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Cultural adaptation of *The Process and Quality of Informed Consent* instrument for Brazilian Portuguese

Adaptação cultural do instrumento *The Process and Quality of Informed Consent* para o português brasileiro

Adaptación cultural del instrumento *The Process and Quality of Informed Consent* al portugués de Brasil

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Objective: to present results of the cultural adaptation of The Process and Quality of Informed Consent to Brazilian Portuguese. **Methods**: descriptive, qualitative-quantitative, and cross-sectional research, developed in 2019, whose procedures were translations, consensual reviews, and equivalence assessment by a committee of judges, back-translation and semantic evaluation. **Results**: 6 judges with a doctorate degree, domain on the subject and knowledge of the English language and 12 patients from clinical studies, everyone over the age of 18, participated. The instrument The Process and Quality of Informed Consent was cross-culturally adapted, which it originally had and, after adaptation to Portuguese, kept 20 items. **Conclusion**: the adapted instrument was able to evaluate the informed consent process in Clinical Research and the interventions aimed at improving it.
Descritor: Consentimento Livre e Esclarecido; Tradução; Comparação transcultural.

Objetivo: apresentar resultados da adaptação cultural do *The Process and Quality of Informed Consent* para o português brasileiro. **Método**: pesquisa descritiva, quali-quantitativa e transversal, desenvolvida em 2019, cujos procedimentos foram de traduções, análises consensuais e avaliação de equivalência por um comitê de juízes, retrotradução e avaliação semântica. **Resultados**: participaram 6 juízes, com título de doutor, domínio sobre a temática e conhecimento do idioma inglês e 12 pacientes de estudos clínicos, maiores de 18 anos. Obteve-se o instrumento *O Processo e a Qualidade do Consentimento Informado* adaptado transculturalmente, que originalmente tinha e, após adaptação para o português, manteve 20 itens. **Conclusão**: o instrumento adaptado demonstrou poder avaliar o processo de consentimento informado em Pesquisas Clínicas e as intervenções destinadas a melhorá-lo.
Descriptors: Informed Consent; Translating; Cross-Cultural Comparison.

Objetivo: presentar los resultados de la adaptación cultural *The Process and Quality of Informed Consent* al portugués brasileño. **Método**: investigación descriptiva, cuali-cuantitativa y transversal, desarrollada en 2019, cuyos procedimientos fueron de traducciones, análisis consensuados y evaluación de equivalencia por un comité de jueces, retrotraducción y evaluación semántica. **Resultados**: Participaron 6 jueces, con título de doctor, dominio sobre la temática y conocimiento del idioma inglés y 12 pacientes de estudios clínicos, mayores de 18 años. Se obtuvo *O Processo e a Qualidade do Consentimento Informado* adaptado transculturalmente, que originalmente tenía y, tras la adaptación al portugués, mantuvo 20 ítems. **Conclusión**: el instrumento adaptado demostró poder avalar el proceso de consentimiento informado en las investigaciones clínicas y las intervenciones destinadas a mejorarlo.
Descriptores: Consentimiento informado; Traducción; Comparación Transcultural.
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INTRODUCTION

In Brazil, the denominations clinical research, clinical trial, or clinical study are used to define scientific investigations in which the researcher applies a treatment and observes its effects on an outcome. In other words, clinical research is research that involves humans, aiming to improve or identify new scientific knowledge about medicines, procedures, or methods to treat health problems and provide results of reach to society[1].

The purpose of producing knowledge through Clinical Research makes the researchers develop their studies with people who participate voluntarily to investigate the formulated hypothesis and objectives[1]. However, it is necessary to consider the damage that can be caused. Thus, regulations are needed to avoid excesses[2-3].

The definitions by regulatory bodies, including Federal Resolution n. 466/2012 of Brazil's National Health Council, show that Clinical Research uses investigative scientific procedures, having the human as the object of study. This perception and approach was reinforced in Brazil since 1996 with Resolution n. 196 of the National Health Council[3–5].

The history of research involving humans has followed questionable ways, such as the uncontrolled episodes of experimentation that occurred in the Nazi concentration camps, for example. From episodes like these, a long trajectory began, aiming to establish appropriate standards for the conduct of human studies. In Brazil, the Resolution 466/2012 incorporates principles of bioethics, such as autonomy, non-maleficence, beneficence, justice, and equity, to guarantee the individual and the collectivities their rights and duties. Section IV of this Resolution deals with the Informed Consent Process. It expresses that the process must be conscious, autonomous, free, and informed on the part of individuals or groups invited to participate in research[4].

The Informed Consent (IC) consists of an informative and voluntary document, which, after signed by the participant or his legal guardian, presents the consent to participate in the research. The IC must contain, in a clear and accessible way, the character and justification of the study, the procedures, the consequences, the risks, and the potential benefits for the study participant. The IC is one of the most important documents of the research protocol, which besides being mandatory for the professional practice and for research involving human participants, assures the respect to the individual's autonomy, as it guarantees their right to deny or accept the procedures to which they will be submitted, after previous explanation[3-6].

Obtaining IC has been the object of some studies for improvements in the process. Currently, four elements are considered for the validity of an Informed Consent: information provided, understanding, voluntaries, and consent[6–8].

The provision of information and understanding must be facilitated by an adequate communication process. Factors that have been emphasized in the human research[9-10].

