INFORMED CONSENT FORM FOR OPTIONAL STORAGE OF SAMPLES FOR THE RESEARCH BIOSAMPLE REPOSITORY

TITLE:	**A PHASE II, SINGLE-ARM STUDY OF ATEZOLIZUMAB IN PATIENTS WITH LOCALLY ADVANCED, UNRESECTABLE STAGE III NON-SMALL CELL LUNG CANCER WHO HAVE NOT PROGRESSED AFTER PLATINUM-BASED CONCURRENT CHEMORADIATION**
PROTOCOL NUMBER:	MO43156
SPONSOR:	F. Hoffmann-La Roche Ltd
STUDY DOCTOR:	Assist. Prof. Martina Vrankar, MD, PhD Phone number: _____
NAME OF INSTITUTION:	Institute of Oncology Ljubljana
INSTITUTION ADDRESS:	Zaloška cesta 2, 1000 Ljubljana, Slovenia
NAME OF ETHICS COMMITTEEE:	Republic of Slovenia National Medical Ethics Committee
ETHICS COMMITTEE APPROVAL DATE:	{Date}

INTRODUCTION

The Research Biosample Repository (RBR) is a collection of samples that will be tested by researchers during Study MO43156 and for future research. Reasons for testing may include:

- Finding out why certain people are more likely to respond to treatments than others
- Finding out how and why diseases act differently in different people
- Developing new treatments for diseases or medical conditions
- Finding out why certain people are more likely to have side effects than others
- Finding out how treatments are processed in the body
- Finding out how treatments affect the body
- Developing better ways for preventing diseases or treating diseases earlier
- Developing or improving tests or tools that help with detecting or understanding diseases and identifying the right medicine for the right patient

You are being asked to donate blood and tumor tissue samples to the RBR. Donating your samples to the RBR is your choice. No matter what you choose, it will not affect your participation in the main study or the regular care you receive from your doctors.

WHAT WILL HAPPEN IF I PARTICIPATE?

Listed below are the procedures for donating samples, along with any potential risks.

Procedure	Potential Risks
Leftover (unused) blood, serum, plasma and tumor tissue samples that were collected during the study (including any additional samples your doctor decided to collect) will be donated to the RBR.	There are no additional risks associated with donating your leftover samples to the RBR.

Samples will be securely stored in the RBR for up to 15 years after the final study results have been reported, and will then be destroyed.

Testing may involve analysis of your genome (DNA), the "instruction book" for the cells in your body. Your samples may be tested for inherited or non-inherited genome variations, to allow for exploration of broad health research questions across disease areas. Testing may include analysis of all of your DNA (whole genome sequencing) or analysis of part of your DNA. Analyses of samples from a large number of people may help researchers learn more about atezolizumab and similar drugs, non-small cell lung cancer (NSCLC) and other diseases, possible links among diseases, mutations and how they might affect a disease or a person's response to treatment, and new avenues for drug development and personalized therapies.

ARE THERE ANY BENEFITS TO DONATING SAMPLES?

You will not receive any direct benefit from donating your samples. However, research performed on these samples may benefit other patients with NSCLC or a similar condition in the future.

WILL I BE PAID IF I DONATE SAMPLES?

You will not be paid for donating samples to the RBR.

Information from research on your RBR samples may lead to discoveries, inventions, or development of commercial products. You and your family will not receive any benefits or payment if this happens.

HOW WILL MY PRIVACY BE PROTECTED?

Your samples and information will be labeled with your patient ID number; they will not be labeled with your name, your picture, or any other personally identifying information. Your samples and information will be kept under the same level of privacy used for the main study. Roche uses many safeguards to protect your privacy.

Information from the analyses will not be given to your insurance company or employer, unless required by law. If the research results are published in a medical journal or presented at a scientific meeting, you will not be identified. Information from the sample analyses will not be shared with you or your doctor, unless required by law, and will not be part of your medical record.

Roche, Roche affiliates, and Roche's collaborators and licensees may study the RBR samples and information in any country worldwide.

Data from analysis of RBR samples may be shared with researchers or government agencies, but only after personal information that can identify you has been removed. These data may be combined with or linked to other data and used for research purposes, to advance science and public health, or for analysis, development, testing, and commercialization of products that treat or diagnose disease, or improve patient care. These data will not include information that identifies you.

CAN I CHANGE MY MIND ABOUT STORING MY SAMPLES IN THE RBR?

You can change your mind at any time. If you want to withdraw your consent for the RBR, tell your study doctor that you no longer want your samples stored or used for research. After you withdraw consent, any samples that remain will be destroyed or will no longer be linked to you. If you change your mind and your samples have already been tested, Roche will still be able to use the results from those tests. If you withdraw or discontinue from the main study, your RBR samples will continue to be stored and used for research unless you specifically ask that they be destroyed.

Signature

I confirm that I have read this consent form, or it has been read to me. I understand the information presented and have had my questions answered. I understand that I will be given a copy of all 5 pages of this form after it has been signed and dated. I willingly consent to allow my samples to be stored in the RBR and used for the research described above.

Patient name (print)	
If applicable – Name of patient's legally authorized representative (print)	Relationship to patient
Patient signature or signature of patient's legally authorized representative	Date

I, the undersigned, have fully explained this informed consent to the patient named above and/or the patient's legally authorized representative.

Name of person conducting informed consent discussion (print)	
Signature of person conducting informed consent discussion	Date
Witness name [a] (print)	
Witness signature [a]	Date

Witness name [a] (print)

Witness signature [a]

Date

[a] If the investigator or Institutional Review Board or Ethics Committee deems a witness signature is necessary (as per ICH Guidelines, Good Clinical Practice [E6], 4.8.9, or local regulations).