# Comprehension of informed consent in clinical research

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**Abstract**

The informed consent form (ICF) is a document which explicitly confirms the consent of a participant in a research project, and should contain all necessary information clarifying the study in which the subject intends to participate. This study evaluates the level of comprehension of an ICF signed by 146 volunteers using a self-administered instrument. The average age of the sample was 47.29 years, and there was a prevalence of women (67.2%), incomplete primary education (53.4%) and no private health care (93.2%). The mean score of correct answers of 146 respondents was 53.1%. There was no association between the percentage of correct answers and the variables of gender, age, education and time of response. There was a significant association between taking the ICF home and the percentage of correct answers. The average value of correct answers found was not acceptable and educational measures must be implemented, seeking an increase in comprehension and the safety of participants.

**Keywords:** Informed consent. Comprehension. Human experimentation.

**Resumo**

**Compreensão do termo de consentimento em pesquisa clínica**

O termo de consentimento livre e esclarecido (TCLE) é documento onde se explicita o consentimento do participante, contendo todas as informações necessárias para que seja elucidada a pesquisa da qual se propõe participar. O objetivo deste trabalho foi avaliar o nível de compreensão do TCLE assinado por 146 voluntários, utilizando instrumento de coleta de dados autoaplicável. A média de idade foi 47,3 anos, com prevalência de participantes do gênero feminino (67,2%), ensino fundamental incompleto (53,4%) e sem assistência privada de saúde (93,2%). A média de acertos foi 53,1%. Não houve associação entre o percentual de acerto e as variáveis gênero, idade, escolaridade e tempo de resposta. Houve associação significativa entre levar a via do TCLE para casa e o percentual de acerto. O valor médio de acertos evidenciou a necessidade de novas medidas educativas, buscando aumentar a compreensão e a segurança dos participantes.

**Palavras-chave:** Consentimento livre e esclarecido. Compreensão. Experimentação humana.

**Resumen**

**Comprensión del consentimiento informado en la investigación clínica**

El consentimiento libre, previo e informado (CLPI) es un documento en el cual se explicita el consentimiento del participante, conteniendo toda la información necesaria para la elucidación sobre la investigación en la cual se propone participar. El objetivo de esta investigación fue evaluar el nivel de comprensión del consentimiento informado firmado por 146 voluntarios utilizando un instrumento auto-aplicable para la recolección de datos. La edad promedio fue de 47,3 años, con prevalencia de participantes de género femenino (67,2%); educación primaria incompleta (53,4%) y sin cobertura privada de salud (93,2%). El promedio de aciertos de los 146 entrevistados fue de 53,1%. No hubo asociación entre el porcentaje de respuestas correctas y las variables de género, edad, educación y tiempo de respuesta. Hubo una asociación significativa entre la posibilidad de llevarse el consentimiento informado a la casa y el porcentaje de respuestas correctas. El valor promedio de aciertos encontrado destacó la necesidad de nuevas medidas educativas, buscando aumentar la comprensión y la seguridad de los participantes.

**Palabras-clave:** Consentimiento Informado. Comprensión. Experimentación humana.

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Research articles

The history of research involving human beings has taken perverse and doubtful paths, involving episodes of mysticism and cruelty: mass sterilization processes [1], medical experiences with prisoners of war [2], monitoring of untreated syphilitic men [3], etc. Nevertheless, in some moments, suitable standards were established for studies with humans, such as the *Nüremberg Code* [4] and the *Helsinki Declaration* [5]. The need to establish ethical and regulatory principles became gradually clear, so that they could guide research with human beings and minimize industrial and financial interests, or totalitarian ideologies and systems.

In this context, the concept of autonomy emerges worldwide, which determines the freedom of the individual to freely manage their life, rationally making their choices. For an individual to participate in a clinical trial, they should be informed, enlightened and assured of their rights and duties, in order to formalize their free decision. The free and informed consent (IC) is an instrument used in health services to record the agreement of a subject to perform a certain procedure. The IC application process and the free understanding of the subjects are essential to ensure the autonomy of the individual and respect for their choices, their life, their body and their social relationships.