The methods of document application and the quality of document preparation need to be improved to enhance the ability of participants to understand. Discussions on these issues contribute to increased interest in assessing the quality of the CI procurement process.

The development and application of psychometric tests of The Process and Quality of Informed Consent (P-QIC) instrument were intended to measure the quality of the consent process in two domains: information and communication[11]. The tool proves useful in determining the evaluation of strengths and weaknesses in the Informed Consent Process. This helps researchers to develop and test interventions to improve the Informed Consent Process.[11].

Thus, this study aims to present results of the cultural adaptation of The Process and Quality of Informed Consent (P-QIC) into Brazilian Portuguese.

METHODS

This is a qualitative-quantitative, descriptive, cross-sectional study that performed the cultural adaptation of the original instrument The Process and Quality of Informed Consent (P-QIC) into the Brazilian Portuguese. Authorization for cultural adaptation of the P-QIC in Brazil was granted by the main author of the instrument[11].

When there are validated and published instruments, it is advisable to translate and culturally adapt them instead of building a new instrument. The process of cultural adaptation transcends translation, because the content is adjusted to obtain semantic, idiomatic, cultural and conceptual equivalence of the items, allowing the application of the instrument in individuals belonging to different cultural contexts[12-18].

The P-QIC was designed to observe whether the essential elements of information and communication are presented to clinical research participants, enabling volunteers to understand the relevance of their participation, the responsibilities, procedures, and purpose of the research in which they are involved.

The original version of the P-QIC is a five-point Likert-type instrument consisting of 20 items, of which 14 are Essential Information Elements and 6 are Essential Informed Consent Communication Elements. The total score ranges from 40 to 100, with higher scores indicating better quality. The following scores can be calculated: total for the Informed Consent Process, for the Essential Elements of Information, and for the Essential Elements of Communication. These can be converted into percentages[11].

The references[18-20], that guided the methodology adopted in this study have a cross-cultural approach, which values the adaptation of instruments for other cultural contexts, considering the relevance of the concepts and the domains of the new culture.

Thus, the following steps[15-17] were followed for the cultural adaptation of the P-QIC: 1) translation of the P-QIC tool into Brazilian Portuguese, resulting in the first Consensus Brazilian Portuguese Version; 2) assessment of the first consensual Brazilian Portuguese version by the Judges Committee and obtaining the second consensual Brazilian Portuguese version; 3) reverse translation and comparison with the original version of the instrument, obtaining the third consensual Brazilian Portuguese version; 4) semantic assessment of the items, resulting in the fourth consensual Brazilian Portuguese version; 5) pre-test and obtaining the final Brazilian Portuguese version. If the Judge's Committee understands that the tool is clear and easy to understand, it is not necessary to apply the pre-test[16]. It is worth mentioning that the reverse translation must be done after evaluation by the Judges Committee to avoid changes in meaning between the Brazilian Portuguese version and the original[18].

The data collection steps took place between the months of June to December 2019.

The cultural adaptation stage, characterized by consensual analyses and assessment of the equivalence of the translations, was carried out online. The participants were professionals who made up the Committee of Judges with a minimum doctoral degree, knowledge of the subject matter, and knowledge of the English language.

The stage related to the analysis and semantic validation of the P-QIC was carried out face-to-face at the Núcleo de Estudos Clínicos (NEC) of the Universidade Federal do Triângulo Mineiro, whose main activity is to conduct national and international multicenter clinical trials in medical specialties such as cardiology, endocrinology, and oncology, among others. In this phase of the study, patients from the NEC were invited as research participants[12], by means of non-probabilistic sampling.

All participants were submitted to the application of the Informed Consent Form (ICF) so that they could be inserted in the studies called clinical trials. This study was submitted and approved by the Research Ethics Committee, Opinion 3.426.346, and can be accessed by Protocol CAAE: 15724219.4.0000.5154.

RESULTS

In the first stage of the study, the Judges Committee was composed of 6 professionals with a mean age of 42.16 ± 5.88 years and 20.16 ± 8.51 years of graduation time, with degrees in Languages (Portuguese/English), Nursing, Nutrition, Physiotherapy and Biological Sciences.

The representatives from Nursing, Nutrition and Physiotherapy had experience in methodologies of Cross-Cultural Adaptation of Instruments. Two participants on the Committee had degrees in Biological Sciences and extensive experience in Clinical Research. Thus, the Judges Committee had a multidisciplinary profile, with professionals representing several Brazilian regions and with domain about the methodology and theme addressed.

In the second stage, the 12 participants were patients of the Núcleo de Estudos Clínicos (NEC). These participants were 50% female and 50% male, 50% retired, 25% self-employed, and 8.33% representing the professions of merchant, janitor, and bricklayer, respectively. Their ages ranged from 48 to 66 years, the average being 57.6 ± 6.89 years. They came from different places, 58.33% from Uberaba-MG and 11.66% from Cametá-PA, Ceres-GO, Ituiutaba-MG, Mesquita-MG, and Patos de Minas-MG. When considering marital status, 58.33% were married/cohabiting, 25% divorced/separated, and 16.67% single. Among the participants, 66.67% had attended elementary school, and 33.33% had attended secondary school. According to the income ranges filled out in the questionnaire of sociodemographic and economic characterization, 58.33% had income in the range of 0 - 1,300.00 Reais, and on average 1.5 ± 0.57 persons survived on this. There were 16.66% of participants in the range 1,301 - 2,000.00 Reais, with 5 ± 1.41 people inserted in this expenditure and 25% were in the range 2,001.00 - 9,000.00 Reais, with 2.66 ± 0.57 making up the consumers of this income.

