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How well are ethical principles applied in the field? Independent monitoring of consent and confidentiality in the 2024–2025 Cameroon Population-based HIV Impact Assessment (CAMPHIA)

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Abstract

Background

Population-based HIV Impact Assessment (PHIA) surveys generate the national estimate on which HIV programmes are steered. As with all research involving human participants, these surveys have to be implemented following international and national ethical guidelines, including respect for informed consent and confidentiality, as specified in the protocol approved by the competent ethics committee. We conducted an independent ethical compliance monitoring of the CAMPHIA 2024–2025 survey in Cameroon.

Methods

Cross-sectional independent monitoring was nested within CAMPHIA, conducted from 5 September to 10 October 2024 in enumeration areas already surveyed across six settings (Adamawa, Littoral, West, South-West, Douala and Yaoundé). Residents aged 15 years and over were interviewed after their CAMPHIA visit by monitors who were independent of the survey teams. Three Ethical Compliance Indices (ECI, 0–100) were constructed as formative composites: information (nine mandatory items), consent and procedures (age-conditional items, with assent and parental authorisation required below 21 years) and confidentiality. Proportions carry Wilson 95% confidence intervals, while index means both normal approximation and bootstrap intervals.

Results

Of 258 respondents monitored (median age 40 years, IQR 28–50; 53.1% women; 7.8% under 21), 236 (91.5%) had taken part in CAMPHIA. The level of participant protection was dependent on the domain under study: information at 87.7 (95% CI: 85.7–89.7), consent and procedure at 93 (95%CI: 91.2–94.8) and confidentiality at 98.3 (95% CI 96.9–99.7). In terms of information, 38 percentage points were covered: almost everything was confidential (100.0%), the blood draw (99.6%) and voluntary participation (98.6%) were near-universal but contact details (69.9%) and compensation arrangements (62.0%) were not. The level of administrative visibility was 35.6%, authorisation was not displayed for 30.1% of cases and ethical clearance was presented in the remaining 30.1%. Two thirds (66.3%) had seen no visual material. Information and consent differed significantly between regions ($p < 0.001$ and $p = 0.005$), confidentiality did not ($p = 0.311$), and the regional orderings of the two were discordant.

Conclusion

Independent ethical compliance monitoring should be integrated into population-based HIV surveys as a quality-assurance mechanism. Strengthening standardised information delivery, visible administrative

and ethical documentation, and regionally consistent procedures could improve participant protection and reinforce public trust in national HIV surveillance, ultimately supporting more credible programme planning.

Clinical Trial:

Not Applicable

Background

Population-based HIV Impact Assessment (PHIA) surveys are central instruments for evaluating national HIV programmes, producing robust population-level estimates of prevalence, incidence, treatment coverage and viral suppression [1–3].

In Cameroon, where HIV prevalence in the general population remains around 2.7% with persistent disparities by sex, age and region [2, 4], the CAMPHIA 2024 survey was designed to track progress towards the 95-95-95 targets and to guide the national response.

A survey of this magnitude, however, is not only a scientific undertaking but also a governance one. Protecting participants requires that information delivery, informed consent, confidentiality and the security of sensitive data meet recognised ethical standards [5–7]. In parallel, regulatory approvals, inter-institutional coordination and the engagement of administrative and community authorities condition the transparency, legitimacy and social acceptability of the survey [8–10].

Yet independent verification of whether these administrative and ethical requirements are actually met in the field remains uncommon in large HIV surveys in sub-Saharan Africa. Building on established frameworks for ethical research with human participants [11–13], we treated ethical compliance as a measurable construct spanning three dimensions — information, consent, and confidentiality — and administrative compliance as the visible presentation of the survey's authorisations. Assessing both dimensions independently is therefore strategic for improving the governance of future public-health surveys in Cameroon.

Methods

Study design and setting

A cross-sectional, independent administrative and ethical monitoring was nested within the CAMPHIA 2024–2025 survey. It was conducted from 5 September to 10 October 2024 in enumeration areas (EAs) already covered by CAMPHIA, distributed across the Adamawa, Littoral, West and South-West regions, including the cities of Douala and Yaoundé.

Study population

Eligible participants were individuals aged 15 years and older residing in the sampled households who consented to the monitoring interview. Because monitoring targeted households already enrolled in CAMPHIA.

Sample size and Sampling

Participants were recruited by convenience within each EA already covered by CAMPHIA study until at least five interviews per EA were obtained. The reference size was estimated with the single-proportion formula (Z = 1.96; expected proportion 50%; 5% margin), giving 215 and 236 after allowing for 20% non-response; 258 participants were ultimately monitored. As sampling was non-probabilistic, confidence intervals are reported descriptively.

CAMPHIA 2024–2025 is the Cameroon round of the Population-based HIV Impact Assessment programme, a household survey designed to produce national and regional estimates of HIV prevalence, incidence, treatment coverage and viral load suppression. Like other PHIA surveys, it follows a two-stage stratified cluster design: enumeration areas are drawn within each stratum with probability proportional to size from the national sampling frame, households are then selected systematically within each area, and all eligible residents aged 15 years and over are invited to take part. Participation involves a structured interview, home-based HIV testing and counselling, and a blood draw for laboratory testing.

The monitoring described here was not a second survey but an independent audit nested within it. Enumeration areas already visited by CAMPHIA teams were purposively selected across six settings to cover the diversity of regions, languages and urban–rural contexts. Within each area, monitors approached households by convenience until at least five interviews had been obtained, and interviewed one resident aged 15 years and over per household, whether or not that person had taken part in CAMPHIA. Non-participants were retained deliberately, since their reasons for declining are themselves informative. A total of 258 respondents were monitored, of whom 236 (91.5%) had taken part.

Data collection

Data were collected on smartphones by ten monitors trained in the study methodology, ethical principles and questionnaire administration, using a structured tool deployed on KoboCollect. Regional and district health authorities, facility managers and CAMPHIA field supervisors were informed beforehand. During each interview, monitors introduced themselves, recorded whether administrative authorisations and ethical clearance had been shown to the participant during CAMPHIA, and documented the information, consent and confidentiality steps actually experienced.

Study variables

Outcome variables

Three Ethical Compliance Indices (ECI), each expressed on a 0–100 scale, constituted the primary outcomes. They were specified before analysis as formative composite indicators following the logic of composite-indicator construction [14, 16], in which every item captures a distinct regulatory obligation.

