Assessment of Safety of Air Travel in Patients with Birt-Hogg-Dube Syndrome

NCT03040115

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Informed Consent document for REDCap survey

UNIVERSITY OF CINCINNATI - Medical
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Assessment of Safety of Air Travel in Patients with Diffuse Cystic Lung Disease-Birt-Hogg Dube Flight Survey

UC IRB Study# 2015-6129 **Sponsor Name:** National Insitutes of Health

Investigator Information:

Nishant Gupta, MD	513-475-8523
Principal Investigator Name	Telephone Number 24 hr Emergency Contact

Subject Name: _____ Date of Birth: _____/_____/____

Birt-Hogg Dube Flight Survey

You have been invited to participate in this research project because you have been diagnosed with Birt Hogg Dube.

This research project is being conducted by investigators in the Rare Lung Disease Consortium, a NIH funded organization consisting of multiple physicians and scientists dedicated towards rare lung diseases across the world. This project is led by Dr. Nishant Gupta. The purpose of this research project is to gather information on the safety of air travel in patients with Birt-Hogg-Dube syndrome (BHD). In addition we aim to establish a contact registry to try to answer subsequent questions through this network of patients.

Your participation in this research study is voluntary. You may choose not to participate. If you decide to participate in this research project, you may withdraw at any time. If you decide that you do not want to complete this survey, just close your browser.

The procedure involves filling out an online survey that will take approximately 15 minutes. Your responses will be confidential, and you may choose to skip any questions that you do not want to answer, including your name and contact information if you wish to remain anonymous. Your name and contact information will not be included in our data analyses. Although your participation in this research may not benefit you personally, it will help us understand how people live with BHD, and guide future research directions.

We will do all we can to maintain confidentiality of your data. In order to keep your information confidential, all data is stored in a password protected electronic format in REDCap--an online data management system designed to protect research data. The clinical information collected for this study will be stored in a computer database at the Data

Management and Coordinating Center at the University of South Florida in Tampa, FL and also
sent to a Federal data repository. A data repository provides a way for researchers to store the information collected during the research study for future research studies. The data management center uses several layers of protection for the clinical data stored in its computer database. It meets all of the local and federal security requirements for research datacenters. Your information is stored only using a study ID.

If you have any questions or concerns about participating in this project, please contact Nishant Gupta, MD at 513-558-4831 or nishant.gupta@uc.edu.

Please call the University of Cincinnati Medical Institutional Review Board at 513-558-5259 (Monday - Friday 8 am to 5 pm) if you:
• Have general questions about giving consent or your rights as a research participant in this research study.
• Have questions, concerns, or complaints about the research.
• Cannot reach the research team or you want to talk to someone else about this research project.
• Think the research has hurt you.
To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

SIGNATURES

I have read or someone has read to me, this Informed Consent Document which describes the purpose and nature of this research. I have had time to review this information and have been encouraged to ask questions. I have received answers to my questions. If I do not participate or if I discontinue my participation, I will not lose any benefits. I will not lose any legal rights if I discontinue. My participation in this research is completely voluntary. I give my consent to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____	_____	_____
Participant's Name (Print)	Participant Signature	Date

PERSON OBTAINING CONSENT:
I have read this form to the participant and/or representative. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information.

_____	_____
Signature and Title of Person Obtaining Consent	Date