**Registry Title: Clinical Registry for Patients Suffering from Empty Nose Syndrome**

**Principal Investigator: Subinoy Das, MD**

**Sponsor: Foundation for Advanced Sinus Care and Research, LLC**

**CONSENT TO PARTICIPATE IN A CLINICAL REGISTRY**

**• This is a consent form for research participation. It contains important information about this registry and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the registry with your friends and family and to ask questions before making your decision whether or not to participate.**

**• Your participation is voluntary. You may refuse to participate in this registry. If you decide to take part in the registry, you may leave the registry at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with the US Institute for Advanced Sinus Care & Research or its affiliates.**

**• You may or may not benefit as a result of participating in this registry. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.**

**• You will be provided with any new information that develops during the registry that may affect your decision whether or not to continue to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this registry for the reasons explained below.**

**1. Why is this registry being done?**

*This registry is being created to support a future registry to assess the impact of empty nose syndrome on quality of life in an objective manner, and serve as a baseline for analyzing the impact of future therapies on improving the quality of life for those patients.*

**2. How many people will take part in this registry?**

*It is estimated that initial enrollment in this registry will be limited to no more than 100 patients.*

**3. What will happen if I take part in this registry?**

*If you take part in this registry, you will be required to fill-out questionnaires that ask you about the impact of a medical disease on your quality of life. You will be required to fill-out questionnaires at various aspects of time as it relates to surgeries or trauma that you may have had to create this disease, and/or therapies you may have had in the past or in the future to treat this disease.*

**4. How long will I be in the registry?**

*If you agree to participate in the registry, you will be enrolled in this registry indefinitely (possibly including past your death) unless you inform us in writing that you wish to stop being in the registry.*

**5. Can I stop being in the registry?**

*You may leave the registry at any time. If you decide to stop participating in the registry, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with the US Institute for Advanced Sinus Care and Research.*

**6. What risks, side effects or discomforts can I expect from being in the registry?**

*There is a minor risk that protected health information that you share with this registry might be inadvertently or purposefully released to third-party sources that could cause you psychological, financial, or emotional harm associated with such disclosure. There are no side-effects or discomforts that are expected during participation in the clinical registry.*

**7. What benefits can I expect from being in the registry?**

*There are no anticipated direct benefits anticipated to any individual in participating in this registry. There are indirect benefits anticipated including potential publications and presentations that increase awareness of this rare disease amongst the medical community, which may spur research interest in developing and investigating potential cures for this disease.*

**8. What other choices do I have if I do not take part in the registry?**

*You may choose to share your clinical quality of life information with other clinical registries or choose to keep your quality of life information private and not share with anyone. You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.*

**9. Will my registry-related information be kept confidential?**

*No. By participating in this clinical registry you agree to make your protected health information that you share in this registry a part of the public domain. Efforts will be made to share your registry-related information with only those persons or business interests related to the registry. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this registry may be disclosed if required by any local, state, or federal laws.*

*Also, your records may be reviewed by the following groups (as applicable to the research):*

*Researchers and staff at the US Institute for Advanced Sinus Care and Research will use, share, and receive your personal health information for this research registry. Authorized staff not involved in the registry may be aware that you are participating in a research registry and have access to your information. If this registry is related to your medical care, your registry-related information may be placed in your permanent hospital, clinic, or physician’s office records.*

*In addition, the following other agencies may have access to the information you provide in this registry.*

* *Federal, state, or international regulatory agencies;*
* *U.S. Food and Drug Administration;*
* *Public or Private Institutional Review Boards;*
* *The sponsor supporting the registry, their agents or registry monitors; and*
* *Public or private drug-development and/or medical device companies including, but not limited to those interested in developing therapies for ENS*
* *Public and private profit and non-profit agencies including, but not limited to those interested in funding research for therapies for ENS.*
* *Public and private laboratories or research companies that analyze data obtained from your health information that you provide in this registry*

*If you elect to receive medical care from the US Institute for Advanced Sinus Care and Research, your registry-related information may be placed in your permanent hospital, clinic, or physician’s office records. Authorized medical staff not involved in the registry may be aware that you are participating in a research registry and have access to your information.*

*The information that is shared with those listed above will no longer be protected by federal privacy rules.*

*If you agree to take part in this registry your health information will be used and shared with others involved in this registry. Also, any new health information about you that comes from tests or other parts of this registry will be shared with those involved in this registry.*

*This authorization will not expire unless you change your mind and revoke it in writing. There is no set date at which your information will be destroyed or no longer used. This is because the information used and created during the registry may be analyzed for many years, and it is not possible to know when this will be completed.*

*Signing this authorization also means that you will not be able to see or copy your registry-related information until the registry is completed. This includes any portion of your medical records that describes registry treatment.*

*You also consent to communication and/or storage of your health information via non-secured means, such as third-party email providers such as Google Inc., Yahoo Inc., non-secured social media sites, non-secured publically accessible websites, non-secured billing companies, and other companies related to this research. You give permission for associates of the US Institute for Advanced Sinus Care and Research to text you via non-secured means, call you, and allow you to transmit data via any unsecured or publically available means of data transfer. You agree to hold the US Institute for Advanced Sinus Care and Research and its employees and owner harmless of any liability that may result in an unauthorized breach of data from any party with access to your health information.*

*If you sign this authorization, you may change your mind at any time. Researchers may continue to use information collected up until the time that you formally changed your mind. If you change your*

*mind, your authorization must be revoked in writing. To revoke your authorization, please write to:*

*US Institute for Advanced Sinus Care and Research*

*c/o ENS Registry Coordinator*

*974-E Bethel Road, Columbus, OH 43214*

**10. What are the costs of taking part in this registry?**

*There is no cost to participate in this registry outside of the time and effort required to collect medical records and/or fill-out questionnaires.*

**11. Will I be paid for taking part in this registry?**

*There is no compensation of any kind for participating in this registry.*

**12. What happens if I am injured because I took part in this registry?**

*If you suffer an injury from participating in this registry, you should notify the researcher or registry immediately.*

**13. What are my rights if I take part in this registry?**

*If you choose to participate in the registry, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you give up your legal rights to the protected health information that you provide in the questionnaires that you fill out as part of the registry under federal guidelines (HIPAA act) and other international, federal, state, and/or local protections you may have had prior to your participation in this registry.*

*You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the registry.*

*You may refuse to participate in this registry without penalty or loss of benefits to which you are otherwise entitled.*

*An Institutional Review Board responsible for human subjects research will review this research project and it must be found acceptable, according to applicable state and federal regulations and designed to protect the rights and welfare of participants in research prior to publication of any results.*

**14. Who can answer my questions about the registry?**

*For questions, concerns, or complaints about the registry you may contact Ms. Melanie Clark at (614) 538-2424 x1151 or email her at ens-usasinus@gmail.com.*

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research registry. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this registry. If necessary, I have asked for this form to be translated from English into my primary language

I am giving up my legal rights to privacy of the protected health information provided voluntarily by signing this form.

**X\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Printed name of subject**

**X\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of subject**