- **ECI-1 (Information)** aggregated nine mandatory items of the information sheet, each recorded as delivered or not: the objectives of the survey; the 15 ml blood draw; the benefits and risks; the expected time burden; the voluntary nature of participation; the right to refuse or withdraw without penalty; confidentiality; any compensation; and the contact details of the principal investigator and the ethics committee.
- **ECI-2 (Consent and procedures)** aggregated the consent items applicable to each respondent, determined by age. For respondents aged 21 years and over the age of legal majority in Cameroon these were the household head's agreement and the signed informed consent for three distinct purposes: participation, the blood draw, and the storage of the sample for future research. For respondents under 21, they were the household head's agreement together with the assent of the respondent and the authorisation of a parent or guardian for the same three purposes.
- **ECI-3 (Confidentiality)** aggregated two items: whether the CAMPHIA interview had been conducted without a third-party present, and whether the HIV result had been returned confidentially.

Secondary outcomes

Administrative governance was measured through a five-step cascade: prior community information about the survey; effective participation; the interviewers stating the purpose of their visit; the presentation of at least one authorisation document; and the presentation of the ethical clearance specifically. Documentary compliance was captured separately by whether a signed copy of each consent form had been given to the participant, and by the monitor's own observation of the hard copy in the household.

Explanatory and stratification variables

Region of residence, health district, sex, age in completed years, and highest level of education completed. Participation status distinguished the 236 respondents who had taken part in CAMPHIA from the 22 who had not, and determined which modules applied.

Process variables: These described how the encounter had been conducted rather than whether it complied: the channel through which the respondent first heard about the survey and the means used by the community mobiliser; the visual materials seen in the neighbourhood; the language used by the interviewers; who conveyed the information; the respondent's self-reported understanding of the consent form, on a four-point scale; whether the opportunity to ask questions had been given; and whether any

compensation had been received or promised. Two open-ended items recorded the participants' comments and the reasons given for not taking part.

Coding conventions

Every compliance item was recoded as binary, with "Yes" scored 1 and "No" or "Does not know" scored 0. Items marked "Not applicable" and blanks were treated as missing and excluded from the denominator of the respondent concerned. One item was reverse-coded, since compliance corresponds to the *absence* of a third party during the interview. This conservative-but-bounded convention follows standard practice for audit checklists, where an unanswered item is evidence of nothing rather than evidence of failure [15]. Each index equals 100 times the mean of the items applicable to that respondent, so respondents contribute on the basis of the obligations that actually applied to them.

Variables not analysed

Nineteen variables were empty across all 258 records and were excluded, including the item on whether information had been conveyed in clear and appropriate language; it is therefore not reported as measured. For each multiple-choice question the database also stored one binary column per response option, split from the coded answer string; these are derived variables and were used only to describe response distributions, never to construct the indices.

Data management and analysis

Data source and preparation

Monitoring data were collected on Kobo Collect, exported, checked and cleaned before analysis. The dataset comprises 258 monitored respondents and 134 variables. Nineteen variables were empty in the export and were excluded from all analyses; one of these, on whether information had been conveyed in clear and appropriate language, had no recorded value for any respondent and is therefore not reported as measured. Variables were coded in two ways in the source file — as text (Yes/No) and as numeric indicators (1/0) — and both were recoded through a single rule so that no item was misclassified by its storage format.

Denominators

Two denominators are distinguished throughout, and each table states which applies. The first is the 258 respondents visited by the monitoring team. The second is the 236 respondents who had actually taken part in CAMPHIA, since the sections on authorisations, information, consent and confidentiality were administered to participants only. Compliance items are therefore reported over 236, and community-level indicators such as prior awareness of the survey over 258. Conflating the two inflates non-compliance mechanically, because respondents who were never asked a question cannot be scored on it.

Primary analysis and sensitivity analyses

The primary analysis covers participants (n = 236) with missing answers excluded from each respondent's denominator. Because the indices are sensitive to this choice, three alternatives are reported in full in Table 3: missing answers scored as non-compliance among participants; the same rule applied to all 258 monitored respondents; and missing answers excluded across all 258 [15]. Reporting a single set of figures without this comparison would misrepresent their stability, and any reader recomputing the indices under a different rule would obtain different values.

Statistical methods

- **Descriptive statistics**: Continuous variables are summarised by median and interquartile range, categorical variables by counts and proportions.
- **Precision of proportions**: Wilson score 95% confidence intervals were used rather than the normal-approximation (Wald) interval, because several items lie close to 100% where the Wald interval performs badly and can exceed the [0, 1] bounds [17, 18].
- **Precision of index means**: Both the normal-approximation interval and a percentile bootstrap interval based on 10,000 resamples are reported. The two agree closely, which indicates that the means are stable despite the strong left skew of the distributions [19].
- **Group comparisons**: Because index distributions are bounded at 100 and markedly skewed, rank-based tests were preferred to t-tests: Kruskal–Wallis across regions contributing at least 15 participants, and Mann–Whitney U by sex. Regions with fewer than 15 participants were excluded from testing and from Fig. 3.
- **Internal consistency**: KR-20 was computed for each index (Supplementary file), together with item–total correlations for ECI-1 [20]. These are reported for transparency, not as validation criteria, for the reason given above: low internal consistency is expected in a formative compliance index and does not invalidate it.

Analyses were performed in Python 3.14 (pandas, NumPy, SciPy) and Microsoft Excel 2021.

Ethical considerations

The study was approved by the National Ethics Committee for Human Health Research in Cameroon (N°2024/14/1757/CE/CNERSH/SP). Written informed consent was obtained from all participants prior to their inclusion in the study. Participants were informed of the confidentiality of the data collected, as well as their right to withdraw at any time without any consequences for their care or their relationship with health services.

Results

A total of 258 respondents were monitored. The South-West contributed 68 respondents (26.4%), Yaoundé 62 (24.0%), Adamawa 61 (23.6%), Douala 47 (18.2%), Littoral 15 (5.8%) and the West 5 (1.9%).

The median age was 40 years (IQR 28–50). Women accounted for 137 respondents (53.1%). Secondary schooling was the most frequent level of education (44.2%). Twenty respondents (7.8%) were aged under 21 years, of whom 14 (5.4%) were recorded as minor participants. Effective participation in CAMPHIA was 91.5% (236/258); 22 respondents (8.5%) had not taken part (Table 1).

