Foundation Fighting Blindness (FFB) Consortium[1]

Governance Document

Version 4.0
July 8, 2019

[1] Consortium is defined as an association of individuals or organizations with the objective of participating in a common activity for a common goal.

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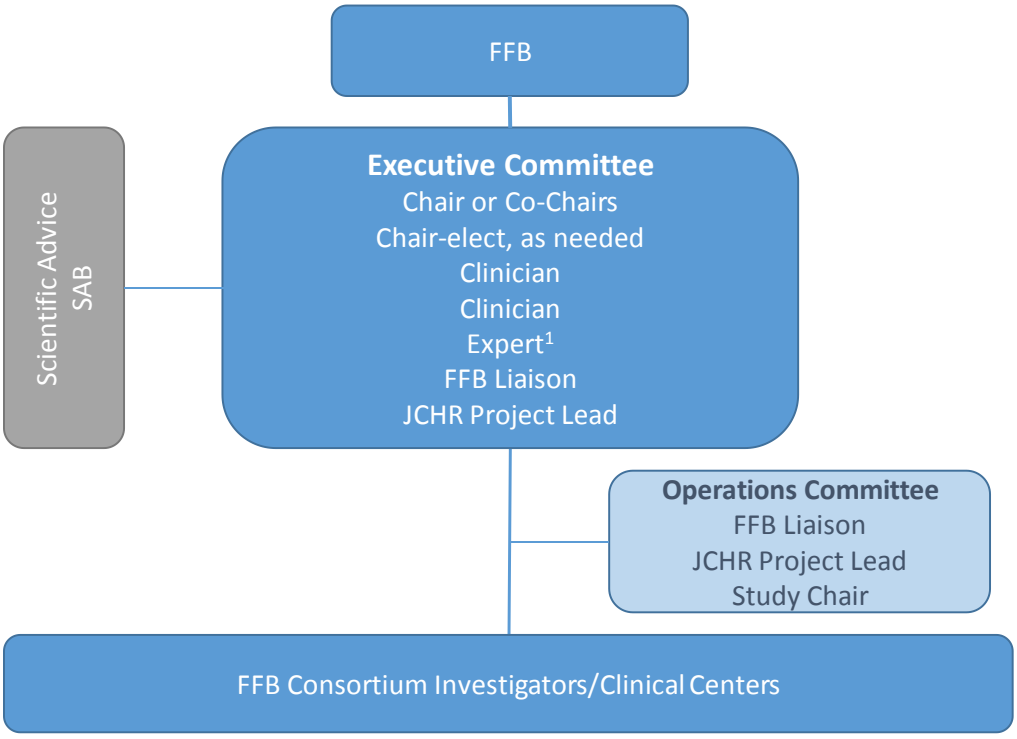
1. Mission Statement

To accelerate the development of treatments for inherited retinal diseases (IRDs) through collaborative and transparent clinical research.

2. Organizational Structure

FFB is accountable for the FFB Consortium. The Consortium is comprised of an Executive Committee, an Operations Committee and the Investigators/Clinical Centers. The FFB Scientific Advisory Board (SAB) will provide scientific advice to the Executive Committee; the Executive Committee may also reach out to other experts to provide specific advice. The Jaeb Center for Health Research (JCHR) is the Coordinating Center for the FFB Consortium, accountable for all operational activities.



[1]For example, Epidemiologist or Biostatistician

2.1 Executive Committee

2.1.1 Membership

The Executive Committee will provide leadership to the Consortium. There will be one consortium chair (or 2 co-chairs), 2-3 clinical scientists, an FFB liaison and the Director of the Coordinating Center at Jaeb Center for Health Research (JCHR). FFB will invite persons to participate in the Executive Committee based on recommendations from FFB Science, ROC members, SAB members and the Consortium Executive Committee.

2.1.2 Roles and Responsibilities

The Executive Committee will be responsible for providing input to this governance document, approving clinical study protocols, and prioritization of hypotheses and analyses. Members will vote on decisions/approvals; in the event of a tie, the chair will cast the final vote. In the event of disagreement on a decision between two co-chairs, FFB will cast the final vote.