For this study, the following phases were considered: translation of the P-QIC into Brazilian Portuguese and the first version of the instrument in Portuguese; assessment by the Judges Committee and the second consensual Brazilian Portuguese version; semantic assessment of the items and obtaining the final version in Brazilian Portuguese; reverse translation, comparison with the original version of the P-QIC and the third version of the instrument in Brazilian Portuguese.

Translation of the P-QIC into Brazilian Portuguese and the first version of the instrument in Portuguese

The original version of the P-QIC was translated into Brazilian Portuguese by two Brazilians proficient in English. The translators produced a Portuguese version separately, which was called Brazilian Portuguese Version 1 (BPV1) and Brazilian Portuguese Version 2 (BPV2). The researchers and translators compared the two translated versions (BPV1 and BPV2) and produced the version called Brazilian Portuguese Consensus Version 1 (BPCV1), as shown in Table 1.

Table 1. Translation of The Process and Quality of Informed Consent (P-QIC) into Brazilian Portuguese and the first version of the instrument in Portuguese, Uberaba, MG, 2019.

Items	Versions	
	OV*	Rate each of the following observations as 5 (done well), 4 (done), 3 (done poorly), 2 (not done) or 1 (not applicable).
	BPV1	Classifique cada uma das observações a seguir como 5 (bem feito), 4 (feito), 3 (mal feito), 2 (não foi feito) ou 1 (não se aplica).
	BPV2	Classifique cada uma das seguintes observações como 5 (bem feito), 4 (feito), 3 (mal feito), 2 (não foi feito) ou 1 (não se aplica)
	BPCV1	Classifique cada uma das observações como 5 (bem feito), 4 (feito), 3 (mal feito), 2 (não foi feito) ou 1 (não se aplica).
1	OV*	Greets and shows interest in the participant as a person.[a]
	BPV1	Cumprimenta e demonstra interesse no participante como pessoa.[a]
	BPV2	Cumprimenta e mostra interesse no participante como pessoa.[a]
	BPCV1	Cumprimenta e demonstra interesse pelo participante como pessoa.[a]
2	OV*	Uses language that is easy to understand; avoids medical jargon.[a]
	BPV1	Usa linguagem fácil de entender; evita o jargão médico.[a]
	BPV2	Usa uma linguagem fácil de entender; evita jargões médicos.[a]
	BPCV1	Usa linguagem fácil de entender; evita os termos médicos.[a]
3	OV*	Provides information regarding why the participant was selected for the study.[b]
	BPV1	Proporciona informação sobre por que o participante foi selecionado para o estudo.[b]
	BPV2	Fornece informação sobre por que o participante foi selecionado para o estudo.[b]
	BPCV1	Informa o porquê o participante foi selecionado para o estudo.[b]
4	OV*	Provides information about the scientific purpose of the study.[b]
	BPV1	Proporciona informação sobre o propósito científico do estudo.[b]
	BPV2	Fornece informação sobre o objetivo científico do estudo.[b]
	BPCV1	Informa o objetivo científico do estudo.[b]
5	OV*	Provides step-by-step information about the study procedures.[b]
	BPV1	Proporciona informação passo a passo sobre os procedimentos do estudo.[b]
	BPV2	Fornece informação passo a passo sobre os procedimentos do estudo.[b]
	BPCV1	Informa passo a passo os procedimentos do estudo.[b]
6	OV*	Provides information about the risks, discomforts, and side effects that may occur as part of the study.[b]
	BPV1	Proporciona informação sobre os riscos, desconfortos, e efeitos colaterais que podem ocorrer como parte do estudo.[b]
	BPV2	Fornece informação sobre os riscos, desconfortos, e efeitos colaterais que podem ocorrer como parte do estudo.[b]
	BPCV1	Informa sobre os riscos, desconfortos e efeitos colaterais decorrentes da participação no estudo.[b]
7	OV*	Provides information about the benefits of participation.[b]
	BPV1	Proporciona informação sobre os benefícios da participação.[b]
	BPV2	Fornece informação sobre os benefícios da participação.[b]
	BPCV1	Informa os benefícios da participação no estudo.[b]
8	OV*	Specifies the duration of study participation.[b]
	BPV1	Especifica a duração da participação no estudo.[b]
	BPV2	Especifica a duração da participação no estudo.[b]
	BPCV1	Especifica a duração da participação no estudo.[b]
9	OV*	Discusses how research-related costs will be covered.[b]
	BPV1	Discute como os custos relacionados à pesquisa serão cobertos.[b]
	BPV2	Discute como os custos relacionados com a pesquisa serão cobertos.[b]
	BPCV1	Discute como as despesas dos participantes, decorrentes do estudo, serão cobertas.[b]
10	OV*	Explains alternatives to participation in the study.[b]
	BPV1	Explica alternativas para a participação no estudo.[b]
	BPV2	Explica as alternativas para a participação no estudo.[b]
	BPCV1	Detalha os métodos para a participação no estudo.[b]
11	OV*	Discusses the difference between the research study and standard treatment.[b]
	BPV1	Discute a diferença entre o estudo de pesquisa e o tratamento padrão.[b]
	BPV2	Discute a diferença entre o estudo de pesquisa e o tratamento padrão.[b]

