Evaluation of Long-Term Safety and Performance of AcrySof PanOptix Trifocal and PanOptix Toric Trifocal IOLs

STUDY ID

ILH297-I001

Protocol v.3

18-Mar-2025

NCT06166901

Evaluation of long-term safety and performance of AcrySof PanOptix Trifocal & PanOptix Toric Trifocal Intraocular Lens (IOLs)

Version 3.0 / 18 March 2025

Sponsor:	Alcon Research LLC 6201 South Freeway Fort Worth, Texas 76134
Study Product:	AcrySof IQ PanOptix Trifocal and AcrySof IQ PanOptix Trifocal Toric IOLs
Protocol Identifiers:	ILH297-I001

Sponsor Approval:

[redacted] Date

[redacted] Date

CONFIDENTIAL

STATEMENT OF COMPLIANCE

This document is a protocol for a human research study. This study will be conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and according to international standards of Good Clinical Practice (GCP), applicable government regulations and Institutional research policies and procedures.

All individuals responsible for the design and conduct of this study have completed Human Subjects Protection Training and are qualified to be conducting this research prior to the enrollment of any subjects.

As Principal Investigator, I agree to conduct this clinical study in accordance with the design and specific provisions of this protocol. Modifications to the study are acceptable only with an approved protocol amendment. I agree to obtain approval from the Institutional Review Board (IRB)/Independent Ethics Committee (IEC) and/or regulatory bodies of competent jurisdiction, for the protocol and informed consent before initiating the study, to obtain consent from subjects prior to their enrollment in the study, to collect and record data as required by this protocol and case report forms, to prepare adverse event and study reports as required by this protocol, to provide documentation of my experience and qualifications to the Sponsor, to disclose any relevant financial interests or agreements related to the Sponsor or the investigation and to maintain study documentation for the period of time required.

I agree to personally conduct or supervise the described investigation. I agree to maintain adequate and accurate records and to make those records available for inspection by the Sponsor, its representatives, applicable regulatory authorities, and the IRB/IEC. I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I certify that I have not been terminated from an investigation due to compliance failure (debarment).

_____ _____

Signature Date (DD MMM YYYY)

_____

Print Name/Title of Principal Investigator

CONFIDENTIALITY STATEMENT

The information contained in this document, especially unpublished data, is the property of Sponsor and therefore is confidential and may not be disclosed unless such disclosure is required by law or regulation. That Sponsor confidential information may be disclosed to the Investigator(s), potential Investigator(s) and necessary Investigator assistant(s) or study personnel. In any event, persons to whom the information is disclosed must be informed that the information is privileged or confidential and may not be further disclosed by them without written authorization from Sponsor. These restrictions on disclosure will apply equally to all future information supplied to the Investigator(s), potential Investigator(s) and necessary Investigator assistant(s) or study personnel, which is indicated as privileged or confidential.

Clinical Study Protocol

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

STUDY SYNOPSIS

Title	**Evaluation of long-term safety and performance of AcrySof PanOptix Trifocal & PanOptix Trifocal Toric Intraocular Lens (IOLs)**
Protocol Numbers	ILH297-I001
Study Sponsor	Alcon Research LLC 6201 South Freeway Fort Worth, Texas 76134
Study Design	This will be a multicenter, ambispective study with a retrospective chart review for preoperative, operative, and post-operative data, and a prospective visit to collect key long-term safety and performance endpoints in a sample of subjects commercially implanted with the subject devices in the real world.
Objectives	The purpose of this Post-Market Clinical Follow-up (PMCF) study is to describe the long-term safety and performance of the AcrySof Panoptix Trifocal toric and non-toric IOL models in subjects bilaterally implanted with these IOLs for 3 to 5 years. In addition, it will ensure the continued acceptability of the benefit-risk ratio and identify possible systematic misuse or off-label use of the device.
Number of Subjects	210 enrolled for 200 evaluable subjects
Main Inclusion / Exclusion Criteria	Inclusion Criteria: 1. Subject must be 18 years old or older 2. Subject or legally authorized representative must be able to understand and sign an Institutional Review Board (IRB)/Independent Ethics Committee (IEC) approved informed consent form. 3. Subject must have had bilateral implantation of AcrySof PanOptix and/or AcrySof PanOptix Toric IOL models for 3 to 5 years prior to enrollment, including implantation up to 90 days before the 3-year timepoint and up to 90 days after the 5-year timepoint. A subject may have a Toric lens in one eye and a non-Toric in the fellow eye. 4. Subject must have a documented medical history and required pre-operative baseline information available for retrospective data collection. Exclusion Criteria: 1. Subject currently participating in another investigational drug or device study. 2. Subject has had corneal refractive surgery after AcrySof PanOptix or AcrySof PanOptix Toric IOL implantation. 3. Subject exposed to a study IOL for a minimum of 3 years (-90 days) prior to Visit 1 that have subsequently undergone an IOL exchange and are no longer implanted with a study IOL at the time of enrollment. 4. Subject is pregnant or nursing at the time of enrollment. 5. Childbirth after IOL implantation. 6. Subject's retrospective data were not properly documented.
Study Device	AcrySof IQ PanOptix IOL TFNT00 / AcrySof IQ PanOptix Toric IOL TFNT20 TFNT30 TFNT40 TFNT50 TFNT60
Endpoints	**Primary Effectiveness Endpoint:** The primary effectiveness endpoint will consist of the mean binocular Best Corrected Distance Visual Acuity (BCDVA) at 4 m at Visit 1 (3-5 years +/- 90 days post-operative). **Primary Safety Endpoints (Evaluated at prospective Visit 1 and from retrospective chart review):** • All adverse events (AEs), including the following: o Cystoid Macular Edema (CME) o Hypopyon

	○ Endophthalmitis ○ Lens dislocation ○ Pupillary block ○ Retinal detachment ○ Secondary Surgical Interventions (explantation/exchange/repositioning) • Device deficiencies [redacted]
Statistical Methods	Appropriate descriptive statistics will be computed and presented for all categorical and continuous endpoints. A full description of statistical methods will be presented in the Statistical Analysis Plan. • For categorical variables, the number and percentage of subjects/eyes within each category of interest will be presented. • For continuous variables, the number of subjects/eyes with non-missing data, mean, standard deviation, range, median, minimum, and maximum. There will be no imputation for missing data. All visual acuity results will be presented in logMAR scale.

ABBREVIATIONS

Abbreviation	Definition
ADE	Adverse Device Effect
AE	Adverse Event
BCDVA	Best Corrected Distance Visual Acuity
CFR	Code of Federal Regulations
CME	Cystoid Macular Edema
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organization
D	Diopter
DCIVA	Distance corrected intermediate visual acuity
DCNVA	Distance corrected near visual acuity
DFE	Dilated Fundus Examination
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
EU	European Union
FAS	Full Analysis Set
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GPCMS	Global Product Complaint System
HIPAA	Health Insurance Portability and Accountability Act of 1996
ICH	International Conference on Harmonization
ICF	Informed consent form
IDE	Investigational Device Exemption
IEC	Independent Ethics Committee
IOL	Intraocular Lens
IOP	Intraocular Pressure
IRB	Institutional Review Board
ISO	International Organization for Standardization
logMAR	Logarithm of the minimum angle of resolution
LRI	Limbal Relaxing Incision
m	Meter
MDR	Medical Device Regulation
MRSE	Manifest Refraction Spherical Equivalent
PCO	Posterior Capsule Opacification
PMCF	Post-Market Clinical Follow-Up
[redacted]	[redacted]
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SOP	Standard Operating Procedures
UADE	Unanticipated Adverse Device Effect
UCDVA	Uncorrected distance visual acuity
UCIVA	Uncorrected intermediate visual acuity
UCNVA	Uncorrected near visual acuity
UV	Ultraviolet

Abbreviation	Definition
VA	Visual Acuity

1 STUDY CONTACT INFORMATION

1.1 Sponsor Contact Information

[redacted]

1.2 Coordinating Principal Investigator Contact Information

The Coordinating Principal Investigator and coordinating institution will be listed in an attachment listing all participating sites.

1.3 Key Study Personnel

1.3.1 Clinical Study Monitor

The clinical study will be monitored by:

ICON Clinical Research
South County Business Park
Leopardstown
Dublin 18, Ireland

Clinical monitors will be assigned based on therapeutic area familiarity and availability.

1.3.2 Global Medical Safety

Medical safety oversight will be provided by Alcon Global Medical Safety Representatives.

1.3.3 Statistician

Biostatistical analysis will be provided by the ICON Clinical Research Biostatistics group.

2 INTRODUCTION / BACKGROUND AND RATIONALE

After removing the crystalline lens, an intraocular lens (IOL) is implanted in the capsular bag. All the study devices are indicated for primary implantation for the visual correction of aphakia and presbyopia in adult patients with or without corneal astigmatism. The AcrySof IQ PanOptix and PanOptix Toric IOL Family models in this PMCF study have been on the market since 2015 and have a well-established safety and performance profile. Based on clinical evidence available, there are no uncertainties concerning residual risks, performance limitations, or need for preventative and/or corrective actions. However, review of clinical data available based on MEDDEV 2.12-2:2012, Section 5, and MDCG 2020-7 EU 2017/745 identified a need for longer term safety and performance outcomes (≥ 3 years) for the AcrySof PanOptix family of IOLs including the AcrySof IQ PanOptix Trifocal and PanOptix IQ Trifocal Toric IOLs. This proactive PMCF study will provide a comprehensive assessment of the long-term safety and performance of the included IOLs.

The ambispective design is justified based on the risk-profile of the device, in order to expeditiously obtain long term safety and performance data which best reflects the current standard of care. An uncontrolled design is also justified as the purpose of the study is to assess long term safety and performance over time. The study population aligns with our indications for the AcrySof IQ PanOptix and PanOptix Toric IOL Family by only recruiting subjects 18 years of age and bilaterally implanted with AcrySof IQ PanOptix and PanOptix Toric IOL Family for the visual correction of aphakia and treatment of the effects of presbyopia. Study endpoints focus on the safety and performance criteria identified from the AcrySof IQ PanOptix Trifocal Intraocular Lenses State of the Art [redacted]. The ability of this study to provide long-term follow-up data is supported by the ISO 11979- 7:2018(E). ISO 11979-7-2018 defines long-term follow-up studies ranging from 1 year for most posterior chamber IOLs to 3 years for an accommodating IOL only if long term safety and effectiveness concerns. In this case, the most restrictive criteria were used and long term 3-to-5-year outcomes of the AcrySof IQ PanOptix and PanOptix Toric IOL Family will be obtained.

In conjunction with current literature and continued post-market surveillance, this study will provide a comprehensive assessment of the long-term safety and performance of AcrySof IQ PanOptix family of IOLs.

3 DEVICE DESCRIPTION

The devices that are the subject of this study are listed in the table below. Multiple model numbers are present in the toric model type.

Table 1. Study Devices

Model Name	Model Numbers	Indications for Use Statements
AcrySof IQ PanOptix IOL	TFNT00	The AcrySof IQ PanOptix IOL is intended for primary implantation in the capsular bag in the posterior chamber for the visual correction of aphakia secondary to removal of a cataractous lens or clear lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision with increased spectacle independence.
AcrySof IQ PanOptix Toric IOL	TFNT20 TFNT30 TFNT40 TFNT50 TFNT60	The AcrySof IQ PanOptix® Toric Trifocal IOL is intended for primary implantation in the capsular bag in the posterior chamber of the human eye for the visual correction of aphakia and pre-existing corneal astigmatism secondary to removal of a cataractous lens or clear lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision with increased spectacle independence.

The AcrySof IQ PanOptix Trifocal IOLs are a UV-absorbing and blue light filtering foldable multifocal IOLs. The single-piece lens is composed of a high refractive index, soft hydrophobic acrylic material, which contains a covalently bonded blue light filtering chromophore. Alcon's proprietary chromophore filters blue light in a manner that approximates the human crystalline lens in the 400 to 475 nm wavelength range (Boettner and Wolter, 1962). In addition to UV absorption, the blue-light filtering chromophore reduces transmittance of blue light wavelengths. The lens is capable of being folded prior to insertion, allowing placement through an incision smaller than the optic diameter of the lens. After surgical insertion into the eye, the lens gently unfolds to a full-size lens body. Each lens has an optical portion and mechanical support elements (haptics). The haptics provide proper positioning of the lens optic within the capsular bag. The optic diffractive structure is in the central 4.5 mm portion of the optic zone and divides the incoming light to create a +2.17 D intermediate and a +3.25 D near add power. The anterior surface is designed with negative spherical aberration to compensate for the positive spherical aberration of the cornea. Additionally, the toric model has a toric component on the posterior surface with axis marks to denote the flat meridian (plus cylinder axis). Alignment of the toric axis marks with the post-operative steep corneal meridian allows the lens to correct preexisting corneal astigmatism.

4 DEVICE ACCOUNTABILITY

Subjects will be recruited from a population that has already undergone lens implantation, therefore there is no device accountability necessary.

5 STUDY OBJECTIVES

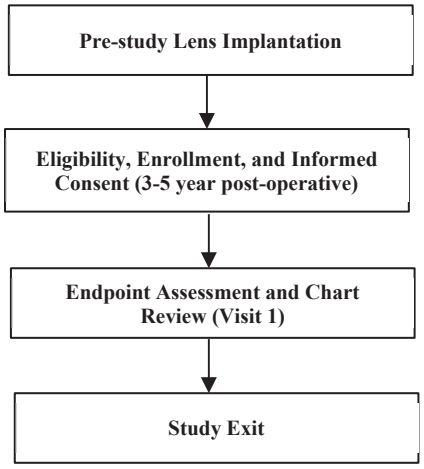
The purpose of this Post-Market Clinical Follow-up (PMCF) study is to describe the long-term safety and performance of the AcrySof Panoptix and AcrySof Panoptix Toric IOL models in subjects bilaterally implanted with these IOLs for 3 to 5 years. In addition, it will ensure the continued acceptability of the benefit-risk ratio and to identify possible systematic misuse or off-label use of the device.

6 STUDY DESIGN

6.1 Overview of Study Design

This will be a multicenter, ambispective study with a retrospective chart review for preoperative, operative, and post-operative safety data, and a prospective visit to collect key safety and performance endpoints in a sample of subjects commercially implanted with the subject devices for at least 3-5 years in the real world. The overall study design is shown in the figure below. Subjects will be recruited who have bilateral implantation of the study model IOLs for 3 to 5 years (+/- 90 days) prior to Visit 1.

Figure 1. Overall Study Design



6.2 Anticipated Duration of the Clinical Investigation

The anticipated study duration is 8-9 months. The anticipated accrual rate is approximately 23 subjects per month across all sites. The Sponsor reserves the right to close the investigational site or terminate the study in its entirety at any time. In the event the study is terminated early, there are no subject transitions required. When the study is completed, data and Sponsor materials will be returned and sites closed out with a final report to the IRB/IEC. Sponsor will inform the IRB/IECs of the study closure or, if applicable, study termination and reasons.

6.3 Evaluation Criteria / Effectiveness and Safety

The endpoints chosen align with those identified in the AcrySof IQ PanOptix Trifocal Intraocular Lenses State of the Art [redacted] Study assessments will be described in Section 7.3. Retrospective data will be collected from the pre-operative and surgical visits and any safety outcomes reported prior to enrollment. Prospective data will be collected at study enrollment 3 to 5 years (+/- 90 days) after IOL implantation.