2.1.3 Term

The term for members of the Executive Committee will be 3-4 years to allow for rotation while ensuring institutional memory; the FFB liaison and Coordinating Center Director may change as needed. This is done so that there are less than 50% new members in any year. A chair-elect will be included 1 year in advance of the appointment of a new chair whenever possible. In the event of two co-chairs, the co-chairs will be rotated off the committee at staggered time points.

2.1.3.1 Reappointments

When mutually agreeable, Executive Committee members may be reappointed to serve an additional term. Reappointments will be based on re-evaluation of qualification and review of past activities and the special knowledge the member brings to the Executive Committee and the Foundation.

2.1.4 Meetings

Meetings will be convened by teleconference, web, or face-to-face. Meetings during the initial year may be monthly as appropriate and no less than quarterly after that. Face-to-face meetings will be planned to coincide with other major events (e.g. AAO, ARVO or FFB-sponsored meeting) as much as feasible. Agenda items will be solicited in advance of the meeting and circulated to attendees. Potential conflicts of interest on an agenda topic must be stated at the beginning of a meeting; persons with such conflicts will not participate in discussions and voting. A conflict of interest is a situation in which a financial or other personal considerations could directly and significantly affect the design, conduct, or reporting of research.

Investigators from the Consortium, FFB Science, SAB members, and external advisors may be invited to Executive Committee meetings to discuss specific agenda items on an as-needed basis when the Committee desires additional scientific or other input.

Decisions and action items from Executive Committee meetings will be documented and archived by the Coordinating Center; members responsible for action items will be notified.

2.2 Operations Committee

2.2.1 Membership

The Operations Committee will comprise of the FFB Liaison, Coordinating Center Director, and the study chair(s), and will be attended by additional support from the Coordinating Center as needed.

2.2.2 Roles and Responsibilities

The Operations Committee will drive the execution of study protocols and be responsible for keeping the Executive Committee informed of any issues. Communications within the Operations Committee will consist of telephone calls, e-mails and in-person meetings. Initially meetings will be convened every 1-2 weeks and then approximately monthly.

2.3 Study Chairs and Clinical Centers/Members

2.3.1 Membership

Clinical Centers and Investigators will be invited to participate in the Consortium by FFB in collaboration with the Executive Committee based on the knowledge of inherited retinal diseases and ability to participate in and contribute to Consortium clinical trials. Clinical Centers and Investigators will be reviewed for Consortium requirements based on standard application forms to assess staffing, facilities, training, and experience. Additional site and personnel certification requirements will need to be completed for each protocol.

2.3.2 Roles and Responsibilities

The Consortium Investigators will be responsible for adhering to the process and policies in this Governance document. Consortium Investigators will provide ideas for studies, input to study protocols and analyses and be active contributors to support the Consortium mission. Investigators are encouraged to participate in Consortium-led studies; however, there may be instances that preclude their participation.

2.3.3 Study Chairs

Investigators of the Consortium will be encouraged to submit protocol ideas; any investigator internal or external to the Consortium may submit a protocol idea. The Executive Committee will review all protocol proposals and decide which move forward, and the prioritization. The

Executive Committee will decide in all cases who should be designated as protocol chair. The submitter would be the likely candidate in most cases.

An instance may arise in which a new study idea is initiated from a source outside the Consortium, such as in the case of a potential industry partnership or a patient advocacy group. In these instances, the Operations Committee will identify one or more protocol chair candidates. The identification of candidates may be informed by input from members of the Executive Committee or the FFB Scientific Advisory Board (SAB), or the external research partner. The Operations Committee will nominate one or more candidates based primarily on subject matter expertise in the disease or genetic area relevant to the study idea. However, if there are no obvious candidates based on the subject matter, the Operations Committee may solicit interest from the FFB Executive Scientific Advisory Board, from all or a subset of the Consortium or the Scientific Advisory Board. The potential study chair(s) will be proposed to the Executive Committee, who will make the final decision. Any investigator selected as protocol chair would be expected to join the Consortium (for the current study and potentially future studies).