	BPCV1	Discute a diferença entre o estudo e o tratamento padrão.[b]
12	OV*	Makes clear that participation is voluntary and avoids coercive pressure.[b]
	BPV1	Deixa claro que a participação é voluntária e evita pressão coerciva.[b]
	BPV2	Deixa claro que a participação é voluntária e evita pressão coerciva.[b]
	BPCV1	Deixa claro que a participação é voluntária e evita coação.[b]
13	OV*	Provides information about how to terminate participation[b]
	BPV1	Proporciona informação sobre como encerrar a participação.[b]
	BPV2	Fornece informação sobre a remuneração pela participação.[b]
	BPCV1	Informa sobre como encerrar a participação no estudo.[b]
14	OV*	Provides information about remuneration for participation[b]
	BPV1	Proporciona informação sobre a remuneração pela participação.[b]
	BPV2	Fornece informação sobre a remuneração pela participação.[b]
	BPCV1	Informa sobre a remuneração pela participação no estudo.[b]
15	OV*	Describes how confidentiality of the data will be maintained/protected.[b]
	BPV1	Descreve como a confidencialidade dos dados será mantida ou protegida.[b]
	BPV2	Descreve como a confidencialidade dos dados será mantida ou protegida.[b]
	BPCV1	Descreve como a confidencialidade dos dados será mantida ou protegida.[b]
16	OV*	Provides institutional review board and investigator contact information.[b]
	BPV1	Proporciona informação sobre o comitê de revisão institucional e os contatos dos pesquisadores.[b]
	BPV2	Fornece informação sobre o grupo de revisão institucional e de contato dos pesquisadores.[b]
	BPCV1	Informa sobre o comitê de ética institucional e os contatos dos pesquisadores.[b]
17	OV*	Stops and answers questions during the interaction; provides specific and complete answers to questions or concerns.[a]
	BPV1	Para e responde perguntas durante a interação; proporciona respostas específicas e completas em relação a questões ou preocupações.[a]
	BPV2	Para e responde perguntas durante a interação; fornece respostas específicas e completas a questões ou preocupações.[a]
	BPCV1	Para e responde perguntas durante a interação; fornece respostas específicas e completas a questões ou preocupações.[a]
18	OV*	Checks for participant understanding of information (e.g., asks participant to explain the study in their own words).[a]
	BPV1	Verifica o entendimento da informação pelo participante (por exemplo, pede para os participantes explicarem o estudo com suas próprias palavras).[a]
	BPV2	Verifica o entendimento da informação pelo participante (por exemplo, pede para os participantes explicarem o estudo em suas próprias palavras).[a]
	BPCV1	Verifica se o participante entendeu a informação (por exemplo, pede para os participantes explicarem o estudo com suas palavras).[a]
19	OV*	Assures that the participant reads or is read aloud the consent form before signing.[a]
	BPV1	Garante que o participante leia ou que alguém leia em voz alta para ele o termo de consentimento antes que ele o assine.[a]
	BPV2	Garante que o participante leia em voz alta o termo de consentimento, ou que alguém leia para ele, antes de assiná-lo.[a]
	BPCV1	Garante que o participante leia ou que alguém leia em voz alta para ele o termo de consentimento antes de assiná-lo.[a]
20	OV*	Offers the participant the opportunity to accept, decline, or take more time to decide about enrollment in the study.[a]
	BPV1	Oferece ao participante a oportunidade de aceitar, recusar ou pensar por mais tempo para decidir sobre o cadastro no estudo.[a]
	BPV2	Oferece ao participante a oportunidade de aceitar, recusar ou levar mais tempo para decidir sobre a inscrição no estudo.[a]
	BPCV1	Oferece ao participante a oportunidade de aceitar, recusar ou pensar por mais tempo para decidir sobre a participação no estudo.[a]
	OV	[a]Essential element of information for informed consent. [b]Essential element of communication.
	BPCV1	[a] Elemento essencial de comunicação. [b] Elemento essencial de informação.

Note: OV = Original Version[10]; BPV1 = Brazilian Portuguese Version 1; BPV2 = Brazilian Portuguese Version 2; BPCV1 = Brazilian Portuguese Consensual Version 1.

Assessment by the Judges Committee and the second consensual Brazilian Portuguese version

The Judges Committee performed the face and content validations, as well as the semantic, idiomatic, cultural, and conceptual equivalences of the items of the Brazilian Portuguese Consensual Version 1 (BPCV1) in relation to the Original Version of the P-QIC.

The committee members performed the face and content validations and analyzed the equivalences between the versions, making, in case of disagreement with the translation, suggestions for wording compatible with Brazilian Portuguese. After the assessment performed individually by each committee member, the analyses of the BPCV1 were forwarded to the researchers, who consolidated the data and forwarded them again to the Judges Committee for consensus. The changes were approved when 80% or more of the judges agreed with them. From this step, the changes made by the Judges Committee were obtained for the creation of the Brazilian Portuguese Consensual Version 2 (BPCV2) (Table 2).

Table 2. Changes made by the Committee of Judges to create the Brazilian Portuguese Consensual Version 2 (BPCV2) of The Process and Quality of Informed Consent Instrument (P-QIC), Uberaba, MG, 2019.