6.3.1 Primary Clinical Endpoint

6.3.1.1 Primary Effectiveness Endpoint

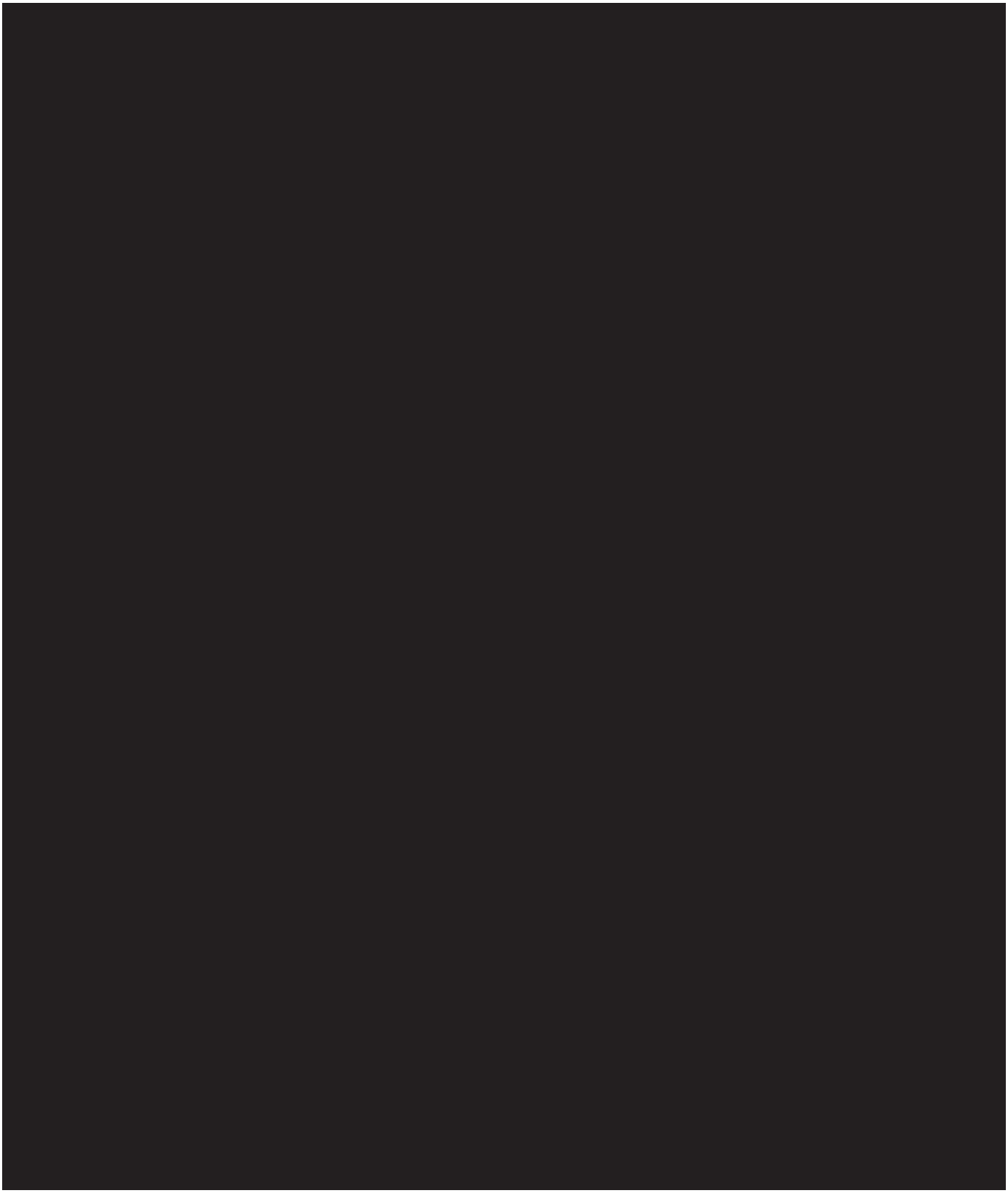
The primary effectiveness endpoint will consist of the mean binocular Best Corrected Distance Visual Acuity (BCDVA) at 4 m at Visit 1 (3-5 years +/- 90 days post-operative).

6.3.1.2 Primary Safety Endpoints

Primary safety endpoints will be assessed at Visit 1 and from retrospective data review and will include the following:

- All adverse events (AEs), including the following:
    - Cystoid Macular Edema (CME)
    - Hypopyon
    - Endophthalmitis
    - Lens dislocation
    - Pupillary block
    - Retinal detachment
    - Secondary Surgical Interventions (explantation/exchange/repositioning)
- Device Deficiencies

[redacted]



6.4 Study Population

The study population consists of adult subjects (18 years or older) who have been bilaterally implanted with the study IOL models (see Section 3) for 3 to 5 years (+/- 90 days).

The purpose of study is to describe to describe the long-term safety and performance of AcrySof Panoptix IOL models in a real-world setting through routine clinical practice. To fulfill the requirements of post-market clinical follow-up, only subjects implanted with the target IOLs will be recruited. Subjects will be recruited from clinical sites in the European Union (English and Spanish speaking countries only). The inclusion and exclusion criteria of this study are less strict to allow the inclusion of a real-world sample per the indication, including patients that have undergone either cataract surgery or refractive lens exchange.

6.4.1 Sample Size

The study will recruit a total of 210 subjects for both AcrySof PanOptix IOL models to obtain 200 evaluable subjects (n=100 non-toric and n=100 toric). A minimum of 100 subjects bilaterally implanted with AcrySof PanOptix non-Toric should be evaluable. In addition, a minimum of 100 subjects with at least one eye implanted with AcrySof PanOptix Toric should be evaluable. Alcon will attempt to enroll all variants in the AcrySof Panoptix Toric family. ISO 22979 and ISO 11979-7 recommend a sample size of n=100 for IOLs where safety and performance risks can be adequately addressed with the sample size required of a Level B clinical investigation. Therefore, a target enrollment of up to 105 (enrolled) to achieve a goal of 100 evaluable subjects for both AcrySof Panoptix toric and non-toric models is justified by ISO standards for IOLs. Based on a pooled standard deviation of 0.07 logMAR and a t-distributed error, a sample size of 100 subjects gives an expected half width of a 95% confidence interval of 0.014 logMAR. Thus, it can be expected with 95% confidence that the estimated mean binocular BCDVA will be within 0.014 logMAR (< 1 letter on a logMAR visual acuity chart) of the true mean with a sample size of at least 100 subjects and a standard deviation of 0.07 logMAR. Descriptive results from this long-term RWE study are sufficient to provide a comparison to shorter term follow-up data of these models, and SotA safety and performance thresholds. Performance and safety outcome measures will be stratified by models (toric and non-toric).

6.4.2 Subject Recruitment

Subjects will be recruited from the clinical practices of the participating Investigators and surrounding metropolitan areas. Additional advertisement is not expected to be required.

6.4.3 Prior and Concomitant Therapy or Medications

Due to the nature of the study, there are no protocol-specific exclusions, precautions, or guidance provided regarding the use of concomitant medications or therapies.

6.4.4 Inclusion Criteria

Subjects will be eligible to participate in the study if **all** of the following conditions exist:

1. Subjects must be 18 years old or older.
2. Subject or legally authorized representative must be able to understand and sign an IRB/IEC approved informed consent form (ICF).
3. Subject must have had bilateral implantation of AcrySof PanOptix or AcrySof PanOptix Toric models for 3 to 5 years prior to enrollment, including implantation up to 90 days before the 3-year timepoint and up to 90 days after the 5-year timepoint. A subject may have a Toric lens in one eye and a non-Toric in the fellow eye.
4. Subject must have a documented medical history and required pre-operative and operative information available for retrospective data collection.

6.4.5 Exclusion Criteria

Subjects will be excluded from participation in the study if any of the following conditions exist:

1. Subject is currently participating in another investigational drug or device study.
2. Subject has had corneal refractive surgery after of AcrySof PanOptix or AcrySof PanOptix Toric IOL implantation.
3. Subject exposed to a study IOL for a minimum of 3 years (-90 days) prior to Visit 1 that have subsequently undergone an IOL exchange and are no longer implanted with a study IOL at the time of enrollment.
4. Subject is pregnant or nursing at the time of enrollment.
5. Childbirth after IOL implantation.
6. Subject's retrospective data were not properly documented.

6.4.6 Exit / Discontinuation Criteria

Subjects will exit the study if **any** of the following conditions exist:

1. Subject voluntarily withdraws from the study.
2. Subject death.
3. Subject completes the protocol.
4. Subject is non-compliant with the protocol (as defined in Section 7.6)
5. Subject's well-being, in the opinion of the Investigator, would be compromised by study continuation.

7 STUDY PROCEDURES

7.1 Informed Consent

All subjects will be provided with a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. The Investigator or his/her representative will explain the nature of the study to the subject and answer all questions regarding the study. Subjects must be informed that their participation is voluntary. Subjects will be required to sign a statement of informed consent that meets the requirements of 21 Code of Federal Regulations (CFR) 50, local regulations, International Conference on Harmonization (ICH) guidelines, Health Insurance Portability and Accountability Act (HIPAA) requirements, where applicable, and the IRB/IEC or study center. The medical record must include a statement that written informed consent was obtained before the subject was enrolled in the study and the date the written consent was obtained. The authorized person obtaining the informed consent must also sign the ICF. Subjects must be re-consented to the most current version of the ICF during their participation in the study. A signed copy of the ICF must be provided to the subject.

7.2 Vulnerable Populations

Members of vulnerable populations will not be specifically targeted for recruitment. However, the intended subject population may include subjects who are considered to be vulnerable by definition. The procedures included in this protocol are sufficient to provide the necessary human subjects' welfare protections to these subjects without the need for additional procedures.

Women of childbearing potential are not excluded from participation. Women who gave birth after IOL implantation or who are pregnant or nursing at the time of enrollment are excluded from participation.

7.3 Prospective Clinical Procedures and Assessments

After obtaining informed consent and confirming eligibility, assessments will be conducted for the enrolled subject as described in the sections below. Retrospective data will be collected regarding the pre-operative, operative, and post-operative activities. All assessments and data collection are described in the sections below.

7.3.1 Demographics

The Investigator or designee will verify that all required demographic details have been documented for each subject enrolled, including age, race, ethnicity, and sex.

7.3.2 Eligibility

Verify that all inclusion criteria listed in Section 6.4.4 are fulfilled by the subject, and that none of the exclusion criteria listed in Section 6.4.5 apply.

7.3.3 Medical History and Concomitant Medications

Document concomitant medications (taken within the past 30 days prior to the date of surgery) and Medical History (within 30 days prior to the date of surgery) in the subject source documents (i.e., subject's chart).

Any medical condition that has a start date preceding surgery and implantation of the study model IOLs (surgery date) will be captured as medical history. Any medical condition that started from/after surgery and implantation of the study model IOLs should be captured as AEs. For subjects with history of IOL exchange, information regarding explanted IOL model and reason for explantation should be extracted from chart review (if available) and recorded as medical history.

In the electronic data capture (EDC) system, only limited information regarding concomitant medications and medical history will be captured, as noted below.

- Medical History: Document all ocular history and targeted systemic history. In the EDC, there is a prepopulated dropdown field with items of interest that is consistent with Table 2.
- Concomitant medications: Document all ocular medications (excluding routine cataract surgical medications) and targeted systemic medications used to treat conditions documented in Medical History and AEs.

Table 2. Targeted Medical History

Diabetes	Sarcoidosis	Sjogren's Syndrome	Autoimmune Disorder
Multiple Sclerosis	Hypertension	Grave's Disease	Sickle Cell Disease
Atherosclerosis	HIV Infection	Rheumatoid Arthritis	

7.3.4 Manifest Refraction

MRSE will be assessed prospectively and retrospectively from the preoperative assessment. Reference Attachment 17.2.3 for further details on prospective manifest refraction procedures.

7.3.5 Binocular Uncorrected Distance Visual Acuity (UCDVA)

For all visual acuity procedures from Section 7.3.5 to Section 7.3.11, please refer to Section 17.2.4 (LogMAR Visual Acuity) for more specific details. Binocular UCDVA is performed for distance VA using ETDRS Sloan Letters Chart for 4 m provided by the Sponsor validated for the specific testing distance at 4 m (see Section 17.2.4).

Note: All visual acuity testing should precede IOP measurement, the administration of eye drops to dilate or anesthetize the eye, or any examination requiring contact with the eye. Results of the binocular UCDVA should be transferred to the database in logMAR notation.

7.3.6 Monocular Best Corrected Distance Visual Acuity (BCDVA)

Subjective refraction should be performed to ensure that the subject is using their best corrected vision to complete the BCDVA testing at each visit. Monocular BCDVA is performed for distance VA using ETDRS Sloan Letters Chart for 4 m provided by the Sponsor validated for the specific testing distance at 4 m (see Section 17.2.4).

Note: All visual acuity testing should precede IOP measurement, the administration of eye drops to dilate or anesthetize the eye, or any examination requiring contact with the eye. Results of the monocular BCDVA should be transferred to the database in logMAR notation.

7.3.7 Binocular Best Corrected Distance Visual Acuity (BCDVA)

Binocular BCDVA is performed with best distance correction using ETDRS Sloan Letters Chart for 4 m provided by the Sponsor validated for the specific testing distance at 4 m (see Section 17.2.4).

Note: All visual acuity testing should precede IOP measurement, the administration of eye drops to dilate or anesthetize the eye, or any examination requiring contact with the eye. Results of the binocular BCDVA should be transferred to the database in logMAR notation.

7.3.8 Binocular Uncorrected Intermediate Visual Acuity (UCIVA)

ETDRS Sloan Intermediate Chart for use at 66 cm with Cord will be provided by the Sponsor for the purposes of this study (see Section 17.2.4). To contribute data for the supportive performance objective of this study, enter results of binocular UCIVA at 66 cm into the study database in logMAR notation.

Testing distance (for confirmation), last line attempted plus total number of letters missed will be recorded.

7.3.9 Binocular Distance Corrected Intermediate Visual Acuity (DCIVA)

Binocular DCIVA, this should be determined with best distance correction at 66 cm using the ETDRS Sloan Intermediate Chart for use at 66 cm with Cord supplied by the Sponsor as described in Section 7.3.8. The result is to be added to the study database in logMAR notation to support analysis of supportive performance. Testing distance (for confirmation), last line attempted plus total number of letters missed will be recorded.

7.3.10 Binocular Uncorrected Near Visual Acuity (UCNVA)

ETDRS Sloan Standard Near Chart with Cord for use at 40 cm will be supplied by the Sponsor (see Section 17.2.4) to support standardization of UCNVA testing. To contribute data for the supportive performance objective of this study, enter results of binocular uncorrected visual acuity at 40 cm into the study database in logMAR notation. Testing distance (for confirmation), last line attempted plus total number of letters missed will be recorded.

7.3.11 Binocular Distance Corrected Near Visual Acuity (DCNVA)

Binocular DCNVA, should be performed with best distance correction at 40 cm using the ETDRS Sloan Standard Near Chart with Cord for use at 40 cm, as described in Section 7.3.10. The result is to be added to the study database in logMAR notation to contribute data to the supportive performance analysis of this study. Testing distance (for confirmation), last line attempted plus total number of letters missed will be recorded.

7.3.12 Biomicroscopy

Slit lamp biomicroscopy should be performed at Visit 1 and any abnormal findings should be recorded in the electronic case report form (eCRF). If available, retrospective post-operative data will be extracted from the chart review.

Subjective PCO Including Posterior Capsulotomy

During the slit lamp examination at Visit 1, assess the presence of PCO.