Table 1
Participant characteristics (N = 258)

Variable	**n**	**%**
Region		
South-west	68	26.4
Yaounde	62	24.0
Adamawa	61	23.6
Douala	47	18.2
Littoral	15	5.8
West	5	1.9
Age		
Median (IQR), years	40 (28–50)	
Sex		
Female	137	53.1
Male	121	46.9
Level of education		
Unschooled	40	15.5
Primary	63	24.4
Secondary	114	44.2
Higher	41	15.9
Age and participation		
Aged under 21 years	20	7.8
of whom flagged "Minor participant"	14	5.4
Took part in CAMPHIA	236	91.5
Did not take part	22	8.5
IQR: Interquartile Range; n: number in the category; %: percentage		

Community information and administrative visibility

Prior information about the survey was reported by 83.3% of the 258 respondents, community mobilisers being the main channel. Two thirds (66.3%) had seen no visual material. Among the 236 participants, 35.6% were shown no administrative authorisation, and ethical clearance was presented in 30.1% of cases (Fig. 1).

Coverage of the information items

Coverage of the nine mandatory information items is shown in Fig. 2. Denominators varied between items, from 206 to 229 valid answers, as answers coded as not applicable were excluded. Four items were reported by more than 95% of respondents: confidentiality (100.0%; 209/209), the 15 ml blood draw (99.6%; 222/223), voluntary participation (98.6%; 213/216) and the objectives of the survey (95.6%; 219/229). Three items lay between 83% and 90%: the right to withdraw (89.6%; 189/211), the time burden (87.4%; 194/222), and the benefits and risks (83.4%; 186/223). The two lowest were contact details (69.9%; 144/206) and possible compensation (62.0%; 129/208). Coverage therefore spanned 38.0 percentage points across the nine items.

Ethical compliance indices

Index values are reported in Table 2. ECI-1 (Information) had a mean of 87.7 (SD 15.3; n = 229; 95% CI 85.7–89.7; bootstrap 95% CI 85.7–89.6), a median of 88.9 (IQR 77.8–100) and a minimum of 33.3; 48.0% of contributing participants scored 100. ECI-2 (Consent and procedures) had a mean of 93.0 (SD 14.1; n = 236; 95% CI 91.2–94.8; bootstrap 95% CI 91.1–94.8) and a median of 100 (IQR 100–100); 77.5% scored 100 and the minimum was 42.9. ECI-3 (Confidentiality and data security) had a mean of 98.3 (SD 11.2; n = 236; 95% CI 96.9–99.7; bootstrap 95% CI 96.8–99.6); 230 participants (97.5%) scored 100, four scored 50 and two scored 0. ECI-1 could not be computed for seven participants, for whom all applicable information items were missing. The normal-approximation and bootstrap intervals coincided to within 0.1 point for all three indices.

Table 2
Ethical compliance indices

Index	N	Mean	SD	95% CI	Bootstrap 95% CI
ICE-1 Information	229	87.7	15.3	85.7–89.7	85.7–89.6
ICE-2 Consent	236	93.0	14.1	91.2–94.8	91.1–94.8
ICE-3 Confidentiality	236	98.3	11.2	96.9–99.7	96.8–99.6
N: total numbers of validated responses; SD: Standards deviation, CI: Confidence Intervall					

Sensitivity to the missing-data rule and the denominator

Index values varied with the analytical rule applied (Table 3). Scoring missing answers as non-compliance among the 236 participants (Sensitivity A) reduced the means to 80.3, 90.8 and 96.0. Applying the same rule to all 258 monitored respondents (Sensitivity B) reduced them further, to 73.4, 83.1 and 87.8. Excluding missing answers across all 258 respondents (Sensitivity C) reproduced the primary values exactly, since respondents who had not taken part had no applicable item and therefore contributed to no denominator. Across the four analyses, the range was 73.4–87.7 for ECI-1, 83.1–93.0 for ECI-2 and 87.8–98.3 for ECI-3.

Table 3
Sensitivity of the indices to the missing-data rule and the denominator

Analysis	Rule for missing answers	N	ICE-1	ICE-2	ICE-3
Primary	Excluded from the denominator	236	87.7 (85.7–89.7)	93.0 (91.2–94.8)	98.3 (96.9–99.7)
Sensitivity A	Scored 0 (non-compliant)	236	80.3 (77.2–83.3)	90.8 (88.4–93.2)	96.0 (94.0–97.9)
Sensitivity B	Scored 0 (non-compliant)	258	73.4 (69.5–77.4)	83.1 (79.3–86.9)	87.8 (84.1–91.5)
Sensitivity C	Excluded from the denominator	258	87.7 (85.7–89.7)	93.0 (91.2–94.8)	98.3 (96.9–99.7)

N: total numbers of validated responses

Variation of ECI by region

Kruskal–Wallis tests were restricted to the five regions contributing at least 15 participants; the West (n = 5) was excluded. ECI-1 differed significantly across regions ($H = 59.08$, $p < 0.001$), with means of 96.9 in Douala, 93.4 in the South-West, 90.6 in Yaoundé, 77.9 in Adamawa and 71.2 in Littoral. ECI-2 also differed significantly ($H = 14.93$, $p = 0.005$), with means of 96.7 in Littoral, 95.7 in Adamawa, 93.3 in Yaoundé, 91.4 in the South-West and 88.2 in Douala. ECI-3 did not differ significantly ($H = 4.77$, $p = 0.311$); regional means ranged from 95.8 in Douala to 100 in Littoral and the South-West (Fig. 3). The regional ordering of ECI-1 and ECI-2 was not concordant.

Variation by sex

Mann–Whitney U tests showed no significant difference between women and men for ECI-1 ($U = 5955$, $p = 0.218$; means 86.3 and 89.2) or ECI-2 ($U = 6562$, $p = 0.346$; means 91.9 and 94.3). ECI-3 differed significantly by sex ($U = 6594$, $p = 0.022$); the mean was 96.9 among women and 100 among men, with medians of 100 in both groups. All six participants scoring below 100 on ECI-3 were women, three of whom were aged 15 years (Fig. 4).