Title: O Processo e a Qualidade do Consentimento Informado (P-QIC)		
Item	Brazilian Portuguese Consensual Version 1	Changes by the Committee of Judges (BPCV2)
Response Options	Classifique cada uma das observações como: 5 (bem feito), 4 (feito), 3 (mal feito), 2 (não foi feito) ou 1 (não se aplica).	***Analise*** cada uma das observações como: 5 ***(muito bom)***, 4 ***(bom)***, 3 ***(razoável)***, 2 ***(ruim)*** ou 1 ***(não se aplica)***.
3	Informa o porquê o participante foi selecionado para o estudo.[b]	Informa ***o motivo pelo qual*** o participante foi selecionado para o estudo.[b]
5	Informa passo a passo os procedimentos do estudo.[b]	Informa ***o*** passo a passo ***dos*** procedimentos do estudo.[b]
6	Informa sobre os riscos, desconfortos e efeitos colaterais decorrentes da participação no estudo.[b]	Informa sobre os riscos, desconfortos e efeitos colaterais ***que podem ocorrer pela*** participação no estudo.[b]
9	Discute como as despesas dos participantes, decorrentes do estudo, serão cobertas.[b]	Discute como ***os custos relacionados à pesquisa*** serão ***pagos***. [b]
10	Detalha os métodos para a participação no estudo.[b]	***Explica como ocorrerá*** a participação no estudo.[b]
11	Discute a diferença entre o estudo e o tratamento padrão.[b]	Discute a diferença entre ***o tratamento proposto no estudo*** e o tratamento padrão.[b]
12	Deixa claro que a participação é voluntária e evita coação.[b]	Deixa claro que a participação é voluntária e evita ***imposição***. [b]
15	Descreve como a confidencialidade dos dados será mantida ou protegida.[b]	Descreve como a confidencialidade dos dados será mantida ***e/ou*** protegida.[b]
16	Informa sobre o comitê de ética institucional e os contatos dos pesquisadores.[b]	Informa ***os contatos do*** comitê de ética institucional e dos pesquisadores.[b]
17	Para e responde perguntas durante a interação; fornece respostas específicas e completas a questões ou preocupações.[a]	Para e responde ***a*** perguntas durante a interação; ***dá*** respostas específicas e completas a questões ou preocupações.[a]
	[a] Elemento essencial de comunicação [b] Elemento essencial de informação	[c] Elemento essencial de comunicação [i] Elemento essencial de informação

Reverse translation, comparison with the original version of the P-QIC and the third version of the instrument in Brazilian Portuguese

The BPCV2 was directed to two translators residing in Brazil and with English as their mother tongue, who were different from those who performed the first phase of the translation. Initially, they were not informed about the objectives of the study. Individually, they did the reverse translation that resulted in the English 1 (EV1) and English 2 (EV2) versions.

After the translations (Table 3), an e-mail was sent to the respective translators responsible to present the original P-QIC instrument, to explain its proposal, and to emphasize the objectives of the study. Then, the two translators compared the reverse translation versions to define the Final English Version (FEV), together with the researchers, through electronic correspondence. Thus, the FEV was defined according to Table 3.

Table 3. Reverse translation of The Process and Quality of Informed Consent (P-QIC) Instrument, Uberaba, MG, 2019.

	English Versions 1 (EV1)	English Versions 2 (EV2)	Final English Versions (FEV)
	Analyze each of the observations as: 5 (Very good), 4 (Good), 3 (Reasonable), 2 (Poor) or 1 (Not applicable).	**Analyze each of the observations as:** 5 (Very good), 4 (Good), 3 (Reasonable), 2 (Poor) or 1 (does not apply).	**Rate each of the observations as:** 5 (Very good), 4 (Good), 3 (Reasonable), 2 (Poor) or 1(does not apply).
1	Greets and shows interest in the participant as a person.[c]	Greets and shows interest in the participant as a person.[c]	Greets and shows interest in the participant as a person.[c]
2	Uses easy to understand language; avoids medical terms.[c]	Uses language that is easy to understand; avoids medical terms.[c]	Uses language that is easy to understand; avoids medical terms.[c]
3	Informs why the participant was selected for the study.[i]	Informs the reason why the participant was chosen for the study.[i]	Informs the reason why the participant was chosen for the study.[i]
4	Informs the scientific purpose of the study.[i]	Informs the scientific objective of the study.[i]	Informs the scientific objective of the study.[i]
5	Informs the step-by-step study procedures.[i]	Informs the step-by-step of the study's procedures.[i]	Informs the step-by-step of the study's procedures.[i]
6	Informs about the risks, discomforts, and side effects that may occur from participating in the study. [i]	Informs the risks, discomforts and side effects that may occur by participating in the study.[i]	Informs the risks, discomforts and side effects that may occur by participating in the study.[i]
7	Informs the benefits of participating in the study.[i]	Informs the benefits of participating in the study.[i]	Informs the benefits of participating in the study.[i]
8	Specifies the duration of study participation.[i]	Specifies the duration of participating in the study.[i]	Specifies the duration of study participation.[i]
9	Discusses how research-related costs will be paid.[i]	Discusses how the costs related to the study will be paid for.[i]	Discusses how the costs related to the study will be paid for.[i]
10	Explains how participation in the study will occur.[i]	Explains how participation in the study will take place.[i]	Explains how participation in the study will take place.[i]
11	Discusses the difference between the treatment proposed in the study and the standard treatment.[i]	Discusses the difference between the treatment proposed in the study and standard treatment.[i]	Discusses the difference between the treatment proposed in the study and standard treatment.[i]