If absent, grade as None. If present, grade as clinically non-significant, clinically significant or clinically significant requiring YAG according to the definitions provided below.

- Clinically Non-significant: Early development of PCO, including fibrosis and proliferation of lens epithelial cells, observable by slit lamp biomicroscopy. Causes no apparent decrease in VA subjectively (e.g., glare) or objectively (e.g., decrease in visual acuity).
- Clinically Significant: Increased PCO with early subjective and objective VA changes but does not require posterior capsulotomy.

- Clinically Significant Requiring YAG: Clinically significant PCO adversely affecting subject's VA and requiring posterior capsulotomy.

For posterior capsulotomy assessment, indicate whether a posterior capsulotomy has been performed. If performed, report the date of the procedure.

If subjective PCO is graded as present, also record whether it is due to residual cataract (e.g., posterior subcapsular cataract).

7.3.13 Tonometry

Perform tonometry assessment in both eyes according to the Investigator's standard of care. Record IOP.

7.3.14 Dilated Fundus Examination

Dilated fundus examination includes ophthalmoscopic assessments of the vitreous, retina, macula, choroid, and optic nerve of both eyes. This assessment must be performed by medically qualified study staff.

7.3.15 Actual Axis of IOL Orientation

Post-operatively, examine each toric IOL via slit lamp subjectively and document the actual IOL orientation in degrees (0-180 degrees) of the IOL axis (designated by the 3 indentions on each side of the toric IOL optic). It is recommended that a slit lamp photograph be printed and kept in the source. Actual axis of orientation should be completed after dilation.

Post-operative Day 1 IOL orientation in degrees (0-180 degrees) of the IOL axis will be extracted from the chart review, if available.

7.3.18 Adverse Events

AEs are collected from the time of initial exposure to the study model IOL(s) and throughout the duration of the study. Any preexisting medical conditions or signs/symptoms present in a subject prior to exposure of the study model IOL(s) (i.e., before cataract surgery) are not considered AEs in the study and should be recorded in the Medical History section of the eCRF. See Section 9.2 and 9.3 for further details.

7.3.19 Device Deficiencies

Record any Device Deficiencies that are reported or observed since the time of initial exposure to the study model IOL(s). Requirements for reporting device deficiencies in the study can be found in Section 9.

7.4 Retrospective Data Collection

If available, retrospective data will be collected regarding the pre-operative, operative, and post-operative activities, as detailed in the sections below.

7.4.1 Biometry and Keratometry

Details of pre-operative biometry performed as per the standard of care will be documented from the chart review including information regarding the biometer model. Keratometry details will also be documented. If more than one set of keratometry data are documented in the source data for one eye (e.g., values from different measurements or devices), select those used in the IOL power and model selection process for entry into the study database.

7.4.2 Pre-Operative Manifest Refractive Error

At the time of study entry, site staff will transfer preoperative sphere, cylinder, and axis for each eye to the study database (retrospective data collection based on the preoperative manifest refraction).

7.4.3 IOL Calculation Method

At the time of study entry, sites will indicate in database, which formula was used for IOL power calculation as per standard of care when available (retrospective data collection).

7.4.4 Predicted Residual Refractive Error

At the time of study entry, sites will document in the study database which residual refraction was expected after study model IOL implantation for both eyes when available. For toric IOLs, the predicted residual cylinder and corresponding axis should be extracted from the chart review, if available (retrospective data collection).

7.4.5 Lens Model and Refractive Power

At the time of study entry, the lens model and refractive power selected preoperatively as per standard of care will be indicated in the study database (retrospective data collection).

7.4.6 Other Surgical Procedures During Cataract or Refractive Lens Exchange Surgery

For any additional procedures that were performed in the context of cataract or refractive lens exchange surgery, such as placement of capsular tension devices or creation of arcuate corneal incisions, these are captured in the study database for better understanding of treatment outcomes. This also includes any limbal relaxing incision (LRI).

7.4.7 Actual Axis of IOL Orientation

If available, collect actual toric IOL orientation in degrees (0-180 degrees) of the IOL axis (designated by the 3 indentions on each side of the IOL optic) from the 1-day post-operative visit.

7.4.8 Retrospective Post-operative Visual Acuity

If available, collect immediate post-operative visual acuity from standard of care post-operative visit (1-6 months post-operative) and any additional post-operative visits that may have occurred: manifest refraction, binocular UCDVA, monocular BCDVA, binocular BCDVA, binocular UCIVA at 66 cm, binocular DCIVA at 66 cm, binocular UCNVA at 40 cm, and binocular DCNVA at 40 cm. Enter immediate post-operative visual acuity into the study database in Snellen or logMAR notation. All VAs will be converted to logMAR for analysis.

7.5 Follow-Up Procedures and Therapy Transitions

In this study, there are no specific follow-up procedures or therapy transitions required. Following study completion, subjects will return to their previous care provider.

Alcon products associated with device deficiencies and/or product-related AEs should, if possible, be returned to Alcon and must include the complaint number, which will be provided by the study Sponsor after the case is entered in the study Sponsor's Global Product Complaint Management System (GPCMS).

Return any recoverable Alcon Product associated with a product-related AE (adverse device effect [ADE], serious adverse device effect [SADE]) or device deficiency to the Sponsor. Procedures vary so Investigators must contact their assigned monitor for detailed guidance. Follow biohazard regulations if the product has touched the eye (i.e., place the product in a biohazard labeled bag). Include the SAE/ADE or device deficiency eCRF in the return package. Maintain a copy of shipment tracking information and all documents submitted with the product.

7.6 Study Timetable / Schedule of Events

A Schedule of Events is provided in the table below. Retrospective assessments will be performed by standard clinical practice of the respective country and the medical institution; however, for the prospective Visit 1, assessments should be conducted in the order set forth in Table 3.

Table 3. Schedule of Events

Event	Retrospective		Prospective	
	Preoperative and Operative Visit	Post-operative Standard of Care & Unplanned Visits	Visit 1 (3-5 Years +/- 90 Days Post-operative)	Unscheduled Visit[a]
Informed Consent			✓	
Eligibility Determination			✓	
Demographics			✓	
Medical History	✓[b]			
Concomitant Medications	✓***	✓	✓	✓**
Biometry & Keratometry	✓			
Pre-operative Manifest Refraction	✓			
Predicted Residual Refractive Error	✓*			
Lens Model & Power	✓			
IOL Calculation Method	✓*			
Other Surgical Procedures During Cataract or Refractive Lens Exchange Surgery	✓*			
[redacted]				
Visual Disturbances (QUVID)			✓	
Manifest Refraction	✓*	✓*	✓	
Binocular UCDVA		✓†	✓	
Monocular BCDVA		✓†	✓	✓**
Binocular BCDVA		✓†	✓	
Binocular UCIVA at 66 cm		✓†	✓	
Binocular DCIVA at 66 cm		✓†	✓	
Binocular UCNVA at 40 cm		✓†	✓	
Binocular DCNVA at 40 cm		✓†	✓	
Slit Lamp Examination (Biomicroscopy)	✓	✓	✓	✓**
Posterior Capsule Opacification (PCO)			✓	✓**
Capsulotomy Assessment			✓	
Tonometry			✓	✓**
Dilated Fundus Examination			✓	✓**
Actual Axis of IOL Orientation	✓*	✓††	✓	
Assessment of Adverse Events	✓	✓	✓[c]	✓**
Assessment of Device Deficiencies	✓*	✓*	✓	✓**
Study Exit			✓	✓**

[a] Prospective visit after Visit 1 to monitor subjects with ongoing AEs
[b] Medical history includes all relevant systemic and all ocular conditions that began prior to surgery and implantation of study IOL(s).
[c] AEs should be assessed at all post-operative visits through Visit 1 and recorded in EDC.
* If available
** As needed
*** Do not enter medications used for cataract surgery in EDC
† Immediate post-operative visual acuity (1-6 months post-operative), if available
†† From 1 day post-operative visit, if available

7.7 Study Protocol Compliance / Treatment Adherence

Based on the study design, protocol compliance consists of completing all the prospective assessments, which are anticipated to require a single study visit. Subjects who decline to complete the prospective assessments will be withdrawn/exited from the study. Withdrawn subjects will not be replaced.

7.8 Deviations from the Clinical Protocol

The Investigator and site personnel should conduct the study in compliance with the protocol and should use continuous vigilance to identify and report protocol deviations. The Investigator may not deviate from the protocol, except when necessary to eliminate an immediate hazard to a study subject, or when the change involves only logistical or administrative aspects of the study. Any significant deviation from the protocol must be reported immediately to the Sponsor or Sponsor's representative and if applicable, to the relevant IRB/IEC, in accordance with the local regulation.

7.9 Subject Withdrawal

7.9.1 Subject Withdrawals

Subjects withdrawn or terminated early will continue to receive Standard of Care treatment. The termination of study participation is not anticipated to affect subject safety. Withdrawn subjects will not be replaced.

7.9.2 Data Collection and Follow-Up for Withdrawn Subjects

If a subject withdraws consent to participate in the study, or is withdrawn by the Investigator, reasons for withdrawal or early termination will be obtained whenever possible.

7.10 Subject Compensation

Subject compensation will be provided for the prospective visits.

7.11 Clinical Study Termination

The study Sponsor reserves the right to suspend or close the investigational site or suspend or terminate the study in its entirety at any time.

If the clinical study is prematurely terminated or suspended by the study Sponsor:

- The study Sponsor must:
    - Immediately notify the Investigator(s) and subsequently provide instructions for study termination.

- Inform the Investigator and the regulatory authorities of the termination/suspension and the reason(s) for the termination/suspension.

- The Investigator must:
  - Promptly notify the IRB/IEC of the termination or suspension and of the reasons.
  - Provide subjects with recommendations for post-study treatment options as needed.

The Investigator may terminate the site's participation in the study for reasonable cause.

8 DATA COLLECTION AND ANALYSIS

8.1 Subject Populations for Analysis

Subject populations for analysis include:

- Full Analysis Set (FAS) population: the FAS population will include all eyes of enrolled subjects who pass the screening. The FAS will be the primary population for all safety analyses and performance analyses.

[redacted]

8.2 Statistical Methods

There is no statistical hypothesis for the endpoints in this study. Appropriate descriptive statistics will be computed and presented for all categorical and continuous endpoints. A full description of statistical methods will be presented in the Statistical Analysis Plan.

- For categorical variables, the number and percentage of subjects/eyes within each category of interest will be presented.
- For continuous variables, the number of subjects/eyes with non-missing data, mean, standard deviation, range, median, minimum, and maximum. There will be no imputation for missing data.

All visual acuity results will be presented in logMAR scale after applying appropriate transformations/conversions.

Performance and safety outcome measures will be stratified by toric and non-toric models. Subjects who have been implanted with at least one toric IOL will be included in the toric group. Descriptive results from this long-term study should be sufficient to provide long-term data on these models, as well as safety and performance thresholds derived from the current State of the Art.

9 SAFETY AND ADVERSE EVENTS AND DEVICE DEFICIENCIES

9.1 General Information

An AE is any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users, or other persons, whether or not related to the investigational medical device. Refer to the Glossary of Terms (Section 17.1) and figures below for categories of AEs and SAEs.

Figure 2. Categorization of All AEs

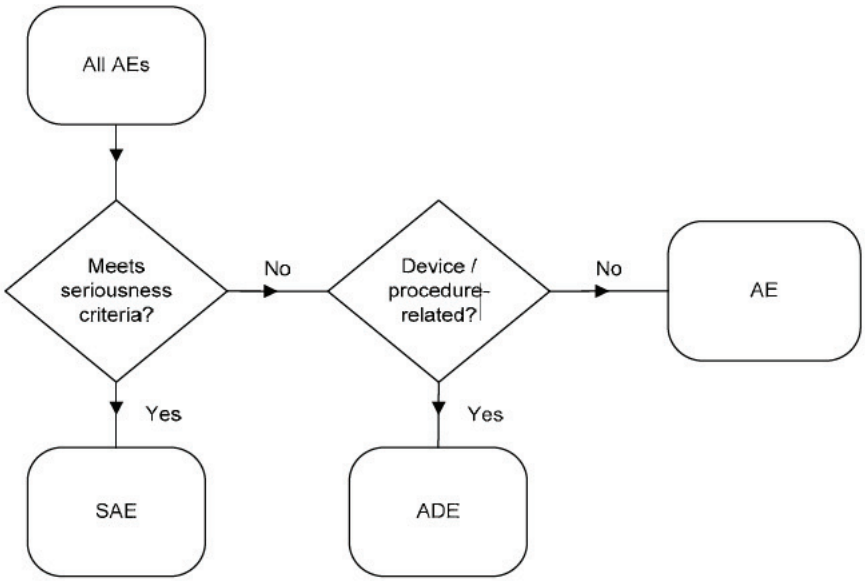
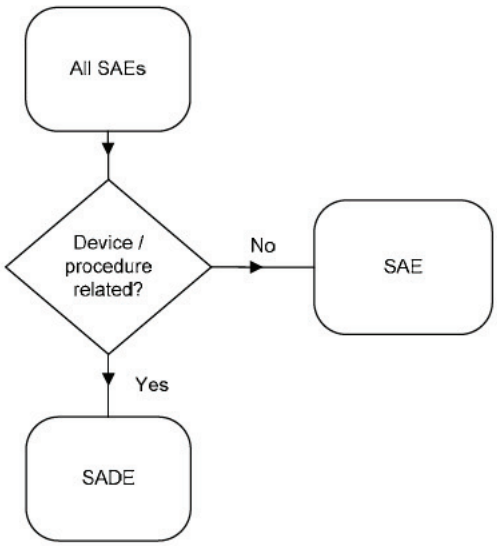


Figure 3. Categorization of All SAEs



Serious Adverse Events

Specific Events Relevant to this Protocol

In addition to reporting all AEs (serious and nonserious) meeting the definitions, the Investigator must report any occurrence of the following as an SAE:

- Cystoid macular edema
- Hypopyon
- Endophthalmitis
- Lens dislocation from posterior chamber
- Pupillary block
- Retinal detachment
- Secondary Surgical Interventions

Any other potentially sight-threatening event may also be considered serious based on the judgment of the Investigator and should be reported appropriately as delineated in Section 9.3.

Device Deficiencies

A device deficiency is an inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety, or performance. A device deficiency may or may not be associated with subject harm (i.e., ADE or SADE); however, not all ADEs or SADEs are due to a device deficiency. The Investigator should determine the applicable category listed in the Device Deficiency eCRF for the identified or suspect device deficiency and report any subject harm separately. Examples of device deficiencies include the following:

- Failure to meet product specifications (e.g., incorrect IOL power)
- IOL defect
- Broken IOL optic
- Broken IOL haptic
- Scratched IOL optic
- Unsealed device packaging
- Suspected product contamination
- Lack of performance

9.2 Monitoring for Adverse Events

At Visit 1, after the subject has had the opportunity to spontaneously mention any problems, the Investigator should inquire about AEs by asking the standard questions shown below and report as applicable:

- "Have you had any health problems since your last study visit?"
- "Have there been any changes in the medicines you take because of a new health issue or worsening of an existing health issue since your last study visit?"

In addition, changes in any protocol-specific parameters and/or questionnaires evaluated during the study are to be reviewed by the Investigator. Any untoward (unfavorable and unintended) change in a protocol-specific parameter or questionnaire response that is clinically relevant, in the opinion of the Investigator, is to be reported as an AE. These clinically relevant changes will be reported regardless of causality.

