Based on the answers you provided us, you fulfill the participation criteria for this program. The next steps are: (1) reading an Infomed Consent Form, because it is important that you undersand the purpose of the program and what the participation in it implies, and (2) filling in a questionnaire.

Informed Consent Form

This form addresses pregnant women who smoke and who are invited to take part in the smoking cessation program for couples described below.

Program title	Smoke-free Together A Mobile Health Intervention for Family Smoking Cessation in Romania
Funder and grant number	National Institutes of Health, USA 1R21TW010896-01
Institution implementing the program	Department of Public Health College of Political, Administrative and Communication Sciences, Babes-Bolyai Cluj-Napoca, Romania 7th Pandurilor St, Cluj-Napoca, Romania, 400376
Research team	Dr. Cristian I. Meghea – Principal Investigator Oana M. Blaga – Subaward Principal Investigator Alexandra Sidor Teodora Frăţilă Iulian Brătulescu Dr. Cristian Iuhas Prof. Răzvan Cherecheș Prof. Kristie Foley Prof. Ken Resnicow

This Informed Consent Form has two parts:

- Information Sheet (to share information about the study with you)
- Certificate of Consent (if you choose to participate)

If you have any questions or you would like to receive more information, please contact us using the contact form or data displayed on the program's website (www.publichealth.ro/iff).

You will be able to save and print a copy of the full Informed Consent Form

Part I: Information Sheet

What is the aim of this program?
The long-term goal of this research program is to develop, implement and evaluate a mobile app for quitting smoking in couples expecting a child. *To participate, it does not matter if you want to quit or not.*
The program is divided into 2 stages and is implemented over a 2-year period. You will participate in the second stage, which takes place between September 2018 and December 2019. Because the program is aimed at couples, we would like to invite your husband or partner in this program in the next days.

Why have I been invited to participate in this research program?
You were invited to participate because you are: (1) a pregnant woman in the second or third trimester of pregnancy, and (2) you smoke, even occasionally. Also, other 59 couples where the pregnant woman smokes will participate in the program.

Do I have to participate in this research program?
No, participation is completely voluntary. It is up to you to decide if you want to take part in this program or not.

Can I opt out of participation after signing the form?
If you decide to participate, you can withdraw from the program at any time without providing further information. If you decide not to participate or if you decide to withdraw from the program, this will not affect your legal rights in any way.

How does the "Smoke-free Together" program work?
The program is now in the second phase, the testing of the mobile application for smoking cessation, aimed at 60 expectant couples in which the woman smokes. They are divided into four groups – three intervention groups, and one continuing with usual care (control group): (1) a mobile app for smoking cessation, (2) over-the-phone counseling sessions with a counselor specializing in smoking cessation, (3) the app and counseling sessions, (4) usual prenatal/postnatal care (control group). The intervention will begin at enrollment and will continue until one month after the birth of the baby.

What will happen if I decide to participate in this program?
If you decide to participate in this program, we will ask you to:

- Sign an informed consent confirming that you understood the aim of the program and you volunteer to participate.

- Provide your name, email and phone number, as well as your partner's name, email and telephone number so that the program team can send him a similar form within 2-5 days of your enrollment, inviting him to sign up.
- Complete the initial questionnaire (15-20 minutes)
- You get access to a brochure with information about quitting smoking during pregnancy.
- Women and their partners will be divided at random and with an equal probability (as if flipping a coin) in one of the four groups of participants in the program.
  Depending on the group you were assigned to, **you may**:
  1. Be contacted by phone to agree upon up to **3 phone counseling sessions** (20-30 minutes each), with a specialized counselor ready to give you support to quit smoking and stay smoke-free. The partners of women in this group can also benefit from up to two phone counseling sessions.
  2. Use the **"Smoke-Free Together" mobile app**, developed within the program. This app is designed by specialists from the program team to provide personalized information about the effects of smoking on your health and your baby, smoking cessation tips and strategies, information on how to stay quit, and a planning and personalized tracking function for quitting smoking.
     Partners of the women who use the app can use a version of the app that provides them with information on the effects of smoking on their health and the baby's health, as well as tips and strategies to help their partner quit smoking and stay smoke-free.
     To enjoy the full functionality of the app, it is important for the user to allow notifications ("push notifications" - which you can adjust later in settings) and **answer the questions asked through the app**. The purpose of the questions is to customize the information included in the app according to the needs of each user.
  3. Benefit from both counseling sessions and the "Smoke-Free Together" mobile app.
  4. Be assigned to the control group who will continue with usual care.

- Approximately **one week after the estimated date of birth,** you will be contacted by SMS or phone call to confirm the date of birth.
  The final stage of your participation is the evaluation of the program, for which you will be contacted by phone **four months after the confirmed date of birth** (three months after the end of your use of the the program). Your partner will be contacted to complete a short questionnaire at that time as well. For you, if at the time of the assessment you are non-smoker, it may include, besides completing a questionnaire, a quick test to determine the level of cotinine in the saliva (to measure precisely if you have managed to remain non-smoker). This test will be sent by courier or post by the program team. We will assist you through the phone in applying the test and ask you to send us a picture of the result.

How much time I will have to commit if I decide to take part in this program?

