Foundation Fighting Blindness (FFB) Clinical Consortium

Collaboration Guidelines: Investigator-Initiated Studies

The Governance Document contains the overarching policies for the FFB Clinical 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, academia, government, and other non-profits, **specifically for investigator-initiated studies where IND/IDE is not applicable or FFB Consortium holds the IND/IDE**.

Version 3.0
Date: December 18, 2025

Version History

VERSION NUMBER	AUTHOR	APPROVER	EFFECTIVE DATE	REVISION DESCRIPTION
1.0	A. Ayala	Executive Committee	May 15, 2020	First version
1.1	A. Ayala	EC approval not required, updates consistent with current Governance Document	August 19, 2021	Update language to clarify DTPA will be required to obtain early dataset or public dataset. Remove DUA Template Appendix, and instead indicate available upon request
2.0	A. Ayala	Executive Committee	October 17, 2022	Revise to make guidelines applicable to investigator-initiated studies where FFB Consortium does not hold the IND or IDE
3.0	J. Shah	A. Ayala	December 18, 2025	Updated logo, added 'Clinical' Consortium, and cleaned up minor typos

The Foundation Fighting Blindness Clinical 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 **specifically for investigator-initiated studies where IND/IDE is not applicable or FFB Consortium holds the IND/IDE**. 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. FFB Consortium will manage and maintain all drafts of the protocol, including versioning, tracking feedback, and documenting approvals.

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

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

4. The study design will be 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.

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

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

7. FFB Consortium will manage and maintain the electronic Trial Master File.

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 Executive Committee approval and a signed Data Transfer and Processing Agreement (template example available upon request).

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 Transfer and Processing Agreement (DTPA).

3. FFB Consortium will create individual, de-identified, study participant datasets available by a data request form on 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). The request form will be

reviewed by the Research Compliance Committee and a DTPA will be implemented before releasing the public datasets.

4. FFB Consortium will update clinicaltrials.gov with the study results within the required timeframe, typically within 1 year of primary outcome completion.

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, abstracts, and presentations produced by the study 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, abstracts, and presentations.

3. 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.

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

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.

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.

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.

H. Statistical Analysis Plan, Efficacy and Safety Reviews

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.

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 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 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 partner will pay for the costs of supplying investigational product to the clinical sites and returning investigational product for disposal, if required. The 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 – when applicable

1. FFB Consortium will apply for and maintain the IND or IDE.
    - *If the partner prefers to hold the IND or IDE, then Collaboration Guidelines: Sponsored Trials should be followed instead of current document.*

2. When applicable, the partner will be responsible for the Investigator's Brochure, with input from the FFB Consortium.

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

4. The 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.

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

6. Should there be a need to conduct a second trial specifically for the purpose of regulatory submission, the 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.

- The Coordinating Center does not provide for payment for injuries to study subjects.

2. A legal agreement will be established between the Coordinating Center and each participating site for the site's participation in the study.

3. A legal agreement will be established between the Coordinating Center and 3rd party vendors.

4. Any data shared with the partner will first require a signed DTPA. All data sharing must comply with international regulations, such as General Data Protection Regulations (GDPR).