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| **Site Information** |

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| **Name of Legal Entity:** |  |
| Address: |  |
| Phone: |  |
| Fax: |  |

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| --- | --- |
| **Type of Practice**: | University/Hospital  Community/Private Practice |
| **IRB Information**: The Jaeb Center for Health Research (JCHR) IRB is accredited by AAHRPP and able to enter into an IRB Reliance Agreement to serve as the IRB for institutions participating as clinical sites. **Do you anticipate that your site will allow the use of JCHR accredited central IRB?** | Yes  No  Uncertain |
| **FWA Number (US Sites):** |  |
| **Estimated time to obtain IRB approval and execute a contract agreement:** | \_\_\_\_\_\_\_ months |
| **Does your site have a database from which to identify potentially eligible patients?** | Yes  No |
| **Percent of patients expected to be able to enroll in My Retina Tracker:** | 0%-25%  25%-50%  50-75%  75-100% |

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| **General Office Requirements Met:**   * Internet access in exam rooms (wireless or wired) * Separate email addresses for each staff member * Secure (limited access) location for study files | Yes  No  Uncertain |

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| **Site Information** |

**Approximate number of patients with IRDs in this practice**

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| --- | --- | --- | --- |
| **IRD** | **# patients total** | **# seen in last 5 years** | **# with confirmed genotyping (of those seen in last 5 years)** |
| LCA/SECORD |  |  |  |
| Dominant RP |  |  |  |
| XLRP |  |  |  |
| Simplex or ARRP |  |  |  |
| Stargardt |  |  |  |
| Cone-Rod Dystrophy |  |  |  |
| Usher Syndrome I |  |  |  |
| Usher Syndrome II |  |  |  |
| Usher Syndrome III |  |  |  |
| Bardet-Biedl |  |  |  |
| Achromatopsia |  |  |  |
| XLRS |  |  |  |

**Equipment**

**Please note** the following equipment is required for Consortium studies (indicate whether you have plans to obtain this equipment): **Octopus 900 Pro and Heidelberg Spectralis.**

The following equipment is preferred for Consortium studies (indicate whether you have plans to obtain this equipment): **MAIA; E-ETDRS Visual Acuity (EVA) Tester; and Diagnosys Espion.**

|  |  |  |
| --- | --- | --- |
| **Equipment** | **Manufacturer** | **Model** |
| ETDRS VA system |  |  |
| SD-OCT |  |  |
| Color Photography |  |  |
| Widefield Imaging |  |  |
| Fundus Autofluorescence |  |  |
| Full Field ERG |  |  |
| Multifocal ERG |  |  |
| Static perimeter |  |  |
| Kinetic perimeter |  |  |
| Fundus-guided perimetery |  |  |
| Dark Adaptometry/FST |  |  |
| Pupillometry |  |  |
| Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |

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| **Personnel Information** |

1. **Investigators**

***Please list the investigator intended to be the Principal Investigator first.***

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| --- | --- | --- | --- | --- | --- |
|  | **Name** | **Degree** | **Email** | **Experience in sponsored clinical trials? (Yes/No) If yes, include clinical trial experience on CV** | **Ever found guilty of scientific research misconduct? (Yes/No) If yes, provide detail.** |
| **PI** |  |  |  |  |  |
| Co-I |  |  |  |  |  |
| Co-I |  |  |  |  |  |

**Attach all investigators’ current, signed and dated CV that details training and previous sponsored clinical study experience (including role as PI, co-Inv, as well as NCT number and # pts enrolled in each trial).**

1. **Requirements for Investigator Qualifications**

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| **Investigators must meet at least ONE of the following. Please check those that apply. Add additional columns as necessary.** | | | |
|  | PI (Name) | Co-I  (Name) | Co-I  (Name) |
| (1) completion of a 1 year retina advanced specialty training program |  |  |  |
| (2) completion of a 1-2 year retina clinical fellowship program |  |  |  |
| (3) recognized expert in the field of IRDs based on previous clinical research publications and experience as a PI |  |  |  |

1. **Study Coordinators**

***Please list the coordinator intended to be the Primary Coordinator first.***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Name** | **Email** | **Years experience in clinical setting** | **Years experience in clinical trials** |
| **Primary** |  |  |  |  |
| Additional |  |  |  |  |
| Additional |  |  |  |  |

1. **Genetic Counselors**

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| --- | --- |
| **Name** | **Please indicate whether on site or otherwise accessible (provide detail)** |
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1. **Technicians**

***Please list names and ‘X’ in boxes for equipment for which individual has experience. If Years Experience varies by type of equipment, please list for each (e.g. VA=5, Photo=10) under that column***

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Name** | **VA** | **OCT** | **Photo** | **ERG** | **Perimetrist** | **FA** | **Years Experience** |
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**Key:**

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| --- | --- |
| VA: VA Technician | ERG: ERG Technician (full field or multifocal) |
| OCT: SD-OCT Technician | Peri: Perimetrist (static, kinetic, or fundus-guided) |
| Photo: Photographer (color or widefield) | FA: Fundus Autofluorescence Technician |

1. **Data Entry**

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| **i. How do you plan to document research/study patient visit records?**  *NOTE: Direct (real time) data entry into the FFB Consortium study website electronic case report form (e-CRF) is highly preferred. Please indicate whether this is possible.* |
|  |
| **ii. Any key data for which the e-CRF is not the source will need to be accessible to the CC.**  **Does your institution require any additional steps (beyond language in contract and informed consent form) to allow CC to access medical records when applicable (i.e. ,when they are the source data)?** |
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| **Study Suggestions (Optional)** |

1. **Patient Population**

**Please describe a patient population that FFB Consortium should study, and provide a rationale**

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1. **Key Design Elements**

**Please describe the proposed sample size, duration, and key outcome measures**

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1. **Expected number of patients your site would be able to enroll with suggested IRD:**

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1. **Alternative Studies**

**Please describe alternative patient populations that you think are worthwhile studying**

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