Foundation Fighting Blindness (FFB) Consortium

Collaboration Guidelines

The Governance Document contains the overarching policies for the FFB Consortium. This document is intended to expand on those policies and provide more details of the Consortium's policy for collaborating with partners from industry, government, and other non-profits.

Version 1.0
Date: May 15, 2020

Version History

VERSION NUMBER	AUTHOR	APPROVER	EFFECTIVE DATE	REVISION DESCRIPTION
1.0	A. Ayala	Operations Committee & Executive Committee	May 15, 2020	First version

The Foundation Fighting Blindness Consortium ("FFB Consortium") is committed to collaborating in a manner that leverages the value of partners while maintaining clinical trial design, investigational ethics and rigorous implementation consistent with academic standards.

The sections below outline the FFB Consortium guidelines regarding external collaboration. Depending on the type of collaboration, some of the guidelines below may not apply or may be modified. The FFB Consortium Operations Committee will need to approve any collaboration with parameters that differ substantially from the guidelines below. All studies with external collaboration will require a Responsibility Assignment Chart (RACI) chart to clearly distinguish the roles of each partner

A. Protocol Development

1. The partner will be invited to provide input on the study design and the major drafts of the study protocol.

2. With partner input, the FFB Consortium will develop the protocol according to Consortium standards (including associated procedures, CRFs, statistical plan, etc.).

3. If the study is being conducted with an industry sponsor to assist in drug or device registration, the FFB Consortium will be responsive to the partner's study design needs as long as they are feasible, result in a sound clinical trial design, and – when implemented – are consistent with academic standards, ICH E6 (R2) Good Clinical Practice, all applicable sections of the Code of Federal Regulations (CFR), and any other regulatory requirements as applicable.

4. All final decisions regarding protocol design, development and implementation will be made by FFB Consortium.

5. At the time of study launch, the protocol will be posted on the FFB Consortium public website and on clinicaltrials.gov.

B. Study Data

1. FFB Consortium will have ownership of the study data and the partner must adhere to the data sharing policies set forth in the FFB Consortium Governance Document. Early access to datasets may be possible under these data sharing policies, but would require a signed data use agreement (see example template in **Appendix A**).

2. At the completion of the study, FFB Consortium will distribute a dataset to the partner for its needs (including for FDA submission if applicable) and its internal use. Before the dataset is made publicly available, the dataset may only be used for purposes authorized in the signed data use agreement.

3. FFB Consortium will post individual, de-identified, study participant data to the Consortium's public website as a "public dataset" after the study is completed and all manuscripts addressing the protocol-defined objectives have been published (typically within one year of the last study participant's visit). At this time, FFB Consortium will also update clinicaltrials.gov with the study results. Once the datasets are made publicly available, they may be accessed and used for any purpose consistent with the FFB Consortium Governance Document.

C. Publications, Presentations, and Publicity

1. FFB Consortium is free to publish and present the study data without restriction.

2. FFB Consortium will provide the partner with the opportunity to review and comment on all manuscripts produced by the study. This policy also applies to abstracts and presentations that are made prior to the information having already been publicly disseminated. Unless FFB Consortium and the partner agree on different time intervals, the partner will be given 14 days to comment on manuscripts and up to an additional 30 days if there is a need for the industry partner to submit patent application materials to obtain patent protection.

3. All press releases and public disclosures about the study will be jointly authored by FFB and the partner.

4. The partner may not publish or present any study results that have not already been publicly disseminated by FFB Consortium, without the approval of FFB Consortium.

D. Data Integrity

1. The FFB Consortium Coordinating Center will oversee data collection through electronic Case Report Forms (eCRFs), data cleaning, data lock, data maintenance, etc.

2. FFB Consortium may provide the partner with details of these procedures to verify that these procedures meet regulatory requirements.

3. The partner may conduct a pre-study qualifying visit and yearly site visit of the Coordinating Center to evaluate issues related to maintaining the database and other Coordinating Center procedures as they pertain to meeting regulatory requirements.