9.3 Procedures for Recording and Reporting

AEs are collected from the time of initial exposure to the study model IOL(s) and throughout the course of the study. Any preexisting medical conditions or signs/symptoms present in a subject prior to exposure to the study model IOL(s) (i.e., before cataract surgery) are not considered AEs in the study and should be recorded in the Medical History section of the eCRF.

In addition, aqueous cells and flare, corneal edema, raised IOP and superficial punctate keratitis are examples of early post-operative findings that are typically observed following ocular surgery. These are not considered AEs if they can be reasonably expected to resolve within 2 weeks and not result in any untoward long term visual outcome impact.

For each recorded event, the ADEs and SAEs documentation must include: AE diagnosis of main symptom, date of occurrence, intensity (severity), treatment (if applicable), outcome, and assessments of the seriousness and causality. In addition, the Investigator must document all device deficiencies reported or observed with the medical devices on the Device Deficiency eCRF. The site must submit all available information on ADEs, SAEs, and device deficiencies to the study Sponsor immediately as follows:

- All SAEs must be reported immediately (within 24 hours) of the Investigator's or site's awareness.
- ADEs that do not meet seriousness criteria and device deficiencies must be reported within 10 calendar days of the Investigator's or site's awareness.
- A printed copy of the completed SAE and ADE and/or Device Deficiency eCRF must be included with product returns.

- Additional relevant information after initial reporting must be entered into the eCRF as soon as the data become available.
- Any changes to concomitant medications must be documented on the appropriate eCRFs.
- All relevant information from Discharge Summary, Autopsy Report, Certificate of Death etc., if applicable, must be documented in the narrative section of the SAE and ADE eCRF.

[redacted]

Study Sponsor representatives may be contacted for any protocol-related question and their contact information is provided in the Project Team Contact List included in the Investigator Site File.

Further, depending upon the nature of the AE or device deficiency being reported, the study Sponsor (or designee) may request copies of applicable portions of the subject's medical records. The Investigator must also report all AEs and device deficiencies that could have led to a SADE according to the requirements of regulatory authorities or IRB/IEC.

Intensity and Causality Assessments

Where appropriate, the Investigator must assess the intensity (severity) of the AE based on medical judgment with consideration of any subjective symptom(s), as defined below:

Intensity (Severity)

Mild: An AE is mild if the subject is aware of but can easily tolerate the sign or symptom.

Moderate: An AE is moderate if the sign or symptom results in discomfort significant enough to cause interference with the subject's usual activities.

Severe: An AE is severe if the sign or symptom is incapacitating and results in the subject's inability to work or engage in their usual activities.

The Investigator must assess the causality for every AE in the study (Related or Not Related to the medical device or study procedure). An assessment of causality will also be performed by the study Sponsor utilizing the same definitions, as shown below:

Causality

Related An AE classified as related may be either definitely related or possibly related where a direct cause and effect relationship with the medical device or study procedure has not been demonstrated, but there is a reasonable possibility that the AE was caused by the medical device or study procedure.

Not Related An AE classified as not related may either be definitely unrelated or simply unlikely to be related (i.e., there are other more likely causes for the AE).

The study Sponsor will assess the AEs and may upgrade the Investigator's assessment of seriousness and/or causality. The study Sponsor will notify the Investigator of any AEs that is upgraded from nonserious to serious or from unrelated to related.

9.4 Return Product Analysis

Alcon study products associated with device deficiencies and/or product-related AEs should be returned and must include the Complaint number, which will be provided by study Sponsor after the case is entered in the study Sponsor's GPCMS.

9.5 Follow-up of Subjects with Adverse Events

The Investigator is responsible for adequate and safe medical care of subjects during the study and for ensuring that appropriate medical care and relevant follow-up procedures are maintained after the study.

The Investigator should provide the study Sponsor with any new safety information (which includes new AEs and changes to previously reported AEs) that may affect the safety evaluation of the study device. For AEs that are unresolved/ongoing at time of subject exit from study, any additional information received at follow-up should be documented in the eCRFs up to study completion (i.e., database lock).

All complaints received after this time period will be considered and processed as spontaneous (following the post-market vigilance procedures) and should be communicated to the medical device's manufacturer as per local requirements.

9.6 Pregnancy in the Clinical Study

Women of childbearing potential are not excluded from participation. Women who gave birth after IOL implantation or who are pregnant or nursing at the time of enrollment are excluded from participation.

9.7 Anticipated Risks / Risk Mitigation

Potential post-operative AEs include corneal stromal edema, cystoid macular edema, endophthalmitis, hypopyon, iritis, lens dislocation, membrane formation on the IOL, pupillary block, retinal detachment, cyclitic membrane, transient or persistent glaucoma, retinal tear, vitritis, iris touch, pupil ovalization, posterior synechiae, ocular inflammation, and endothelial cell loss. Post-operatively, the subject may experience ocular discomfort or pain, inflammation, decreased vision, decreased contrast sensitivity, decreased color perception, and visual disturbances.

Surgical intervention (e.g., IOL repositioning, replacement, or explantation) may be appropriate, if the IOL position significantly differs from the intended placement, or in some cases of post-operative residual refractive error, ocular infection, subject dissatisfaction, or visual disturbances (e.g., glare, halos, starbursts, hazy vision, blurred vision, double vision, visual distortions, and color distortions).

Alternatively, spectacles or contact lenses may be prescribed to resolve post-operative residual refractive error. Other secondary surgical interventions include, but are not limited to: refractive laser treatment, paracentesis, vitreous aspirations, iridectomy for pupillary block, wound leak repair, and retinal detachment repair.

Refer to the Directions for Use (DFU) for the study device for additional information.

Due to the retrospective, non-interventional nature of the study, the potential risks described above are expected to have occurred prior to study enrollment. Any risk to subjects in this clinical study will be minimized by clinical oversight and monitoring.

9.8 Anticipated Clinical Benefits

There is no direct clinical benefit to study participants. Participant benefits from improved visual acuity will have already been realized at the time of enrollment. Indirectly, participants may benefit from the identification of safety and/or performance signals generated by the study.

10 DATA HANDLING AND RECORD KEEPING

10.1 Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the General Data Protection Regulation (GDPR; EU 2016/679), and applicable national and local regulations. Those regulations require a signed subject authorization informing the subject of the following:

- What information will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to access their personal data collected, to have any inaccurate or incomplete data corrected, to request the deletion of their personal data collected or the restriction of its use.

In the event that a subject decides to withdraw his/her consent to participate in the study, no new data will be collected, but data that have already been collected will be used as necessary to fulfill the purposes of the study. For subjects who withdraw their consent to participate in the study, attempts should be made to obtain permission to collect at least vital status (i.e., that the subject is alive) at the end of their scheduled study period.

10.2 Source Documents

Source Data are the clinical findings and observations, laboratory and test data, and other information contained in *Source Documents*. *Source Documents* are the original records (and certified copies of original records); including, but not limited to, hospital medical records, physician or office charts, physician or nursing notes, subject diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, x-rays, etc. When applicable, information recorded on the eCRF shall match the *Source Data* recorded on the *Source Documents*.

10.3 Case Report Forms

The study eCRF is the primary data collection instrument for the study. All data requested on the eCRF must be recorded. All missing data must be explained. If a space on the eCRF is left blank because the procedure was not done or the question was not asked, enter “N/D”. If the item is not applicable to the individual case, enter “N/A”.

An eCRF will be completed for each subject enrolled into the clinical study. The Investigator will review, approve and sign/date each completed eCRF; the Investigator’s signature serving as

attestation of the Investigator's responsibility for ensuring that all clinical data entered on the eCRF are complete, accurate and authentic.

The electronic data capture method utilized will be in compliance with the Food and Drug Administration (FDA)'s electronic records and electronic signatures regulations at 21 CFR Part 11.

10.4 Clinical Reports

The Investigator is responsible for the preparation and submission of annual progress reports as required by local IRBs/IECs. The Sponsor or designee is responsible for the preparation of the final Clinical Study Report, which will be submitted to appropriate IRBs/IECs by the Investigator.

A Coordinating Investigator may be identified by the study Sponsor to review and endorse the final study report. In cases where a Coordinating Investigator is engaged, the study Sponsor will select the Coordinating Investigator based upon their experience, qualifications, active study participation, and their willingness and availability to take on this role.

10.5 Records Retention

The Sponsor shall keep relevant clinical records for a period of at least 15 years after the last device has been placed on the market. The Investigator shall maintain relevant clinical records for 10 years. Investigators will notify the Sponsor at least 60 days prior to any destruction of records at the address listed below:

Alcon Research LLC
6201 South Freeway
Fort Worth, Texas 76134

Or via email to:

Record.Retention@Alcon.com.

11 DATA HANDLING AND ADMINISTRATIVE REQUIREMENTS

11.1 Subject Confidentiality

The Investigator must ensure that the subject's identity is kept confidential throughout the course of the study. In particular, the Investigator must keep an enrollment log with confidential identifying information that corresponds to the subject numbers and initials of each study participant. The study Sponsor may collect a copy of the enrollment log ***without any directly identifying subject information***.

The study Sponsor may share subject-level data collected in this study with qualified researchers to help facilitate product development or enhancements in research that is not directly related to the study objectives.

11.2 Completion of Source Documents and Case Report Forms

The nature and location of all source documents will be identified to ensure that original data required to complete the case report forms (CRFs) exist and are accessible for verification if required. Discrepancies shall be appropriately documented via the query resolution process.

If electronic records are maintained, the method of verification must be determined in advance of starting the study. The Investigator or delegate would verify the accuracy of data.

At a minimum, source documents include the following information for each subject:

- Subject identification (name, sex, race/ethnicity)
- Documentation of subject eligibility
- Dates of visits
- Documentation that protocol-specific procedures were performed
- Results of study parameters, as required by the protocol
- Documentation of AEs and other safety parameters (if applicable)
- Records regarding medical histories and the use of concomitant therapies during the data collection period
- Date of visit time points and reason for early discontinuation (if applicable)

It is required that the author of an entry in the source documents be identifiable. Direct access to source documentation (medical records) must be allowed for the purpose of verifying that the data recorded on the CRF are consistent with the original source data.

Only designated individuals at the site will complete the CRFs. The CRFs must be completed following the clinical study visit schedule. It is expected that all data reported have corresponding entries in the source documents. The Principal Investigator is responsible for reviewing and certifying that the CRFs are accurate and complete. The only subject identifiers recorded on the CRFs will be subject number and subject demographic information.

11.3 Data Review and Clarifications

A review of CRF data to the subject's source data will be completed by the Investigator or delegate to ensure completeness and accuracy. After the CRFs have been completed, additional data clarifications and/or additions may be needed as a result of the data cleaning process. Data clarifications are documented and are part of each subject's CRF.

11.4 Sponsor and Monitoring Responsibilities

The study Sponsor will select Principal Investigators that are qualified by education, training, and experience to assume responsibility for the proper conduct of this clinical study.

The study Sponsor is financially funding this clinical study and will compensate the Investigator and/or the institution(s) at which the study is conducted in accordance with a signed clinical study agreement.

The study Sponsor will designate a monitor to conduct remote monitoring, which will be limited to the Site Regulatory binder to avoid exposure to subject health information.

11.5 Regulatory Documentation and Records Retention

The Investigator is required to maintain up-to-date, complete documentation as indicated by the study Sponsor and consistent with the terms of the clinical study agreement.

11.6 Quality Assurance and Quality Control

The study Sponsor will secure agreement from all involved parties to ensure direct access to all study-related sites, source data and documents, and reports for the purpose of auditing by the study Sponsor and inspection by domestic and foreign regulatory authorities. Quality control will be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly.

12 PROTOCOL AMENDMENTS AFTER STUDY INITIATION

Should changes in the study plan or protocol become necessary in the course of the clinical study, those specific changes will be discussed and agreed upon by the Sponsor, its acting representative if appropriate, Investigator, and appropriate IRB/IEC approval obtained before the changes are implemented. All changes must be documented as protocol amendments. For studies conducted under an investigational device exemption (IDE), FDA approval and/or notification may be required in addition to the IRB approval.

13 ETHICAL CONSIDERATIONS

This study is to be conducted according to US and international standards of GCP, including ISO 14155 GCPs, applicable government regulations and Institutional research policies and procedures.

Although not all aspects of ISO 14155 guidelines are applicable to this study, subject safety and data integrity are not impacted.

- The standard operating procedures of the study Sponsor and contract research organizations (CROs) participating in the conduct of the clinical study and all other applicable regulations shall apply.
- Notifications and timelines for reporting protocol deviations should be based upon applicable Ethics Committee requirements.

This protocol and any amendments will be submitted to a properly constituted IRB/IEC, in agreement with local legal regulations, for formal approval of the study conduct. The decision of the IRB/IEC concerning the conduct of the study will be made in writing to the Investigator and a copy of this decision will be provided to the Sponsor before commencement of this study.

The study Sponsor will select Principal Investigators that are qualified by education, training, and experience to assume responsibility for the proper conduct of this clinical study. For this study, the Principal Investigators and Sub-Investigators must be health care professionals appropriately trained and/or licensed to perform IOL implantation after cataract surgery or to provide follow-up care for subjects having received an IOL during cataract surgery.

The Investigator must ensure that all personnel involved in the conduct of the study are qualified to perform their assigned responsibilities through relevant education, training, and experience. The Investigator and all clinical study staff must conduct the clinical study in compliance with the protocol. The Investigator is not allowed to deviate from the protocol except to protect the rights, safety, and well-being of human subjects under emergency circumstances. Emergency deviations may proceed without prior approval of the Sponsor but shall be documented and reported to the

Sponsor as soon as possible. Deviations from this protocol, regulatory requirements and/or GCP must be recorded and reported to the Sponsor prior to database lock. If needed, corrective and preventive action should be identified, implemented, and documented within the study records. Use of waivers to deviate from the clinical protocol is prohibited.

Before clinical study initiation, this protocol, the ICF, any other written information given to subjects, and any advertisements planned for subject recruitment must be approved by an IRB/IEC. The Investigator must provide documentation of the IRB/IEC approval to the study Sponsor. The approval must be dated and must identify the applicable protocol, amendments (if any), ICF, all applicable recruiting materials, written information for subject, and subject compensation programs. The IRB/IEC must be provided with a copy of the Package Insert/Directions for Use, any periodic safety updates, and all other information as required by local regulation and/or the IRB/IEC. At the end of the study, the Investigator must notify the IRB/IEC about the study's completion. The IRB/IEC also must be notified if the study is terminated prematurely. Finally, the Investigator must report to the IRB/IEC on the progress of the study at intervals stipulated by the IRB/IEC.

Voluntary informed consent must be obtained in writing from every subject or legal representative, as applicable, and the process shall be documented before any data are being collected for this clinical study. The Investigator must have a defined process for obtaining consent. Specifically, the Investigator, or their delegate, must explain the clinical study to each potential subject and the subject must indicate voluntary consent by signing and dating the approved ICF. The subject must be provided an opportunity to ask questions of the Investigator, and if required by local regulation, other qualified personnel. The Investigator must provide the subject with a consent form written in a language the subject understands. The consent document must meet all applicable local laws and provide subjects with information regarding the purpose, procedures, requirements, and restrictions of the study, along with any known risks and potential benefits associated with the study, the available compensation, and the established provisions for maintaining confidentiality of personal, protected health information. Subjects will be told about the voluntary nature of participation in the study and must be provided with contact information for the appropriate individuals should questions or concerns arise during the study. The subject also must be told that their records may be accessed by appropriate authorities and Sponsor-designated personnel. The Investigator must keep the original, signed copy of the consent (filed in subject's medical records) and must provide a duplicate of the signed copy to each subject according to local regulations.

