

RESEARCH SUBJECT CONSENT FORM

Title: Amyloidosis Research Consortium Patient Experience Survey:
2022 Community Survey for Caregivers and Patients with
Amyloidosis

Protocol No.: ARC005

Sponsor: Amyloidosis Research Consortium

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**Study-Related
Phone Number(s):** 617-467-5170

DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research participant.

What should I know about this research?

- This form explains this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to collect data and information on patient and caregiver experience with diagnosis and treatment of amyloidosis and how this experience has changed over time. The data generated from this survey will be used to across our programs and to provide evidence-informed guidance to decision-makers, researchers, and health professionals.

Who and how many people are being asked to participate in this research?

Individuals or caregivers of individuals with amyloidosis are invited to take part in this research. About 900 participants will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last 20 minutes.

What happens to me if I agree to take part in this research?

This research relies on an online survey. Therefore, your participation is limited to answering the survey questions online and you will not have direct contact with the research team.

The survey consists of approximately 60 questions. There are unique surveys for patients and caregivers to complete. While you can leave in the middle of the survey and return to the same page you left off, we encourage completing the survey in one sitting.

Data collected via this one-time online survey will be aggregated and analyzed by the research team at ARC. Quotes from the text fields may be used in reporting but will not be attributed to

you. You may choose not to provide any quotes. The report and manuscript that will summarize the results of this study will report only aggregate numbers and is slated to be completed by the end of 2024. Once published, study findings will be available at arci.org.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to answer the one-time online survey. There will be no follow-up survey or additional responsibilities. You will not be contacted or asked to provide any additional information.

Could being in this research hurt me?

Participation in an online survey is voluntary and has minimal risk to you. It does not include physical risks, legal risks, social risks, or economic risks. However, you may experience discomfort answering questions about experiences you or your family have related to amyloidosis, which may be associated with psychological risks (such as embarrassment).

Your answers are confidential. The datasets that will be downloaded from the online survey vendor's website will be stored in a password-protected manner that only the research team will have access to. Privacy risks, such as disclosure of private information is not possible as it is not collected.

Will it cost me money to take part in this research?

Taking part in this research may lead to added costs to you, such as: costs of internet access or a device to access the internet.

Will being in this research benefit me?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include learning more about the patient and caregiver experience with diagnosis and treatment of amyloidosis and how this experience has changed over time. If you provide your name and email at the end of the survey, you will be entered into a drawing to win one of ten gift cards worth \$150 each.

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research?

This research does not collect information such as your private personally identifiable information. If you wish to be entered into the optional drawing to receive a gift card, or to be

added to ARC's mailing list, you will be asked to provide your name and email address at the end of the survey. This information will only be used for these two purposes, which are both optional. Your private information (your answers to the survey questions, excluding your name and email) will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- North Star Review Board, Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, data will be aggregated, and no individual data will be singled out. The aggregated reporting ensures your survey responses are confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

The deidentified data collected in this research might be used for future research or distributed to another investigator for future research without your consent.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

To discuss study-related concerns or complaints with someone who is not part of the survey team, please contact North Star Review Board at 877-673-8439 (toll free) or info@northstarreviewboard.org.

What if I am injured because of taking part in this research?

There is no risk of injury or sickness because of taking part in this research.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include: not completing the entire survey, or answers you provide which are outside a reasonable range or highly improbable. To limit the possibility of out of reasonable range responses, the survey has some logical validation rules in place. For example, in a question asking in the past 30 days, how many days have you experienced an event; only a response between 0-30 will be accepted. The vast majority of questions are multiple choice and this minimizes the risk of removal from the research.

What happens if I agree to be in this research, but I change my mind later?

If you decide to leave the research early by exiting the survey before the last question, there are no risks with this decision. Any responses you answered prior to leaving the survey may be used as part of the aggregated data. No contact or notification to the research team is required.

Will I be paid for taking part in this research?

You will not be paid for taking part in this research. You have the option of entering a drawing to win one of ten gift cards worth \$150 each at the end of the survey.

Statement of Consent:

By clicking on the survey link and continuing to the online survey, you provide your consent to participate in this study.