

Informed Consent Form for Participation in a Research Study

ATP Radon Testing Study

Protocol ID: HREBA.CC-24-0461

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Funder(s)/Sponsor: Alberta Health

WHY AM I BEING ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being invited to participate in this research study because you are a participant in Alberta's Tomorrow Project (ATP). The purpose of the ATP Radon Testing study is to help better understand residential radon levels and exposure in Alberta.

Radon is an odourless, tasteless, invisible, and radioactive gas that occurs naturally in the ground. Radon can enter buildings through cracks in the foundation, and can build up in indoor air. When radon gas decays, it emits alpha particles (a type of radiation) that can damage DNA. Radon exposure is one of the leading causes of lung cancer, second to tobacco smoke. The Prairies have some of the highest residential radon levels in the world. Fortunately, if your home radon levels are high there are effective and proven mitigation solutions to reduce radon to low levels. ATP is partnering with the Evict Radon National Study at the University of Calgary to invite 5000 ATP participants to test the Radon levels in their homes. Through this project you also have the option of collecting toenail clippings as toenails can be analyzed for environmental exposures, such as arsenic and lead. There may also be new methods of measuring a person's life-time radon exposure using the collected toenail samples.

This consent form provides information about the study to help you with making an informed decision. Please read this document carefully and contact us with any questions you may have. You are encouraged to ask questions. When all your questions have been answered to your satisfaction, you can decide if you want to participate in the study or not.

Taking part in this study is voluntary. You may choose whether or not you take part. If you choose to participate, you may leave the study at any time without giving a reason

and without penalty. Deciding not to take part or deciding to leave this study early will not result in any penalty or affect current or future care or employment. You do not have to take part in this study in order to stay a participant in ATP. If you choose to not participate in this study, it will not affect your status as an ATP participant.

If you decide to participate in this study, you will need to electronically sign and date this consent form. A copy of the consent form will be emailed to you.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

We plan to enroll up to 5000 ATP participants for this study.

WHAT WILL HAPPEN DURING THIS STUDY?

This study should take about 7 months to complete. If you decide to participate:

- You will provide your contact information (name, mailing address, email address, and phone number). ATP will then provide this to the Evict Radon National Study investigators at the University of Calgary.
- The Evict Radon National Study will then mail you a package containing the radon testing device and a toenail clipping collection kit (if applicable).
- You will be asked to register your radon testing device.
- You will be asked to complete two surveys through the Evict Radon National Study (one at the beginning of radon testing and one at the end). The purpose of the surveys is to gather more detailed information about your home and activity patterns, which impact your personal risk of radon exposure.
- You will be asked to set up the radon testing device in your home for 4 months (120 days). After this, you will be asked to mail back the testing device using a pre-paid package.
- If you choose, you can also collect toenail clippings over the same 4-month period using the collection kit provided. These would be sent back with your radon testing device.
- The radon testing device will be analyzed by an accredited laboratory and the results will be returned to you by the Evict Radon National Study to the email address you provide. The results will also be sent to ATP and made available in your Participant Portal.
- The data that you provide in the Evict Radon National Study surveys will be sent to ATP to become part of the ATP data repository and available for future research use. The toenail clippings will be transferred to ATP and stored in the ATP biobank for future research use.
- Your de-identified radon test results and survey data will be used for research.

For this study, the radon testing results will be stored at ATP and some data will be sent to Alberta Health for reporting purposes. Alberta Health will not see any of your personal information. All results will be de-identified and will be aggregated (or grouped) before they are released.

RETURN OF RESULTS:

The radon test results will be returned to you by the Evict Radon National Study and sent to the email address you provide in this consent form. They will also be available in your ATP Participant Portal.

WHAT ARE MY RESPONSIBILITIES SHOULD I DECIDE TO PARTICIPATE IN THIS STUDY?

If you choose to participate in this study, you will be expected to:

- Provide your contact information (including name, email, mailing address) and allow this information to be sent to the Evict Radon National Study, who will send you a kit by mail to do the radon testing in your home.
- Register your radon test kit using the Evict Radon National Study website and set it up in your home for 4 months (120 days). After this you will return it using the pre-paid package provided.
- Complete online surveys through the Evict Radon National Study.
- You may also be asked to provide your feedback about the study to help us improve our study processes.
- You may be recontacted in the future for follow-up surveys or other activities related to this study – you will be informed of these at the time and have the option to participate or not.