Internal consistency and item performance

Internal consistency was variable (Supplementary Tables S2 and S3). KR-20 was 0.61 for ECI-1 (9 items; 189 complete cases), 0.26 for ECI-2 (4 items; 216 complete cases) and 0.50 for ECI-3 (2 items; 224 complete cases). Item–total correlations for ECI-1 ranged from 0.05 to 0.51: contact details 0.51, benefits and risks 0.45, time burden 0.44, right to withdraw 0.40, possible compensation 0.28, objectives of the survey 0.23, voluntary participation 0.11 and the 15 ml blood draw 0.05. The correlation for the confidentiality item was not computable, as responses showed no variance across the 189 complete cases. Individual index values are reported in Supplementary Table S1.

Discussion

Principal findings

This independent monitoring quantified administrative and ethical compliance in CAMPHIA 2024–2025 from the participant's perspective, in 258 respondents across six settings. Three findings emerge. First, adherence to the core obligations that protect participants was high, and highest for confidentiality (98.3), followed by consent and procedures (93.0) and information (87.7). Within the information dimension, coverage ranged from 62.0% for possible compensation to 100% for confidentiality. Second, the visible presentation of administrative authorisations and of ethical clearance was substantially weaker than participant protection itself, with roughly one third of participants shown ethical clearance. Third, compliance was not uniform across the country: information and consent differed significantly between regions, whereas confidentiality was near-uniform.

Information delivery was the weakest and most variable dimension

ECI-1 was the lowest index and the only one showing wide dispersion. This ordering is consistent with the wider evidence on consent. In a meta-analysis covering three decades, the pooled proportion of trial participants who understood confidentiality was 66.2%, voluntariness 74.7%, freedom to withdraw 75.8% and the study purpose 69.6%, and this proportion did not improve over the period examined [21]. In sub-Saharan Africa specifically, comprehension of consent concepts varies markedly between countries and with the complexity of the study [22]. Our indicator is not a comprehension test: it records whether the participant reported having received each item. Reported delivery therefore represents an upper bound on understanding, and the distance between the two is well documented in African research settings [22, 23].

The item-level pattern locates this shortfall precisely. The elements that define the research act itself were delivered almost universally: confidentiality (100.0%), the 15 ml blood draw (99.6%), voluntary participation (98.6%) and the objectives of the survey (95.6%). These same items had the weakest item–total correlations (0.05 for the blood draw, 0.11 for voluntary participation, and not computable for confidentiality), which is the expected consequence of restricted variance near a ceiling rather than evidence of poor item performance [15]. The deficit is concentrated instead in two administrative

disclosure items: contact details (69.9%) and possible compensation (62.0%), which together account for most of the dispersion of ECI-1 and carry the highest and the fifth-highest item–total correlations (0.51 and 0.28). Almost the whole of the information gap therefore concerns what happens after the interview — how to reach the team, and what the participant is entitled to — rather than the core elements of consent.

This distinction does not make the gap minor. CIOMS requires that participants be told how to contact the research team and what compensation, if any, is provided [24], and the Declaration of Helsinki requires that each potential participant be adequately informed of the aims and methods, sources of funding, anticipated benefits and potential risks, and of the right to refuse or withdraw without reprisal [12]. Contact details are the operational precondition for exercising the right to withdraw, to ask questions or to report a problem, so a coverage of 69.9% weakens rights that were otherwise well communicated (89.6% for the right to withdraw). Benefits and risks, at 83.4%, remains the lowest-covered of the substantive disclosure items and is explicitly required by both instruments [12, 24].

That two thirds of respondents had seen no visual material is relevant here. In multilingual, mixed-literacy settings, translated text alone is a limited vehicle for consent information, and non-textual supports such as pictograms, audio and short multimedia have been developed specifically to address this constraint [23]. With 15.5% of respondents unschooled and a further 24.4% educated only to primary level, this limitation applies directly to the CAMPHIA population.

Consent and procedures were largely complied with

ECI-2 was high, and three quarters of participants scored 100. The index was deliberately age-conditional, requiring assent together with parental authorisation for participation, blood draw and sample storage in respondents under 21 years. This structure reflects guidance requiring both the assent of the minor and the permission of a legally authorised representative [12, 24]. The two lowest ECI-2 values in the dataset were recorded for female respondents aged 15 and 18 years, indicating that the residual weakness in this dimension concerns the adolescent-specific procedures rather than adult consent. Specific consent for the storage of biological specimens is itself a distinct requirement under CIOMS and cannot be inferred from consent to the blood draw [24]; its inclusion as a separate item is therefore appropriate.

Confidentiality was well protected, with a residual signal in adolescent girls

ECI-3 was the highest and least dispersed index. This is a substantive result rather than an artefact of having only two items, because both items relate to circumstances that are genuinely difficult to control in household-based HIV surveys. PHIA-type surveys conduct home-based counselling and rapid testing with immediate return of results [25], and they subsequently return viral load results to a health facility chosen by the participant, which extends the confidentiality requirement across the specimen and data chain [26]. Confidentiality — alongside convenience and credibility — is among the principal determinants

of the acceptability of HIV counselling and testing in this region [27], so a shortfall on this dimension would carry consequences for participation as well as for protection.

The statistically significant sex difference ($p = 0.022$) should be read with care. Medians were identical, all six participants scoring below 100 were women, and three of those were aged 15 years. The difference therefore rests on a small number of adolescent girls, in whom obtaining a private interview space within the household is plausibly harder. Given the small numbers, this should be treated as a signal for targeted supervision rather than as an established sex effect.

Administrative visibility, not ethical approval, was the main gap

The weakest results concerned the display of administrative authorisations and of ethical clearance. This distinction matters. International standards require that research be reviewed and approved before it begins, and that approval be documented [5, 24]; they do not require that the approval document be presented to each individual participant. The observed gap is therefore one of field practice and visibility, not of regulatory status. It nonetheless matters ethically. Transparency, accountability towards host communities and collaborative partnership are recognised requirements for research conducted in low-resource settings [8, 13], and community engagement is a longstanding grand challenge for global health research rather than an optional courtesy [10]. Researchers in developing-country settings have themselves identified the visible operation of the review system as a determinant of trust in research [9]. Where a national survey collects blood for HIV testing, visible proof of authorisation is a low-cost mechanism for distinguishing an approved survey from unaccredited data collection.