In the year 1901, in Prussia, the government approved an instruction on medical interventions with non-diagnostic, therapeutic or immunization purposes, including criteria such as the participation of minors, consent and clarification [6]. According to Melo and Lima, in the year 1931 the Ministry of the Interior of Germany established *detailed regulations on different therapeutic procedures of human experimentation* [7], which aimed *to curb abuse and disrespect for human dignity in research*, because the participant needed to authorize the procedures that would be carried out. With the rise of Nazism, the concept of human being was redefined and, consequently, those who could enjoy such protection, resulting in research practices that shocked humanity.

After the world discovered the atrocities committed in World War II, several segments mobilized themselves and developed guidelines and standards aimed to ensure the autonomy of the individual, who were used until then as guinea pigs in scientific experiments. The creation of the *Nuremberg Code* [4] (1947), after the trial of war crimes in Nazi camps, and the *Declaration of Helsinki* [5] (1964), drafted by the World Medical Association, led the scientific community to a more respectful research conduct and directed toward the participant's autonomy, with their consent as the autonomy foundation.

However, obtaining the signed document – Informed Consent (IC) – does not mean that there was free, independent, voluntary, open consent and that the participant has really understood all the risks and benefits of the action. Several factors (patient's stress, educational level, economic vulnerability, access to health services) can be limitations to the perfect exercise of free and informed consent. In the research field, the relationship with the physician or health professional also influences the volunteer's decision-making process.

For Bento, Hardy and Osis [8], members of the working classes without a higher education degree are unable to evaluate the technical competence of a physician and therefore they focus their evaluation in attitudes – for example, if the physician is kind, dedicated and calm. The physician-patient relationship is an additional item to this factor and it creates one more step in obtaining consent. Some authors identified signatures under coercion, caused by the provision of treatment, by social asymmetries between researcher and participant [9-10], by secondary induction to the remuneration of participants under economic hardship [11] or even by offering access to health care services [12].

Gradually, an increasing number of articles were published that demonstrate that signing the IC form does not represent any guarantee that the process to obtain it had respected the participants' freedom of choice. Many studies show [13-18] misapprehension by volunteers on the experimental and therapeutic aspects of clinical trials; in fact, some may not be even aware that they are participating in the research [19]. Others may believe that the research is conducted primarily for their own benefit, and not for general knowledge or for the benefit of future patients [20], a belief that has been called *therapeutic misconception* [21].

The quality of informed consents is, according to Paris *et al.* [22] obviously insufficient, and methods require improvement so that the volunteers' understanding is also improved. Some studies differentiate subjective understanding (that which shows what the volunteer thinks they understood) from objective understanding (what the volunteer really understood). In this study [22], only objective understanding was taken into consideration because, for them, the important thing was that volunteers had a genuine understanding without considering the notion of having understood.

Discussions on these issues contributed to the emergence of greater interest in evaluating the consent process. Greater attention was given to the strategies of research groups to invite participants and inform them of the research activities and purposes, indicating the use of group dynamics, printed materials and videos to obtain their signatures on the informed consent form. Especially in contexts where the educational level among the population is low, these strategies, when well implemented, have a far greater protection effectiveness than a simple check of language adequacy on the informed consent form and their check list, a mandatory part of the IC [23].

This study was conducted in order to assess the level of understanding of the IC based on the responses to the survey developed in accordance with the score percentage, relating it to some variables obtained in specific survey.

## Method

This is a descriptive survey with quantitative and qualitative approach. The volunteers were selected due to their contact with researchers of Antônio Pedro University Hospital, at the Federal Fluminense University (UFF), from six different studies performed at the clinical research unit of UFF, each study having their research team. The surveys were applied by two nurses in private rooms without interference of the researchers from each team.

Men and women were included in the research, who signed a research IC form in the last thirty days. Participants were submitted to a closed survey, validated by two professionals working in the ethics field. A test of the instrument was conducted with five people, of both sexes, who had different educational levels: one with incomplete primary education, two with incomplete secondary education and a high school graduate.

After signing the IC, each volunteer received a copy of the understanding assessment survey and were instructed on how to fill it out. When the whole process was understood, the starting time of the survey was recorded; when they finished answering it, the ending time was informed. The second survey, whose response time was not recorded, evaluates the way of obtaining the IC and consists of five statements. The volunteer must choose one of three responses: "*yes*", "*no*" or "*I do not know*".

Tables containing absolute frequencies (n) and relative frequencies (%) were presented to conduct the statistical analysis of categorical variables such as gender, age, education and healthcare insurance. The remaining responses were analyzed by association tests of categorical variables, such as Chi-square and Fisher exact tests. In the case of figures, mean comparison and association tests were used according to the data characteristics. They were considered statistically significant for analysis of $p$ values < 0.05.

