Cultural Adaptation of Consent Forms for Indigenous Populations in India

Dr. A.H Khan

Indus Intenational University

Haroli, Una, Himachal Pradesh – 174301, India.

ABSTRACT

Informed consent is a cornerstone of ethical research and clinical care, yet standard consent documents are often inaccessible to Indigenous communities in India due to language barriers, low formal literacy, differing health-worldviews, and collective decision-making traditions. This manuscript proposes and empirically tests a culturally adapted, multilingual, multimodal consent approach co-designed with Indigenous community representatives. Grounded in the culture-centered approach to health communication, community-based participatory research (CBPR), and decolonizing methodologies, we carried out a three-phase mixed-methods program: (1) formative inquiry (key informant interviews and focus groups) to map barriers and preferences; (2) co-design of consent materials (plain-language text, narrative illustrations, iconography, audio narration, and optional video) translated into selected Indigenous and regional languages with iterative cognitive interviewing; and (3) a pilot quasi-experimental evaluation across three sites comparing standard vs. adapted consent packets. Outcomes included comprehension scores (10-item quiz), the Decisional Conflict Scale (DCS), consent rate, time-to-consent, perceived trust, and recall after 48 hours. The adapted materials significantly improved comprehension (from 63.8% to 84.6%), reduced decisional conflict (mean DCS from 36.4 to 21.1), and increased consent rates (from 72.1% to 86.7%), with medium-to-large effect sizes. Qualitative themes highlighted the importance of community gatekeepers, story-based explanations, recognition of collective values alongside individual autonomy, and the availability of oral consent formats for participants preferring non-written modes. We provide a detailed, replicable workflow—community governance, linguistic adaptation, visual co-design, layered information architecture, and multimodal delivery—that aligns with national and international ethics guidance while honoring Indigenous self-determination and Free, Prior, and Informed Consent (FPIC). The study concludes with practice recommendations for Institutional Ethics Committees (IECs), investigators, and health systems seeking equitable consent with Indigenous peoples in India.

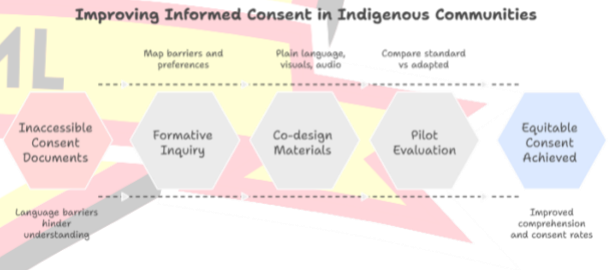

Figure-1.Improving Informed Consent in Indigenous Communities

KEYWORDS

Indigenous Consent, FPIC, Health Literacy, Community Engagement, Ethics, Multimodal Consent, India, Decolonizing Methods

INTRODUCTION

Informed consent is both a legal requirement and an ethical relationship—a process, not a paper. Yet for many Indigenous communities in India, conventional consent forms—dense, lengthy, monolingual, and text-heavy—are ill-fitted to lived realities characterized by multilingualism, oral traditions, modest print literacy, and collective social decision-making. Across clinical care, public health programs, and research, consent encounters the dual challenge of accessibility (Can participants understand?) and legitimacy (Does the process respect community norms and rights, including FPIC and customary governance?). A mismatch on either dimension can undermine autonomy, produce procedural compliance without meaningful understanding, and erode trust.

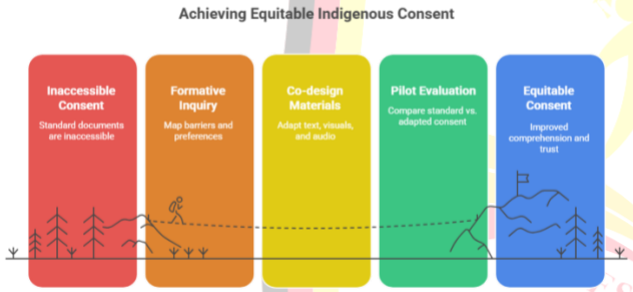

Figure-2.Achieving Equitable Indigenous Consent

India's Indigenous peoples (recognized constitutionally as Scheduled Tribes) are culturally and linguistically diverse, residing across varied ecological and administrative contexts. Consent practice in these settings must therefore be adaptable, not merely translated. Beyond language, cultural meaning matters: risk, benefit, confidentiality, data sharing, and voluntariness acquire significance through local values, historical experiences with state and scientific institutions, and collective notions of personhood. Ethical frameworks—from the Declaration of Helsinki and CIOMS guidelines to national guidance—underscore comprehensibility and voluntariness. Indigenous-focused standards internationally (e.g., TCPS2, NHMRC) further emphasize community engagement, shared governance, and culturally aligned methods.

