Grant application form - Project v2017 - A

Submission Date	2017-06-29 18:41:39
Name of applicant	Lucian Miron
Job title	Professor of Medical Oncology
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A short CV of the applicant (or the principal investigator) should be provided here.	Personal data Name: Lucian Miron Adress: Soficu Street no 22, Iasi, Romania Phone: 0040744397003 Professional experience 1992 – present – MD Medical Oncology 1998 – PhD graduation 2002 – present – Head of the Medical Oncology Department, Regional Institute of Oncology, Iasi 2015 – present Professor of Medical Oncology, University of Medicine and Pharmacy Gr T Popa Iasi Research Experience 2010 - Grant director for the grant “Research on the polymorphism of the aromatase gene as a predictive factor of hormone therapy efficacy in metastatic breast cancer” 2007-2017 - Member of 6 clinical research grants 2005-2017 – Principal Investigator/Study coordinator for over thirty clinical trials that took place in the Regional Institute of Oncology Member of the editorial board of five national journals and on the Journal of BUON (Balkan Union of Oncologists) Publications Books – 15 Book chapters – 22 Papers in ISI journals – 17 Papers in peer-reviewed journals – 55 Papers/abstracts presented at national/international conferences conferences - 190
Submission date of this form	30-06-2017
Is the person responsible for the project different to the person named in box A	No
Title of the project	Multidisciplinary approach for improving sexual health in female cancer survivors

Comprehensive description of the project: rationale, methods, approach, outcome (max 500 words)	Rationale: With the advances in cancer diagnosis and treatment, the number of cancer survivors is constantly increasing, creating a special subgroup of the population whose needs are often unmet. Cancer survivors must readjust both professionally and socially to a disease-free lifestyle, a task that can be significantly impaired by chronic treatment side-effects, lack of communication with their physicians or psychologists or the absence of a support group. In many countries, sexuality is not frequent topic of discussion with cancer patients. This is due to both physician's and patient's reluctance. Additionally, in Eastern Europe countries, women may be afraid to discuss such issues with a physician or a psychologist and thus may have numerous misconceptions and prejudices. Currently, there is no standardized approach for addressing the sexual health issues of female cancer survivors in Romania. The aim of the study is to assess the effect of a multidisciplinary approach on sexual health in this population and, with the aid of the data we gather, to create a brochure that answers frequently asked questions in this area. Method Prospective randomized clinical trial Approach 100 patients who are premenopausal cancer survivors (all cancers) Inclusion criteria: - women aged 18-55 - diagnosed with a non-metastatic cancer for which they have received either surgery, chemotherapy radiotherapy or a combination of the three - have finished their cancer treatment at least three months prior to study enrollment and are currently considered "cancer free" All female cancer survivors that fulfil the inclusion criteria will be asked if they are interested to participate in the study. If they agree, they will be asked to answer several sexuality-related questions derived from three validated questionnaires: SF-36, EORTC QlQ-C30 and QLACS. Those that are not considered to have a satisfactory reproductive health will be randomly divided in one of two groups: - group A – observation only - group B – multidisciplinary counseling (three scheduled sessions with an oncologist, a psychologist and a gynecologist). For group B, the first session will be mandatory, and additional sessions are left at the discretion of the participant. During these sessions, the investigators will identify potential physical/psychological/social issues that can lead to sexual problems in these women and, if possible, will try to address them either by counselling either by prescribing standard of care medication. Six months after randomization, all participants will undergo the same questionnaire assessing reproductive health. It will assess if multidisciplinary counselling has improved sexual health in female cancer survivors. All sessions will be recorded. At the end of the study, a frequently asked questions (FAQ) brochure will be created so that other cancer survivors benefit from the information acquired throughout the project Outcome 1. Assessing the potential improvement of sexual health in female cancer survivors by means of multidisciplinary assessment 2. Creating a brochure that tries to answer these individuals' most frequently asked questions. The brochure can then be offered to all female cancer survivors
When would it start / finish? (Max 20 words)	Project will start in January 2018 Project will end in June 2020
Where will it take place – country / town, establishment? (Max 20 words)	The project will take place in Iasi (city), Romania (country) in the Regional Institute of Oncology