Data were analyzed by categorization, according to the created themes based on the type of statement answered in the survey. Those statements that solely relied on the provision of information by the professional responsible for the informed consent process were classified as objective. The others were classified as subjective statements, in which information relied on the volunteer's interpretation and understanding.

The statistical program used for data analysis was Sigmastat 3.1. The study was conducted in accordance with the current legislation.

## Results

The sample consisted of 146 subjects randomly selected from six different studies at the clinical research unit of UFF. The addressed topics were neurology, cardiology, dermatology and pulmonology. Each participant belonged to only one study. Since the surveys were identified by sequential numbers, it was not possible to determine how many participants belonged to each area. Data collection began in December 2012 and ended in January 2014.

**Table 1.** Sample distribution according to socioeconomic and response time variables (n = 146)

| Gender | no. (%) |
|---|---|
| Male | 45 (30.8) |
| Female | 101 (69.2) |
| Educational Level | |
| Elementary school dropouts | 78 (53.4) |
| Elementary school graduates | 5 (3.4) |
| High school dropouts | 31 (21.2) |
| High school graduates | 24 (16.4) |
| College dropouts | 6 (4.1) |
| College graduates | 2 (1.5) |
| Health care insurance | |
| Yes | 10 (6.8) |
| No | 136 (93.2) |

The mean age was 47.29 years, with a minimum of 20 years, a maximum of 73 years and




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a standard deviation of 12.21. There was a predominant number of female participants (69.2%), incomplete primary education (53.4%) and absence of private health care (93.2%). The average response time to the surveys was 6.91 minutes, with a minimum of 3 minutes and maximum of 17 minutes (Table 1). There was no statistically significant correlation between educational level and survey completion time ($p$ = 0.36).

### *Overall assessment of the IC knowledge per statement*

The volunteers' responses were analyzed for accuracy and error, based on the initial evaluation of two bioethics scholars of Antônio Pedro University Hospital, who validated the survey. The overall assessment of knowledge was calculated and categorized in knowledge levels: low (> 25% of expected responses), moderately lower (25% to 50%), moderately higher (50% to 75%) and high (<75% of expected responses). This classification used interquartile ranges (P25, P50, P75) in a similar manner to that described in the literature [24].

According to assessment of 15 statements, it was observed that the error or accuracy score is not homogeneous to individual questions. Four statements (1, 3, 4 and 9) – 26.6% of the total – had a high percentage of knowledge, and the same percentage (26.6%) was obtained in questions rated as low level (7, 12, 15 and 16). The responses to other questions were categorized as moderately higher (2, 5, 13 and 14) and moderately lower knowledge (10, 11 and 17), respectively 26.6% and 20% of the set. Statements 6 and 8 were not evaluated because there are several types of studies with different designs, therefore, there is not a single correct answer.

### *Overall assessment of knowledge per participant*

Ninety participants (61.6%) had a moderately higher knowledge of the IC information, with accuracy score between 52.9% and 72.2%. Only one respondent (0.7%) scored higher than 75%. A respondent scored below 25% (0.7%), and 54 participants (37%) had a score between 25% and 50%. There was no statistically significant correlation between accuracy score and educational level ($p$ = 0.82), gender ($p$ = 0.7), age ($p$ = 0.2) and response time ($p$ = 0.87).

### *Data categorization*

The statements submitted to the survey participants were categorized into two groups: one with objective information about the study, and the other with subjective information.

#### *Objective information*

Most participants believed that the IC had been evaluated by an ethics group (statement 2 – 70.5%). When the participants were asked about the length of the study (statement 5), 69.2% of them confirmed the information given by the physician during the informed consent process, 28.8% said they were not informed, and 1.3% did not know how to answer it. On the research originality and its procedures and treatment (statement 6), 41.8% believed that they were all new. In relation to third party access to collected data (statement 9), 79.5% thought that others could have access to them, 17.8% did not think so, and 2.7% did not know how to answer it.

Regarding the liability for injuries and/or diseases resulting from research (statement 12), 59.6% of the participants said they did not know who would be the party responsible in case of indemnity, 33.6% did not know how to answer it and only 6.8% said they had been properly informed. For the reporting of adverse events or just to have their doubts cleared about the research, most respondents had the phone number of the physician responsible for the study (statement 13 – 69.9%). Most participants did not know how many volunteers were part of the research (statement 15 – 87.7%). Concerning the information that research could be interrupted at any time (statement 16), most volunteers were not aware of that (82.9%), and only 11.6% knew that this could occur.