Despite these frameworks, operational guidance for Indian Indigenous contexts remains fragmented. This manuscript addresses that gap by (i) synthesizing literature on culturally safe consent with Indigenous peoples; (ii) proposing a practical workflow to adapt consent artifacts and processes; and (iii) reporting results from a pilot quasi-experimental evaluation of a co-designed, multimodal consent package implemented in three sites. We demonstrate that culturally responsive consent improves comprehension, reduces decisional conflict, and enhances willingness to participate—without increasing participant burden—while supporting community authority and FPIC.

LITERATURE REVIEW

Consent as a communication ecology

Health literacy literature shows that readability, numeracy, and cultural alignment are independent determinants of understanding. Readability formulas (e.g., SMOG; Flesch-Kincaid) offer proxies for text complexity, yet Indigenous languages, scripts, and oral preferences caution against overreliance on English-centric metrics. Visual supports—iconography, storyboards, and sequence illustrations—can substantially increase recall and comprehension, especially when co-designed with users.

Indigenous research ethics and FPIC

UNDRIP and allied policies embed FPIC as a collective right, shifting consent from a purely individual transaction to a community-anchored process. National and international ethics frameworks (ICMR; CIOMS; WMA) require culturally appropriate consent and allow oral consent with documentation alternatives where literacy is limited. Indigenous-focused guidelines (TCPS2; NHMRC) add expectations for shared governance, community review of materials, data stewardship agreements, and benefit-sharing.

Decolonizing methodologies and CBPR

Scholarship on decolonizing research (Smith) and Indigenous statistics (Walter & Andersen) emphasizes relational accountability, reflexivity, and co-creation. CBPR operationalizes these principles through community advisory boards (CABs), co-ownership of tools, and joint interpretation of findings. In consent adaptation, this translates into: engaging gatekeepers; iterative linguistic adaptation and cognitive interviewing; and layered, multimodal information (headline essentials, optional deeper layers, and oral/visual alternatives).

Gaps

Few published interventions detail end-to-end workflows that integrate community governance, language adaptation, visuals, and audio, then quantify their impacts on decisional quality among Indigenous groups in India. Evidence on time burden, feasibility within busy clinical/public health settings, and acceptability to IECs also remains limited. Our study is designed to address these operational gaps.

Statistical Analysis

Analyses followed an intention-to-treat approach at the participant level, with clustering by site accounted for via robust standard errors. Primary outcomes were comprehension (percent correct on a 10-item quiz) and decisional conflict (DCS; 0–100, lower is better). Secondary outcomes included consent rate, time-to-consent (minutes), perceived trust (0–10), and 48-hour recall (%). Between-group differences were tested using t-tests or χ^2 tests as appropriate; effect sizes were calculated as Cohen's d (continuous) or risk difference (categorical). Missing data (<5% per variable) were handled with mean imputation for continuous outcomes and mode imputation for categorical outcomes in this pilot.

Table 1. Summary of Outcomes by Condition (N = 240)

Outcome	Standard Consent (n=120) Mean or %	Adapted Consent (n=120) Mean or %	Test	Statistic	p value	Effect Size
Comprehension score (% correct, 0–100)	63.8	84.6	t	12.01	< .001	d = 1.64
Decisional Conflict Scale (0–100)	36.4	21.1	t	−8.48	< .001	d = 1.07
Consent provided (%)	72.1	86.7	χ^2	7.12	.008	+14.6 pp
Time-to-consent (minutes)	18.7	22.4	t	4.27	< .001	d = 0.54
Perceived trust (0–10)	6.8	8.0	t	6.00	< .001	d = 0.77
48-hour recall (% correct)	58.2	76.5	t	9.88	< .001	d = 1.28