Objectives and needs identified. (Max 100 words)	Needs identified: currently, there are no data regarding sexual functioning in cancer survivors from Eastern Europe countries. Additionally, there are no standard guidelines for addressing issues in sexual function that arise in female cancer survivors. Objectives: O1: to identify the prevalence of sexual dysfunction in female cancer survivors from North-East Romania O2: to identify potential factors that are associated with an impaired sexual health O3: to assess the effect of a multidisciplinary approach on sexual health in female cancer survivors O4: to create relevant informative brochures specifically designed for this population group
Sector in the area of contraception, sexual and reproductive health:	Sexual health
Is it a 'new' project?	Yes
What outcomes will be measured? List. (Max 50 words)	• Sexual health in female cancer survivors (SF-36, EORTC QlQ-C30 and QLACS) • Psychological issues, gynecological dysfunctions and cancer-related problems that affect sexual health • Effect of multidisciplinary counselling on improving sexual health in this population group (SF-36, EORTC QlQ-C30 and QLACS in the two groups six months after randomization)
Do you foresee any reasons (political, climatic, etc) why this project may be adversely affected? (Max 20 words)	This project may be affected by the women's willingness to openly talk about sexual health, especially after undergoing cancer treatments.
Are there other partners or organisations supporting this same project?	No
Will this be part of a larger fund or stand alone? (Max 20 words)	This project is a pilot project that currently stands alone. If successful, it will lead to additional projects/larger funds.
Have you already obtained any funding or still awaiting a response towards this project?	No
How much money is required for the project in total?	9750 EURO
How much are you requesting from ESC?	9750 EURO
Please provide a detailed budget here. This must include total costs and, if appropriate, list those costs associated with your grant from the ESC.	Questionnaires - right to use questionnaires + printing - 300 Euro Staffing – 7650 euro - Staff involved in screening for sexual dysfunction – 7 euro per patient screened x 200 patients = 1400 euro - 35 euro/consultation x 3 consultations (per participant) x 50 participants in the intervention group = 5250 euro - staff involved in data management – 1000 euro Costs associated with creating the FAQ brochure – 1800 euro - selecting data, editing text and creating the brochure – 500 euro - layout and design - 300 euro - printing costs – 1000 euro

The ESC may not be in a position to fully fund all applications; you must indicate whether / how part funding may impact your project. (Max 100 words)	Part funding means we will have to cut from the staffing budget. That will probably decrease the number of patients we can enroll in this clinical study.
Who will oversee the budget & keep accounts? Provide name, title, contact number and email address	Prof. Dr. Lucian Miron 0040744397003 lucmir@gmail.com
If you or your department has received funding from ESC for a project or course before, please give details of the date of funding, contact person and title of project or course.	Our department has not received funding ftom ESC for a project or course before

We, as responsible agents for this project, agree to the following 8 points:

	yes
We agree that all monies will be spent appropriately	✔
We agree to work with the nominated Mentor	✔
We agree to advise you at the earliest time if this project is delayed or cannot be completed	✔
We agree to provide an interim report(s) part way through the project and a final report to the ESC within 6 months of the end of the project.	✔
We agree to provide the ESC with an interim budget(s) and a detailed budget at the end of the project. NOTE funding will be awarded in stages and will be dependent on appropriate reporting.	✔
We agree to provide receipts for monies spent if requested.	✔
We agree that if we need to make any significant changes to the duration, contents or funding of the project after it has been awarded, I/we will advise the nominated mentor.	✔
We agree to acknowledge the ESC as a donor in any publications and oral communications resulting from this project. Ideally any manuscript should be sent to the ESC journal in the first instance.	✔

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