#### *Subjective information*

In relation to the respondents' understanding regarding their participation in a study when they signed the IC (statement 1), 89.7% said they were aware of it, and 10.3% claimed they did not to know about it. When faced with the information that the main reason of the research is to improve the future treatment compared to the current therapy (statement 3), most participants agreed (84.2%), and some participants found that the main objective is to improve the treatment that is being performed at the moment (15.8%). The perception that they are helping future patients (statement 8) appears in the answers of 95.9% of respondents. Regarding the volunteers' responsibility in the study (statement 4), 77.4% said they had duties and responsibilities, and 20.5% denied this fact. As for direct research

benefits (statement 7), the majority (82.9%) thinks there is some benefit, and only 15% acknowledge that it is likely that the research does not bring any benefits.

The idea of research confidentiality (statement 10) was unknown by the majority of respondents (67.1%). Moreover, there was a high percentage of participants who reported the research as the only alternative offered by the physician who monitored them (statement 11 – 62.3%). The permanence in the research as a participant's choice was confirmed by 73.3% of respondents (statement 14), and the knowledge of changes during the treatment (statement 17) was affirmed by 47.3% of them.

### *Procedures for obtaining the IC form*

In relation to the 146 respondents, 32.2% of them said they had not taken their IC copy home. Most respondents reported having read the IC alone (78.1%), without the help of a friend or relative to understand the content (84.2%), but with physician's explanation before signing it (76.7%). In regard to the formation of groups for a brief explanation of the study, 97.9% of respondents confirmed that they had not participated in this type of event. There was a significant association between taking their IC copy home and the accuracy score per respondent ($p < 0.05$) (Table 2).

**Table 2. Association between the IC process and accuracy score (n = 146)**

| Afirmações | no. | % | P |
|---|---|---|---|
| **I took the IC form home** | | | |
| Yes | 99 | 67.8 | **0.0027** |
| No | 47 | 32.2 | |
| I don't know | 0 | 0 | |
| **I read the IC form alone** | | | |
| Yes | 114 | 78.1 | 0.82 |
| No | 28 | 19.2 | |
| I don't know | 4 | 2.7 | |
| **A relative or friend helped me understand the IC form** | | | |
| Yes | 23 | 15.8 | 0.93 |
| No | 123 | 84.2 | |
| I don't know | 0 | 0 | |
| **The physician (or other professional) explained the IC form to me** | | | |
| Yes | 112 | 76.7 | 0.74 |
| No | 34 | 23.3 | |
| I don't know | 0 | 0 | |
| **The physician (or professional) discussed the IC form with me and other group patients** | | | |
| Yes | 3 | 2.1 | 0.2 |
| No | 143 | 97.9 | |
| I don't know | 0 | 0 | |

## Discussion

The mean accuracy score of the 146 respondents was 53.14%, which is close to the score found by Araújo [24] in Minas Gerais – despite using different collection instruments and approaches - but lower than the scores found by other researchers in developing and developed countries [25-29]. However, more research is required for precisely stating the level of understanding among research participants in several regions of Brazil.

Christopher *et al.* [30], in a study on the readability of informed consent forms with 154 participants in biomedical research on mental illness, found that 35% of the population did not have the minimum educational level required to understand the document. In another study, Riecken and Ravich [31], 28% of 156 war veterans, interviewed ten weeks after signing the IC, did not know they had been included in a study, and only 10% of them were able to correctly explain the research objectives. According to the same line of study, in an oncologic study in the United States [32], 74% of participants did not understand that the proposed treatment was not the standard treatment, when they were included in the study.

In our study, there was no association between accuracy score and gender, age, response time and educational level variables. This differs from the studies of Araújo [24], Rajaraman *et al*. [33] and Joffe [29]. The study developed by Fitzgerald *et al.* [34] in Haiti, with poorly educated volunteers, found that research participants from developing countries are able understand more than 80% of a complex IC if initiatives are taken to secure this knowledge, instead of a simple meeting with the researcher.