2.4 Coordinating Center

The Coordinating Center will coordinate activities (calls, meetings, communications) of all Consortium committees and members, coordinate development and maintain version control of all study documents, oversee conduct of all aspects of study protocols (including training, certification, IRB coverage, recruitment, retention, adverse event monitoring, closeout), develop and maintain a multi-functional study website and data management system for supporting Consortium activities (including online system for validated data entry/edit/signoff of data collection forms), develop and implement a quality assurance program that includes monitoring of protocol adherence as well as quality control of data at all stages of each study (both remote and on-site), and conduct data analyses as needed for manuscripts, abstracts, presentations, and committee reviews.

2.5 Reading Centers and Other Vendors

The FFB Liaison and the Coordinating Center Director will collaborate on selecting vendors to support the Consortium clinical studies. The activities of the reading centers and other vendors will be defined by study protocols and contracts/service agreements.

2.6 Data Safety Monitoring Committees

Each interventional clinical study will have a separate Data Safety Monitoring Committee (DSMC) that will be responsible for reviewing the ethical conduct of the study and monitoring the data for evidence of adverse or beneficial treatment effects. The DSMCs are advisory to the Executive Committee. The DSMCs will operate under a single written charter describing

standard operating procedures for the Consortium, and details of study specific oversight or interim analyses will be described in each interventional study protocol and/or statistical analysis plan. The DSMCs will typically include an independent expert in each of the following areas: clinical trials, biostatistics, and the disease being studied. A minimum of three persons will be on the DSMC; these persons may not participate in the study in any other way.

3. Policies

3.1 Adherence to Good Clinical Practices (GCP)

All Consortium-led studies are to be conducted in accordance with applicable GCP regulations and guidelines per the International Committee on Harmonization (ICH) and US Code of Federal Regulations (CFR), including compliance with electronic records and electronic signatures (21 CFR, Part 11).

3.1.1 IRB/Ethics Committee Review and Approval

All protocols are to be conducted in accordance with IRB regulations (US 21 CFR Part 56.103) or applicable International Ethics Committee regulations. Investigators at each site must obtain approval from a properly constituted/accredited IRB/EC prior to initiating the study and a re-approval on at least an annual basis.

3.1.1.1 Central IRB is Preferred

While many clinical centers have their own local IRB, it is strongly preferred that a central IRB be used for the review and approval for each study to ensure oversight across study sites. For multi-center studies with a coordinating center at the JCHR, JCHR's Institutional Review Board (IRB) is able to enter into an IRB Reliance Agreement to serve as the IRB of record for institutions participating as clinical sites.

3.1.2 Informed Consent

Written informed consent/assent is to be obtained from each patient prior to any study-related activities or procedures in a study, and/or from the patient's legally authorized representative as per US 21CFR Part 50 and relevant country regulations.

3.1.3 Adverse Events

Adverse events will be assessed, documented, and recorded in the appropriate case report form throughout each study. Specific reporting and monitoring requirements and procedures for each study will be documented in the study protocol and procedures. Intervention studies will have adverse events monitored by a Medical Monitor, either internal or external to JCHR; this will be defined for each protocol.

3.1.4 Documentation and Record Retention

Source documents may include a patient's medical records, hospital charts, clinic charts, the investigator's patient study files, as well as the results of diagnostic tests such as ERGs, optical imaging, and laboratory tests. The investigator's access to the electronic CRFs on the study website serves as part of the investigator's record of a patient's study-related data.

For each study, the following information should be entered into the patient's medical record: patient's name and contact information; date the patient entered the study; study protocol title or number; dates of all visits; occurrence and status of any adverse events; vital signs; laboratory findings; visual acuity worksheets; results of any abnormal findings from any examination; printouts of any digital imaging/testing (e.g., FAF, OCT, fundus photos, etc.) and back-up copies of electronic records; date the patient exited the study, and if early discontinuation, the reason for early exit.

All study related correspondence, patient records, consent forms, patient privacy documentation, records of the distribution and use of all investigational products, and all CRFs (electronically on the website) should be maintained on file and at the site.