Regional heterogeneity points to fieldwork practice rather than population differences

Information and consent scores differed significantly between regions, while confidentiality did not. Importantly, the regional ordering was not concordant across the two indices: Douala had the highest ECI-1 and the lowest ECI-2, and Littoral the reverse. A single gradient of stronger and weaker regions therefore does not describe the data. This pattern is more compatible with team-level variation in how each step of the protocol was executed than with population-level differences in comprehension or willingness to report. Ongoing oversight of approved studies is a recognised capacity gap for ethics review systems in the WHO African Region, where committees report monitoring of ongoing research among their main unmet needs [28], and structural and functional limitations of biomedical research ethics committees in sub-Saharan Africa have been documented repeatedly [29]. Standard operational guidance places responsibility for the ongoing conduct of approved research with the review system as well as the investigator [5]. Region-specific supervision, rather than uniform retraining, follows from these results.

Interpretation of the reliability statistics

KR-20 was 0.61, 0.26 and 0.50 for ECI-1, ECI-2 and ECI-3 respectively. These values do not undermine the indices, for a reason that is structural rather than empirical. The three indices are formative, or causal-indicator, composites: each item represents a distinct regulatory obligation that contributes to compliance, rather than a manifestation of a single underlying trait [16, 30]. In such models there is no theoretical expectation that items covary, dropping an item changes the construct, and internal-consistency coefficients — which were derived for reflective scales [31] — are not validity criteria [15, 30]. This is standard in composite-indicator construction, where the relevant checks are the specification of the item set, the treatment of missing data and the robustness of the aggregation, not inter-item correlation [14]. Reporting KR-20 nonetheless serves transparency, and the item–total correlations identify which items carry the discriminating information for future rounds.

The missing-data rule materially changes the estimates

Across the four analyses, ECI-1 ranged from 73.4 to 87.7, ECI-2 from 83.1 to 93.0 and ECI-3 from 87.8 to 98.3. The choice of rule therefore moves the headline figure by up to 14.3 points. Two properties of Table 3 are worth stating explicitly. Sensitivity C reproduces the primary analysis exactly, because respondents who did not take part in CAMPHIA have no applicable item and so cannot enter any denominator under an exclusion rule; the denominator question is thus only consequential when missing answers are scored as failures. Conversely, Sensitivity B — scoring missing answers as non-compliance across all 258 respondents — assigns failure to respondents who were never asked the question, and mechanically inflates non-compliance. Treating an unanswered item as evidence of nothing rather than evidence of failure is the convention recommended for audit-type instruments [15], and uncertainty and robustness analysis of this kind is a standard step in composite-indicator construction [14]. Presenting a single figure without this comparison would have overstated its stability.

Contribution of the study

Independent, participant-side verification of ethical performance during a national HIV survey is uncommon. PHIA methodology reports describe consent programming on tablets, community mobilisation and fieldworker training as elements of survey preparation, and report data-completeness metrics [25], but they do not document external verification of the consent process as experienced by participants. Ethics review systems in the region, for their part, identify monitoring of ongoing research as a capacity constraint [28, 29]. This study shows that a short-structured instrument, administered by an independent team shortly after the survey visit and analysed with pre-specified coding rules, can produce quantified, region-disaggregated compliance estimates within a five-week window. The instrument is transferable to other PHIA rounds and to other national surveys.

Strengths and limitations

The main strengths are the independence of the monitoring team from the CAMPHIA field teams, the participant-side perspective, the pre-specification of binary coding and of the applicable-item logic, the

explicit separation of the two denominators, and the reporting of both normal-approximation and bootstrap intervals [19] together with a full sensitivity analysis [14, 15].

Several limitations qualify these findings. First, recruitment was by convenience within enumeration areas, so the sample is not probabilistic; confidence intervals are descriptive and the estimates cannot be weighted to the national CAMPHIA sample. Second, regional representation was uneven, and the West (n = 5) had to be excluded from formal testing and from Fig. 3, so the national picture is effectively based on five settings. Third, all measures are self-reported and were not verified against CAMPHIA consent records; recall of consent information is incomplete even shortly after the event [21], which may lower reported compliance independently of what field teams actually did. Fourth, courtesy and social-desirability bias may act in the opposite direction, since respondents interviewed in their homes by a team identified with the health sector may over-report satisfactory conduct [32]; the net direction of these two biases cannot be determined from these data. Fifth, the indices measure delivery and procedure, not comprehension or voluntariness as experienced, which the consent literature identifies as the decisive dimensions [21, 22]. This limitation is compounded by the loss of the item on whether information had been conveyed in clear and appropriate language, which was empty in the export and could not be analysed. Sixth, ECI-2 and ECI-3 show pronounced ceiling effects, which limits their capacity to discriminate between teams and reduces the power of group comparisons. Finally, monitoring covered a five-week window, so any drift in field practice over the full CAMPHIA data-collection period would not be captured.

Implications

Four operational implications follow directly from the results. A standardised closing checklist should make compensation arrangements and team contact details compulsory items at the end of every consent conversation, since these two items alone account for the bulk of the information deficit (62.0% and 69.9% coverage) and are explicitly required by international guidance [12, 24]. Information materials should include non-textual supports appropriate to a population in which two fifths have primary schooling or none [23]. Administrative authorisation and ethical clearance should be carried and shown as a routine step of household introduction, and community information should be diversified beyond mobilisers [8, 10]. Lastly, supervisory spot-checks should be targeted regionally and, for confidentiality, at interviews with adolescent participants, consistent with the monitoring responsibilities set out in WHO operational guidance [5, 28].

Conclusion

Independent monitoring of CAMPHIA 2024–2025 shows that the obligations protecting participants directly were largely met. Confidentiality was near-universal, consent procedures were complied with in more than nine cases in ten, and the elements defining the research act — its objectives, the blood draw,

the voluntary nature of participation — were communicated to almost everyone. On the substance of participant protection, the survey performed well.

The shortfalls were concentrated elsewhere, and they share a common character. What was least consistently delivered was not consent but its administrative surroundings: how to reach the research team, what compensation participants were entitled to, and visible proof that the survey was authorised and ethically approved. Roughly one participant in three was shown the ethical clearance. None of this reflects a regulatory failure — approval was obtained and documented — but where a national survey collects blood for HIV testing in people's homes, visible proof of mandate is what distinguishes an approved survey from unaccredited data collection. That is a matter of trust, and trust is the resource on which the next survey round will draw.