Your participation and your partner's (if enrolled) in this program starts when you sign this document and ends four months after your baby's birth, when you will be contacted for the final evaluation of the program. If you and your partner are assigned to one of the groups that benefit from the phone counseling or mobile app, you will be able to receive these counseling sessions and use the app for up to one month after the birth of the baby.
Depending on the group to which you and your partner will be assigned, you will need to dedicate about **half an hour today**, **20-30 minutes for each telephone counseling session**, according to your preferences (if you will benefit from counseling sessions) and **20-30 minutes once in the fourth month after birth,** when we will call you to evaluate the success of the research program. The use of the mobile phone app (if you will be assigned to it) is reccommended daily for a few minutes**.**

What are the risks associated with my participation in this research program?
The potential risks associated with this program are minimal and have a low severity. The probability of physical risks is low. Participants are not required to perform activities that may result in physical injury. The probability of psychological risks is also low. Other possible but unlikely risks include issues related to the safety of research data, risks against which the research team takes all appropriate measures to protect personal data.

What are the possible benefits of participating in this program?
As a result of participating in this program, you will find information that may motivate you to quit smoking or stay quit. The health benefits include immediate relief for the pregnant woman and her husband or life partner, to the fetus, during birth, for the baby, and for the entire family, on the long term.
The results gathered and evaluated in this program have the potential to make a significant contribution to improving the health of mothers and children in Romania.
One of the long-term goals is to adopt the counseling program as an extension of the national STOP FUMAT program. The program will contribute to the knowledge of smoking prevention during pregnancy, the results that will be published would potentially help the public health system in Romania and other health systems to adopt effective prevention and smoking cessation campaigns addressed to young families.

How much does it cost to participate in this program?
Participation in this program is free.

Will I be financially rewarded for participating in this study?
Participation in this study is voluntary. If you decide to participate, as a token of our appreciation for your time, you will be rewarded with two gifts for the baby, in the amount of 150 RON, one week after you are included in the study and four months after the birth of your baby, after completing the final evaluation. In addition, within 90 days after enrollment, a

drawing gives you 1 in 10 chances to win an ISARA baby carrier valued at approximately 600 RON. The drawing will be conducted by Babes-Bolyai University under the Romanian laws and regulations with no involvement from Michigan State University. If your partner joins you, you will also be rewarded another gift in the amount of 50 RON, after his enrollment. These gifts will be delivered via postal or courier services to the address specified by you, on the territory of Romania.

How will my privacy be protected?

Your confidentiality will be protected to the maximum extent allowable by law in Romania and the USA. You will not be judged for any of the information or opinions you express in the questionnaires or during the discussions with our counselors, in the event you will receive these counseling sessions. The information you provide will be stored through the Qualtrics online platform. Qualtrics is a secure, password-protected, web-based platform that provides industry standard data security measures designed to prevent unauthorized access, disclosure, alteration, and use of the data collected by users of its service (for more information, see https://qualtrics.msu.edu/).

Also, only members of the program team, our counselors, members of the Human Subjects Protection Program from Michigan State University, National Institutes of Health employees and the Ethics Committee at UBB will have access to these documents. All documents resulted from this program will be kept for a period of five years after program completion.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of reporting suicidal situations. The Certificate cannot be used to refuse a request for information from personnel of the National Institute of Health that is needed for auditing or program evaluation by National Institute of Health which is funding this program. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

A description of this clinical trial is available on http://www.ClinicalTrials.gov. This web site

will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

Who I can contact if I have any questions regarding this program?

We encourage you to ask questions. If you have questions or concerns about this program, such as scientific issues, what your participation involves, or to report an adverse event, please contact Oana Blaga, at oana.blaga@publichealth.ro, or at Pandurilor Street nr 7, postal code 400376, Cluj-Napoca, room 909, telefon 0264-402.215. You can also contact the Principal Investigator, Dr. Cristian Meghea, at cristian.meghea@hc.msu.edu.

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Human Research Subject Protection Program at Michigan State University at +1-517-355-2180, Fax +1-517-432-4503, e-mail irb@msu.edu or by post at 4000 Collins Rd, Suite 136, Lansing, MI 48910, SUA.

Part II: Certificate of Consent

I have read the foregoing information. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. **By clicking on the buttons below I consent voluntarily to participate in this this program testing a smoking cessation program addressed to couples who are expecting a baby.**

Program title: Smoke-free together (O Intervenție Mobilă pentru Renunțarea la Fumat în Familiile din România**)**

- ☐ Members of the research team and counselors who work in this program will have access to all the information I will offer during my participation.
- ☐ Members of the research team will use the contact details of my husband/partner (name, email, phone number) to invite him to participate in this program.
- ☐ There is a possibility for me to receive up to 3 telephone counseling sessions with a counselor specially trained to offer me support to stop smoking; the number of sessions would be determined by my preferences and needs.
- ☐ There is a possibility for my partner to receive up to 4 telephone counseling sessions with a counselor specially trained to discuss couple smoking cessation support strategies; the number of sessions would be determined by my partner's preferences and needs.
- ☐ There is a possibility that I will use a mobile app containing personalized information about the effects of smoking on maternal and child health, tips and strategies for quitting smoking, information on staying quit, as well as a personalized quit plan and tracking feature.
- ☐ There is a possibility that my partner will use a mobile app containing information about the health effects of smoking, as well as tips and strategies for offering support in quitting smoking.
- ☐ Irrespective if my husband and I are assigned to one of the groups using the app or receiving counseling sessions, I will be contacted 4 months after birth to fill out a short questionnaire and to have my smoking status evaluated.

My name and date below confirm my voluntary agreement to participate in this program.

Name, Surname ☐

Date ☐

Approved by a Michigan State University Institutional Review Board effective 4/25/2019.
This version supersedes all previous versions. MSU Study ID STUDY00000645.