14 STUDY FINANCES

14.1 Funding Source

This study is financed by Alcon Research LLC. The Sponsor will secure a human clinical study insurance certificate according to applicable country regulations, when required.

14.2 Conflicts of Interest

Investigators are required to provide financial disclosure information to allow the Sponsor to submit the complete and accurate certification or disclosure statements required under US FDA 21 CFR 54. In addition, the Investigator must provide to the Sponsor a commitment to promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following the completion of the study.

Potential conflicts of interest will be subject to the processes and procedures of the institutions where the potential conflict exists.

15 PUBLICATION PLAN

Neither the complete nor any part of the results of the study carried out under this protocol, nor any of the information provided by the Sponsor for the purposes of performing the study, will be published or passed on to any third party without the consent of the study Sponsor. Any Investigator involved with this study is obligated to provide the Sponsor with complete test results and all data derived from the study.

At the conclusion of the study, a multi-center manuscript may be prepared for publication in a reputable scientific journal. The publication of the principal results from any single center experience within the study is not allowed until the publication of the multi-center results. Any and all exceptions to this rule require the prior written approval of the Sponsor. Investigators may publish study results, provided Sponsor receives a copy of any proposed oral presentation or written publication at least 60 days in advance of submission for publication for review. Sponsor has the right to comment on the appropriateness of the data analysis and presentation and have that comment reflected in the presentation. Investigator will meet with Sponsor prior to submission for publication for the purpose of making good faith efforts to discuss and resolve any issues or disagreement. Upon Sponsor's request, Investigator shall remove from any such oral presentation or written publication any material provided to Investigator by Sponsor or any confidential material. In addition, if requested in writing by Sponsor, Investigator will withhold such publication an additional 60 days to allow for filing a patent application or taking such other measures as Sponsor deems appropriate to establish and preserve its proprietary rights.

The clinical study will be registered in a publicly accessible clinical trial registry in accordance with the Sponsor's choice, and/or applicable national regulatory requirements. Clinical study results will be posted within the registry in accordance with registry requirements.

16 REFERENCES

16.1 References Applicable to All Clinical Studies

- ISO 11979-7:2018 Ophthalmic Implants – Intraocular lenses – Part 7: Clinical Investigations
- ISO 22979:2017 Ophthalmic implants — Intraocular lenses — Guidance on assessment of the need for clinical investigation of intraocular lens design modifications
- ISO 14155:2020 Clinical Investigation of Medical Devices for Human Subjects - Good Clinical Practice

16.2 References Applicable to Clinical Studies Conducted in the United States

- 21 CFR 11: Electronic Records; Electronic Signatures
- 21 CFR 50: Protection of Human Subjects
- 21 CFR 54: Financial Disclosures by Clinical Investigators
- 21 CFR 56: Institutional Review Boards
- 42 CFR 11: Clinical Trials Registration and Results Information Submission
- 45 CFR 164: Security and Privacy

16.3 References Applicable to Clinical Studies Conducted In Canada

- Medical Device Regulations SQR/98-282, Part 59: Mandatory Problem Reporting

16.4 Cited References

1 Literature Search Report for State of the Art: AcrySof IQ PanOptix Trifocal Intraocular Lenses Review Period: 01 Jan 2018 to 28 Jun 2023. Fort Worth (TX): Alcon Research, LLC; 2023 Sep. Document ID No.: V V-RIM-0152541, Version 1.0.

17 APPENDICES AND ATTACHMENTS

17.1 Glossary of Terms

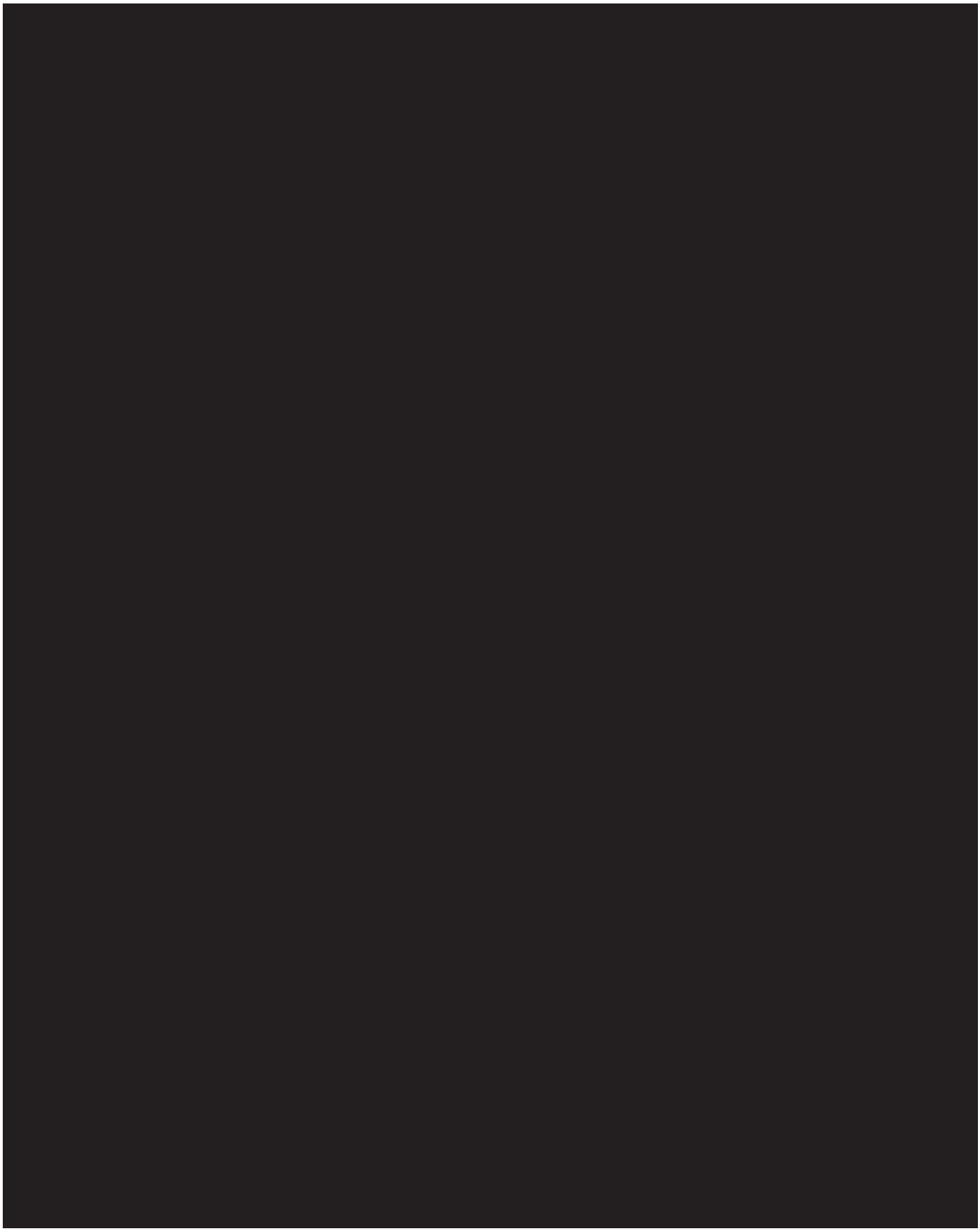
Names of Test Product(s)	Throughout this document, test product(s) will be referred to as AcrySof IQ PanOptix Trifocal and AcrySof IQ PanOptix Trifocal Toric IOLs.
Adverse Device Effect (ADE)	Adverse event related to the use of an investigational medical device or comparator. *Note: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation; any malfunction; and use error or intentional misuse.*
Adverse Event (AE)	Untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users, or other persons, whether or not related to the investigational medical device or comparator, and whether anticipated or unanticipated. *Note: For subjects, this definition includes events related to the investigational medical device, comparator, or the procedures involved. For users or other persons, this definition is restricted to the use of the investigational medical device or comparator.* Requirements for reporting Adverse Events in the study can be found in Section 9.3.
Anticipated Serious Adverse Device Effect (ASADE)	An effect which, by its nature, incidence, severity, or outcome, has been identified in the risk assessment.
Clinical Investigation Plan (CIP)	The document(s) stating the rationale, objectives, design, and prespecified analysis, methodology, organization, monitoring, conduct, and record-keeping of the clinical investigation. *Note: The protocol and other documents referenced in the protocol (for example, the Statistical Analysis Plan, the Manual of Procedures, the Deviations and Evaluability Plan, and the Protocol Monitoring Plan) comprise the CIP.*
Clinical Investigation Report (CIR) / Clinical Study Report	The document describing the design, execution, statistical analysis, and results of a clinical investigation. The Clinical Investigation Report is synonymous with the Clinical Study Report.
Device Deficiency	Inadequacy of a medical device with respect to its identity, quality, durability, reliability, usability, safety, or performance. *Note: This definition includes malfunctions, use errors, and inadequacy in the information supplied by the manufacturer, including labeling related to the investigational medical device or the comparator.* Requirements for reporting Device Deficiencies in the study can be found in Section 9.

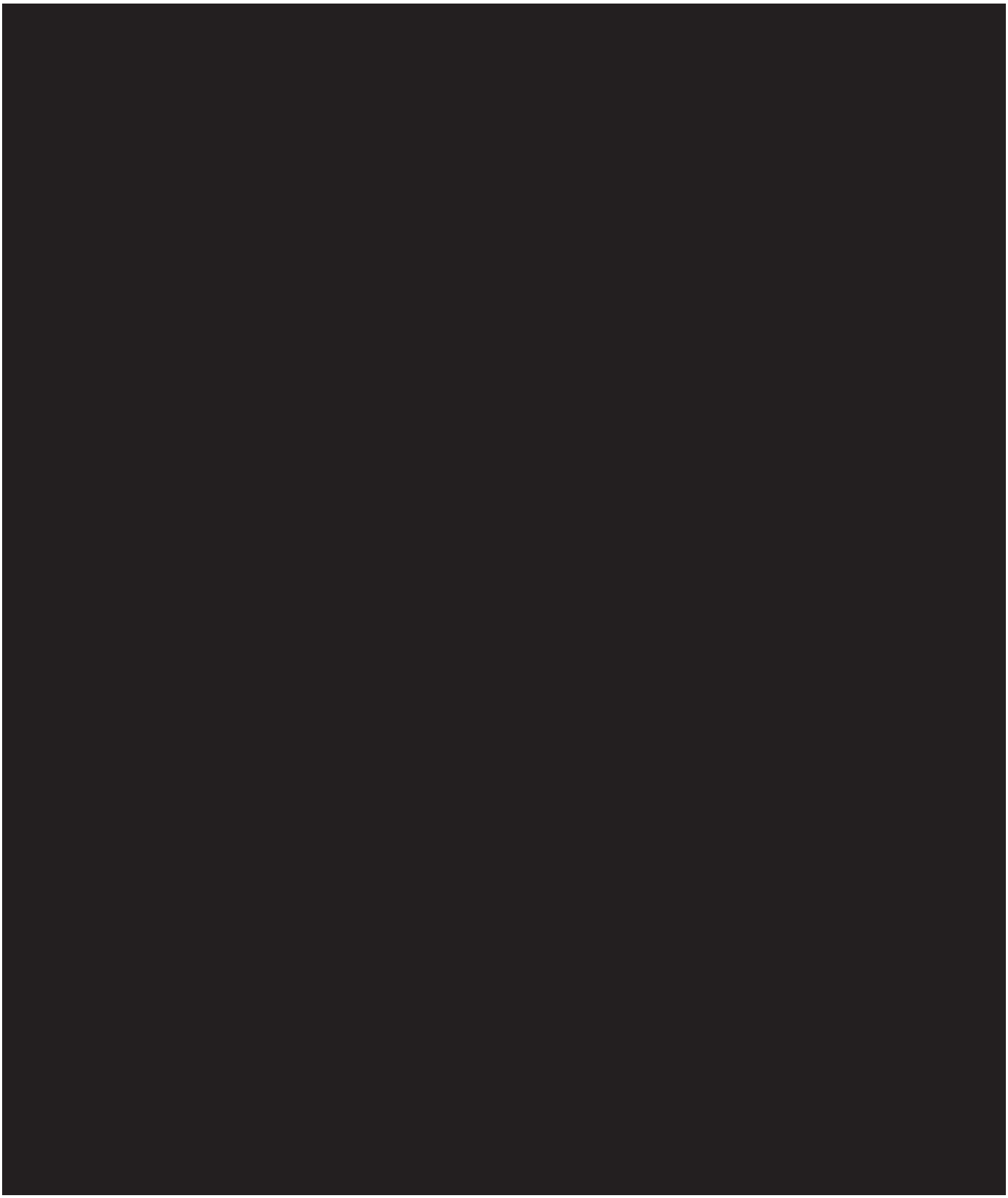
Interventional Clinical Trial	A pre- or post-market clinical investigation where the assignment of a subject to a particular medical device is decided in advance by a clinical investigational plan or diagnostic or monitoring procedures requested in the CIP are in addition to those available as normal clinical practice and burden the subject.
Malfunction	Failure of an investigational medical device to perform in accordance with its intended purpose when used in accordance with the instructions for use or clinical investigation plan (CIP) or Investigator's brochure (IB).
Noninterventional Study	Clinical investigation that draws inferences about the possible effect of an intervention on subjects, but the Investigator has not assigned subjects into intervention groups based on a protocol and has not made any attempts to collect data on variables beyond those available throughout the course of normal clinical practice and burden to the subject. *NOTE: The term "noninterventional" is synonymous with "observational."*
Nonserious Adverse Event	Adverse event that does not meet the criteria for a serious adverse event.
Postmarketing / Postauthorization study	Any study conducted within the conditions laid down in product labelling and other conditions laid down for the marketing of the product or under normal conditions of use. A postmarketing study falls either within the definitions of an interventional or a noninterventional study and may also fall within the definition of a postapproval study.
Product Complaint	Any oral, electronic, or written communication that alleges deficiencies related to the identity (labeling), quality, durability, reliability, safety, effectiveness, or performance of a marketed product, including failure of the product, labeling, or packaging to meet specifications, whether or not the product is related to or caused the alleged deficiency. A complaint may allege that an adverse event or medical device malfunction has occurred.
Serious Adverse Device Effect (SADE)	Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.
Serious Adverse Event (SAE)	Adverse event that led to any of the following: • Death. • A serious deterioration in the health of the subject, users, or other persons as defined by one or more of the following: a) a life-threatening illness or injury *Note: Life-threatening means that the individual was at immediate risk of death from the event as it occurred, i.e., it does not include an event which hypothetically might have caused death had it occurred in a more severe form.* b) any potentially sight-threatening event or permanent impairment to a body structure or a body function, including chronic diseases. c) inpatient hospitalization or prolonged hospitalization.

