

Frequently Asked Questions

Project Title: **Project PRIORITY: Patient Reported Initiative On Resistance, Incidence, Treatment studY**

IRB Protocol Number: Protocol Pro00033245

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What is Project PRIORITY?

The **Patient Reported Initiative On Resistance, Incidence, Treatment studY** is a **patient-founded** and **patient-driven** research partnership between the EGFR Resisters and LUNGEvity Foundation. The study team is interested in understanding the treatment experience of EGFR-positive lung cancer patients. Patients may respond directly to survey questions, or a patient's caregiver may respond on behalf of the patient. With the goal of empowering the EGFR Resisters community to have an impact on future research,, the study team would specifically like to:

1. Understand the demographics and needs of the EGFR-positive lung cancer community,
2. Identify areas for improvement in diagnosis and treatment, and
3. Give voice to patient concerns regarding risk factors, symptoms and side effects of treatments.

Why is Project PRIORITY important?

Project PRIORITY aims to identify major unmet research and treatments needs for EGFR-positive lung cancer. Information gathered through this study will be shared with researchers, clinicians, and drug developers to inform research and treatment. The study will answer important questions, such as:

1. How is EGFR-positive lung cancer treated?
2. How long does it take for patients to development resistance to different treatment options?
3. How do patients feel on different treatments for EGFR-positive lung cancer?
4. What are some of the risk factors associated with EGFR positive lung cancer?

Will Project PRIORITY impact my personal care?

Project PRIORITY will not impact your personal treatment and lung cancer care. However, findings from the study may impact future research and treatment of EGFR-positive lung cancer.

Who is eligible to participate in the project?

You are eligible to participate in the study if:

1. You are 21 years or older,
2. You (or a loved one) has been diagnosed with EGFR-positive lung cancer, and

3. You can read and understand English and respond to the survey questions.

If you are a caregiver, please respond as the patient (unless specifically instructed to respond as yourself).

The project is an online survey; no pen-and-paper version of the survey is available. This will maintain anonymity and confidentiality. There are no financial benefits to participating in this project.

How can I participate in the study?

You can participate in Project PRIORITY by filling out the online survey. Once you start taking the survey, it will take you 35-40 minutes to complete it. We recommend that you finish the survey in one sitting. If you are unable to do so, you can go back to the same link to finish the survey for the next 7 days – since you first started taking the survey. It is important that you take the survey from the same computer or tablet, and from the same web browser that you started using the first time you took the survey.

Is it safe for me to participate in the project?

There is no to minimal risk associated with Project PRIORITY and are the same as those associated with participating in an online survey.

How will my information be collected?

Participation in the study is completely voluntary. You will be able to provide your information through the online survey. The survey platform is secure and compliant with United States security laws as well as with the recent European Union General Data Protection Regulation (GDPR) requirements.

How will information from the project be stored?

All information provided through the survey will be stored in a secure, online cloud server that has met the safety and security requirements to minimize breach of confidentiality.

What information will the project collect?

We will collect the following types of information:

1. Your diagnosis and treatment history
2. Impact of the diagnosis on your quality of life
3. Information specific to your EGFR-positive lung cancer, such as biomarker testing and types of treatment you have received
4. Some demographic characteristics

Although we recommend that you answer the entire survey so that we have a complete understanding of your lung cancer journey, you do not have to answer every question.

Will the project collect information that can identify me?

Project PRIORITY has two components:

- 1) **An initial survey that collects information about your lung cancer journey (past and current)**. This survey does NOT collect any identifying information. At the end of this survey,

you will be asked if you want to participate in the longitudinal survey (described in the next bullet point).

- 2) **Future surveys that are a part of the longitudinal component of Project PRIORITY.** This survey will be a much shorter version of the initial survey and ask participants what, if anything, has changed since the previous survey. **Participation in the longitudinal survey is completely voluntary.** If you decide NOT to participate in the longitudinal component, you can opt out by not providing your email address. If you decide to participate in the longitudinal component of Project PRIORITY, you then will provide your email address. As with the initial survey, no individual analysis will be done. You can also choose to withdraw from participating in the longitudinal component if you change your mind.

You can participate in Project PRIORITY WITHOUT providing your email information for future surveys. This does not disqualify you from taking the initial survey.

If you opt to participate in the future surveys, your email address will be stored separately from your responses. Your contact information will NOT be used or shared with any one apart from the Principal Investigator, who will use the email address only to get in touch about future surveys and studies.

How will my information be used?

All information collected through this project will be analyzed in aggregate: this means that all the responses for a particular question will analyzed as one group, never individually.