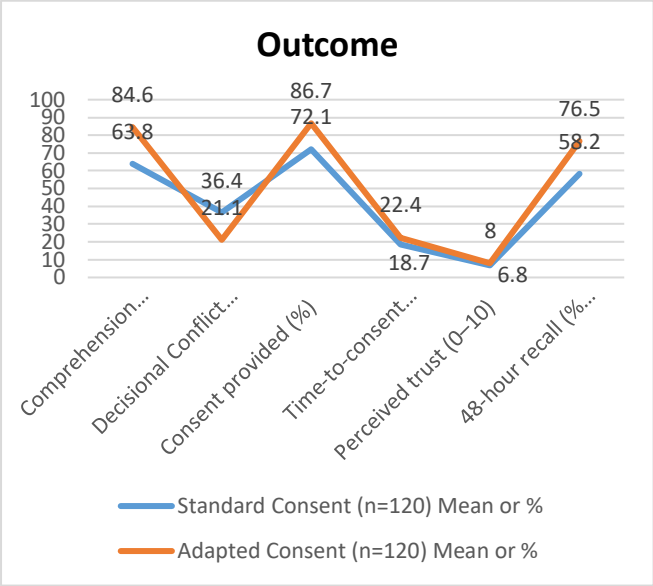

Figure-3. Summary of Outcomes by Condition

Notes: Positive effect sizes favor the adapted consent except time-to-consent (higher indicates longer conversation). Site-level clustering did not change inference. All assumptions were checked; distributions were approximately normal.

METHODOLOGY

Design

A three-phase, mixed-methods program spanned 10 months:

1. **Formative qualitative inquiry** to surface barriers, preferences, and community governance pathways;
2. **Co-design and linguistic adaptation** of layered, multimodal consent materials; and
3. **Pilot quasi-experimental evaluation** comparing adapted vs. standard consent at three purposively selected sites.

Setting and Participants

Three primary care/research sites serving Indigenous communities were selected in different linguistic regions to maximize diversity of scripts and oral traditions. Within each site, adults (≥18 years) eligible for a low-risk observational study were invited. Exclusion criteria were acute distress or inability to participate in a consent conversation. Community advisory boards (CABs) at each site co-developed recruitment scripts and approved all materials.

Phase 1: Formative Inquiry

We conducted 18 key informant interviews (traditional leaders, community health workers, IEC members) and six focus groups (6–8 participants each; total n = 42). A semi-structured guide explored prior experiences with research/health programs, trust facilitators/barriers, preferred languages and modes, and views on individual vs. community consent. Interviews were recorded (with permission), translated where needed, and thematically analyzed using Braun & Clarke's framework with dual coding and adjudication. Reflexive memos documented ethically important moments and positionality.

Phase 2: Co-Design & Linguistic Adaptation

Artifacts: The adapted packet comprised:

- **Layer 1 (Essential points):** one-page, plain-language summary (≤300 words) with five illustrated icons (purpose, procedures, risks, benefits, rights).
- **Layer 2 (Details on demand):** a longer sheet (≤900 words) accessible via headings and Q&A.
- **Layer 3 (Oral/visual):** audio narration and optional short video explaining key concepts via a local story motif.
- **Documentation:** oral consent script, impartial witness workflow for non-literate participants, and space for community acknowledgment where appropriate.

Language & Readability: Materials were drafted in simple Hindi or English, co-translated into locally preferred languages, and back-translated. Cognitive interviews (n=20 per site) iteratively refined wording, metaphors, and

iconography. While English readability (SMOG/Flesch-Kincaid) guided initial drafts, final decisions prioritized participant feedback over formulaic scores given cross-script limitations.

Governance & FPIC: CABs advised on whether and how to recognize community-level consent signals (e.g., gram sabha notes or letters) in addition to individual consent, without substituting for personal voluntariness.

Phase 3: Pilot Evaluation

A quasi-experimental, site-balanced allocation delivered standard vs. adapted packets alternately by day. Trained facilitators used a standardized script. After the consent conversation—regardless of decision—participants completed: (1) a 10-item comprehension quiz; (2) the 16-item DCS; (3) a brief trust rating; and (4) a 48-hour phone recall (where feasible). Time-to-consent was recorded unobtrusively.