A study developed in 2007 [35] demonstrated a multivariate analysis of factors that hinder the understanding of the IC and found that participants who best understand the texts are those with higher educational levels, with reading habits, Internet access facility and with a higher income. Contrary to our expectations and what is evidenced in the literature, the respondent with the highest percentage of correct answers (82.9%) did not have the highest educational level. This can be explained by the engagement and commitment of some subjects with their treatment, which is independent of their social and educational levels. Private medical patients, with good social and educational level, often fail to understand certain prescriptions, requiring assistance to organize their drug intake schedules.

Cohn *et al.*[36] demonstrated that the most efficient method to improve understanding of the volunteer is the inclusion of a third person – although this is not always sufficient – the research team or an individual unrelated to the research, who could spend more time discussing information with the volunteer. For Bento *et al.*[8], the consent approach in two stages (individual and group) provides an expectation of expanded understanding, because in a group the answers to questions of a participant can clarify others or raise new questions. In particular, participants may feel more at ease to formulate intimate questions, dispelling doubts on aspects of the research that seemed intimidating to expose to the group.

The Census of Instituto Brasileiro de Geografia e Estatística (Brazilian Institute of Geography and Statistics – IBGE)[39] in the municipality of Niterói showed that 24% of the population have not completed elementary education, 12.7% of them have completed elementary education, 28.8% are high school graduates and 23.9% have a college degree. The population distribution is not the same found in this study, which reinforces the idea that the scenario under study does not reflect society as a whole, only the portion that seeks public health care.

Social vulnerability permeates many issues addressed in this study. Although there was no significant association and due to not being an unexpected fact, 93.2% of respondents do not have private health insurance, and public health services are the only resource available for treatment and follow-up – a higher percentage than the one presented by Silva *et al.*[38]: in the year 2003, 82.8% of subjects, and in 2008 it was reduced to 79.9%. A question that could be raised regards the number of volunteers who would continue in the research if they had other form of healthcare.

Another important data of our research is that 62.3% of subjects did not know of other treatment option, *i.e.*, the professional who attended them, made the referral to the research and was not clear as to possibility of continuing the treatment and monitoring of this subject. In a study conducted in a private research clinic in Rio de Janeiro, Lacativa[39] cites that 59% of respondents reported participating in a study to better understand their health problems and other diseases that they could develop and that only 21% of them participated because they either did not access to medical care or such access was difficult in their city.

82.9% of our respondents state that they believe that research should bring some sort of personal benefit. Although it is a mandatory IC item, respondents did not see their participation as essential for future advances in science, nor they accepted the idea that there was a possibility of not having any benefits. Morrison *et al.*[40], in a study in the United States, found that the informed consent had been given based on altruistic hopes that the research would generate knowledge to reduce the incidence of cancer. Economically disadvantaged participants from rural communities were motivated by the fact of supporting the research, without self-interest.

In this study, 78.1% of respondents report having read the IC form without the help of another person. Other studies have questioned if this would be the best process aimed at a greater understanding, although we have not found any significant association. Some studies[41-42] point to the participation of other professional as essential to the understanding of the IC and participant's safety. According to Sherlock and Brownie[43], the use of educational materials in order to obtain the IC, as well as multimedia interactive process leads to increased understanding of the participants on the implications of the procedure. Joffe[32] concluded that the presence of a nurse, a thorough reading of the IC and postponing the signing of the IC in the initial discussion were factors associated with increased knowledge.

Regarding the way to obtain the IC, we identified a higher percentage of correct answers in the volunteer group that claimed to have taken the IC home. Indeed, the possibility of a new detailed reading, as well as discussion with other family members or friends, allows greater depth of understanding. Although this does not solve the understanding ability, it certainly facilitates the process, which, however, also depends on not using terms or words whose meaning is not easily grasped, among other factors.

Regarding the use of equipment, there is a proposal in India that IC processes are recorded – audio and image – and kept on file. These resources should be helpful in documentation standards, in order to prove that the process was carried out correctly and that the subject did not have doubts about the positive and negative aspects of their participation. However, Sontakke and Kinge[44] point out that, due to poverty and illiteracy, participants can be easily led to act in accordance with the researcher's request, before the recording.