E. Clinical Sites

1. The FFB Consortium will select the participating sites and establish the procedures for their certification. Certification includes the review and approval of regulatory documents such that the clinical site is approved to receive investigational product and subsequently enroll patients, when applicable.

2. The partner may review these procedures, including the certification requirements, to verify that they are in accord with regulatory requirements.

3. The FFB Consortium Coordinating Center will be responsible for the certification of the sites.

F. Site Monitoring

1. FFB Consortium will determine how the study will be monitored and document these decisions in a monitoring plan.

2. The partner may review the FFB Consortium site monitoring plan to verify that it meets regulatory requirements.

3. The partner will not be permitted to contact the clinical sites, request data or conduct monitoring visits without approval from FFB Consortium. Permission may be granted in the event of a pending FDA audit.

4. If the partner determines that additional monitoring is needed for regulatory purposes, FFB Consortium will consider this request but will have the right to reject the request. Financial support for any additional monitoring will be provided by the partner.

5. The monitoring will be overseen by the FFB Consortium Coordinating Center, which will have the option of conducting this monitoring itself and/or subcontract portions of the monitoring to an external partner.

G. Adverse Event Reporting

1. FFB Consortium will establish a system for adverse event reporting, review, and coding.

2. The partner may review this plan to verify that it is in accord with regulatory requirements and will meet the partner's needs for its regulatory submission, if applicable.

H. Efficacy and Safety Reviews, Stopping Decisions

1. FFB Consortium will be responsible for developing the statistical analysis plan.

2. The partner may review the statistical analysis plan to verify that it is in accord with regulatory requirements and will meet the partner's needs for its regulatory submission, if applicable. Regulators may also need to review this document.

3. For applicable studies, an independent Data and Safety Monitoring Committee (DSMC) will review all data (masked or unmasked) as appropriate and make suggestions to the FFB Consortium regarding protocol modifications and stopping a study for efficacy or safety. The partner will not be provided with the study data (other than the aforementioned masked adverse event data) until either the conclusion of the study or the DSMC's decision that such data can be provided.

I. Investigational Product – when applicable

1. The industry partner will be responsible for providing the investigational product, placebos (when applicable), packaging of the investigational product, all necessary manufacturing information for the IND or IDE and any related materials. The industry partner will agree to provide the investigational product and related materials for the duration of the study.

2. In the case that the partner is providing the investigational drug or investigational device for the study, a Quality Plan must be in place. The investigational drug will be manufactured in accordance with Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) standards. Investigational devices will be manufactured in accordance with GMP standards.

3. The FFB Consortium will develop procedures for supplying the investigational product to the clinical sites, maintaining accountability of the investigational product at the site, and disposal or return of the investigational product. The industry partner will pay for the costs of supplying investigational product to the clinical sites and returning investigational product for disposal, if required. The industry partner, if requested, will supply the investigational product and related materials directly to the clinical sites.

J. Laboratory Measurements

1. FFB Consortium will determine those laboratory measures it deems necessary for the study.

2. The partner may identify those additional laboratory measures required for regulatory or other purposes. FFB Consortium will be responsive to these needs as long as they do not adversely affect the conduct, data validity or safety of the study.

3. FFB Consortium will have the final decision on the use of a central laboratory.

K. Vendors and Suppliers

1. FFB Consortium will determine the necessary vendors and suppliers of study equipment based on the protocol-specified study procedures. FFB Consortium will make the final decision for vendor selection and vendor qualification and may request input from the partner.

L. Regulatory Submission

1. FFB Consortium will have the option of applying for and maintaining the IND or IDE. The industry partner will assume this function, if requested by FFB Consortium. When applicable, the partner will be responsible for the Investigator's Brochure, with input from the FFB Consortium.

2. Regulatory submissions such as Clinical Trial Applications (CTA) to countries in Europe will be the responsibility of the industry partner.