12	It is made clear that participation is voluntary and avoids imposition.[i]	Makes it clear that participation is voluntary and avoids exposure.[i]	It is made clear that participation is voluntary and avoids imposition.[i]
13	Informs about how to terminate participation in the study.[i]	Informs about how to cease participation in the study.[i]	Informs about how to terminate participation in the study.[i]
14	Informs about the remuneration for participating in the study.[i]	Informs about remuneration for participating in the study.[i]	Informs about remuneration for participating in the study.[i]
15	Describes how data confidentiality will be maintained and/or protected.[i]	Describes how data confidentiality will be maintained and/or protected.[i]	Describes how data confidentiality will be maintained and/or protected.[i]
16	Informs the contacts of the institutional ethics committee and the researchers.[i]	Informs the contact information of the institutional ethics committee and researchers.[i]	Informs the contact information of the institutional ethics committee and researchers.[i]
17	Stops and answers questions during the interaction; gives specific and complete answers to questions or concerns.[c]	Stops and answers question during the interactions; gives specific and full answers to questions or concerns.[c]	Stops and answers questions during the interaction; gives specific and complete answers to questions or concerns.[c]
18	Checks if the participant understood the information (for example, asks participants to explain the study in their own words).[c]	Checks whether participant understood the information (for example, asks participants to explain the study in their own words).[c]	Checks whether participant understood the information (for example, asks participants to explain the study in their own words).[c]
19	Ensures that the participant reads, or someone reads aloud, the consent form before signing it.[c]	Ensures that the participant reads the term of consent or has someone read it out loud to them before signing it.[c]	Ensures that the participant reads the term of consent or has someone read it out loud to them before signing it.[c]
20	Gives the participant the opportunity to accept, decline or think longer to decide on participating in the study.[c]	Offers the participant the opportunity to accept, refuse or take some more time to decide about participation in the study.[c]	Offers the participant the opportunity to accept, refuse or take some more time to decide about participation in the study.[c]
	[c] Essential element of communication. [i] Essential element of information.	[c] Essential element of communication. [i] Essential element of information.	[c] Essential element of communication. [i] Essential element of information.

The presentation of the result of the FEV was forwarded to the main author of the P-QIC to verify her agreement with the version. Thus, the Brazilian Portuguese Version Consensual 3 (BPCV3) resulted.

Semantic assessment of the items and obtaining the final version in Brazilian Portuguese

This step verified the problems of understanding of the P-QIC questions by the target population. The items of the BPCV2 were adjusted to compose the Brazilian Portuguese Consensual Version 3 (BPCV3). For the semantic analysis, the present study used a questionnaire proposed by researchers from the DISABKIDS[24] group. This questionnaire is composed of a Generic Measure and a Specific Modules. The first part presents seven questions that assessed the importance of the instrument, the degree of difficulty to answer the items, and contemplated the possibility of modification in the instrument applied. The second part assessed the translated and adapted instrument. It analyzed its importance and understanding by the respondent, the clarity and agreement with the answers, the way the respondent would express the item, and the meaning of each item for themselves.

Twelve clinical research participants were selected by non-probability sampling and necessarily submitted to the application of the ICF at the NEC. Upon accepting the invitation, they signed the ICF, answered the questionnaire of sociodemographic and economic characterization and the BPCV3 of the P-QIC instrument, and then the Semantic Evaluation questionnaire. All of them answered the Generic Measures.

The Generic Measures were divided into four respondents for each subset of items for effective participation. Thus, as the P-QIC instrument is made up of the domains, Essential Elements of Communication (with 6 items) and Essential Elements of Information (with 14 items); the items referring to the Essential Elements of Communication (1, 2, 17, 18, 19 and 20) had 4 respondents for the subset and the items of the Essential Elements of Information were divided into two subsets with 7 items (3, 4, 5, 6, 7, 8, 9 and 10, 11, 12, 13, 14, 15, 16), with 4 respondents for each subset.

In the overall assessment, 41.66% of the participants considered the P-QIC instrument very good and 58.34% good. When analyzing the comprehension of the questions, 83% evaluated that they were easy to understand and 16.67% considered them sometimes difficult to understand. The respondents, who considered the questions sometimes difficult to understand, mentioned that the difficulty was in relation to the meaning of some words that they did not know and, therefore, could not identify their meanings. These were discussed and clarified. Regarding the answer options for each item of the P-QIC instrument, 83% had no difficulty using them, and 16.67% reported some difficulty. It was possible to notice that the difficulty was not in choosing the answer option, but in having to go back to the reading of the item to select the appropriate response.

When asked about the importance of the items for the status of Clinical Research Participants, 100% rated them as very important.

About changing something in the instrument, 91.67% of the participants answered that they would not like to, and 8.33% answered yes. They mentioned that the P-QIC presents too much information, being extensive and time-consuming to fill out. They asked about the possibility of making it more compact. However, the instrument contemplates the guidelines required by the Brazilian Federal Resolution n. 466/2012 for the Informed Consent Process.

Thus, it was decided not to change the instrument as the participant suggested. When asked if they would like to add anything to the questionnaire and about having any questions they did not want to answer, 100% of the participants made no suggestions and did not object to answering any of the items. In the specific semantic assessment, 100% of the respondents considered the items important for the condition of Clinical Research Participant, 66.67%

understood the items, and 33.3% were unaware of the meaning of any word present in the analyzed subset. Thus, Table 4 shows the Final Version of Brazilian Portuguese.

