, on July 29, 2021 (Ref. No: KAHER/EC21/22/021). All participant information was handled with strict confidentiality.

SUMMARY

Present study examines clinical trial sponsors' Awareness, Perceptions, and practices regarding the ethical use of surplus human biospecimens. An interventional study in Belagavi used a validated questionnaire to assess baseline understanding, followed by educational training and a one-month post-assessment. Pre-intervention findings showed limited knowledge and moderate attitudes and practices. After training, participants demonstrated highly significant improvements across all domains, indicating the effectiveness of structured education. The study highlights gaps in ethical literacy among early-career professionals and underscores the need for continuous training, stronger governance, and harmonized international guidelines to ensure responsible and transparent biospecimen use.

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