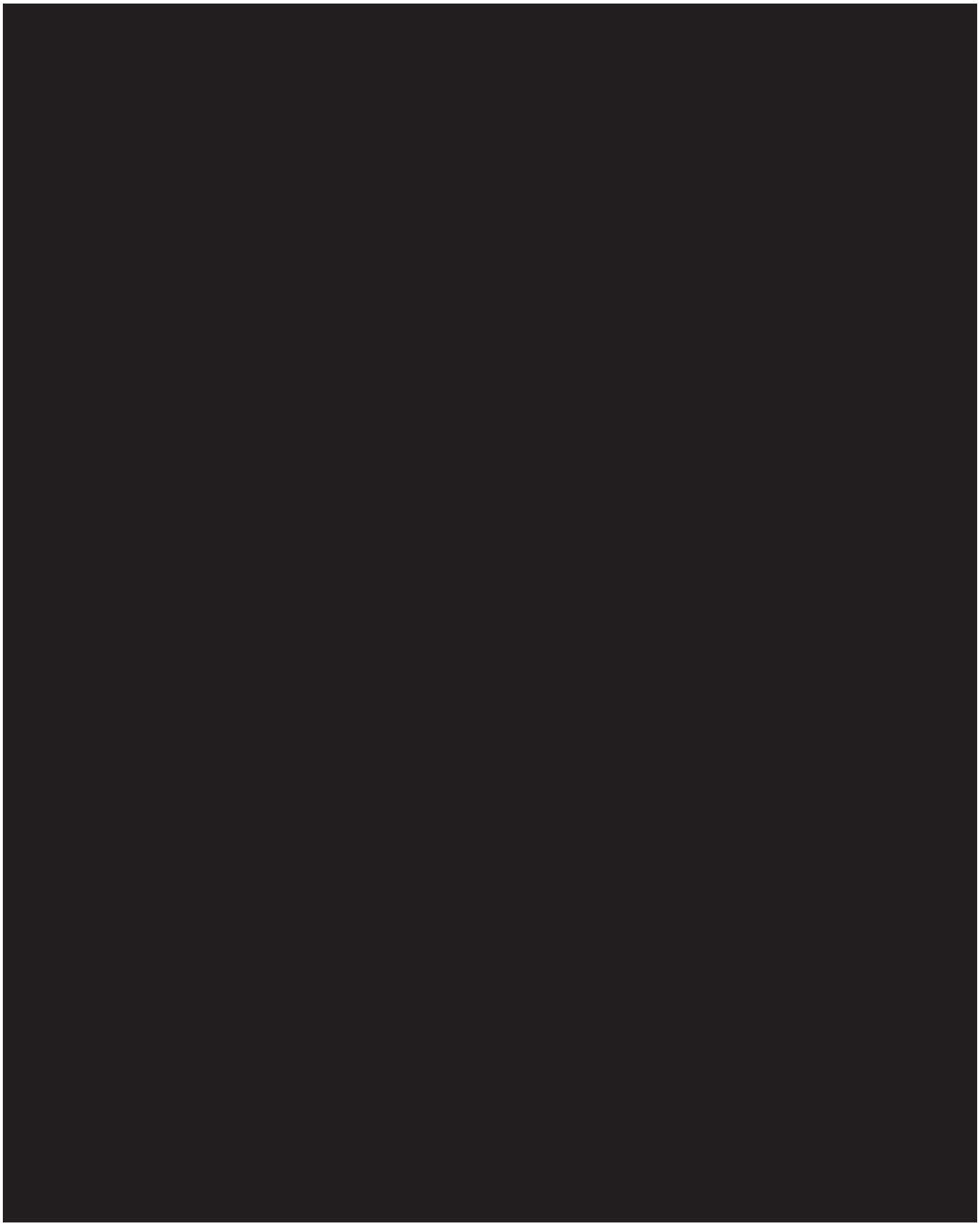
	d) a medical or surgical intervention to prevent a) or b). This includes any ocular secondary surgical intervention excluding posterior capsulotomy e) any indirect harm as a consequence of incorrect diagnostic test results when used within manufacturer's instructions for use. • Fetal distress, fetal death, congenital abnormality, or birth defect, including physical or mental impairment. *Note: Planned hospitalization for a preexisting condition, or a procedure required by the CIP without serious deterioration in health, is not considered a serious adverse event.* *Refer to Section 9 for additional SAEs.*
Serious Health Threat	Signal from any adverse event or device deficiency that indicates an imminent risk of death, serious deterioration in state of health or a serious deterioration in the health in subjects, users, or other persons and that requires prompt remedial action for other subjects, users, or other persons. *Note: This would include events that are of significant and unexpected nature such that they become alarming as a potential serious health hazard or possibility of multiple deaths occurring at short intervals.*
Study Start	The start of the study is considered to coincide with the enrollment of the first patient.
Study Completion	The completion of the study is considered to coincide with the study-level last subject last visit or the decision to terminate the study, whichever is later.
Unanticipated Serious Adverse Device Effect (USADE)	Serious adverse device effect, which by its nature, incidence, severity, or outcome has not been identified in the risk assessment.
Use Error	User action or lack of user action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user. *Note:* *a) Use error includes the inability of the user to complete a task.* *b) Use errors can result from a mismatch between the characteristics of the user, user interface, task, or use environment.* *c) Users might be aware or unaware that a use error has occurred.* *d) An unexpected physiological response of the patient is not by itself considered a use error.* *e) A malfunction of a medical device that causes an unexpected result is not considered a use error.*
Vulnerable Subject	An individual who is unable to fully understand all aspects of the investigation that are relevant to the decision to participate, or who could be manipulated or unduly influenced as a result of a compromised position, expectation of benefits or fear of retaliatory response.

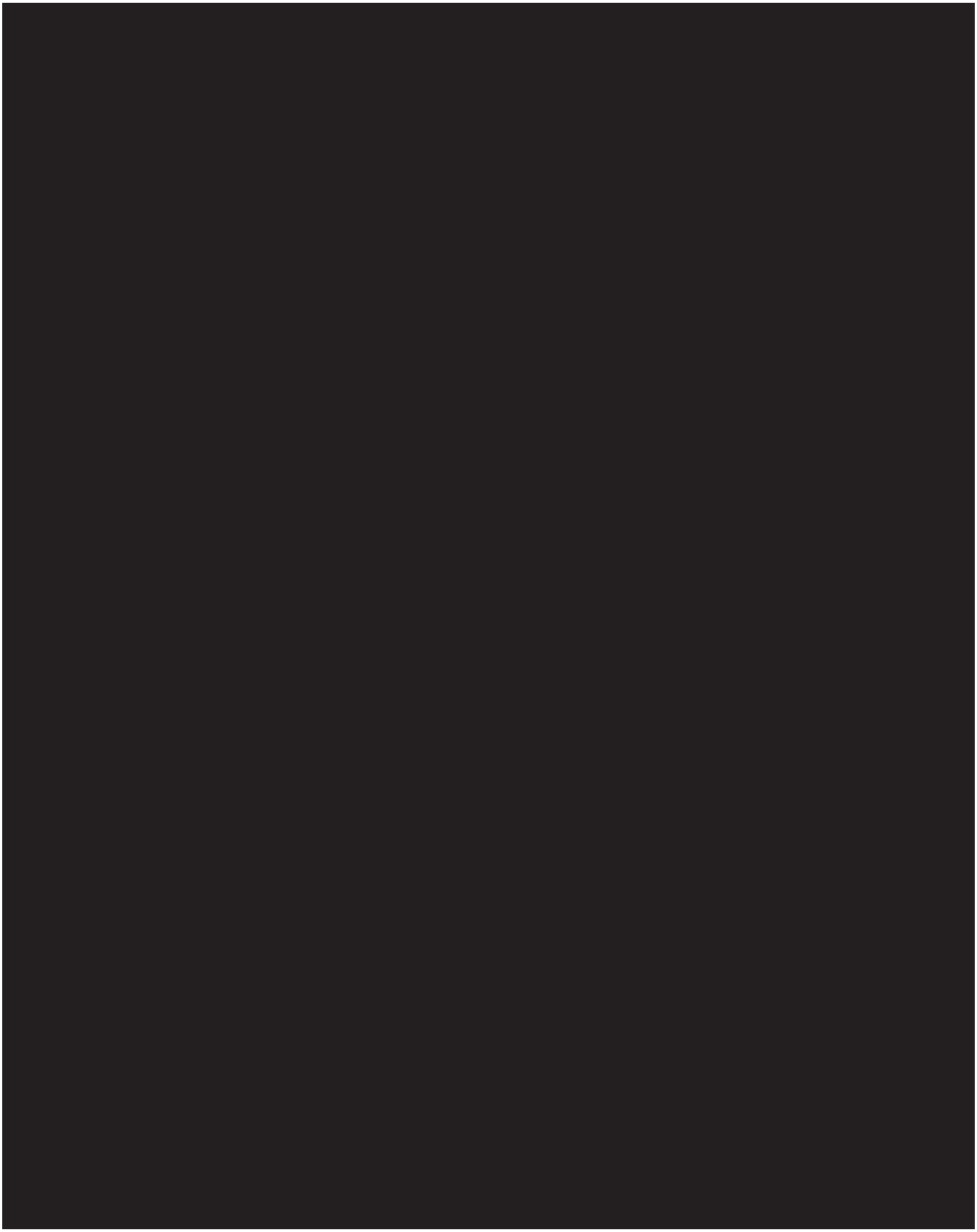
17.2 Attachments

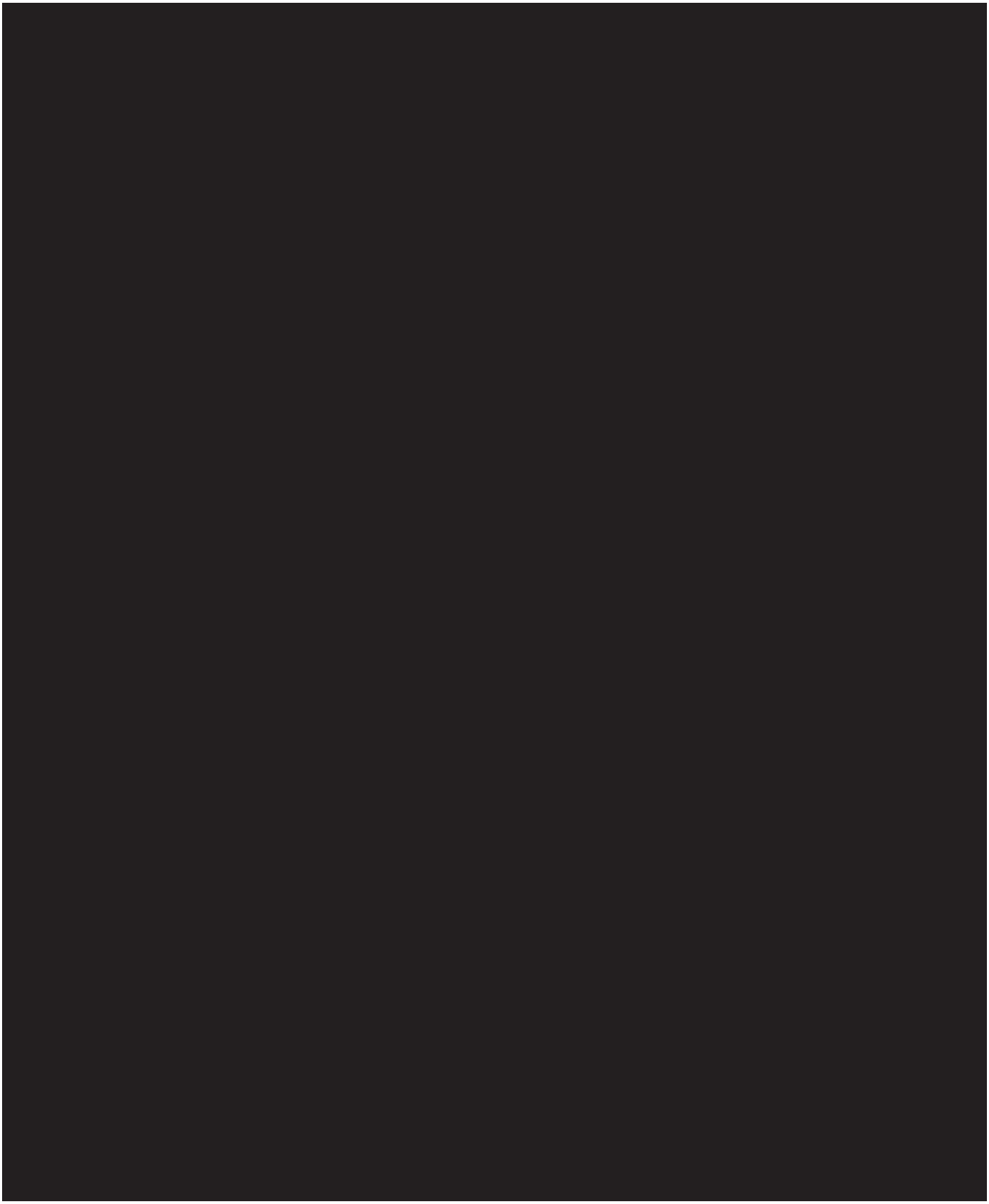
Note that the attached questionnaires are proprietary and licensed to Alcon. Copies provided here for reference should not be used for the study. For the clinical study, please use the copies provided separately.

