RESEARCH INFORMED CONSENT

Effectiveness and Outcomes of the Creighton University
Commit to Quit Smoking Cessation Program

Protocol Number 12-16326

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Creighton University IRB
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Introductory Statement
You have been asked to participate in a registry of smokers who have used the Alegent Creighton Clinic - Cardiology smoking cessation services. A registry is a type of study where the study team will collect specific information from you and will follow your progress into the future, but there will be no treatment or intervention as part of the study. The study team is interested in collecting information about the number of people who successfully quit smoking and remain smoke-free after completing the Commit to Quit program and the health of the participants in the future. Before you agree to participate in this study, the risks and benefits of the study will be explained to you. You may then agree to participate or decline. This consent form describes the purpose, procedures, possible benefits and risks of the study. Once you understand the study, you will be asked to sign this form if you wish to participate. You are not under any obligation to participate in this or any research project.

Read this information carefully and please ask the study staff if you have any questions.

Study Purpose and Procedures
The purpose of this study is to determine how many people who complete the Alegent Creighton Clinic - Cardiology Commit to Quit program successfully quit smoking and if they remain smoke-free in the long term. This study will not involve an intervention or assignment to a specific treatment or study group. If you agree to participate, we will only be observing and collecting information about your medical and smoking history and whether or not you are currently smoking each time we follow-up with you. We will also be asking you about your health and will ask whether you have had any problems that are typically associated with smoking, such as heart attack, cancer, or lung problems. Participation in this study will not change the treatment or services that you receive for smoking cessation.

If you participate in this registry, we will give you a choice to be contacted either by email to complete a web-based survey or by telephone. If you choose to be contacted by email, someone may still contact you by telephone if we have not received your response to the survey within 2 weeks.

Please select your preference of telephone or email contact:

☐ Email: ____________________________

☐ Telephone (provide telephone number even if email is preferred contact method): ________________

We will contact you every three months after you complete the Commit to Quit program for the first year, and then at 18 months and two years after you finish the program. After the first two years, we will contact you once a year. All of the follow-up contact will be by email/internet or by telephone. You will not be asked to return to the clinic for any of the follow-up for this study.

If you prefer not to be contacted for long term follow-up, we would like to ask for your permission to use the information that we normally collect for all participants in the Commit to Quit program in our research database. If you choose this option, we will use the Smoking Assessment that you complete prior to or during your first session of Commit to Quit and the standard three and six month follow-up surveys in our database, but we will not continue to contact you in the future.

Risks of Participating in the Study
Participation in this study poses no more risk than is encountered in everyday life. The primary risk to participation in the study is the unlikely possibility of accidental disclosure of personal information.
Confidentiality Risk
A possible risk involved in this study involves the potential social and psychological risks associated with accidental disclosure of confidential medical information from the data collected throughout the study. Several procedures will be in place to prevent such an occurrence.

Benefits of Participating in the Study
The benefits to participation in this study will be that the researchers will be able to gather valuable information about the long term health outcomes of people who have received smoking cessation support from Alegent Creighton Clinic - Cardiology. This study will also provide more information about the effectiveness of different types of treatments to help people quit smoking. There are no direct benefits to you for participation in the study.

Disclosure of Appropriate Alternatives
Participation in this study will not change your smoking cessation treatment from Alegent Creighton Clinic - Cardiology. There are no alternatives to participation in the study. If you decline to participate in the study, your treatment will not change.

Confidentiality
We will do everything we can to keep your records confidential. However it can not be guaranteed. We may need to report certain information to agencies as required by law.

Both records that identify you and this consent form signed by you may be looked at by others. The list of people that may look at your research records are:

- The investigator and their research staff and students
- The Creighton University Institutional Review Board (IRB) and other internal departments that provide support and oversight at Creighton University.

We may present the research findings at professional meetings or publish the results of this research study in relevant journals. However, we will always keep your name, address or other identifying information private.

We will also ask you to sign a separate form called the HIPAA Authorization which will give you more specific information concerning the use of your health information.

Compensation for Participation
There is no compensation for participation in the study.

Contact Information
If you would like to speak to someone about this research project, you may call Tammy Burns, PharmD at (402) 717-0717 or Shavonne Washington-Krauth, MA at (402) 280-5287.

Consequences of Subject’s Decision to Withdraw
You may withdraw from the study at any time. Withdrawal from the study will not impact any services that you may receive at Alegent Creighton Clinic or participation in any other research studies.

If you withdraw from the study, you will be given two options. First, you may withdraw and agree to allow the investigators to look at your medical records to check for any health issues that are possibly related to smoking. Second, you may withdraw and request that the investigators do not have access to
your medical records. However, all data collected before you withdraw will be included in the study data and may not be removed.

**Signature Clause**

You are free to refuse to participate in this research project or to withdraw your consent and discontinue participation in the project at any time without penalty or loss of benefits to which you are otherwise entitled, or any effect on your medical care.

*My signature below indicates that all my questions have been answered. I agree to participate in the project as described above.*

☐ I agree to participate in the long term follow-up study.

☐ I agree to allow the study team to use the information that is routinely collected for the Commit to Quit program (the Smoking Assessment and the six month follow-up survey), but do not want to participate in the long term follow-up study.

________________________________________________________
Printed Name of Subject

________________________________________  ____________
Signature of Subject                      Date Signed

The Creighton University Institutional Review Board (IRB) offers you an opportunity (anonymously if you so choose) to discuss problems, concerns, and questions; obtain information; or offer input about this project with an IRB administrator who is not associated with this particular research project. You may call or write to the Institutional Review Board at (402) 280-2126; address the letter to the Institutional Review Board, Creighton University, 2500 California Plaza, Omaha, NE 68178 or by email at irb@creighton.edu.

*A copy of this form has been given to me.*  Subject’s Initials

**For the Research Investigator**—I have discussed with this subject the procedures described above and the risks involved; I believe he/she understands the contents of the consent document and is competent to give legally effective and informed consent.

________________________________________  ____________
Signature of Responsible Investigator      Date Signed

We would appreciate your feedback on your experience as a research participant at Creighton University; please fill out our survey at [http://www.creighton.edu/participantsurvey](http://www.creighton.edu/participantsurvey)
Bill of Rights for Research Participants

As a participant in a research study, you have the right:

1. To have enough time to decide whether or not to be in the research study, and to make that decision without any pressure from the people who are conducting the research.

2. To refuse to be in the study at all, or to stop participating at any time after you begin the study.

3. To be told what the study is trying to find out, what will happen to you, and what you will be asked to do if you are in the study.

4. To be told about the reasonably foreseeable risks of being in the study.

5. To be told about the possible benefits of being in the study.

6. To be told whether there are any costs associated with being in the study and whether you will be compensated for participating in the study.

7. To be told who will have access to information collected about you and how your confidentiality will be protected.

8. To be told whom to contact with questions about the research, about research-related injury, and about your rights as a research subject.

9. If the study involves treatment or therapy:
   
a. To be told about the other non-research treatment choices you have.

b. To be told where treatment is available should you have a research-related injury, and who will pay for research-related treatment.