SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Unità Sanitaria Locale di Reggio Emilia
IRCCS Istituto in tecnologie avanzate e modelli assistenziali in oncologia

OECI COMPREHENSIVE Cancer Centre

Evaluating a Clinical Ethics Committee (CEC) implementation process in an Oncologic Research Hospital. A process evaluation study using Normalization Process Theory

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Sponsor: Azienda Usl-IRCCS di Reggio Emilia, Bioethics Unit
PI: Dr. Marta Perin

Information Sheet

Dear Colleague,
You have been invited to participate in this study, sponsored by the Bioethics Unit of the Azienda USL-IRCCS of Reggio Emilia.

The study, " Evaluating a Clinical Ethics Committee (CEC) implementation process in an Oncologic Research Hospital. A process evaluation study using Normalization Process Theory" is an observational study, which means that it does not involve any additional instrumental or laboratory investigations.

The Clinical Ethics Committee (CEC) of the Azienda USL-IRCCS of Reggio Emilia was deliberated by the General Director on 13/07/2020. The CEC is a service established to support health professionals, patients and their families in ethically complex and sometimes conflicting situations, by providing ethical counseling in the presence of difficult decision-making processes and value conflicts in clinical practice.
The CEC is promoted by the Bioethics Unit, which has overseen its development and implementation. The overall objective of the present study is to evaluate the CEC implementation process 16 months after its establishment (October 2020-February 2022), in order to explore not only how the CEC has been integrated into practice, but also to gather valuable information on the barriers and facilitating aspects that characterize its use in the local context.

The study comprehends a quantitative and qualitative evaluation. The first one aims at measuring the activities carried out by the CEC and assessing the level of dissemination, knowledge and use of the service among the Company's healthcare professionals. The second one aims at qualitatively exploring by semi-structured interviews, the opinions and perspectives on the service, in terms of barriers/facilitators, expectations and needs, from service users and figures involved in the implementation process itself.

You can decide independently whether to participate in this Study. You can also discuss it with other people. If anything is unclear, you are free to ask for all the necessary information from the Researcher who proposed this Study to you. Her references are at the bottom of this information sheet.
If you decide to participate, the Researcher will ask you to sign a Form to confirm that you have read and understand all aspects of the Study and wish to participate in it.

What will happen if I decide to participate?

If you decide to participate in the study, we will ask you to take part in an interview. Your participation will consist of answering questions in an interview (which may possibly be conducted via video conference) of an approximate duration of 30-45 minutes, which will be administered to you by a specially trained interviewer. The interview will be audio-recorded with your consent and will be deleted after its transcription.

The interviewer will contact you by telephone about your willingness to take part in the study. If you accept this proposal, you can arrange with her to meet at a time and place suitable for you to answer the interview questions.

The interview will be audio-recorded, its contents transcribed and anonymized, and the transcripts will be subjected to qualitative analysis by a group of researchers experienced in the field. Then the recording will be erased. At the same time as the meeting, you will be asked to sign a specific consent, which includes the possibility of audio-recording, transcribing and analyzing the contents of the interview.

What will happen if I decide not to participate?

If you decide not to participate in the study, there will be no impact on your work.

Will I be able to drop out of the study at any time?

You may discontinue your participation in the Study at any time, with no consequence to the quality of work.

What are the benefits of taking part to this research?

Participation in this observational study does not directly benefit you personally. However, by participating in this Study you will contribute to improving our knowledge about the implementation process, and thus the limitations and facilitating aspects, of a multidisciplinary Clinical Ethics Committee.

What are the risks?

There are no specific risks associated with participation in this Study. No experimental drugs are expected to be used. However, you will be informed promptly if information becomes available that may influence your willingness to continue participation.

Will my personal data remain anonymous?

All information related to your participation in this Study will be treated in a strictly confidential manner in accordance with the rules of Good Clinical Practice (Legislative Decree 211/2003), as well as those related to the protection and processing of personal data, in accordance with the

European Regulation No. 679/2016, so-called GDPR, and the Italian legislation currently in force on Privacy.
Personal data will be associated with a code, from which it will be impossible to trace your identity: only the researcher will be able to link the code to your name.
The investigating researhcer who will follow you in the Study, the persons in charge of monitoring the Study, and the Regulatory Authorities may have access to your personal data, in compliance with and subject to the limitations provided for by European Regulation No. 679/2016, Legislative Decree 196/2003, as amended by Legislative Decree 101/2018, and the Guidelines of the Guarantor for the Protection of Personal Data (Resolution No. 52 of 24/07/2008, as amended and supplemented). The personnel in charge of the Firm are in any case obliged to maintain the confidentiality of such information.

Insurance Coverage

Since this is an observational study involving the mere collection and analysis of data, no insurance coverage is provided.

How will the results of the survey be used?

All of your data will be collected by the investigating researcher and no one, except authorized individuals as specified above, will be able to trace your identity.
The results of this Study may be disclosed and/or published in a scientific journal. However, your identity will never be disclosed.

Who can I contact for further information?

If you have any questions or would like further information, please do not hesitate to contact the study investigator Dr. Marta Perin who proposed you to participate in this observational study.
Dr. Marta Perin
E-mail: marta.perin@ausl.re.it

We remind you that, at the end of the study, you can ask the investigating researcher to view the results of the investigation carried out thanks to your contribution.