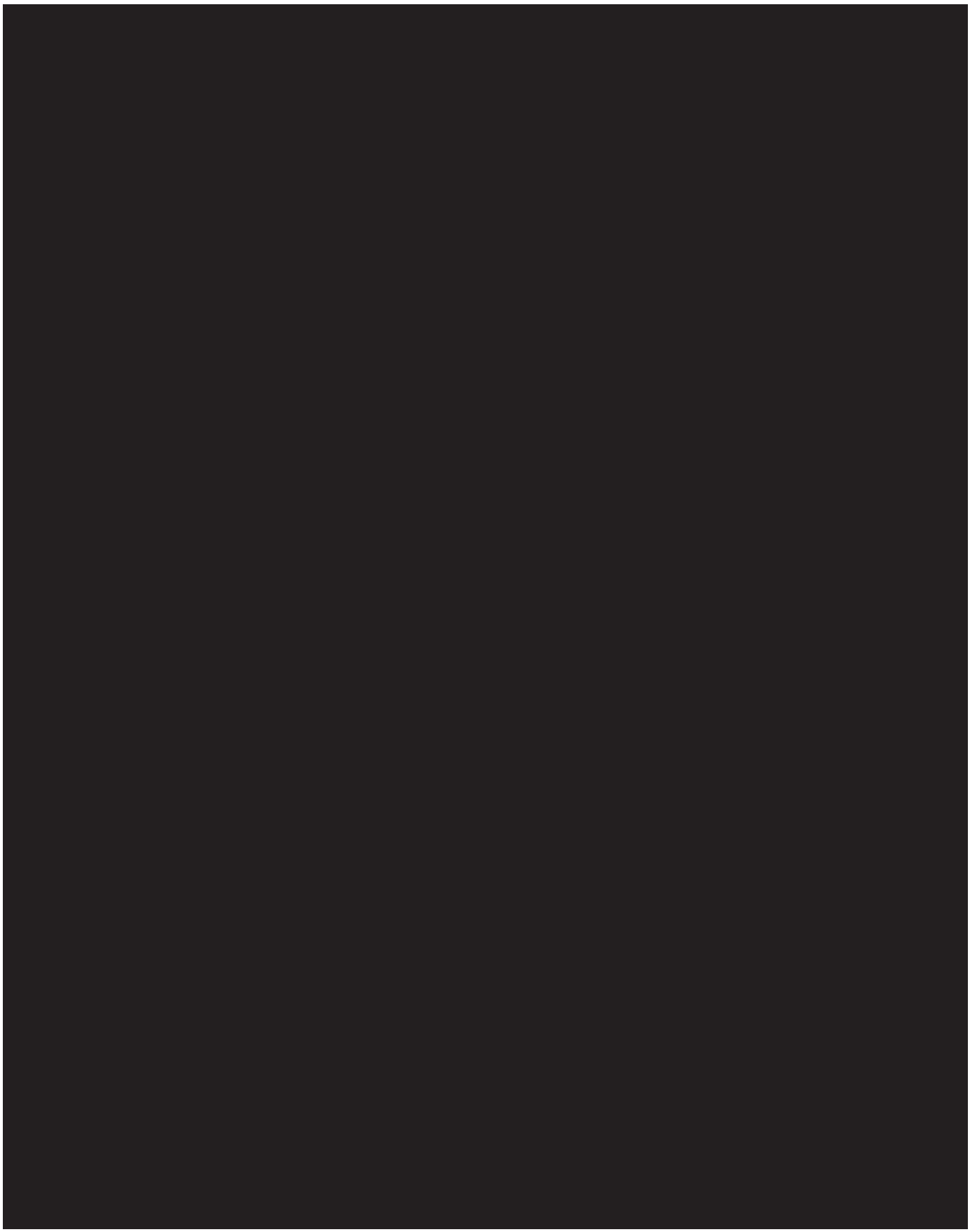


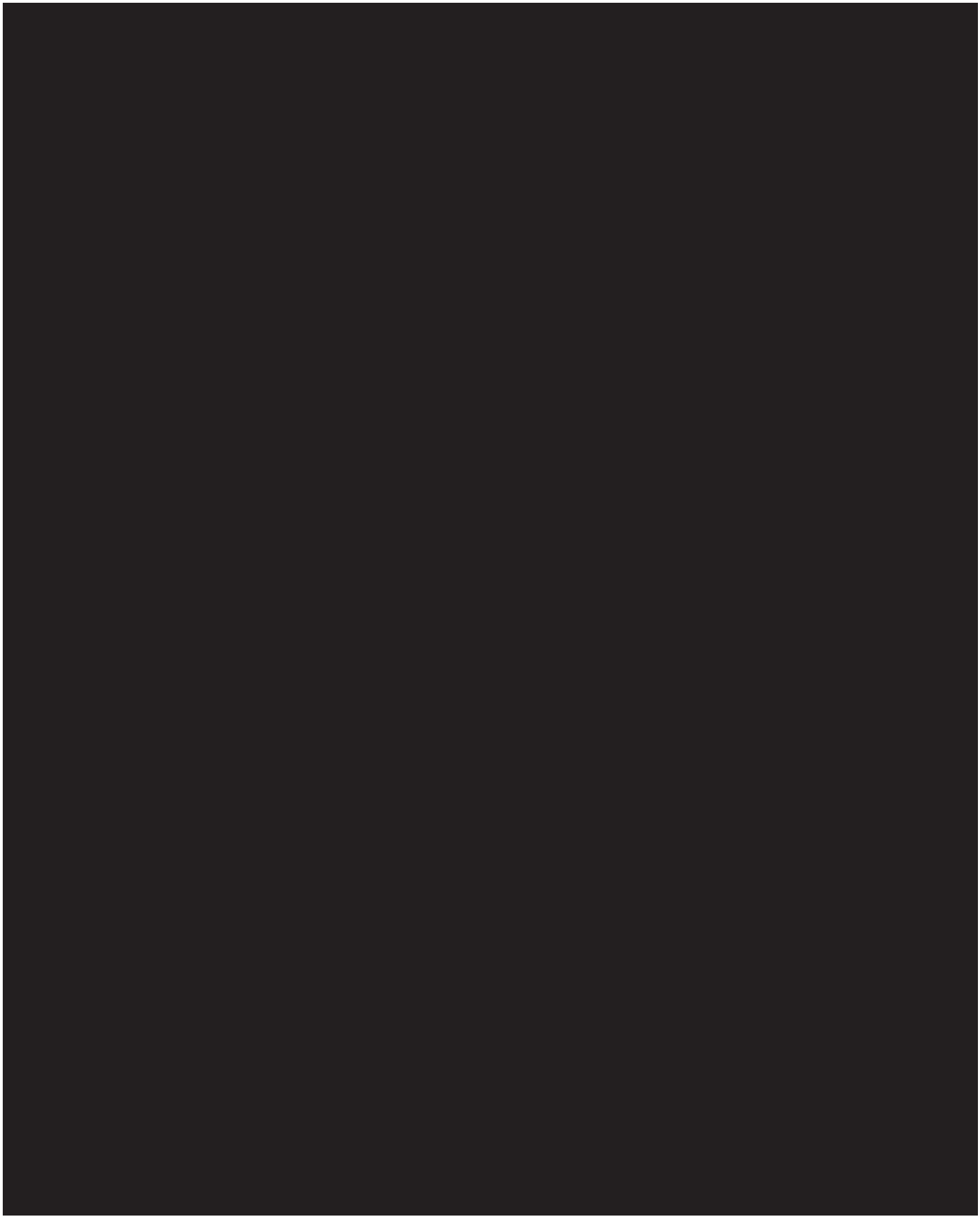


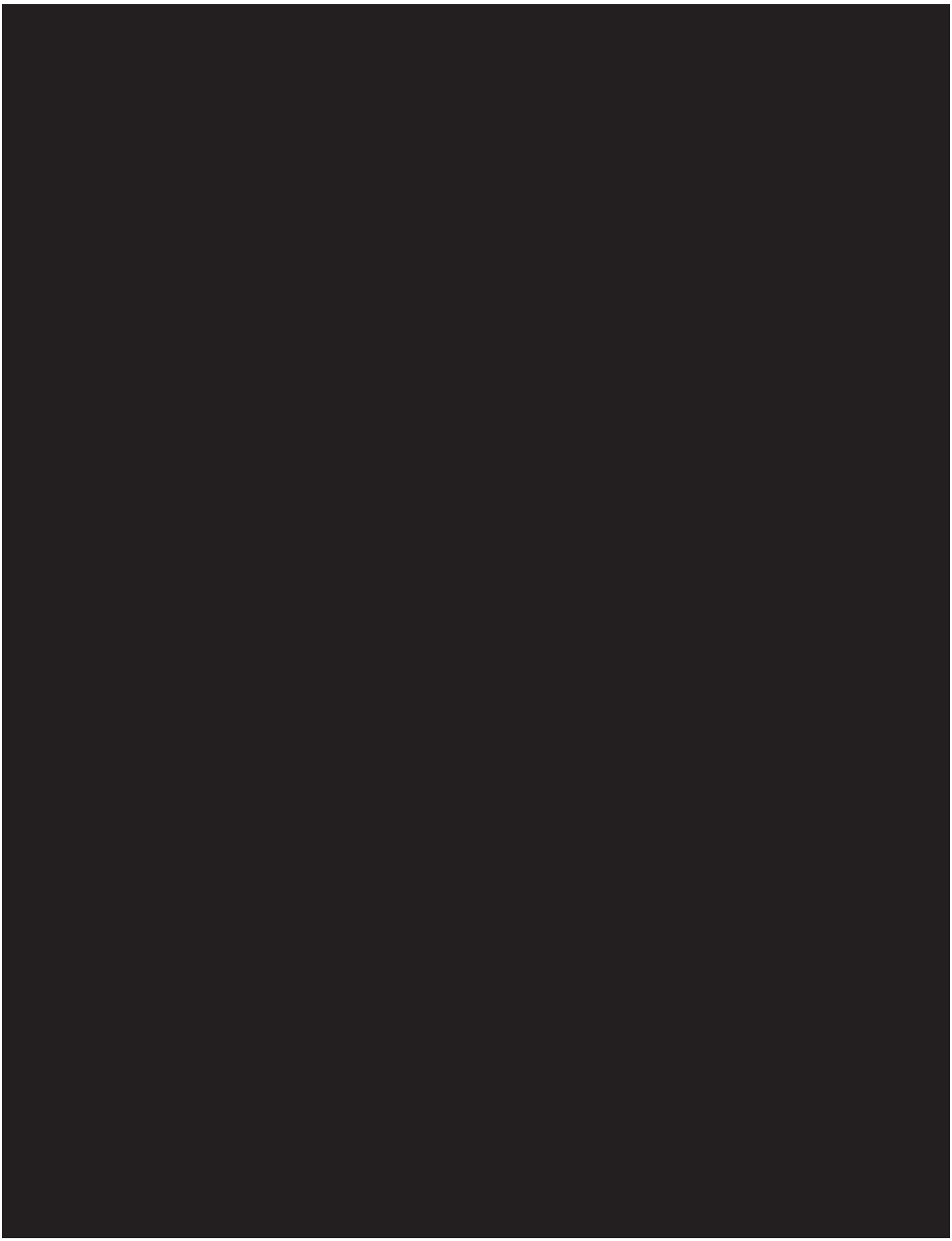


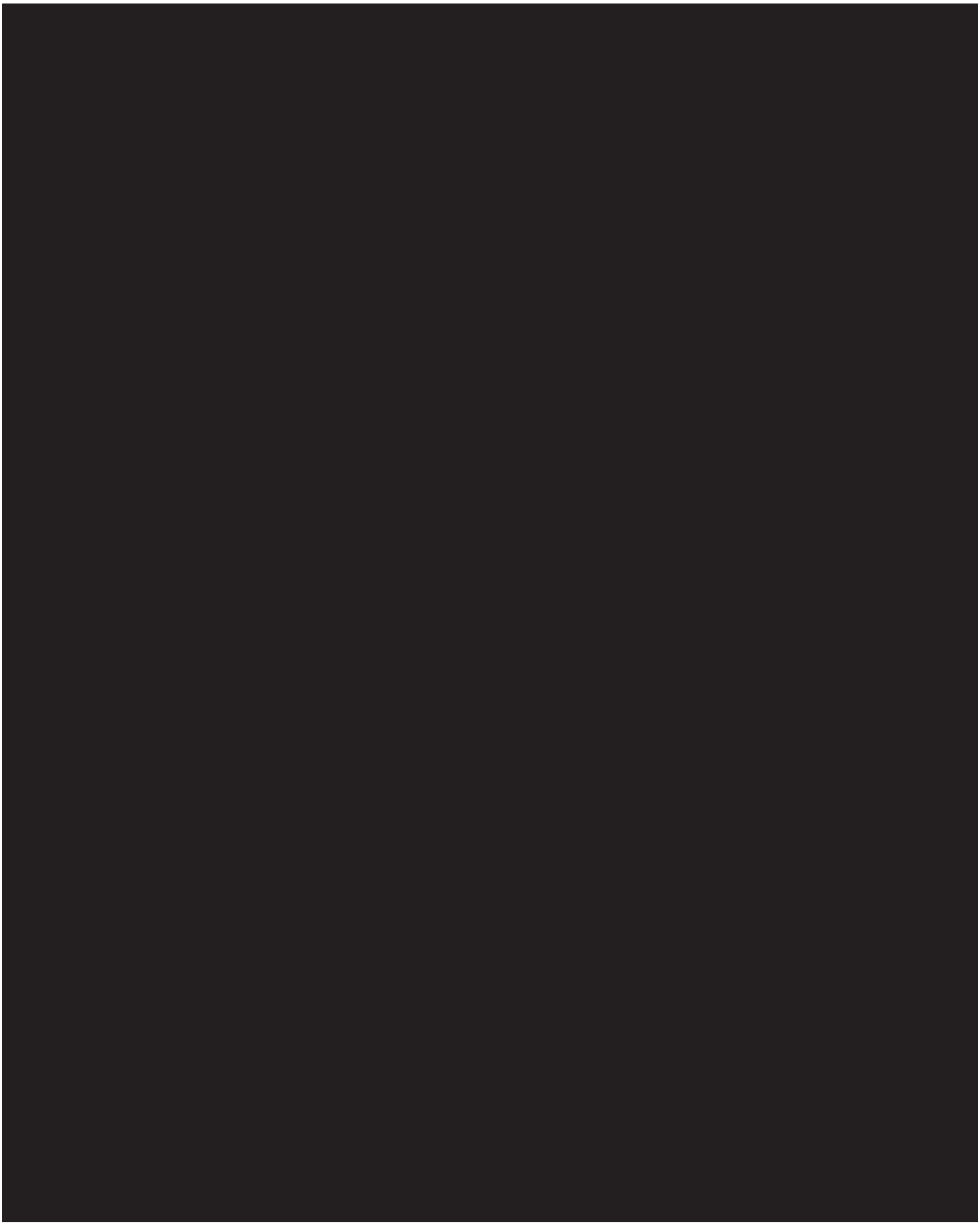


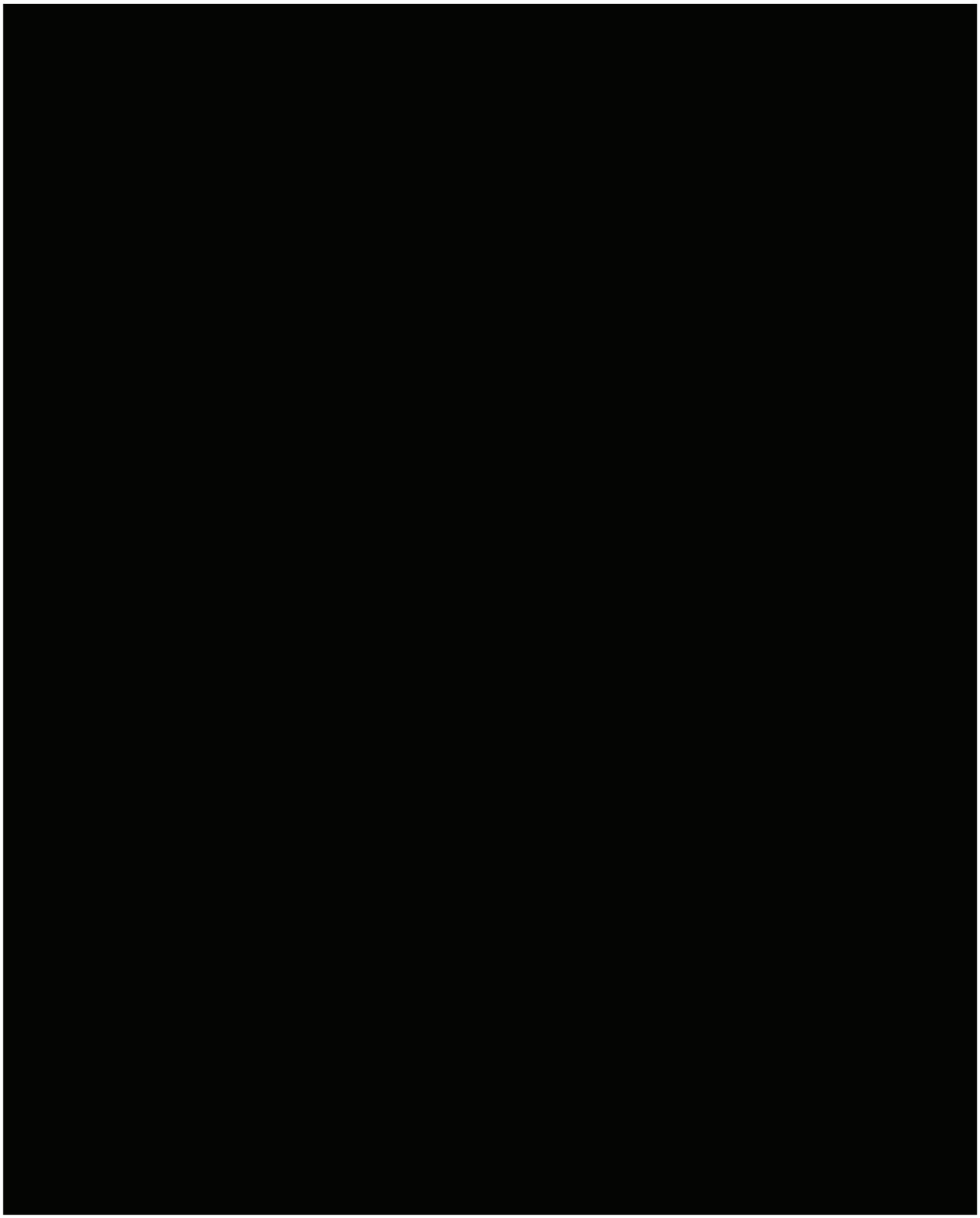