Toenail Clipping Collection (Optional)

An optional activity is to collect toenail clippings over the 4 months your home is being tested for radon. A collection kit will be provided in the radon testing kit package mailed to you, but you can choose whether or not to collect toenail clippings. If you decide to take part in this activity:

- Toenails should be in generally good health (no fungus, etc.)
- You are willing to not wear nail polish on your toes two weeks prior to each cut.
- You, or a caregiver, are willing or are physically able to collect **ALL** toenail clippings over the whole period.

- You will not conduct the radon test for more than 120 days (i.e., after 4 months, you will ensure to return your radon test kit and toenail collections).

WHAT WILL HAPPEN IF I CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to end your participation in this research study (called early withdrawal) at any time without having to provide a reason and without penalty. If you choose to withdraw early from the study without finishing the procedures, please contact ATP. If you choose to withdraw from this radon testing study, it will not affect your continuing participation in Alberta's Tomorrow Project.

Information that was recorded before you withdrew will be used by ATP for this study, but no additional information will be collected after you withdraw your permission.

If you no longer want your data or samples to be used in this study, you should let ATP know in writing. We will ensure the samples that have not already been used are destroyed. If tests have already been done on your sample(s) it will not be possible to withdraw those results. However, no further testing will be done.

WHAT ARE THE RISKS/DISCOMFORTS OF PARTICIPATING IN THIS STUDY?

You will receive the results of the radon testing, which will estimate the radon levels in your home. It is up to you whether or not to act upon your radon test results. Please know, however, there are effective solutions to high radon exposure. There are NO HARMS associated with taking part in this study.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING IN THIS STUDY?

Participation in this study may not be of personal benefit to you, other than receiving your home's radon testing results. However, based on the results of this study, it is hoped that in the long-term, radon exposure and risks can be better understood or improved. The Evict Radon team conducts many quality assurance controls (duplicates, blanks and controlled positives) to ensure participants obtain the most accurate readings possible. This is not commonly performed by other radon testing entities but is integral to gold-standard research.

HOW WILL MY PERSONAL INFORMATION BE KEPT PRIVATE?

Data and Biosample Storage:

If you decide to participate, Alberta's Tomorrow Project will only collect information we need for this study. We will do everything in our due diligence to ensure that this data is

kept private/confidential. Data collected using the online surveys will reside on secure AHS and Evict Radon/University of Calgary servers and be kept confidential and will only be used for research and reporting purposes. The data you provide for this radon testing study through the home metrics and activity patterns survey will be held by Evict Radon and it will be added to ATP's existing data repository. The toenails you provide will be added to ATP's existing repository along with the biosamples you have already provided to ATP through previous study centre visits.

Your personal contact information provided in this consent will be sent from ATP to the Evict Radon National Study so that they can send you the radon testing kit. Your information will be transferred using a secured and encrypted file transfer process.

When we receive your study materials, we will separate anything that identifies you from all other information (survey responses and samples). Names and contact information will be stored in a separate database that will be accessed only by a limited number of staff working for ATP. This will be for the purpose of contacting you for additional information. We will then put all of the survey data into a large research database. We will identify all information in the research database using a set of unique identification numbers. All biosamples will be labeled with your unique identification number, and kept in locked facilities in the biobank. Access to the locked facilities will be limited only to staff who manage the biobank. All information will be stored on secure computer servers located in restricted access, high security facilities. All ATP staff have signed oaths of confidentiality, and completed training about information security and privacy.

De-identified results of this study will be sent to Alberta Health for reporting purposes. These data would be released at an aggregate, or group level, so Alberta Health will not know who you are.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated. Every effort will be made to keep your information confidential, and to follow the ethical and legal rules about collecting, using, and disclosing this information. Very rarely, by law, ATP may have to release information including names and therefore absolute confidentiality cannot be guaranteed. However, every effort will be made to make sure that your information is kept confidential.

After the radon testing study has been completed, we will still need to securely store your data that was collected as part of the study. We will keep your data and study records stored until the end of the ATP study, which is estimated to be in 2062.

Future Uses of the Data and/or Samples:

Researchers may apply to access the research data and samples that are stored by ATP in Alberta. Each researcher must get ethical approval for their research by completing an application that is reviewed by an independent organization, and must

submit a written application to ATP. He or she will receive only de-identified information which may include dates collected in the study, such as full dates or a portion of the date given, like the season and year you report on a questionnaire (e.g. dates you conducted radon testing). Data or samples released to approved researchers will not include your date of birth.

ATP always conducts reviews of each request to ensure no information increases the risk of re-identification of any participant. If a request involves dates (such as date of hospitalization), and ATP's review finds that release of the information could increase the risk of re-identification (e.g. data is only being requested for a small number of participants), the date(s) will not be released. Researchers will also be required to sign an agreement stating that the data and samples will be used only for the approved research. Researchers may also request permission to analyze some of the stored samples. Because all of the information the researcher receives would be de-identified, it will be extremely unlikely that you could ever be identified from these types of studies.

