



**CINTESIS**  
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Early Referral study for palliative care  
consultancy



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## Does the identification of patients with palliative needs in non specialised palliative care hospital services improve early referral for palliative care consultancy? A mixed-methods study.

*Standard operating procedures manual for collaborating centres*



**FCT** Fundação para a Ciência e a Tecnologia  
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## Early Referral study for palliative care consultancy

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## Context

Measurement generates clinical evidence and information necessary for decision-making in the care of the patient. The systematic collection of information through outcome measures taken directly from the patient has the potential to benefit palliative clinical practice at the individual and population level: facilitates identification and screening of physical, psychological, spiritual and social needs that would be overlooked; Provides information on disease progression and treatment impact, facilitates communication between clinicians, patients and relatives, establishing priorities and managing outcomes of treatment and disease progression. It also allows to aggregate and investigate data collected at various levels. The Integrated Palliative care Outcome Scale (IPOS) was designed to be used in clinical practice, and research.

## Objectives of this study

Identify patients with palliative needs in non-palliative hospital services, promoting early referral to palliative care consultancy.

For this we intend to

1. Use the questionnaire for 6 weeks to see if the items fit the study objective
1. Meet with each service in week 6/7 and discuss changes that can be made, namely, withdraw and/or add items
  - (1) Use the new measure and reference patients to the institution's palliative care team in the remaining 6/7 weeks

## Protocol Summary:

This study is multicentre and Multiphasic:

PHASE I: Use of the questionnaire **without referencing** for 6 weeks.

PHASE II: meeting for possible change

Phase III: use of the questionnaire **with referral of patients identified as having urgent palliative needs** for 6 weeks

PHASE IV: analysis and dissemination

*This document refers **only** to procedures relating to **phases I to III**.*

## Purpose of this document:

This study is multicentric. The variation in the physical space, population attended, number and type of clinicians, integration with other health services, human resources, support from the institution to which it belongs, organization of models of care provided, among other factors, implies that the data collection stage needs to be as standardised as possible. This Standard Operations Procedures Manual ensures this standardisation, presenting a description of the procedures relevant to the collaborating centres during Phases I to III of this study.