Each center will archive all relevant study data records and keep them on file for a period of time that covers all minimums specified by each governing office/agency for that center and the given study as a whole, whichever is the greatest. Record retention will be defined for each study in adherence to the Coordinating Center's SOPs.

The Clinical Center should contact the Coordinating Center or FFB prior to a planned document destruction.

3.1.5 Policy for Email and Website Use

All investigators and coordinators must have a unique email address that they check regularly. All study personnel must log onto the study website only using their individually created password and must not share their password with others. An electronic signature on an electronic case report form indicates that the data have been reviewed and accepted by the signatory. Electronic signatures will consist of the combination of the personnel identification number and password individually assigned by JCHR. It is unlawful to forge an electronic signature.

3.1.6 Adherence to Protocol and Study Procedures

All study investigators and their staff must adhere to protocols and study procedures to the best of their ability. The investigator must not implement any deviation from or changes of a protocol without approval by the Coordinating Center and prior review and documented approval/favorable opinion from the IRB/EC of a protocol amendment, except where necessary to eliminate immediate hazards to study patients, or when the changes involve only logistical or

administrative aspects of the study (e.g., change in monitors, change of telephone numbers; in these cases, Coordinating Center must still be informed of the change).

Investigators will recruit patients in Consortium-led studies meeting the protocol-specified criteria and without prejudice of gender and ethnicity.

3.1.7 Protection of Patient Privacy and Confidentiality

The Clinical Centers and Investigators will protect patient privacy and take appropriate precautions to maintain confidentiality of medical records and confidential information. However, as part of the quality assurance and legal responsibilities of an investigator, Clinical Centers must permit representatives of the Coordinating Center, authorized representatives, and/or the FDA or other appropriate governmental or regulatory authorities to examine at any reasonable time during normal business hours (a) the facilities where the Study is being conducted; (b) raw Study data including original subject records; (c) medical records in paper and electronic format supporting eligibility criteria and/or safety assessments; and (c) any other relevant information (and to make copies) necessary for the Coordinating Center to confirm that the Study is being conducted in conformance with the protocol and in compliance with applicable FDA or any national or governmental laws and regulations and the ICH guidelines as adopted by the FDA (where relevant). The Clinical Center and Investigator must agree to take reasonable actions requested by the Coordinating Center to cure deficiencies noted during an audit or inspection. In addition, the Coordinating Center has the right to review and comment on any correspondence to a governmental authority generated as a result of an inspection or audit relating directly to the Study prior to submission by Institution or Principal Investigator, so long as such review does not unduly delay such response. During an onsite audit or inspection, the Coordinating Center may check to ensure that the informed consent was properly completed, including printed names, dates, and signatures, and therefore would be able to read the participant name. However, identifying information would be redacted prior to transmitting to the Coordinating Center for remote documentation or inspection. Study data are considered confidential until presented at a national meeting or published as an abstract or manuscript.

Written authorization and other documentation in accordance with the relevant country and local privacy requirements (where applicable) is to be obtained from each patient prior to enrollment into the study, and/or from the patient's legally authorized representative in accordance with the applicable privacy requirements (e.g., the Health Insurance Portability and Accountability Act Standards for Privacy of Individually Identifiable Health Information ("HIPAA")). For European Union (EU) sites, personal data of European Union citizens will be handled pursuant to the General Data Protection Regulation ("GDPR"). The Coordinating Center will honor any reasonable request by a study subject, pursuant to the GDPR, for access to or erasure, transfer, rectification, or accounting of personal data gathered as a part of any FFB Consortium protocol, or for withdrawal of consent to personal data processing. As applicable, the Coordinating Center

will undertake all reasonable efforts to procure study subjects' explicit, opt-in consent for data processing pursuant to Article 9 of the GDPR.

Only de-identified or anonymized patient data will be shared or appear in any publication.

The investigators will maintain the highest degree of confidentiality permitted for the clinical and research information obtained from participants in Consortium-led studies. Medical and research records will be maintained in the strictest confidence.

