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**RESEARCH DATA REQUEST FORM**

**INSTRUCTIONS:** Researchers who wish to access data from the ***TSC Natural History Database*** ***(NHD)*** must submit this **REQUEST FORM** to the **TSC NHD-BSR Steering Committee** for approval. Please be sure that you have completed all sections. Incomplete requests will not be considered.

**SECTION 1 – GENERAL INFORMATION**

|  |  |
| --- | --- |
| PRINCIPAL INVESTIGATOR NAME |  |
| NAME OF INSTITUTION |  |
| DEPARTMENT |  |
| MAILING ADDRESS |  |
| CITY, STATE, ZIP |  |
| TELEPHONE |  |
| EMAIL ADDRESS |  |
| RESEARCH PROPOSAL TITLE |  |
| DOES YOUR PROJECT HAVE IRB APPROVAL? | YES IF YES, IRB APPROVAL PERIOD:  NO IF NO, COMMENT: |
| WILL YOUR PROJECT INVOLVE THE USE OF SEIZURE TRACKER DATA STORED WITHIN THE NHD? | YES  NO |

**CONFIDENTIALITY AGREEMENT & ACKNOWLEDGMENT**

I understand that the TS Alliance will share data from the TSC Natural History Database if the TSC NHD-BSR Steering Committee approves my research approval. If data request involves Seizure Tracker data, a representative of Seizure Tracker will also review the proposal. I agree that the information I receive is to be considered confidential and that I will not disclose, publish, or reveal any information without written permission from the TS Alliance.

I understand that if the TSC NHD-BSR Steering Committee approves my proposal, I will receive a **Data Share Agreement** to sign which includes guidelines for data sharing and protection.

     

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Principal Investigator Signature Date

(typed name is acceptable)

**FOR OFFICE USE ONLY:**

|  |  |
| --- | --- |
| PROPOSAL RECEIVED ON: | ID #: |
| DATE SENT TO COMMITTEE: | SENT BY: |
| TSC NHD-BSR SC DECISION:  APPROVED  NOT APPROVED REASON: |  |
| OTHER: |  |

**SECTION 2 – RESEARCH PROPOSAL**

1. **DATA REQUEST: Please specify the data variables you want from the NHD. Check all that apply. Data variables may be represented by multiple question and answer responses. If you are unsure, please provide additional details in Section IV below.**

**General**

**Date of Birth  Biological Sex  Race**

**How was the diagnosis made? Clinical or Molecular  TSC Variant(s) Detected**

**Additional Phenotypes**

**Epilepsy  SEGA**

**Cardiac Rhabdomyoma  Angiofibromas**

**Liver Hamartoma  Ophthalmological Conditions**

**LAM  Angiomyolipoma**

**Neuropsychiatric**

**Are you looking for specific participant pools (e.g., participants enrolled in a specific clinical trial or participants that have taken a specific medication?) Please describe below.**

1. **BACKGROUND: Include a clear and concise evaluation of existing knowledge and specifically identify what new information your project intends to add.**

1. **RATIONALE: Provide a basis for your proposed research project.**

1. **ADDITIONAL DETAILS (optional): Provide any additional details or questions.**