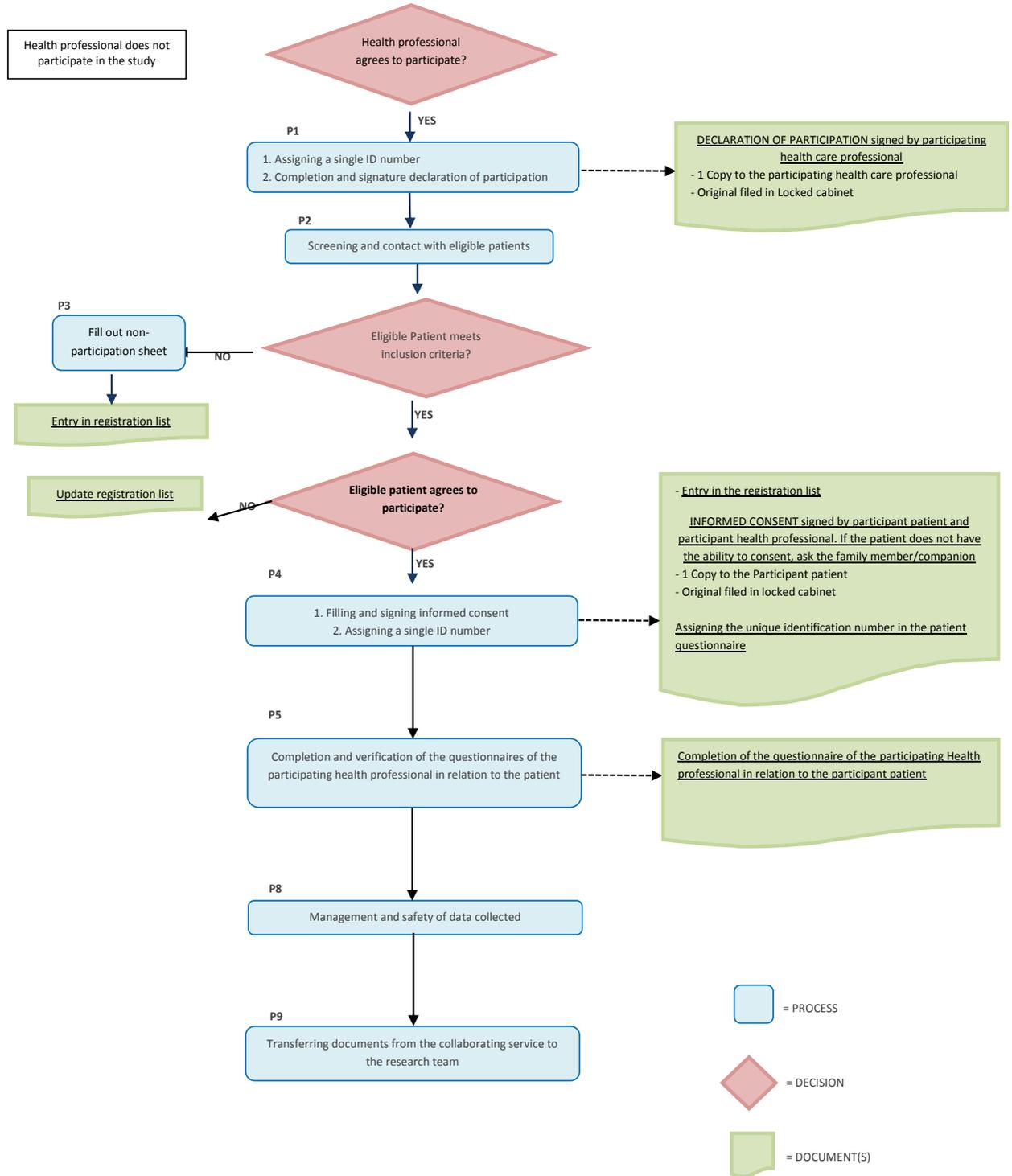
## How to use this document:

The following page contains a flowchart summarizing **the main procedures** of this study. Each blue rectangle represents a process, corresponding to a procedure (P). Each red diamond corresponds to a decision/action. The green rectangles indicate the documents referring to each step.

The following pages describe the procedures in detail.

If doubts arise during this phase of the study, the collaborators are asked to first review this Manual of procedures. If the questions persist, please contact the research team.

## Flowchart of Procedures



## **P1: Declaration of participation of the health professional and assigning identification numbers**

### **Context**

It is necessary to obtain a declaration of participation duly signed and dated by the participating health professional for the purposes of the study documentation.

### **Procedure**

1. The participating health care professional may place any questions that will be answered by the research team.
2. The health professional agrees to participate and will be assigned *a unique identification number*. This number is composed of two digits.
3. Once the unique identification number is assigned, the participating health care professional will have to sign and date the declaration of participation.
4. All participating health professionals will have a copy of their declaration of participation.
5. The signed statements of participation will be kept in a safe, lock place, *separate* from the study process, as the document contains information that can identify the participants.

## P2: Screening and contact with eligible patients

### Context

This study adopts a *consecutive sample* data collection approach. This means that *all individuals of the population of each collaborating service* must be screened and considered to participate in the study. In practice, this means *all patients who are in the care of the participating health professionals, regardless of the model of the care provision*.

### Procedure

1. All patients must be screened by the participating health professionals, preferably in the first contact with the patient, from the moment the data collection period begins (if there is no such possibility, it can be done in later Meetings). In case the first contact coincides with a first consultation, (and the patient is not known to the participating health professional) will be at the discretion of the participating health professional to make the screening at that time, or, wait for a second contact.

2. Patients should be screened in relation to the following inclusion criteria:

#### **Inclusion criteria**

- 18 years or older
- With advanced disease diagnosis (oncological or non-oncological) without possibility of cure
- Being cared for in the service where the participating health professional works
- Ability to give written informed consent to participate in the study or, if not capable of consenting, with a family member/caregiver who can give consent

3. If the patient is considered ineligible, a *non-Participation sheet* must be completed. This sheet does not contain any identifying information (see P3). Before the ineligible patients are approached, the participating health professionals need to confirm that this approach is correct one for each patient (see P 2.6).