3.1.8 Data Quality Assurance and Monitoring

3.1.8.1 Site/staff Training

Clinical Centers and Investigators are expected to maintain training records for staff participating in studies. This includes certification of visual acuity technicians, ocular imaging technicians, coordinators, perimetrists, genetic counselors, and others as specified in study protocols.

Good Clinical Practices (GCP) training is required every three years by investigators and coordinators. In addition, for each protocol, Investigators and study staff will be required to be trained in study specific procedures prior to initiating the study at their site. Requirements will be defined for each protocol.

3.1.8.2 Remote Monitoring and Site Audits

Clinical Centers are expected to have their own system to ensure quality of data entered into the eCRFs. The Coordinating Center will use remote data monitoring on a routine basis to identify potential inconsistencies in data as well as on-site data monitoring for assessment of potential issues.

Clinical Centers are to notify the Coordinating Center if they have been selected by the FDA or other government inspection agency that they are to be audited for a FFB Consortium-sponsored study.

3.2 Financial Disclosure and Conflict of Interest

All Consortium investigators, coordinators, committee members, and other key personnel will be required to disclose all financial interests and working relationships with any entity whose financial interests potentially could be affected by the conduct or outcome of Consortium-led research. This disclosure will be required separately for each protocol and will require an update according to criteria set for the given protocol, likely annually. Financial disclosures must be updated within 30 days when there is a new financial disclosure due to a change in a Consortium protocol, or a change in the Consortium investigator or staff's finances.

Any person serving as a member of the Executive Committee (or other committees as applicable) who has financial disclosures relevant to a company involved in discussions to collaborate with

the Consortium will forego discussion and voting privileges regarding decisions on the collaboration. This policy will prevent putting any Consortium investigator in an inappropriate position and will ensure that financial biases are eliminated when voting takes place.

3.3 Potential Investigator Misconduct and Issue Escalation

3.3.1 Serious Breach of GCP and Protocol Adherence

Major protocol deviations (e.g., related to eligibility, informed consent, recording of adverse events, or study treatments) may jeopardize patient privacy, safety and integrity of a study and are not acceptable at any Consortium Clinical Center. This is monitored by the Coordinating Center and becomes a concern when a clinic is making more mistakes than expected, particularly major ones (e.g. entering ineligible patients).

3.3.2 Assessment and Reporting

Assessment of any potential investigator or staff serious misconduct will done via an on-site monitoring visit. Potential issues will be discussed at the Operations Committee first and then escalated to the Executive Committee if there is evidence of serious misconduct. If GCP violations are serious they will be reported to the governing IRB/EC and may also be reported to the FDA or other regulatory agency. The Executive Committee, and potentially the DSMC will make a decision regarding suspension or halting of study activity at that site.

3.3.3 Corrective and Preventative Actions

A written corrective action and preventative action plan for any case of serious misconduct will be put into place by the Coordinating Center in collaboration with the Operations Committee.

3.4 Editorial Policy

3.4.1 Manuscripts and Presentations

All manuscript and presentation ideas related to any aspect of a Consortium-led study including but not limited to the study protocol, study results, and study conduct that is not already information in the public domain must receive the approval of the Executive Committee. The topic for a manuscript or presentation may be initiated by the Executive Committee, or by any investigator, who may send a suggestion to the Study Chair for Executive Committee consideration.

Typically, the "primary" manuscript for a study will refer to the manuscript that contains the analysis of the primary outcome of the study, and all other manuscripts will be considered "secondary" manuscripts. There may be studies with multiple objectives that will result in multiple publications to address them, in which case there might be more than one primary manuscript. The Executive Committee will make the determination of whether a manuscript is primary or secondary.

The Executive Committee must approve all manuscripts about the study or any ancillary study in a timely fashion (e.g., 1 week) prior to submission for publication. The manuscripts will also be submitted to FFB for comment prior to submission. Primary manuscripts must also be approved by the DSMC (if there is a DSMC). The DSMC will be sent secondary manuscripts for comment, but approval will not be required.

Abstracts for presentations must be submitted to the Executive Committee for approval at least one month prior to the submission deadline. If data are needed for the abstract that have not been previously compiled and verified by the Coordinating Center, the Coordinating Center must be contacted at least 8 weeks prior to the submission date in order to have the abstract ready for Executive Committee approval one month ahead of the deadline.