Table 4. Final Version of Brazilian Portuguese of The Process and Quality of Informed Consent (P-QIC) Instrument, Uberaba, MG, 2019.

O Processo e a Qualidade do Consentimento Informado (P-QIC)
Classifique cada uma das observações como 5 (Muito bom) 4 (Bom) 3 (Razoável) 2 (Ruim) 1 (Não se aplica)
Cumprimenta e demonstra interesse pelo participante como pessoa.[c]
Usa linguagem fácil de entender; evita termos médicos.[c]
Informa o motivo pelo qual o participante foi selecionado para o estudo.[i]
Informa o objetivo científico do estudo.[i]
Informa o passo a passo dos procedimentos do estudo.[i]
Informa sobre os riscos, desconfortos e efeitos colaterais que podem ocorrer pela participação no estudo.[i]
Informa os benefícios da participação no estudo.[i]
Especifica a duração da participação no estudo.[i]
Discute como os custos relacionados à pesquisa serão pagos.[i]
Explica como ocorrerá a participação no estudo.[i]
Discute a diferença entre o tratamento proposto no estudo e o tratamento padrão.[i]
Deixa claro que a participação é voluntária e evita ***forçar a decisão***.[i]
Informa sobre como encerrar a participação no estudo.[i]
Informa sobre ***o pagamento*** pela participação no estudo.[i]
Descreve como a confidencialidade dos dados será mantida e/ou protegida.[i]
Informa os telefones do comitê de ética institucional e dos pesquisadores.[i]
Para e responde a perguntas durante a interação; ***dá respostas a perguntas e preocupações***.[c]
Verifica se o participante entendeu a informação (por exemplo, pede para os participantes explicarem o estudo com suas próprias palavras).[c]
Garante que o participante leia, ou que alguém leia em voz alta para ele, o termo de consentimento antes de assiná-lo.[c]
Oferece ao participante a oportunidade de aceitar, recusar ou pensar por mais tempo para decidir sobre a participação no estudo.[c]
[c] Elemento essencial de comunicação. [i] Elemento essencial de informação.

DISCUSSION

This research followed the criteria pointed out in other studies[16-17,21-22], such as: selection of bilingual translators, production of the Brazilian Portuguese versions 1 and 2, as well as the consensus version, for better adaptation to the understanding of the Brazilian population, represented by the Clinical Research participants.

Analyzing the data in Table 1, we observe that there were representative choices in the use of words, expressions, and syntax for translation of the Brazilian Portuguese versions 1 and 2, as well as in the consensus version (BPCV1) made by the translators. Analyzing comparatively, it was observed:

- Lexical replacements: “demonstra” [demonstrate] and “mostra” [shows] (item 1); “proporciona informação” and “fornece informação” [provides information] to “informa” [informs] (items 3, 4, 5, 6, 13, 14, 16); “encerrar” [close] and “interromper” [stop] (item 13); “o cadastro”, “a inscrição” [register at] and “a participação” [to

participate] (item 20);

- Use or omission of (in)definite articles: “usa linguagem” [uses language] and “usa uma linguagem” [uses a language] (item 2); “explica alternativas” [explains alternatives] and “explica as alternativas” [explains the alternatives] (item 10);
- Use or not of plural: “jargão médico”, “jargões médicos” [medical jargon] to “termos médicos” [medical terms] (item 2);
- Performing the same translation in the items 8, 11, 12, 15.

For the production of the consensus version, the translators arrived at more synthetic, objective and adequate expressions to the terms of the Federal Resolution 466/2012 , as in item 20 “Oferece ao participante a oportunidade de aceitar, recusar ou pensar por mais tempo para decidir sobre a participação no estudo” [Offers the participant the opportunity to accept, refuse, or think longer to decide about study participation], that is, people are invited to “participar” [to participate], distinct discursive action of “cadastro” [registration] or “inscrição” [register at] in the study, and yet “Informa sobre o comitê de ética institucional e os contatos dos pesquisadores” [Informs about the institutional ethics committee and the researchers' contacts], that is, considering the literal translation the options presented were “comitê de revisão institucional” or “grupo de revisão institucional” [institutional review committee/group].

Regarding the changes presented in Table 2, the Judges' Committee suggested changes in 12 statements. The suggestions involved linguistic strategies by opting for simpler expressions, for example, “decorrentes” [resulting] by “que podem ocorrer” [that may occur] (item 6); “despesas” [expenses] by “custos” [costs], “cobertas” [covered] by “pagos” [paid] (item 9); “detalha os métodos para” [details the methods for] by “explica como ocorrerá” [explains how it will happen] (item 10); “coação” [duress] by “imposição” [imposition] (item 12). In the P-QIC structure, items are categorized as "a" and "b", "a" as "essential communication element" and "b" as "essential information element". The judges suggested the categorization as "c" to relate to "communication" and "i" to "information", thus making it easy to associate and correlate in the Brazilian Portuguese version.