4. If the patient is considered eligible, he will be given the information sheet of the study and the opportunity to discuss the study and ask questions. If the patient agrees to participate after his/her questions are answered, the consent process is followed (see P4).

5. If an eligible patient declines participation, it is necessary to fill out a *non-participation sheet* (see P3).

6. It is necessary to create a *Registration list* to maintain details of all patients who are screened and/or addressed to participate, as well as the response to the request for participation (ineligible/declined/agreed) and the model of care delivery where the patient was approached. This way the same patient will not be addressed two or more times.

7. If the patient is considered eligible to participate in the study, *before* addressing the patient, the participating health care professional must confirm in the *registration list* that the patient has not yet been approached and has not declined participation in Study. (see P 2.6).

## P3: Filling the non participation sheet

### Context

The study sample will never be completely representative of the entire population of patients with palliative needs. It is necessary to understand how the sample differs from the population to which it belongs. To do this, it is necessary to collect some demographic data about individuals who will not participate in the study. These include those who are triaged as ineligible (do not meet the inclusion criteria) and those who refuse to participate.

### Procedure

1. It is necessary to fill out a *non-Participation sheet* for each patient screened as ineligible (does not comply with the inclusion criteria), **as well as** for each patient who refuses to participate in the study.
2. The *non-Participation sheet* is completed anonymously, without information that can potentially identify the patient and without a single identification number.
3. After a *non-Participation sheet* is completed for a patient, it cannot be screened again and will never be able to participate in the study (even if it has a favourable clinical outcome, and therefore becomes eligible). To do this, it is necessary to keep the registration list always up-to-date, because the *non-participation sheet* does not contain the patient's identifying data.
4. Point 1 of the *non-Participation sheet* refers to the reason why the patient was considered ineligible or why they declined participation.
5. Points 2 and 3 of the non-participation sheet relate to demographic and clinical information, namely age, gender, literary qualifications, diagnosis and life expectancy.
6. *Non-Participation sheets* must be stored in a safe place with a lock and later returned to the research team (see P8).

## P4: Informed consent for participant patient and attribution of unique identification number

### Context

It is necessary to obtain the informed consent duly signed and dated by the participant patient, in accordance with good research practices and the Helsinki Declaration.

### Procedure

1. The eligible patient-prospective participant should read the patient information sheet and put any questions that will be answered by the participating health care professional.
2. The eligible patient will have at least 24 hours to decide whether to participate in the study.
3. The eligible patient **can see THE IPOS questionnaires** part of the consent process, with the opportunity to ask questions. We do not advise you to show the remaining items, especially those of a more sensitive nature, such as the surprise question (you would be surprised if this patient died in the next 12 months).
4. Once the eligible patient agrees to participate, they have assigned *A unique identification number*. This number is made up of 3 digits. It will be necessary to complete the reference regarding the model of care provided to the participant patient and the number referring to the participant patient. The references that should be used to identify the Care delivery model are:
  - 01 – External consultation (ambulatory)
  - 02 – Inpatient
  - 03 – Day Hospital
  - 04 – Other (Please specify)
5. Once the unique identification number is assigned, the participant patient will have to complete, sign and date the informed consent – original and copy – which will also be signed by a participating health professional. *The informed consents will be signed by both parties in person.*
6. If the participant patient does not have the ability to consent, the family/companion should be approached and the study should be explained to him, and then ask him to give consent for the patient to participate in the study.
6. All participating patients will have a copy of their signed informed consent.
7. The original signed informed consents will be archived in a safe, lockable place, *separate* from the study process, as the document contains information that can identify the participants. A registration list will be compiled with the names of all participating patients (see P 2.6).
8. The original signed informed consents will later be returned to the research team (see P8).

## P5: Completion & Verification of questionnaires

### Context

It is important to make data collection as complete as possible, avoiding missing data. Ideally, all items from all questionnaires are filled in.