In the future, a portion of the data and samples donated by ATP participants may be combined with data and samples donated by people taking part in similar studies in British Columbia, Saskatchewan, Manitoba, Quebec, Ontario and the Atlantic Provinces. This means that a portion of data and samples may be stored centrally outside Alberta. These data and samples will be managed by the Canadian Partnership for Tomorrow's Health (CanPath; formerly the Canadian Partnership for Tomorrow Project, CPTP), and access by researchers will be managed in a way similar to that described for ATP in Alberta. If a portion of data or samples are transferred out of Alberta to a central location for CanPath, strict conditions for transfer and storage will be in place. Administrators of the data and samples sent to the CanPath will not know the identity of any person who donated data or samples to the study.

Your data and samples will be used for research, and will not be sold. However, research using your data and samples might lead to the commercialization of a medical or genetic test or product. This might be done by a university, hospital, commercial company, or some combination. This means researchers, possibly including commercial companies, might benefit financially. If a commercial product is developed from this study, you will not obtain any personal financial benefit.

Occasionally, analyses of data or samples may be done by staff working for ATP. These analyses may be done for quality control purposes, or for training of staff. Researchers or ATP staff who are granted access to data and samples will not know the identity of the people who donated them to Alberta's Tomorrow Project.

In the future, we may also share the data or results of this study (as well as data previously collected by ATP) with other organizations in order to help with research and health safety efforts related to radon, lung cancer risk, general cancer risk, or other related topics. The data will always be de-identified, so the organization and/or investigator will not know who you are, but may include dates collected in the study.

These organizations may include, but would not be limited to, the Public Health Agency of Canada (PHAC), Health Canada, and provincial, national or international repositories. Some of your health or radon information may be placed in central databases that may be public, along with information from many other people. Your name or any other information that could directly identify you will not be included. Any information and/or samples sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. However, all study information and/or samples that is transferred outside of Canada will be coded and undergo a process of de-identification so that your data or samples do not contain any personal identifying information such as your name, date of birth, address, health insurance number or contact information. Any information will be transferred in compliance with all relevant Canadian privacy laws. By signing this consent form, you are consenting to the disclosure of your coded information to organizations located outside of Canada.

Data Linkage:

We are asking your permission to access past, current and future health records and other administrative databases and repositories. Information in health records and administrative databases and repositories may help researchers understand more about the causes of cancer and other health conditions. Health records and administrative databases can also help explain how patterns of health and social services used over time may be associated with long-term health. Examples of databases that the ATP may need to access include, but are not limited to, the Federal Vital Statistics database (records of causes of death), pharmacy databases (records of medicines prescribed), and screening databases (records of cancer screening tests completed). We may also link to Statistics Canada and the Canadian Institute for Health Information (CIHI). If we link with Statistics Canada or CIHI, ATP will disclose participant identifiers, such as health card number and date of birth, to Statistics Canada or CIHI over a secured and encrypted file, who will use these data to extract certain types of information regarding the participants from a Statistics Canada or CIHI database, and send that information back to ATP. ATP will **not** make any requests to see any notes kept in doctors' offices.

We are also asking your permission to access past, current, and future data and samples collected in other research studies that you have consented to. This includes past, current, and future information provided for other research studies you participate in and samples that you provide for research that is stored in research biobanks. Such linkage will help researchers understand more about the causes of cancer and other diseases from information you have already provided for research without duplicating data collection efforts.

The researcher or study staff may need to look at your medical files/records or at those kept by other health care providers that you may have seen in the past (e.g., your family doctor). Any information that they get from these records will be only what is needed for the purpose of this study. It will be kept confidential to the extent permitted by the

applicable laws and will not be disclosed or made publicly available, except as described in this consent document. In some circumstances, researchers are required by law to release information about participants to local authorities such as positive HIV or Hepatitis results.

Individuals of the following organizations may look at your medical records, including your name, for quality assurance purposes and/or to verify that the information collected for this study is correct and follows proper laws and/or guidelines:

- Alberta's Tomorrow Project, the research group coordinating this study;
- The Health Research Ethics Board of Alberta which oversees the ethical conduct of this study

WILL THERE BE COSTS INVOLVED WITH PARTICIPATING IN THIS STUDY?

There will not be costs involved in participating. If you decide to participate in this study, the radon testing kit and associated mailing costs will be provided to you at no cost.

WILL I BE COMPENSATED FOR PARTICIPATING IN THIS STUDY?

You will not be paid for taking part in this study.