Three implications follow. First, the information gap is narrow and therefore correctable: a compulsory closing checklist covering compensation and team contact details would address most of it, and non-textual materials would serve a population in which two fifths have primary schooling or none. Second, because compliance varied between regions without a consistent gradient — the strongest region for information was the weakest for consent — supervision should be targeted region by region rather than delivered as uniform retraining. Third, the residual confidentiality signal concerned adolescent girls, for whom private interview space within the household is hardest to secure, and warrants specific supervisory attention.

More broadly, this study demonstrates that participant-side ethical performance can be measured rather than assumed. A short-structured instrument, administered by an independent team shortly after the survey visit and analysed under pre-specified coding rules, yielded quantified and disaggregated compliance estimates within a five-week window. Ethics committees in the region consistently identify monitoring of ongoing research as their principal unmet capacity; this approach offers one practical and low-cost way of meeting it. Embedding such monitoring in future PHIA rounds and other national surveys would convert ethical compliance from a matter of prior approval into one of verified practice.

Abbreviations

CAMPHIA
Cameroon Population-based HIV Impact Assessment
EA
Enumeration Area
ECI
Ethical compliance indices
HIV
Human Immunodeficiency Virus
IQR
Interquartile Range

PHIA
Population-based HIV Impact Assessment

Declarations

Ethical considerations

This study was conducted in accordance with the principles of the Declaration of Helsinki and national regulations. Ethical approval was obtained from the National Ethics Committee for Human Health Research in Cameroon (reference N°2024/14/1757/CE/CNERSH/SP). Written informed consent was obtained from all participants. Confidentiality was strictly maintained by removing all personal identifiers, and anonymised datasets were used for analysis to ensure the protection of participants' privacy.

Consent for publication

Not applicable.

Availability of data and materials

All relevant data are within the manuscript and its Supporting Information files.

Supplementary File

Supplementary File 1: Individual-Level Index Scores and Reliability Assessment (.docx)

Supplementary File 2. CAMPHIA Monitoring_Questionnaire

Competing interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Authors' contributions

JN, JPYAN, and **FNT** conceptualized the study, designed the methodology, oversaw data collection, analysed the data, drafted the manuscript, contributed to interpretation of the results, critically reviewed the manuscript, and approved the final version for submission.

FAN, RKD, WNY, MB, CDT, RKT and **EADS** contributed to conceptualize the study, designed the methodology, drafted the manuscript, contributed to interpretation of the results, critically reviewed the

manuscript, and approved the final version for submission.

JA and **ACZKB** contributed to conceptualize the study, designed the methodology, drafted the manuscript, contributed to interpretation of the results, critically reviewed the manuscript, and approved the final version for submission, study administration.