### Procedure

1. The health professional should have enough time to familiarize himself and complete the questionnaire.
2. The *questionnaires* will BE sent in PDF format, as well as paper format and sent to the collaborating services.
3. The participating health care professional should assign the unique identification numbers of the study to each questionnaire *before* completion.
4. In the health professional questionnaire there will be a space to place the identification number of the participant patient to whom the health professional questionnaire refers. The *name* of the participant patient never appears in the questionnaires.
4. It may be the physician or nurse to complete the questionnaire in relation to the participant patient, considering that in most institutions it is the physician who makes the referral to the palliative care team.
5. In the first 6 weeks of completing the questionnaires, health professionals will not make any reference to the palliative care team based on the questionnaire information. Only after the meeting with the research team and the final version of the questionnaire is decided, health professionals will be able to reference patients based on the questionnaire. This is not to be mixed with clinical practice

**For example:** a) Data collection starts on October 1. From 1 October to 11 November, there will be no referral of participating patients based on the questionnaire data. Participating health professionals can take notes on how the questionnaire may (or might not) be helping to identify patients with palliative needs, as well as to note suggestions for changing the questionnaire.

b) The meeting with the research team will be held in the week of November 12 for decision of the final version of the questionnaire

c) From 19 November until 30 December, the physician responsible will reference patients with urgent palliative needs for the palliative care team and identify all others who will have non-urgent palliative needs. Data collection ends on December 31st.

6. All original questionnaires must be sent to the research team (see P8).

## **P6: Withdrawal of participation in the study**

### **Context**

Participants in this study may withdraw from participating at any time. Understanding the reasons for withdrawal can help us draw better studies in the future. It is important to record the reasons for withdrawal, but never identify who did.

### **Procedure**

1 Participants in this study may decide to withdraw from participating at any time. It is not mandatory to give a justification, but the sharing should be encouraged, provided that the participant patient/health professional is comfortable in doing so.

2. It is important to record the reasons for withdrawal and to report them to the research team for but never identify the patient participant who dropped out.

## P7: Management and security of data collected

### Context

The questionnaires in this study include questions about physical, psychological and social issues. This information is of personal nature and should always be considered as confidential. The management of this information should always be done carefully to avoid causing maleficence to the participating patients.

### Procedure

1. All information must be collected, stored and managed in strict accordance with the Data Protection Act of 1998:

- a) All information collected during this study should be considered confidential.
- b) The questionnaires completed by the participating health care professional should be anonymised by the use of the *unique identification number*.
- c) The only document where the participant's name appears alongside the *unique identification number* of the study is the registration list.
- d). The *Registration list* must be stored **in a locked *place and separated from all other study documentation***.

## **P8: Transfer of documents from the Collaborating Centre to the research team**

### **Context**

This study requires that the data collected in the collaborating services be returned to the research team. The information collected is considered sensitive and its management must always be done with care to avoid losing questionnaires and cause maleficence to the participating patients.

### **Procedure**

1. The collaborators are asked to send the informed consents signed to the research team. They are also asked to send the original completed questionnaires.
2. The collaborating centres can choose to send the documents by mail (the address will be sent) or in hand (to be arranged).
3. We ask collaborating centres to wait for contact from the research team *before submitting any documents*.
4. The registration list can never be sent in the original format. The names will have to be removed from the sheet (e.g. cut the sheet so that the list of names is deleted or take a copy so that the list of names is not included in the copy)
5. The research team will always inform the reception of any documents sent by each collaborating center.

## P9: Information on the results of the study to participants

### Context

Some participating patients will be interested in learning the results of the study. The communication of results to participants is an important part of the relationship between all participants (patients and health professionals) and helps to improve the recruitment of future studies. The participating patients will be asked to indicate in the informed consent if they would like to be informed of the results of the study.

### Procedure

1. The registration list will be the information indicated in the informed consent of the participant patient, regarding the interest in knowing the results of the study.
2. Once the study is closed, reports will be compiled, one of which is in simple language to be disseminated by the collaborating services. *This may take a few months.*
3. It will be the responsibility of the collaborating centers to disseminate the results reported to all participants who have indicated that they are interested. The research team will never be able to do so by breaking the anonymity of the participating patients.
4. *Before submitting the results to participants, each collaborating center must confirm that the participating patients have not died.* Results should only be sent to the participating patients who are alive at the time the collaborating centers receive the results, and never to the addresses of deceased participant patients in order to avoid emotional distress of their relatives.