3. The industry partner will perform registration and submission specific analysis and preparation as needed. In preparation for Annual Reports, however, the CC may perform the data freeze and supply masked tables and listings to the partner.

4. FFB Consortium and the industry partner will provide one another with a copy of all documents submitted under the IND, IDE or CTA.

5. Should there be a need to conduct a second trial specifically for the purpose of regulatory submission, the industry partner will have the option of conducting the second trial independently from the FFB Consortium or may contract with the FFB Consortium to conduct the second trial as long as FFB Consortium agrees that such a trial is an appropriate use of FFB Consortium resources at that time.

M. FFB Consortium Policies

1. The partner will be provided with a copy of the FFB Consortium policies, which are also available for download from https://public.jaeb.org/ffb.

N. Study Committees and Oversight

1. The partner will appoint an individual to serve as the liaison with the FFB Consortium.

2. The liaison will receive reports on the progress of the study (e.g., enrollment and data accrual) and may join periodic meetings or conference calls at the discretion of the FFB Consortium.

O. Legal Agreements

1. A legal agreement will be established between the partner and the Coordinating Center. The legal agreement will contain: an indemnification section that specifies the situations in which the partner will provide indemnification, a confidentiality section agreeable to both parties, and an intellectual property section agreeable to both parties.

2. A legal agreement will be established between the Coordinating Center and each participating site for the site's participation in the study. The partner may choose to establish a Confidential Disclosure Agreement (CDA) with each site.

3. Any data shared with the partner will first require a signed Data Use Agreement and signed Data Protection Agreement (if applicable). All data sharing must comply with international regulations, such as General Data Protection Regulations (GDPR).

Appendix A: Data Use Agreement Template

This Data Use Agreement is made and entered into as of _____ ("Effective Date"), by and between the **Jaeb Center for Health Research Foundation, Inc.,** 15310 Amberly Drive, Suite 350, Tampa, FL 33647 (JCHR) and (Recipient)., address, city, state] ("Recipient"). JCHR is providing Recipient with a compiled or de-identified data set ("Data"), which contains no Protected Health Information (PHI)/personal data as defined in 45 CFR sec. 164.514(e)(2).

1. JCHR will provide the following Data to Recipient:
   _____
   _____

2. Recipient may use the Data for the following purpose(s) (Note: if Data is intended to inform a regulatory/FDA submission, list that here):
   _____

3. Recipient agrees to use appropriate safeguards to prevent use or disclosure of the Data other than as provided for by this Agreement or as otherwise required by law or regulation.

4. Recipient agrees to report to JCHR any use or disclosure of the Data not provided for by the Agreement of which it becomes aware. Recipient will take reasonable steps to limit any such further use or disclosure.

5. Recipient agrees that this Data will only be used internally and will not be used for public reporting or presentation.

6. Recipient agrees to ensure that any agent, including a subcontractor, to whom it provides the Data in accordance with this agreement, agrees to the same restrictions and conditions that apply through this Agreement.

7. Recipient understands that Data are not locked until the end of a study; therefore, interim Data that is shared with Recipient may change in the future due to ongoing monitoring.

For Regulatory Submissions (Such as FDA Submissions):

8. Recipient agrees to name the Foundation Fighting Blindness (FFB) Consortium as the source of this data.

9. Recipient agrees to provide the analysis to JCHR for review at least one (1) month prior to submission.

10. Recipient will not submit any conclusions that have not been reconciled by JCHR review and vetted by the FFB Consortium Executive Committee.

11. This Agreement shall be effective on the Effective Date set forth above and shall continue as long as Recipient (or any agent or subcontractor of Recipient) retains the data until such time that the Data become publicly available.

END OF ARTICLES

PAGE OF EXECUTION TO FOLLOW

Partner		**Jaeb Center for Health Research Foundation, Inc.**	
Signature:		Signature:	
Name:		Name:	Roy W. Beck, MD, PhD
Title:		Title:	Executive Director
Date:		Date:	