This study and its documentation have been approved by the Ethics Committee Area Vasta Emilia Nord.

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Informed Consent Form

I _____

Born in_____on the_____declare that I have received from Dr._____on the_____full explanations regarding the the study in question, as stated in the informative sheet attached, a copy of which was delivered to me on the _____

As a result of what I have learned, I declare:

1) That I have been informed of the purposes, procedures, duration of this study, possible advantages and disadvantages, and agree to participate in this study sponsored by the Bioethics Unit of the Azienda USL-IRCCS of Reggio Emilia

2) That I have been provided with a summary of the information regarding the characteristics of the study, that I have been able to discuss them, that I have been able to ask any questions I have deemed necessary, and that I have received satisfactory answers in this regard.

3) That I am aware that I am free to refuse to participate in the study and that I can withdraw my consent at any time during the duration of the study.

4) That my participation in the study is completely voluntary.

5) That I have been informed and agree that my data may be made available not only to the study managers and their delegates, but also to national and international Health Authorities, the Ethics Committee, should they be requested; and I have also been informed that my data may be subject to communication to national and international scientific congresses or publication for scientific reasons in national and international medical journals, but that in any case my identity will be protected by confidentiality (i.e., the data will always be used in ANONYMOUS and AGGREGATE form).

6) That the audio recordings will be transcribed, anonymized, and deleted, so I will no longer have the opportunity to request them

7) That I have also been informed of my right to have free access to the records of the trial and the evaluation made by the AVEN Ethics Committee

8) That I have been given a copy of this consent to retain

By signing this form I consent □ not consent □ and consequently, I consent □ not consent □ to be audioregistered.

Participant's Name and Surname _____
Date _____
Partecipant's Signature_____

Researcher's Name and Surname_____
Date_____
Researcher's Signature_____

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Informative sheet and consent to the processing of personal data

Data holders and related purposes
The Bioethics Unito of the Azienda USL-IRCCS of Reggio Emilia, which promoted the study described to you, in accordance with the responsibilities provided by the rules of good clinical practice (Legislative Decree 211/2003) and the legislation on the protection of personal data (GDPR 679/2016 and Legislative Decree 196/2003 as amended by Legislative Decree. 101/2018), will process your personal data, and in particular those related to your experience with thecounseling and training activities promoted by the Clinical Ethics Committee (CEC) of the Azienda USL-IRCCS of Reggio Emilia, as well as other data related to biographical data, gender, age, education, exclusively in relation to the objective of the study.

The purpose of the study is to provide an evaluation of the CEC development and implementation process, 16 months after it entered into force.

For this purpose, the data indicated will be collected by the Bioethics Unit and will not be transferred to countries outside the European Union that do not guarantee an adequate level of personal data protection.

The personal data you provide for the purposes described above will be processed on the basis of your express consent, which is, therefore, the legal basis for processing.

The processing of the aforementioned personal data is indispensable for the conduct of the study: refusal to provide them will not allow you to participate in the study.

Type of data
The researcher who will follow you in the study will identify you with a code: the data collected in the course of the study will be recorded, processed and stored together with this code, and your personal data as specified above. Only the researcher and authorized individuals will be able to link this code to your identity.

Data management
The data, processed by means including electronic means, will be disseminated only in a strictly anonymous form, for example through scientific publications, statistics and scientific conferences. Your participation in the study implies that, in accordance with the regulations on clinical trials,the staff of the Sponsor, the Ethics Committee and the Italian and foreign health authorities will beable to know your data, also contained in your original clinical documentation, in such a way as to ensure the confidentiality of your identity.

Exercise of rights
You may exercise the rights set forth in Article 15 and Sections 3 and 4 of EU Regulation 2016/679 (e.g. access your personal data, supplement them, update them, rectify them, object to their

processing for legitimate reasons, exercise the right to be forgotten and to data portability, etc.) by directly contacting the testing center, in the person delegated to data processing Dr. Marta Perin - marta.perin@ausl.re.it
We would like to remind you that, in the event that you perceive a violation of your rights regarding the protection of personal data, you may file a complaint with the Guarantor for the Protection of Personal Data and that your data will be kept only for the time necessary to achieve the purposes for which they were collected and processed**.**

The duration of the study is estimated to be 10 months.

Interview recordings will be destroyed immediately after verbatim transcription. The transcripts and essential documents related to the study will be kept with the Promoter for at least seven years after the completion of the trial, or for a longer period of time in accordance with applicable regulations. Pursuant to Article 2e of Legislative Decree 101/2018, supervision of trials qualifies as processing for reasons of substantial public interest under Article 9(2)(g) of the EU Regulation.

You may contact the Data Protection Officer for the A.U.S.L. of Reggio Emilia at the following email address: dpo@ausl.re.it.

You may terminate your participation in the study at any time and without providing any justification, in which case no further data concerning you will be collected, without prejudice to the use of any data already collected to determine, without altering them, the results of the research.

Consent
By signing this form I consent [ ] I do not consent [ ]
to the processing of my personal data for research purposes to the extent and in the manner indicated in the information provided to me herewith

Participant's name and Surname _____

Signature _____

Date _____