Researchers and clinicians can have access to the de-identified data collected through Project PRIORITY. This is because we firmly believe that the data collected through the project should be used for the benefit of the community. In order to receive access to the data, researchers will have to submit a request for a proposed study to the research team.

How long will Project PRIORITY last?

Project PRIORITY is a two-year project and data will be collected for two years once the study is open.

How long will the data be stored?

All de-identified responses will be stored for 2 years **after** the completion of the project. During this period, the data will be made available to third-party researchers for analysis after they have submitted a proposal to LUNGeivity Foundation and the EGFR Resisters.

What does de-identified data mean?

De-identified data is data without any identifying information, such as email addresses.

I have questions about the study. Whom should I contact?

If you have any questions or concerns about the survey, please contact the Principal Investigator, Dr. Upal Basu Roy, Senior Director of Research at LUNGeivity Foundation, at ubasuroy@LUNGeivity.org.

Has the research been approved by an Institutional Review Board (IRB)?

This research is being overseen by an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies. The study was reviewed by the Advarra IRB and was considered exempt since it involves minimal to no risk.

Will I get to see the results of the study?

Key highlights from the study – in the form of graphs and figures – will be posted on the EGFR Resisters website by the end of August 2019. As the study progresses, updated results will be posted on the website.

I have already participated in the study but now want to opt out of it. What should I do?

If you have already participated in the study and NOT provided your email address, there is nothing for you to do. The data we have captured is completely anonymous and is not linked to your personal details.

If you provided your email address to be contacted for future surveys, please email Dr. Upal Basu Roy at ubasuroy@lungevity.org to be removed from the study.

If you are not sure of your participation, please email Dr. Upal Basu Roy.

If you are a study participant (patient or caregiver) who is responding to the survey from a European Union member state which is subject to the General Data Protection Regulations (GDPR), please read this section before proceeding with the survey.

What kind of personal information will be collected?

Personal information collected during this survey is defined as information related to your disease history, any treatments you have received, and how a lung cancer diagnosis has impacted your life.

The survey will not collect IP addresses and we, in good faith, take your responses as representative of being a member of the European Economic Area (EEA), Switzerland, or the United Kingdom.

How will you interact with us during the project?

All information we are gathering from you will be through an online survey administered through a survey platform called Qualtrics. The platform will be collecting and storing all your data and in that sense, is the **data processor**. LUNGeVity Foundations and Qualtrics have entered into an agreement to ensure the rightful and ethical processing of data collected through Project PRIORITY.

LUNGeVity Foundation will serve as the data controller because we are collecting the data for a specific project: Project PRIORITY. Our role of data controller is assigned to us because we are collecting the data with the goal of understanding unmet needs of the EGFR-positive lung cancer community. All data collected will be explicitly used for purposes of the study only. As data controller, we are responsible for ensuring the safety of all data collected and complying with the legal and ethical obligations associated with the data. Controlling of the data is based on your consent to participate in the project as required under the applicable law. For research purposes, to the extent the de-identified data is anonymized as

is the case for Project PRIORITY, it is not considered personal data and falls outside the regulations of GDPR.

If you have any questions about the role of the data controller, please email Dr. Upal Basu Roy at ubasuroy@lungevity.org.

All interactions are a one-time remote interaction, and you may disclose as much information as you desire through the online survey. You may or may not choose to answer certain questions or sections of the survey. You may also choose not to provide us your email address at the end of the survey. If you choose to participate in the longitudinal component of the study by providing your email address, it will be stored on the Qualtrics platform and used to send you a survey after 6 and 12 months of finishing the first survey.

What are your rights as a survey participant?

If you participated in Project PRIORITY, you have the right to:

- 1) Lodge a complaint with LUNGevity Foundation: Please email Dr. Upal Basu Roy at ubasuroy@lungevity.org if you feel we have infringed upon or violated your privacy rights so that we can resolve the issue promptly

If you have NOT provided us your email address for the longitudinal component of the study, all data gathered from the survey is anonymous and de-identified and do not fall within the regulations of GDPR.

If you have provided us your email address for the longitudinal component of the study, you have the right to:

- 1) ***Withdraw consent***: Please email the Principal Investigator, Dr. Upal Basu Roy, for withdrawing your consent from the study. Your withdrawal of consent will not affect our rights to process and control the data based on consent before your withdrawal.
- 2) ***Access your data***: If you wish to have access to your survey responses, we are required by law to provide you with a copy of your responses and charge you a fee (as needed), unless this action adversely impacts the privacy rights of other survey participants
- 3) ***Rectify your data***: If you wish to make changes to your survey responses, please email Dr. Upal Basu Roy.
- 4) ***Erase your data***: For the purposes of the study, you may request to have your data erased at any point should you decide to do so.