WHAT ARE MY RIGHTS AS A PARTICIPANT IN THIS STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study. All updates will be listed on the study website at <https://myatp.ca>. You have the right to be informed of the results of this study once the entire study is complete. You may visit the ATP website at <https://myatp.ca> for any updates, or you may also contact ATP if you would like to be informed of these results.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights against the researchers, sponsor, institutions or their agents involved for compensation, nor does this form relieve these parties from their legal and professional responsibilities.

IS THERE ANY CONFLICT OF INTEREST RELATED TO THIS STUDY?

ATP is receiving financial payment from Alberta Health to cover the cost of conducting this study. The researcher will not receive any direct benefit for conducting the study.

Radon testing in Canada must be managed by C-NRPP (Canadian National Radon

Proficiency Program) certified professionals. Prior to selecting a test device for this study, the lead researchers of Evict Radon evaluated a number of products currently on the market and determined that RadTrak3 long term radon test device manufactured by Radonova and distributed in Canada by RadonWest was the best fit to offer the most scientifically reliable results to all parties. Radonova Inc. are the *only* radon test provider (on Earth) of kits with ISO 17025 Certification – meaning they are the only radon test manufacturer and testing laboratory certified to meet international standards that specify rigorous requirements for a quality management system. For research, using devices with ISO 17025 is essential, and so other test providers are not eligible. This does not, however, constitute an endorsement of RadonWest, Radonova or their products by ATP, Alberta Health Services, Evict Radon, or the University of Calgary. ATP, Alberta Health Services, Evict Radon and the University of Calgary cannot certify the quality or reliability of any equipment sold by RadonWest or Radonova. The leaders and associated organizations of this study do NOT benefit in any way from the sale of test kits and have no financial relationship with RadonWest or Radonova. The collaborators involved (outlined at <https://evictradon.org/scientists/>) have absolutely NO financial relationship with any radon testing or mitigation retail or industrial entity.

WHERE CAN I FIND ONLINE INFORMATION ABOUT THIS STUDY?

A description of this study will be available on <https://myatp.ca>. This website will not include information that can identify you. You can search for this website at any time.

WHO DO I CONTACT FOR QUESTIONS RELATED TO THIS STUDY?

If you have questions about taking part in this study please contact Alberta's Tomorrow Project:

Call us on our toll-free telephone:
1-877-919-9292

Send us an e-mail to:
tomorrow@albertahealthservices.ca

Write a letter to:
Alberta's Tomorrow Project,
Arthur Child Comprehensive Cancer Centre
3395 Hospital Drive NW, Calgary, Alberta, T2N 5G2

If you have questions about your rights as a participant or about ethical issues related to this study and you would like to talk to someone who is not involved in the conduct of the study, please contact the Office of the Health Research Ethics Board of Alberta.

Email: info@hreba.ca

Toll Free: 1-877-423-5727

UNDERSTANDING AND SIGNATURES PAGE

	<u>Yes</u>	<u>No</u>
Do you understand that you have been asked to take part in a research study?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand why this study is being done?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand the potential benefits and risks/discomforts of taking part in this study?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand what you will be asked to do should you decide to take part in this study?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that you are free to leave the study at any time, without out having to give reason or without penalty?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that we will be collecting information about you for use in this study only?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that by signing this consent form that you do not give up any of your legal rights?	<input type="checkbox"/>	<input type="checkbox"/>
Do you feel that you had enough time and opportunity to consider the information provided to you by way of asking questions, having conversations with others and considering your options?	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that your samples and data will be kept in the ATP repository for use in future health research.	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that you are providing permission for ATP to link to past, current, and future data and biosamples I provide to other research studies and research biobanks that I have consented to	<input type="checkbox"/>	<input type="checkbox"/>
Do you understand that you may be recontacted in the future for follow-up surveys or other activities related to this study.	<input type="checkbox"/>	<input type="checkbox"/>

	<u>Yes</u>	<u>No</u>
<u>Would you like to take part in the toenail collection portion of this research study (optional)?</u>

Please provide the contact information that will be sent to Evict Radon for the purpose of mailing you the radon testing kit and for receiving your radon test results:

First name:
Last name:
Mailing address:
Street:
City/town:
Province:
Postal Code:

Email address:
Confirm email address:
Phone:

By signing this form I agree to participate in this study and will be testing the radon level in my home.

Signature of Participant

Printed Name

Date

STUDY TEAM ACKNOWLEDGEMENT

I believe the person signing this form understands what is involved in this research study and has freely decided to participate.

Signature of Person Conducting
the Consent Discussion

Printed Name

Date

You will be emailed a copy of this consent form prior to participating in this optional research.