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Figures

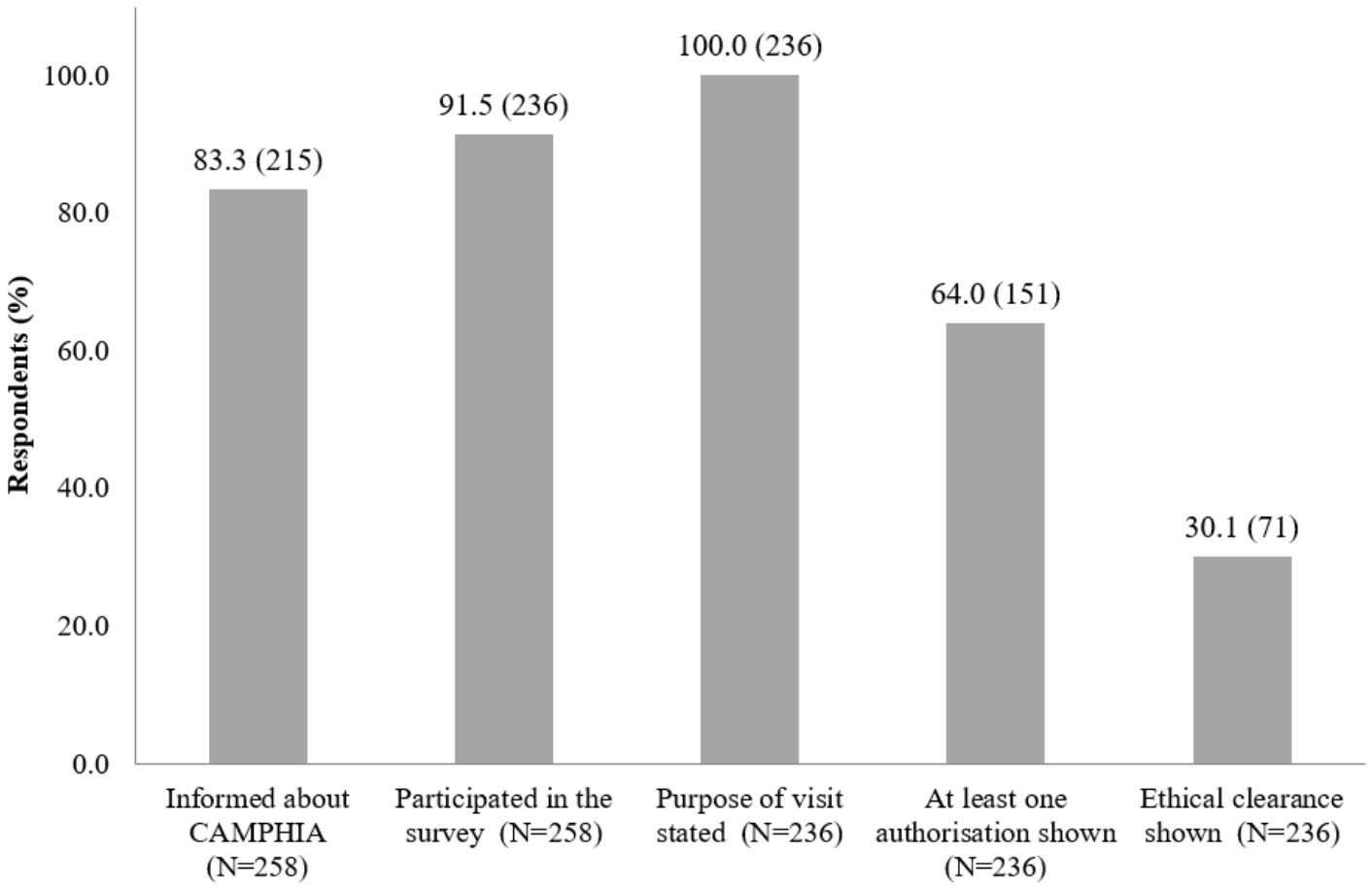


Figure 1

Governance: from community information to ethical clearance

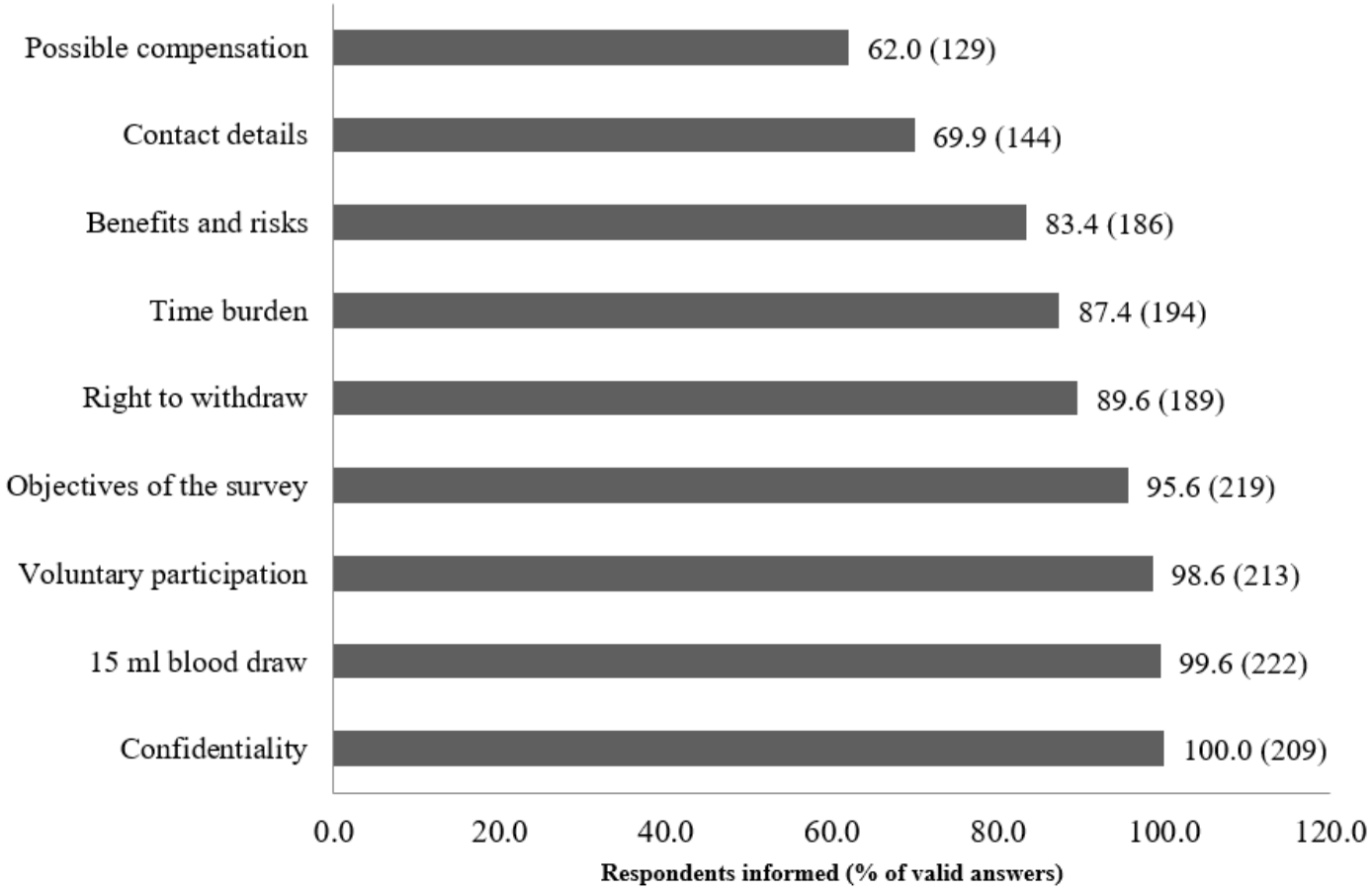


Figure 2

Coverage of the nine information items (ECI-1)

