DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Consent to Participate in a Research Study
ATOMIC ARI-AT-002: Phase 2 Trial of Brigatinib after Treatment with Next-Generation ALK inhibitors in Refractory ALK Rearranged NSCLC

Consent Addendum

You are being asked to read, sign and date this addendum consent form before you may continue to receive study drug brigatinib. You are being asked because you have consented to participate in the main study (brigatinib) and your disease has worsened. If the study drug is working, you may continue for as long as you receive benefit or until you decide to stop the study. Once study drug has been discontinued, the follow up visits begin as described in the main study consent. All foreseeable risks or discomforts and other alternative treatment options as described in the main informed consent form are still applicable. If you are interested in learning more about his study, please continue reading below.

Accumulating evidence indicates a small number of subjects who receive brigatininb may derive clinical benefit despite initial growth of their tumor(s); therefore if you are eligible you may continue to receive study drug brigatinib, at a higher dose, by signing and dating this consent form.

Brigatinib has been approved by the FDA for patients with metastatic non-small cell lung cancer (NSCLC) and alterations in the ALK gene whose cancer has progressed during their initial therapy.

The uses of Brigatinib in this study have not been approved by the FDA, therefore Brigatinib is considered an investigational drug. The word “investigational” means the study drug is still being tested in research studies and is not approved by the U.S. Food and Drug Administration (FDA).

This document provides you with new information/ additional information about the study.

All parts of the informed consent that you have signed before remain valid, as does your consent to it, except any that are specifically revised by this document.

If you agree to be in this study, you will be asked to sign and date this consent form. You will be permitted to continue receiving the study drug, brigatinib, beyond your initial tumor growth as long as you meet the following criteria:

- Your doctor has assessed the potential clinical benefit of continuing the study drug, brigatinib
- You do not have rapid tumor growth or clinical deterioration
- The symptoms you are having from your disease are stable
- You can tolerate brigatinib

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If you agree to continue to receive the study drug, we will need to determine if you are eligible for Cohort C. You will undergo all screening procedures listed previously in the Main ICF, and will be required to undergo a fresh tumor tissue biopsy, to evaluate your tumor to see if your non-small cell lung cancer has transformed/mutated into small cell lung cancer.

A biopsy would only be performed if it was considered safe and feasible.

If your cancer has mutated, it would not be beneficial for you to continue study treatment, and you study doctor will discuss other options with you.

_____	_____	_____
Signature of Subject	Date	Time
_____		
Printed Signature of Subject		
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time
_____		
Printed Signature of Person Obtaining Consent		