3.4.2 Authorship

Since every investigator cannot have an active role in writing a paper, the Operations Committee will establish a Writing Committee for each paper with the advice of the Executive Committee. Investigators may volunteer for these writing assignments. Writing Committees may also include representatives from Reading Centers, consultants who were involved in the implementation or monitoring of the protocol, or vendors with ownership or intellectual property related to the procedures performed. The Operations Committee will also determine the first author for each paper; typically this will be the study chair for primary manuscripts.

For primary manuscripts, the XXX Study Investigator Group will be listed as the author on the title page, if group authorship is permitted by the journal. Each clinical site with an investigator who enrolled at least one patient along with the study personnel at that site will be listed at the

end of the paper in descending order of recruitment, if this meets with journal approval. Sources of support for the study will be listed. Members of the Writing Committee, Executive Committee, DSMC, reading centers, and sites will be listed.

For secondary manuscripts, the investigators involved in writing the paper will be listed by name followed by "for the XXX Study Investigator Group."

Authorship credit should be based only on (1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; and (2) drafting the article or revising it critically for important intellectual content; and (3) final approval of the version to be published. Conditions 1, 2, and 3 must all be met. To qualify for authorship, each author must meet at least one criterion in each of the three categories.

Category 1

- Conception and design
- Acquisition of data
- Analysis and interpretation of data

Category 2

- Drafting of the manuscript
- Critical revision of the manuscript for important intellectual content (this does not include reviewing the manuscript for journal submission approval)

Category 3

- Statistical analysis
- Obtaining funding
- Administrative, technical, or material support
- Supervision
- Other (specify)

3.4.3 Publicity

The Executive Committee and FFB must give approval prior to any press release or other publicity about the trial using information not already in the public domain.

3.5 Collaboration and Transparency

3.5.1 Multi-centered studies

The Consortium-led studies will be conducted as multi-centered trials to increase the robustness of study results and enable patients from different regions to participate.

3.5.2 Availability of Study Protocols and Procedures

To further the mission of the Consortium, sharing of study protocols and procedures will be allowed; requests will go through the Executive Committee.

3.5.3 Data Sharing Policy

To further the mission of the Consortium, sharing of study data will be planned according to the following policies.

3.5.3.1 Release and Use of Consortium Data to the Public

In an effort to maximize the usefulness and availability of its data for widespread scientific and clinical benefit, Consortium research data (from either a Consortium protocol or a Consortium ancillary study) will be made available to the public (i.e., as a public dataset) once the study is completed and the primary manuscripts are published. Study images may also be made available at this time, upon request for direct download from the Coordinating Center.

Persons wishing to use publicly available Consortium data or images may do so independently from the Consortium but should be explicit when presenting their analyses in any forum that they do not speak for, nor represent, the opinions of the Consortium. Use of these Consortium data or images requires that the following disclaimer be added to any paper, review, presentation or other distribution of the data exactly as follows:

- *"The source of the data is the FFB Consortium, but the analyses, content and conclusions presented herein are solely the responsibility of the authors and have not been reviewed or approved by the Consortium and may not reflect the views of FFB."*

3.5.3.2 Release and Use of Consortium Data that Are Not Yet Publicly Available

Consortium data (from either a Consortium protocol or a Consortium ancillary study) that has not yet been released for public use (i.e., as a public dataset), including Consortium data obtained from an investigator's own patients, cannot be used for public reporting or presentation until the Consortium data is publicly available (i.e., as a public dataset), unless prior approval is received by the Executive Committee.

- Note: The only exception to this is the unlikely scenario that study data are not made public (i.e., as a public dataset) within 12 months following formal closeout of the study. In this case, the investigator would have the right to report or present Consortium data obtained from his or her own patients without prior Executive Committee approval.

Requests for Executive Committee approval to use Consortium data that are not publicly available (i.e., as a public dataset) should be submitted to the Coordinating Center. The Executive Committee review will include a determination of whether analysis and presentation or publication of the requested data would negatively impact the Consortium study objectives or any planned or pending reporting on the full study dataset.

