Foundation Fighting Blindness (FFB) Clinical Consortium

Collaboration Guidelines: Sponsored Trials

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 sponsored trials where the partner holds the IND/IDE.**

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Version History

VERSION NUMBER	AUTHOR	APPROVER	EFFECTIVE DATE	REVISION DESCRIPTION
1.0	A. Ayala	Executive Committee	October 17, 2022	First version
2.0	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 sponsored trials where the partner 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. The partner will manage and maintain all drafts of the protocol, including versioning, tracking, and documenting approvals. FFB Consortium will maintain copies of all official versions of the protocol.

2. The partner and FFB Consortium will jointly provide input on study design and drafts of the study protocol. This will include routine joint meetings to discuss drafts and amendments to the protocol.
    - The protocol will adhere to Consortium standards (including associated procedures, CRFs, statistical plan, etc.).
    - 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.

3. Partner will have final say in protocol development decisions, but will require acknowledgement by FFB Consortium as follows.
    - The final protocol (and any protocol amendments) must be approved by the FFB Consortium Executive Committee.
    - The final protocol document (and any protocol amendments) will include a signature line for (1) partner representative, (2) FFB Consortium investigator representative [likely the study chair], (3) FFB Consortium Coordinating Center Director, and (4) FFB representative to demonstrate approval by all parties.

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

5. FFB Consortium will manage and maintain the electronic Trial Master File (eTMF) on the Coordinating Center's Box fileserver. FFB Consortium will provide the partner with a copy of the eTMF at the end of the study.

B. Study Data

1. The partner will own the study data. FFB Consortium will maintain ability to create and share public datasets (B3 below) and to publish and present study data (C2 below).

2. FFB Consortium will manage the study data and will provide the dataset to the partner according to milestones, formats, and purposes agreed upon 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."
    - Public datasets will not be made available until all of the following have occurred.
        i. Approval or withdrawal of drug application
        ii. The study is completed and the study database is locked
        iii. All manuscripts addressing the protocol-defined objectives have been published (typically within one year of the last study participant's visit).
    - The data request form will be reviewed by the FFB Consortium Research Compliance Committee to confirm compliance with international data privacy standards 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 and partner will agree upon a Publication Plan, which FFB Consortium will maintain for each study. The partner will have the opportunity to provide input and to review on a periodic basis.

2. FFB Consortium is free to publish and present the study data.
    - Data will not be published until the primary outcome is complete and data are locked.
    - The partner will be notified of intention 60 days prior to publication or presentation.
    - Manuscripts/abstracts/presentations will be provided to the partner with 14 days to provide input.

3. The partner is free to publish and present the study data.
    - Manuscripts/abstracts/presentations will be provided to the FFB Consortium with 14 days to provide input.
    - A disclaimer that the statements may not reflect the views of the FFB Consortium will be included.

4. Press releases and public disclosures may be jointly authored or independently authored. In the event of the latter:
    - A draft will be provided to the other party with opportunity to provide input with 14 days to provide input.
    - The partner will maintain final approval of FFB Consortium releases.
    - A disclaimer that the statements may not reflect the views of the FFB Consortium may be included, if necessary.

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 will 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, with advance notice.

E. Clinical Sites

1. The FFB Consortium will select the participating sites and establish the procedures for their certification.
    - The partner will maintain final approval of participating sites.
    - If the partner wishes to include a site that is not already part of the Consortium, the site would need to go through the application process and meet the minimum requirements of the Consortium, according to the policies of the FFB Consortium.

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. The partner and FFB Consortium will jointly develop the monitoring plan. The partner will have final say in decisions.

2. The partner may contact the clinical sites or conduct monitoring visits without approval from FFB Consortium. FFB Consortium should be informed of any site visit plans by the partner.

3. 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.

4. 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.

H. Statistical Analysis Plan, Efficacy and Safety Reviews

1. The partner and FFB Consortium will jointly develop the statistical analysis plan. The partner will have final say in decisions, but will require acknowledgement by FFB Consortium as follows.
    - The final statistical analysis plan document (and any amendments) will include a signature line for (1) partner representative and (2) FFB Consortium senior statistician, and (3) FFB Consortium Coordinating Center Director to demonstrate approval by all parties.

2. For applicable studies, an independent Data and Safety Monitoring Committee (DSMC) will be jointly proposed by the partner and FFB Consortium. The DSMC will review all data (masked or unmasked) as appropriate and make suggestions regarding protocol modifications and

stopping a study for efficacy or safety. For blinded studies, 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. The partner will be involved in open session of DSMC meetings in accordance with the DSMC charter for the specific study.

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 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. Laboratory measures will be jointly discussed during protocol development. The partner will have final say in decisions.

2. The use of a central laboratory will be jointly discussed during protocol development. The partner will have final say in decisions.

K. Vendors and Suppliers

1. The necessary vendors and suppliers of study equipment based on the protocol-specified study procedures will be jointly discussed during protocol development. The partner will have final say in decisions.

2. FFB Consortium will complete vendor qualification and may request input from the partner.

L. Regulatory Submission

1. The partner will apply for and maintain the IND or IDE. When applicable, the partner will be responsible for the Investigator's Brochure, with input from the FFB Consortium.
    - *If the partner prefers FFB Consortium hold the IND or IDE, then Collaboration Guidelines: Investigator Initiated Studies should be followed instead of current document.*

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

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

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

5. Should there be a need to conduct additional trials specifically for the purpose of regulatory submission, the partner will have the option of conducting subsequent trials independently from the FFB Consortium or may contract with the FFB Consortium to conduct subsequent trials 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. The partner may choose to establish a Confidential Disclosure Agreement (CDA) with each site. Site payments will be made by the Coordinating Center.

3. A legal agreement will be established between the Coordinating Center and 3rd party vendors. The partner may choose to establish a Confidential Disclosure Agreement (CDA) with each site. Vendor payments will be made by the Coordinating Center.

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).