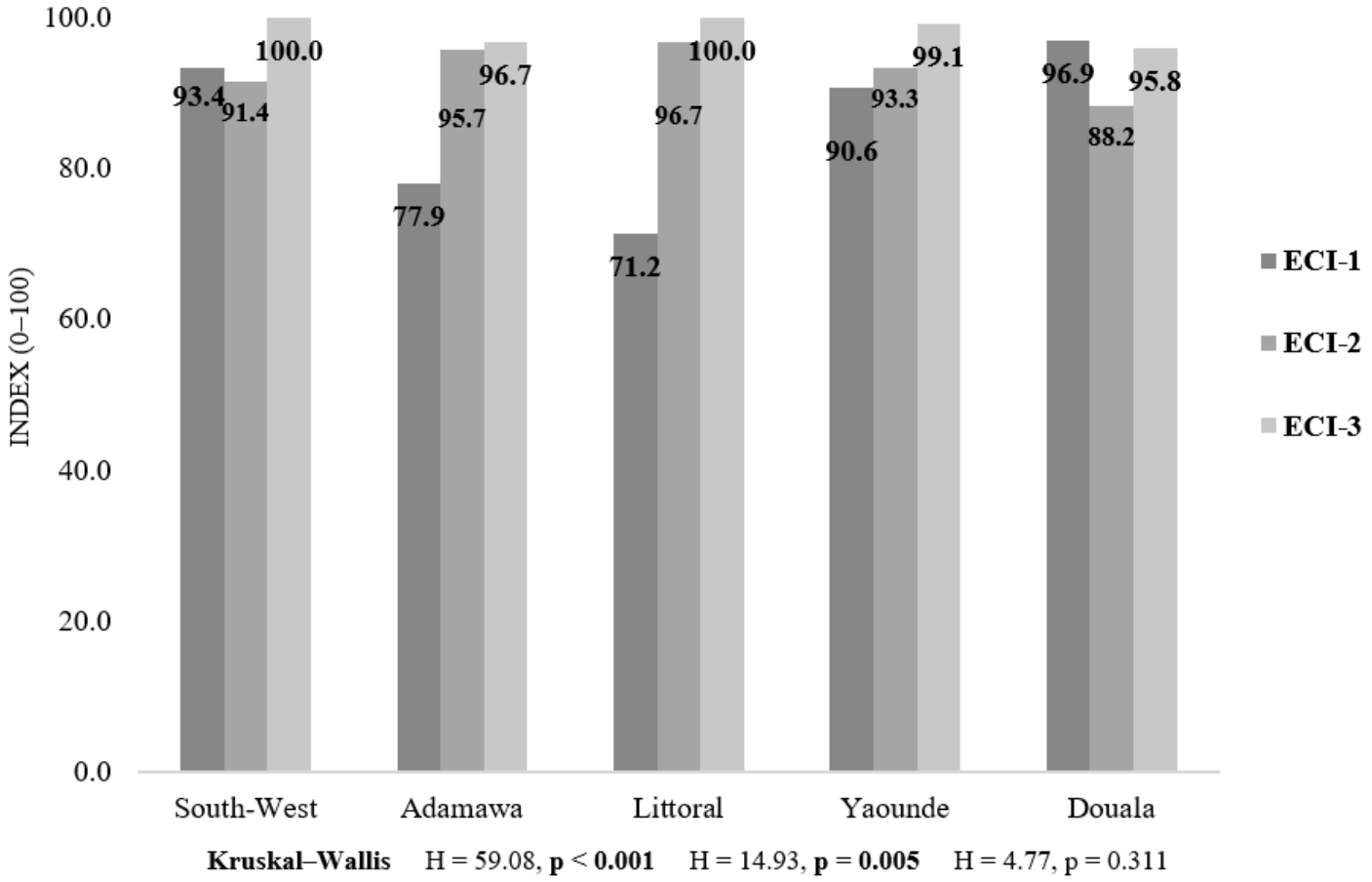


Figure 3

Ethical compliance indices by region

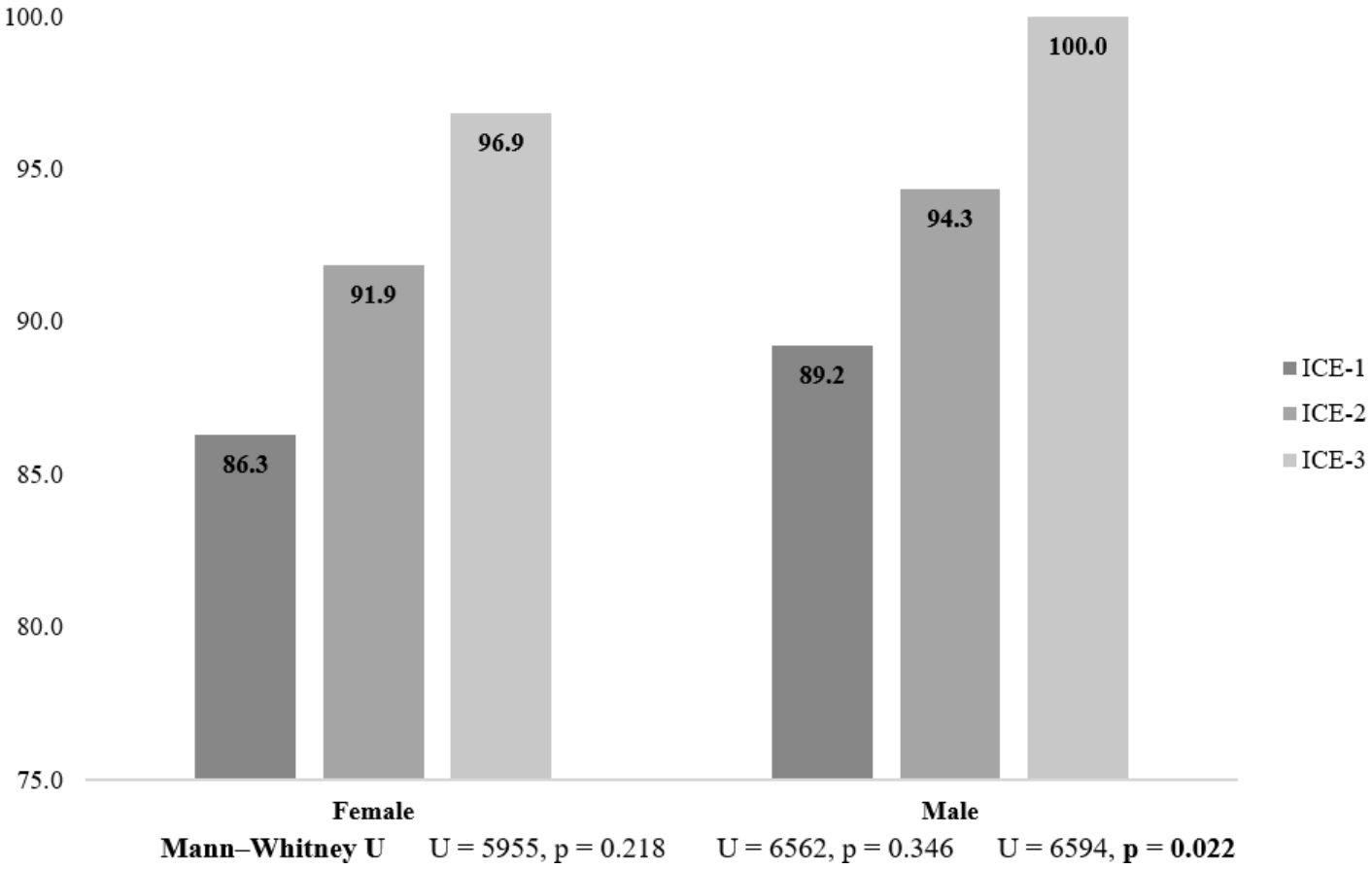


Figure 4

Ethical compliance indices by sex

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- CAMPHIAMonitoringQuestionnaire.docx
- SupplementaryFileIndividualLevelIndexScoresandReliabilityAssessment.docx
- DatabaseCAMPHIA2024Monitoring.xlsx