



Psychometric Evaluation of the Chinese Version of the Informed Consent Process Scale



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Background

- ◆ Informed consent is essential for the ethical conduct of clinical research and is a culturally sensitive issue.
- ◆ In the existing literature, a measurable Chinese version of the scale to evaluate the informed consent process has not been explored.

Objective

- ◆ To develop and psychometrically test the Chinese version of the Informed Consent Process Scale (ICPS) for the clinical participants.

Methods

- ◆ The subjects were recruited from three hospitals located in northern, middle, and southern Taiwan.
- ◆ Data were collected from the subjects who had experienced signing research informed consent forms within the previous three years and aged over 20.
- ◆ A cross-sectional survey was administered followed by an exploratory factor analysis (EFA).

Results

- ◆ The instrument was composed of a total of 24 items, but one of these items was an open-ended question, which was not included in the quantitative analysis.
After conducting EFA, 3 items (i.e., item 4, item 5 and item 21) were deleted due to their factor loadings < .5.
The ICPS is composed of 3 factors with 20 items showing evidence of acceptable reliability and validity.
- ◆ Three major factors were found (Table 1):
Factor 1 — Understanding of the research
Factor 2 — Trust and confidence
Factor 3 — Doubt and uncertainty
- ◆ The total variance is 52.954 with Cronbach's α of .917.

Conclusion

- ◆ The psychometric results indicated good internal consistency and validity for this newly constructed instrument.
- ◆ The study suggested conducting a confirmatory factor analysis (CFA) to further test the construct validity.

Table 1. Factors and item loadings in ICPS-CV (N = 375).

Item ^a	Factor loading			Variance (%)	Cronbach's α
	Factor 1	Factor 2	Factor 3		
Factor 1: Understanding of the research				26.763	.925
7. understand the consent document	.759	.210	.144		
12. The researcher well explained to me	.713	.373	.164		
14. Adequate time to complete the research	.702	.362	.138		
9. Know well about the research	.695	.320	.100		
10. Understand the risks of the research	.693	.146	.087		
2. Adequate time for decision making	.634	.337	.106		
11. Assistance provided when questions occurred	.620	.431	.143		
8. I am well-informed on the research	.599	.302	.147		
3. Confidential is assured	.587	.362	.089		
18. Informed decision	.581	.425	.247		
Factor 2: Trust and confidence				16.817	.865
15. Friendly researchers	.442	.658	.104		
16. I have a good deal of faith in the medical environment where the research took place	.363	.622	.201		
6. Easy and comfortable atmosphere	.401	.601	.183		
24. Be able to make a right decision	.293	.589	.186		
13. Professional researcher	.542	.568	.170		
23. Researchers are helpful with any questions occurred	.215	.538	.078		
Factor 3: Doubt and uncertainty				9.374	.713
19. The decision is difficult to make	-.001	.211	.707		
20. Having second thought about my decision	.107	.187	.620		
22. Uncertainty	.232	-.013	.591		
17. Researchers do not explain everything	.082	.071	.531		
Total				52.954	.917