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| --- |
| ***TO BE COMPLETED BY REQUESTOR*** |
| Name of Requestor: |  |
| Name of Company/Institutional Affiliation (associated with request) |  |
| Requestor’s Contact Info: | **Address:** **Phone:****Email:**  |
| From which study/consortium/ database are you requesting data? | **RUSH2A – Baseline thru 4-Year Data** |
| Based on the study status, please indicate which kind of dataset you are requesting.  | [x]  A public dataset for a study that has ended (which contains all key time points and key datapoints for all participants as permitted under international data processing regulations)**RUSH2A datasets as listed in the Appendix below** |
| Confirm that you understand that you will only be granted the minimum necessary data to fulfill your purpose. | [ ]  Yes, I understand that I will only be granted the minimum necessary data to fulfill my purpose(s). |
| For what purpose(s) will you be using the data (e.g., to conduct research exploring ABC outcomes relating to diabetic retinopathy)? | [ ]  Healthcare/clinical research (explain):[ ]  Statistical exploration (explain):[ ]  Other (explain): |
| How do you intend to use the data (check all that apply)? | [ ]  Internal purposes (e.g., education, research planning)[ ]  Perform analyses for publication/presentation[ ]  To support an Agency submission (e.g., FDA, NIH)[ ]  Other (explain): |
| Do you intend to share any of this data with anyone outside of your immediate team that would not inherently be bound by the terms of an agreement with you/your organization? | [ ]  No[ ]  Yes (explain): |
| Are you able to review/sign agreements for these purposes? | [ ]  Yes[ ]  No (provide name and contact information for the applicable institutional official, like the Data Protection Officer): |
| Attestation: I understand that the requested data may include personal data from data subjects as human subject participants that resided in the European Economic Area, and/or Brazil, at the time the data was collected. As such, the intended data processing must comply with the requirements of the General Data Protection Regulation (GDPR) and Lei Geral de Proteção de Dados (LGPD, Brazil’s GDPR equivalent), as applicable. This means that I/my organization must review and sign a Data Transfer and Processing Agreement (DTPA) with the Jaeb Center for Health Research, and must follow all terms thereof. |
| Signature/Date of Requestor: |  |
| **Upon completion submit to both:** **RCC@jaeb.org** **and** **ffb@jaeb.org** |

**Appendix: Data Sharing Summary**

Data Collected – Baseline thru 4-Year Data

|  |  |
| --- | --- |
|   | **RUSH2A**  |
| **Clinical Center Data**   |
| Demographics  | X  |
| Medical History   | X  |
| Medications  | X  |
| Adverse Events  | X  |
| Patient Reported Outcomes   | X  |
| Genetic Data  | X  |
| Ophthalmic Exam  | OU  |
| Visual Acuity  | OU  |
| Full-field Stimulus Threshold   | SE  |
| Electroretinogram   | SE  |
| **Reading Center Data** (see specifications in table below)  |
| OCT Volume  | SE  |
| Microperimetry  | SE  |
| Static Perimetry | SE  |
| Kinetic Perimetry  |  OU  |

Note: The available follow-up data (BL vs. BL+4yr vs. annual visits) depends on which vision cohort the study participant is in.

Reading Center Data Specifications

|  |  |  |
| --- | --- | --- |
| **Test** | **Testing Specifications** | **Key Grading Items** |
| **OCT [Volume]**  | * + Spectralis
	+ One Dense Preset Volume Scan (30° x 25°, 121 Section, ART set to 9, High Resolution) macula centered
	+ One 7 Line Raster (30° x 5°, 7 Section, ART set to 25, High Resolution) macula centered
 | * + Presence and size/location of cysts
	+ Presence of SRF, VMT and ERM in the center
	+ CSF thickness
	+ EZ area
 |
| **Microperimetry**  | * + MAIA
	+ “RUSH2A grid” (89 stimuli)
	+ 4-2 strategy
 | * + Average threshold (mean sensitivity)
	+ Fixation stability
	+ 95% BCEA
	+ Pointwise sensitivity – threshold value for each of the 89 locations
 |
| **Static Perimetry**  | * + Octopus 900 Pro
	+ Static GATE testing with “185pt grid” with size V test target
 | * + Volume of full field hill of vision
	+ 30-degree hill of vision
	+ Mean sensitivity
	+ Pointwise sensitivity – threshold value for each of the 186 locations
 |
| **Kinetic Perimetry**  | * + Octopus 900 Pro
	+ Kinetic testing with V4e, III4e, I4e
 | * + V4e isopter
	+ V4e Scotoma
	+ III4e isopter
	+ III4e Scotoma
	+ I4e isopter
	+ I4e Scotoma
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