In research[21-22], as in this study, they used the percentage of 80% as a parameter to make the proposed modifications suggested by the Committee of Judges consensual. In addition, they recommended the constitution of a multidisciplinary PhD with experience in the subject under study and/or in the methodology of cultural adaptation of measurement instruments. They considered that the process carried out virtually hinders the methodological path and that face-to-face meetings would be more effective. In this study, the virtual consensus and decisions

were successful, with the response time being an easily solved obstacle due to the degree of complexity of the instrument to be culturally adapted. The suggested adjustments sought to simplify the understanding of the items of the P-QIC instrument by the participants of Clinical Research, favoring the understanding by a many people.

As for the reverse translation, presented in Table 3, the translators proposed keeping the term "Rate" in the statement as in the original instrument, because it conveys the idea of "classificar". In addition, they suggest that in item 10 the meaning is different from the original, as in BPCV1. However, the way it is described is the one that best adapts to the requirements of the Federal Resolution n. 466, of December 12, 2012, of the National Health Council, for the Informed Consent Process[4].

Regarding semantic validation, related studies show that when subjects of the target population belonging to lower educational levels understand the items, consequently, the others will also understand[20] and that although the understanding of the ICF by the clinical research participant is essential, Brazilian studies on the subject are still scarce[6]. They identified that the best understanding of the texts of the ICFs is given by participants with higher levels of education and higher salaries. As the sample of this study fits the profile of lower income brackets and lower education levels, the relevance of a tool such as the P-QIC.

In this semantic validation stage, the division into subsets has proved to be efficient to assess the understanding of the items. These were presented to the groups, and they were asked to reproduce them. The item was correctly understood when it left no doubts in its reproduction. However, if the researcher has identified that the item was understood differently than it should have been, it was necessary to explain to the group what it meant.

Therefore, there were reformulations to express what was desired. In these issues, the DISABKIDS[24] semantic assessment tool contemplates the primary purpose of the study in question, and the distribution of the items in subsets with a restricted number of respondents favors effective participation. As the items contemplate the ethical and scientific regulatory norms of research involving human subjects, we realize the importance of the tool in semantic assessment (P-QIC) for the clarification of clinical research participants. The participants considered the answer options clear and in accordance with the questions. Some items received suggestions for reformulation:

- Item 12, “Deixa claro que a participação é voluntária e evita imposição” [Make it clear that participation is voluntary and avoid imposition] reported difficulty in understanding the word "imposição” [imposition]. After explanation, he suggested changing it to "sem ser forçado” [without being forced]. Thus, the researchers chose to

change it to "evita forçar a decisão" [avoids forcing the decision].

- Item 14, "Informa sobre a remuneração pela participação no estudo" [Informs about the remuneration for participation in the study], did not understand the word "remuneração" [remuneration]. When clarified, they suggested replacing it with "pagamento" [payment];
- Item 16, "Informa os contatos do comitê de ética institucional e dos pesquisadores" [Informs the institutional ethics committee and researchers' contacts], one respondent suggested changing it to "Informa os telefones do comitê de ética institucional e dos pesquisadores" [Informs the institutional ethics committee and researchers' phone numbers]. The researchers chose to comply, aiming for a better understanding and clarity of the instrument by the clinical research participants.
- Item 17, "Para e responde a perguntas durante a interação; dá respostas específicas e completas a questões ou preocupações" [Stops and answers questions during interaction; gives specific and complete answers to questions or concerns], the word "interação" [interaction] be replaced by "consulta" [appointment] and "questões" [questions] by "perguntas" [answers/issues, queries] and remove "específicas e completas" [specific and complete]. After discussion among the researchers, it was decided not to change the word "interação" [interaction], as the Informed Consent can be applied during the medical consultation or at another time scheduled for this process. The other suggestions were accepted, as they made the item more succinct and clearer for the target population.

The pre-test was not applied because BPCV3 maintained its equivalence in an applied situation, since the items of the tool were interpreted during the semantic evaluation process and adapted to the understanding of the target population. In addition, the tool has proved to be simple and easy to understand. The comprehension problems observed were solved by changing the wording of the items pointed out.

When rewriting, what each item meant to themselves, all participants described it as requested and used short, succinct sentences. In this way, it was perceived that there were no difficulties in interpreting the items. There were doubts about the meaning of some words, which were clarified before describing what the item meant to themselves.

CONCLUSION

The present study allowed the production of a culturally adapted instrument to evaluate the Informed Consent Process in a population of participants in Clinical Research.

Among the methodological limitations, it is recognized the need for application with a larger number of participants who will go through the process of application of ICFs from Clinical Research to validate its psychometric properties, to evidence the construct validity and reliability of the measures. Ideally, this application should focus on different regions of the country, to consider linguistic diversity and variation. Despite this need, the cultural adaptation of this instrument met the needs of the target audience and can be used by Brazilian Clinical Research centers to evaluate the Informed Consent Process.

Measurement instruments such as the P-QIC, adapted to Brazilian Portuguese, favor clinical practice by identifying gaps in essential communication and information elements of the informed consent process. Thus, scientific evidence and the quality of the informed consent process are favored, with emphasis on the care for the participant, the language used and the interaction for understanding, the methodological clarity, the time, and costs arising from the study, the confidentiality, and the freedom of choice.

Although the purpose of the instrument is focused on Clinical Research, it is observed that this instrument can be used for the analysis of the ICF application process in research in other areas such as Applied Social Sciences and Human Sciences. In addition, the P-QIC can be used for teaching new researchers through educational approaches in undergraduate and graduate courses; as well as criteria method for analyzing the quality of the ICF in research protocols by reporters of research ethics committees from institutions all over the country.

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