At the time of the request, it must be made clear whether the request is for data release only without further Consortium involvement or whether a scientific collaboration with the

Consortium is desired. In cases where use of data or images is approved by the Executive Committee for use without Consortium scientific collaboration, the following will also be required:

- The ancillary study investigators must send a copy of the manuscript to the Consortium Coordinating Center when accepted for publication.

- The following disclaimer must be added to any paper, review, presentation or other distribution of the data exactly as follows:

    - *"The source of the data is the FFB Consortium, but the analyses, content and conclusions presented herein are solely the responsibility of the authors and have not been reviewed or approved by the Consortium and may not reflect the view of FFB."*

3.6 New Studies

3.6.1 New Protocols

Protocol ideas may be submitted by individuals inside or outside the Consortium. A Consortium Protocol Idea Form can be used to propose a new study idea. Ideas will be first reviewed with the Executive Committee for merit, feasibility, and prioritization. All protocol ideas that are favorably reviewed by the Executive Committee will also be reviewed by Consortium Members for additional input and interest, and by the FFB's Clinical Subcommittee to the Research Oversight Committee for ultimate approval to proceed to full protocol development process.

3.6.2 Ancillary Studies

An ancillary study is one in which research procedures not part of the primary protocol is performed on a subject participating in a current Consortium protocol.

There are two main types of ancillary studies.

1) A Consortium ancillary study:

    a. A Consortium ancillary study is one that is coordinated by the Coordinating Center with oversight by the Executive Committee.

    b. This type of ancillary study would follow all of the same governance policies and oversight as a Consortium protocol, including the following:

        i. The ancillary study idea must be submitted for review by the Executive Committee according to the same review process as described above for new protocols, section 3.6.1. An Ancillary Study Idea Form should be submitted for this review.

ii. Use of Consortium ancillary study data would follow the data sharing policy noted in section 3.5.3.

iii. The editorial policy for a Consortium ancillary study is the same as for any other Consortium manuscript as noted in section 3.4.

2) An independent ancillary study:

a. An independent ancillary study is one in which study resources and the Coordinating Center are not involved. The operations and funding would be the responsibility of the investigator(s).

b. Although the independent ancillary study would not be coordinated or overseen by the Consortium, it must be reviewed and approved by the Executive Committee. The primary purpose of this review would be to determine that the ancillary study objectives do not interfere with the objectives of the primary protocol. The Coordinating Center should be contacted to propose an independent ancillary study.

c. Use of the independent ancillary study data that is not collected as part of any Consortium protocol would not be bound by Consortium governance in any way and can be used/published at the discretion of the investigator. However, the author must include a disclaimer: *"These data were collected as an independent ancillary study to an FFB Consortium protocol. Data collection, analyses, content and conclusions presented herein are solely the responsibility of the authors and have not been reviewed or approved by the Consortium and may not reflect the view of FFB."*

d. Use of any Consortium study data that was collected in conjunction with the ancillary study data (i.e., even just for an investigator's own patients) would follow the data sharing policy noted in section 3.5.3.

i. Note: This includes the requirement that any planned reporting of such data prior to the publication of the primary Consortium study results needs approval by the Executive Committee, as stated in section 3.5.3, to assure such publication would not jeopardize the overall study.

3.7 Competing Studies

A 'competing' study is defined as one in which subject eligibility criteria overlap with that of a Consortium study. Sites are required to inform the Coordinating Center of studies in which they are participating that have eligibility criteria that overlap with a Consortium protocol in which they are concurrently participating. Sites should determine a management plan for competing

studies internally. Assistance from the Operations Committee will be available for sites that would like advice on how to manage their competing studies.

3.8 Funding of Clinical Studies and Sites

3.8.1 Funded through Private Donations

The Consortium is funded through private donations made to the Foundation Fighting Blindness for the purpose of findings treatments for inherited retinal diseases. Care must be taken to conserve resources to ensure highly efficient usage of the funding.