## Pilot phase

### Context

This study is multicentric and the collaborating centres include non-specialized palliative care services from different hospitals. The variation in the physical space, population attended, number and type of clinicians, integration with other health services, human resources, support from the institution to which it belongs to, organization of models of care provided, among other factors, implies that the data collection phase must be as standardised as possible. This Manual of procedures ensures this standardisation.

### Procedure

1. Each participating center will have the autonomy to manage the procedures and logistics of the study locally.

2. In the first 2 weeks of the data collection period we ask each collaborating centre to consider these and other issues they deem pertinent:

- Who checks eligibility of patients and who addresses eligible patients
- When eligible patients are approached (e.g. before or after a consultation)
- Physical space where eligible patients are approached (e.g. waiting room)
- Is the eligible patient accompanied?
- Available locations to store the registration list, signed consents and completed questionnaires (must be separated and have key), as well as the remaining study documentation
- Who fills out the study documentation
- When you fill out the study documentation
- Where and when will the participating health professional fill out the questionnaire?
- Participating services with trainees/interns may consider engaging them to give them the opportunity to have experience collaborating in a research study.
- Other situations that the participating services consider pertinent, considering their reality

3. The logistical issues mentioned above should be decided/resolved during the pilot phase so that the data collection period is as standardized as possible in each collaborating service.

## References

- 1998 Data Protection Act
- Universal Declaration of Human Rights
- Nuremberg Code
- Declaration of Helsinki
- Convention for the Protection of human rights and the dignity of humans in relation to the applications of biology and medicine

## DOCUMENTS

1. Statement by Service Director agreeing to participate in the study
2. Participant Health Professional Participation statement
3. Eligible Patient Information Sheet
4. Patient Registration List
5. Non-participation sheet
6. Informed consent of participant patient
7. Informed consent of the participating patient's family/companion
8. Questionnaire

The questionnaires of the participating health professional in relation to the participant patient will be sent to each collaborating service also in paper format.

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**DECLARATION OF PARTICIPATION of the health  
professional**

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This study intends to use a palliative needs questionnaire for the Portuguese population. With this, we hope to better identify people who have these needs to provide better service. To this end, we ask for your participation which will consist of fill a questionnaire in relation to the participant patient.

There are no right or wrong answers. All data collected is confidential.

If you agree to participate in this study, please sign in the space below and thank you for agreeing to give your important contribution to this study.

I, (full name) \_\_\_\_\_ I became aware of the objective of the study and what I have to do to participate in the study. I hereby declare that I agree to participate in this research study.

Signature \_\_\_\_\_ date \_\_\_\_/\_\_\_\_/\_\_\_\_

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Patient Information Sheet

## Early referral study for palliative care consultancy

### A MEASURE TO BETTER IDENTIFY AND PERCEIVE SYMPTOMS, CONCERNS AND NEEDS IN ADVANCED ILLNESS

We would like to invite you to participate in our research study. Before deciding we would like to explain why this investigation is being developed and what we will ask you to do. If you have any questions, do not hesitate to put them to the person who handed you this sheet.

#### Objective of the study

People with advanced disease may have a number of symptoms, as well as concerns. Health professionals often acknowledge these symptoms and concerns and offer help, but sometimes they may not identify them.

One of the best ways to make sure that symptoms and concerns are identified is using a questionnaire. We are currently trying to figure out what the best questions are to identify symptoms and problems and test these questions.

#### Why was I invited to participate?

All adults enrolled in this service are being invited to participate in this study.

#### Do I have to participate?

The decision to participate in this study is entirely yours. If you agree to participate, you will be asked to sign an informed consent sheet. You may withdraw from the study at any time after signing consent without having to explain your withdrawal. This will not affect in any way the care you will receive.

#### What happens if I participate?

Your health care professional will fill out a questionnaire with questions about your health and concerns related to your illness.