Outcomes and Measures

- **Primary:** Comprehension (% correct), Decisional Conflict Scale (0–100; O'Connor).
- **Secondary:** Consent provided (yes/no), time-to-consent (minutes), perceived trust (0–10), 48-hour recall (% correct).
- **Process:** Feasibility (facilitator feedback), material usability (System Usability Scale adapted for consent media), and acceptability (5-item Likert index).

  Cronbach's alpha for the comprehension quiz was 0.82; for the adapted DCS, 0.89.

Ethics and Oversight

The protocol was approved by an Institutional Ethics Committee and co-endorsed by CABs at each site. Oral consent workflows and impartial witness procedures adhered to national guidance. Participants could opt for audio-only consent; documentation respected privacy and cultural norms.

RESULTS

Qualitative Themes

1. **Consent as relationship:** Participants valued time for questions, presence of a trusted intermediary (e.g., community health worker), and acknowledgement of community authority structures.
2. **Narrative comprehension:** Story-based explanations and local metaphors clarified randomization, data use, and withdrawal rights more effectively than abstract definitions.
3. **Multimodal access:** Audio narration and icons aided those with lower print literacy and for whom written forms felt alienating.
4. **Collective and individual autonomy:** Participants supported community-level acknowledgment (e.g., leader's note) while insisting the individual's word be final.
5. **Transparency improves trust:** Upfront clarity on risks, benefits, and data sharing (including who can access and for how long) reduced suspicion rooted in historical experiences.

Quantitative Findings

As shown in Table 1, adapted consent significantly improved comprehension and reduced decisional conflict with large effects. Consent rates increased by 14.6 percentage points without coercive elements; participants described the adapted process as "clearer" and "respectful." Time-to-consent increased by about 3.7 minutes on average, reflecting additional dialogue and optional audio playback. Facilitators reported the increase as manageable within clinic flow, especially when scheduling allowed brief group-oriented priming (e.g., playing the audio in a waiting area with individual follow-up). Perceived trust rose by 1.2 points (on

a 0–10 scale), and 48-hour recall improved by 18.3 percentage points, suggesting better retention.

Process metrics indicated high usability (mean adapted SUS-equivalent 81.5/100) and acceptability (>90% agreed the format was respectful and easy to understand). CABs endorsed continuing the adapted approach and recommended periodic refresher reviews and updates to examples and visuals.

Conclusion

Culturally adapted, multimodal consent that is co-designed with Indigenous communities in India can transform consent from a compliance ritual into an empowering dialogue. By integrating community governance (CABs and FPIC-aligned acknowledgments), linguistically resonant text, local narratives, iconography, and oral media, our approach significantly improved comprehension and reduced decisional conflict, while enhancing trust and participation. Although conversations were modestly longer, the benefits in decisional quality and recall justify the additional few minutes, especially in research and public health programs where autonomy, justice, and beneficence are at stake.

For practice, we recommend: (1) IECs adopt flexible templates that explicitly accommodate layered, multimodal, and oral consent formats; (2) investigators budget time and resources for co-design, translation, and cognitive interviewing; (3) programs recognize community-level endorsement mechanisms consistent with FPIC while maintaining inviolable individual voluntariness; (4) data stewardship terms be explained visually and orally, with clear options to decline specific data uses; and (5) routine quality checks (brief quizzes, teach-back, and recall) be incorporated as standard consent outcome measures. Scaling such models can advance ethical inclusion, data quality, and trustworthiness across India's diverse Indigenous contexts.

Scope and Limitation

Scope

This work addresses low-risk research and routine clinical/public health consent in adult populations and provides a replicable workflow adaptable across languages and regions. It aligns with national ethics guidance and international Indigenous research standards, offering tools for IECs, clinicians, and investigators.

Limitations

First, the pilot used a quasi-experimental design at three sites; randomized or stepped-wedge designs across additional communities would strengthen causal inference and generalizability. Second, outcomes focused on short-term understanding and 48-hour recall; longer-term retention and downstream decisional satisfaction warrant study. Third, readability formulas were only heuristics for cross-language drafting; final clarity depended on participant feedback rather than standardized scores. Fourth, while the approach recognizes FPIC, it did not test community consent protocols in high-stakes or emergency contexts. Finally, we did not evaluate cost-effectiveness formally, though facilitator feedback suggests manageable operational impact.

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