3.8.2 Contracts

Each Consortium-led study will have its own budget and contract between FFB and the Coordinating Center and between the Coordinating Center and Clinical Centers and vendors. It will be preferred to have a Master Service Agreement in place with Individual Project Assessment for each protocol. Additional funding to cover institutional indirect cost rates or overhead fees will not be available.

Funding of the Consortium is expected to produce data leading to development of treatments for IRDs. Contracts with the Clinical Centers will be based on a fee-for-service based on the number of patients enrolled into the study and the number of examinations completed in addition to some start-up costs. The focus will be on the number of patients enrolled in the studies and quality data collected.

Depending on the study, all study visits, including but not limited to screening, baseline and follow-up, and any standard of care appointments, may be charged to the study participant or their insurance carrier or health care system as permitted according to each country's laws and regulations. Depending on the study, the study participant may also be responsible for any deductible or co-payments as defined by their particular insurance carrier. Certain study procedures including obtaining informed consent, and non-standard examination will not be incurred by the study participant and will be covered by the study. Participation of the study coordinator will be paid on a by-patient/by-visit basis, as will the investigator to ensure adequate compensation for completed work.

Traveling to study sites can be challenging for patients with IRDs; to assist with transportation, patients will be offered a stipend on a by-visit basis for transportation and their participation. The amount and the mechanism for payment will be described in the informed consent form.

3.9 My Retina Tracker

My Retina Tracker (MRT) is a patient-driven registry for patients with IRDs sponsored by FFB. Consortium Clinical Members are expected to actively encourage their clinic patients to register

and participate in MRT and inform patients that they can request their physician/genetic counselor to put data into MRT on the patient's behalf.

4. Glossary of Abbreviations

AAO	American Academy of Ophthalmology
AE	Adverse event
ARVO	Association for Research in Vision and Ophthalmology
CFR	US Code of Federal Regulations
CRF	Case report form
eCRF	Electronic case report form
DSMC	Data Safety Monitoring Committee
EC	Ethics Committee
ERG	electroretinograph
EU	European Union
FAF	Fundus autofluorescence
FFB	Foundation Fighting Blindness
FDA	Food and Drug Administration
FFB	Foundation Fighting Blindness
GCP	Good Clinical Practices
HIPAA	Health Insurance Portability Act of America
ICH	International Committee of Harmonization
IRB	Institutional Review Board
IRDs	Inherited Retinal Diseases
JCHR	Jaeb Center for Health Research, Tampa, FL
MRT	My Retina Tracker
OCT	Optical Coherence Tomography
ROC	Research Oversight Committee at FFB
US	United States

5. Amendments to the Consortium Governance

This is a controlled document for which the Executive Committee is accountable. Changes to the governance of the Consortium may be proposed by any Consortium Member and discussed and voted on by the Executive Committee. Changes to the document, date for the change and rationale for the change will be summarized in the Summary of Changes.

5.1 Summary of Changes

Version	Author(s)	Approver	Effective Date	Revision Description
1.0	J. Cheetham, A. Ayala	P. Zilliox	May 13, 2016	First Version of Document
2.0	J. Cheetham, A. Ayala	P. Zilliox	March 30, 2017	• Clarification: Financial disclosure requirements tied to each protocol • Clarification: FFB CRI Consortium will not pay indirect fees • Clarification: billing to insurance "may" be required instead of "will" be required for SOC tests, depending on the study • New policy: new protocol ideas and ancillary studies
3.0	A. Ayala, J. Cheetham	S. Rose	November 26, 2018	• Modified data sharing policy for use of Consortium data to the public to require a disclaimer • Modified ancillary studies policy to define Consortium sponsored ancillary vs independent ancillary study • Removed CRI references • Added section on GDPR • Updated site/staff training requirements
4.0	A. Ayala, R. Sitten	T. Durham	July 8, 2019	• Updated the figure in the Organizational Structure section • Added a subsection for Executive Committee reappointments • Expanded study chair selection policy to included instances where a new protocol idea is submitted by someone who is not an investigator in the Consortium • Added more explicit language with regards to access to records at site visits • Added collaborators to list of possible Writing Committee members