#### What are the possible benefits of my participation?

We cannot guarantee that the study will benefit you directly, but the information and knowledge we will have of this study helps us to improve the way we identify and treat symptoms and concerns of people with advanced disease.

#### Will my participation be kept confidential?

Yes. All information collected will be kept confidential and in a safe place by the study staff.

## Early referral study for palliative care consultancy

### What if there's a problem?

If you have any concerns about any aspect of this study, you should talk to whoever gave you this sheet. If that person does not know how to answer your question, you will talk to a member of the research team who will do everything possible to answer your questions.

### What happens to the results of the study?

The results will be made available to other health services and professionals through published scientific articles, presentations in conferences and reports to various health entities in Portugal. No participant will be identified in any of these documents. If You would like to have a copy of any of these documents, please inform us.

### What do I do now?

This information sheet has been provided to you so that you can reflect on the possibility of participating in this research study. You don't have to answer immediately and if you prefer, you can take this sheet home and talk to someone or write down some questions you still have. Please inform the person who gave you this sheet if you are interested in participating. If you want to participate, one of your health professionals from this service will fill out the questionnaire we are testing with some of your clinical information. If you prefer not to participate, then we will keep this information so that we do not ask again.

### Finally....

**Thank you for your time and for considering participating in this research study. We understand that dealing with a disease is not easy and we do not want to occupy your time and energy. However, without the realization of this work, we will not advance with a more standardised way of identifying symptoms and other concerns of people with advanced chronic diseases. We hope that the results of this study will help to significantly improve the way symptoms and concerns are identified by this and other health services in Portugal.**

The research team



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**NON-PARTICIPATION SHEET**

To be completed by the participating health care professional. Please keep the registration list always up to **date**.

**1. REASON FOR NON-PARTICIPATION**

- Ineligible patient
- Age < 18 years
- Undiagnosed patient with potentially threatening incurable disease of life time
- Another reason: \_\_\_\_\_
- Patient was eligible but declined to participate. Reason: \_\_\_\_\_

**2. Demographics**

Age \_\_\_\_\_ Years

Sex:  Female  Male

- Qualifications:  Does not read or write
- Reads and writes
  - 1st Cycle of Basic Education (1st-4th year)
  - 2nd Cycle of Basic Education (5th-6th grade)
  - 3rd Cycle of Basic Education (7th-9th grade)
  - Secondary education (10th-12th grade)
  - High School
  - Higher education (polytechnic or university)

Geographic area of Residence:  North  Centre  South

**3. CLINICAL DATA**

Date of admission to the service: \_\_\_/\_\_\_/\_\_\_\_\_

Admission Diagnosis(ICD-9) \_\_\_\_\_

Life expectancy:  Less than 6 months  6 months to 1 year  More than 1 year

Phase of illness:  Stable  Unstable  Deteriorating  Terminal

DATE: \_\_\_/\_\_\_/\_\_\_\_\_

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**INFORMED CONSENT**

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intends to use a palliative needs questionnaire for the Portuguese population. We consider this research important, because with this knowledge, we can help to identify these needs more quickly and provide better service to people who have those needs. To do this, we ask for your participation that will consist of answering a questionnaire at two different moments.

There are no right or wrong answers. All data collected is confidential. If you decide not to participate or give up the middle, there will be no problem, having all the freedom to do so.

If you agree to participate in this study, please sign in the space below. You must request and save a copy of this document for you.

Thank you for agreeing to give your important contribution to this study.

I, (full name) \_\_\_\_\_ I am aware of the objective of the study and what I have to do to participate in the study. I was informed about all the aspects I consider important and the questions I had have been answered. I have been informed that I am entitled to refuse to participate and that my refusal to do so will have no consequences for me. I hereby declare that I agree to participate in the investigation.

Please indicate if you would like to know the results of the study.

Yes \_\_\_\_\_ No \_\_\_\_\_

Signature \_\_\_\_\_

Interviewer \_\_\_\_\_

Date \_\_\_\_ (dd)/ \_\_\_\_ (mm)/ \_\_\_\_ (yyyy)