## Final considerations

The mean value of accuracy scores found in this study is not acceptable, and educational

measures and changes in specific procedures must be implemented, seeking to increase the understanding of the participants to provide them with greater security at the time of signing the IC. Among the suggested changes: production of educational materials for participants in clear and objective language; educational material for researchers, addressing in a practical way the basic legislation, good clinical practices and the importance of the IC process; provision of permanent courses at the institution in partnership with the CEP. Other resources that could prove to be effective, can be used in the IC process such as the inclusion of multimedia equipment, group discussions and participation of other professionals.

There was no association between accuracy score and gender, age, education and response time variables. There was also no evidence of association between accuracy scores and ways of obtaining the IC form, except for the act of taking the signed IC form home. It is advisable to incorporate the signing of the IC form in a second contact as a standard procedure.

This study has limitations, especially in regard to the research scenario. All participants were selected in the same place, making it difficult to generalize data. However, the collection was held in a public institution, largely reflecting the reality of the population who uses the Sistema Único de Saúde (Brazilian Unified Health System – SUS) in the city of Niterói, state of Rio de Janeiro. In order to confirm, compare and deepen the information gathered in this research, the performance of further studies is crucial to evaluate the understanding of volunteers from different regions of Brazil, even considering different social parameters.

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**Participation of the Authors**

Clarissa de Assumpção designed and performed the data collection, the analysis and wrote the article. Nínive da Silva Pinto took part in the data collection. Luis Guillermo Coca Velarde took part in the statistical analysis. Osvaldo José Moreira do Nascimento was the co-advisor. Beni Olej designed and advised the study.

## Annex

### Free and informed consent assessment survey - QuACo

Volunteer's number:

Gender: Age: Educational level:

Date of signing of the IC form in the study:

Healthcare insurance:

Starting time: Ending time:

Choose only one answer, that which seems more suitable, thinking about the research you participated in or is currently participating. *Your* opinion is what matters to us.

| | | | |
|---|---|---|---|
| 1. When I signed the IC form, I understood that I was going to participate in a study. | YES | NO | I DO NOT KNOW |
| 2. The IC form which I signed was approved by the hospital ethics group before I received it. | YES | NO | I DO NOT KNOW |
| 3. The main reason for the research is the improvement of future treatment. | YES | NO | I DO NOT KNOW |
| 4. I have no duty or task to follow through. | YES | NO | I DO NOT KNOW |
| 5. I was informed of the length of my participation in the research. | YES | NO | I DO NOT KNOW |
| 6. All research treatments and procedures are already used. | YES | NO | I DO NOT KNOW |
| 7. The research may not bring direct benefits to me. | YES | NO | I DO NOT KNOW |
| 8. By participating in the research, I am helping future patients. | YES | NO | I DO NOT KNOW |
| 9. Due to my participation in the research, the government, sponsors and other individuals engaged in the study may have access to my medical information. | YES | NO | I DO NOT KNOW |
| 10. Everyone will know that I am taking part in a study and will also know about my disease. | YES | NO | I DO NOT KNOW |
| 11. My physician did not offer any other option to me in addition to the research treatment. | YES | NO | I DO NOT KNOW |
| 12. The IC form which I signed describes the party who will pay for the costs, if I am injured or develop any disease as a consequence of the research. | YES | NO | I DO NOT KNOW |
| 13. The IC form which I sign lists the persons with whom I have to contact if I have any doubts regarding the research or if I feel anything. | YES | NO | I DO NOT KNOW |
| 14. I have to continue participating in the study even if I do not want. | YES | NO | I DO NOT KNOW |
| 15. I do not know how many volunteers participate in the same research I am participating. | YES | NO | I DO NOT KNOW |
| 16. The physician informed me that the research may end at any moment. | YES | NO | I DO NOT KNOW |
| 17. If there is any change in the research that involves my treatment, I will not know it. | YES | NO | I DO NOT KNOW |

**Free and informed consent obtainment form**

Choose only one answer, that which seems more suitable, thinking about the day you signed the document to participate in the research you were or is currently part of. *Your* opinion is what matters to us.

1. I took the IC form home.

( ) YES ( ) NO ( ) I DO NOT KNOW

2. I read the IC form alone.

( ) YES ( ) NO ( ) I DO NOT KNOW

3. A relative or friend helped me understand the IC form.

( ) YES ( ) NO ( ) I DO NOT KNOW

4. The physician (or other professional) explained the IC form to me.

( ) YES ( ) NO ( ) I DO NOT KNOW

5. The physician (or professional) discussed the IC form with me and other group patients.

( ) YES ( ) NO ( ) I DO NOT KNOW