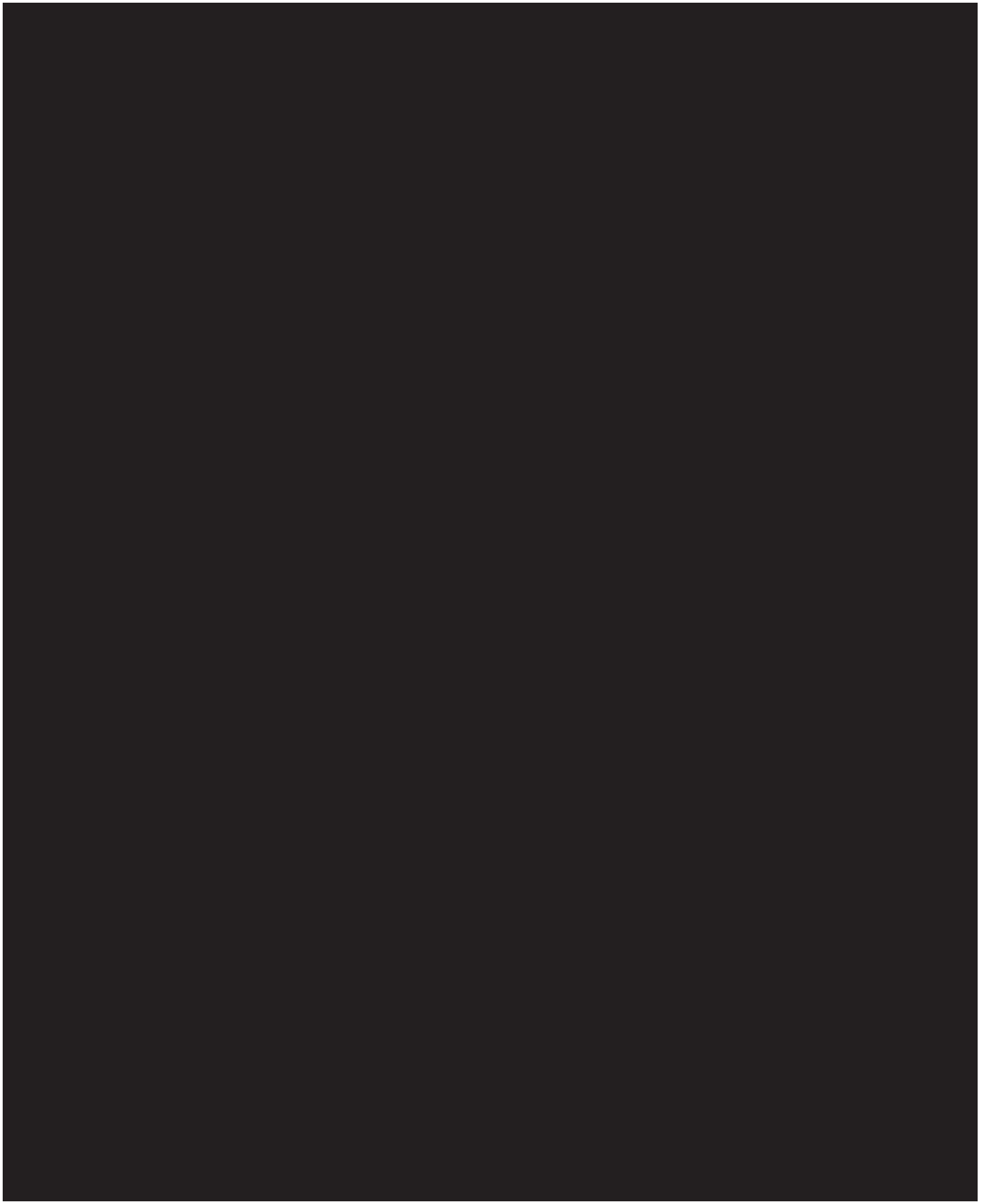




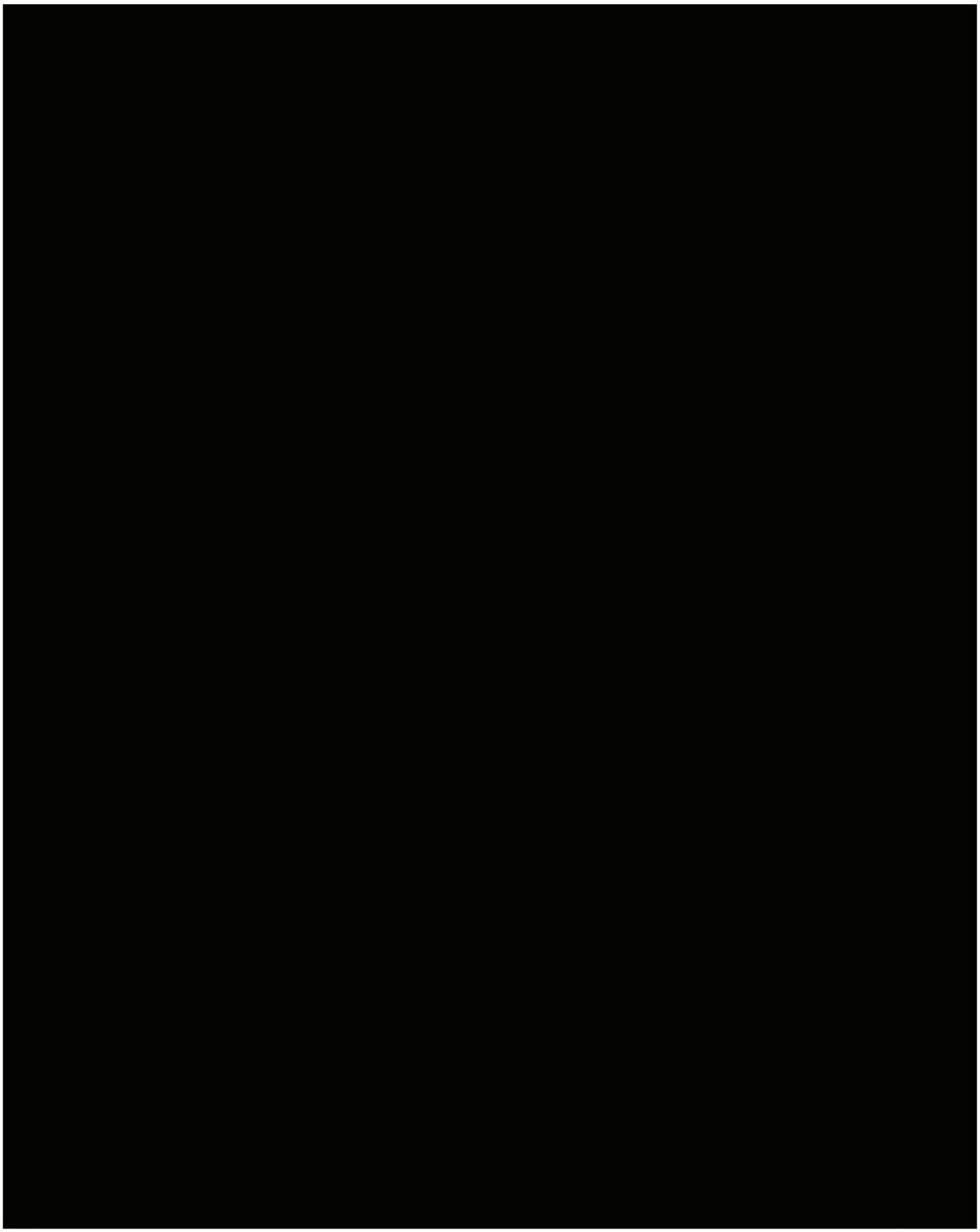




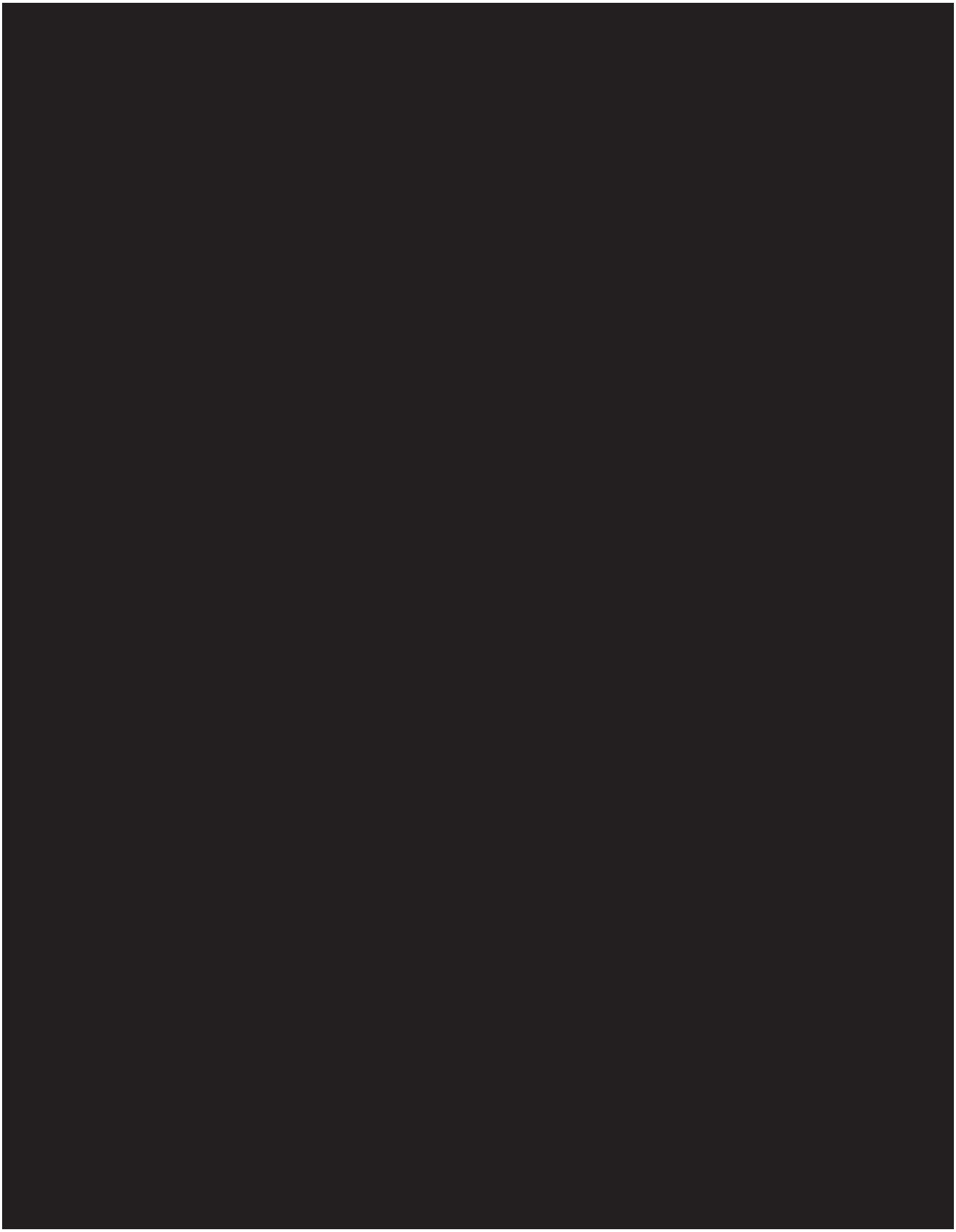




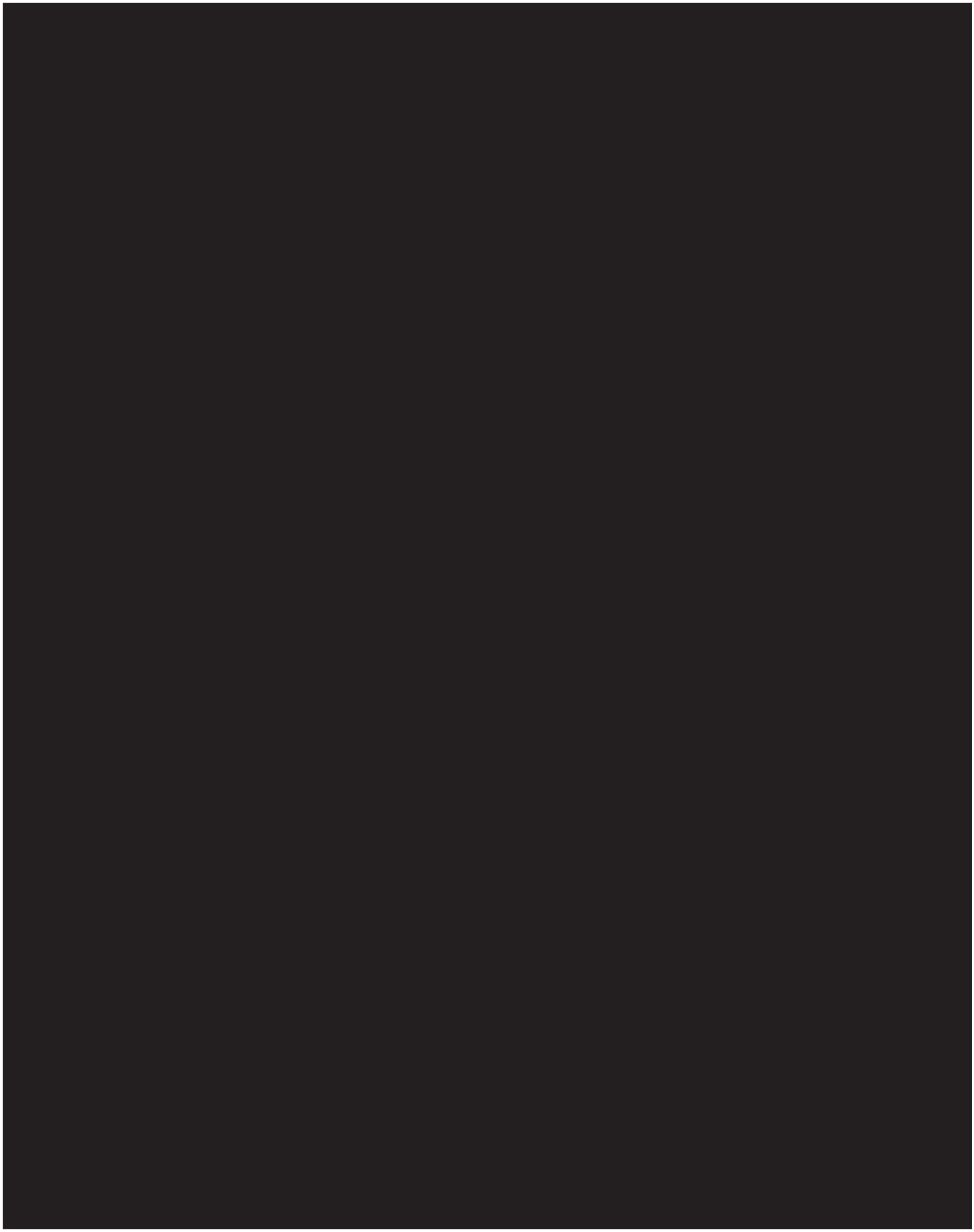
[redacted]

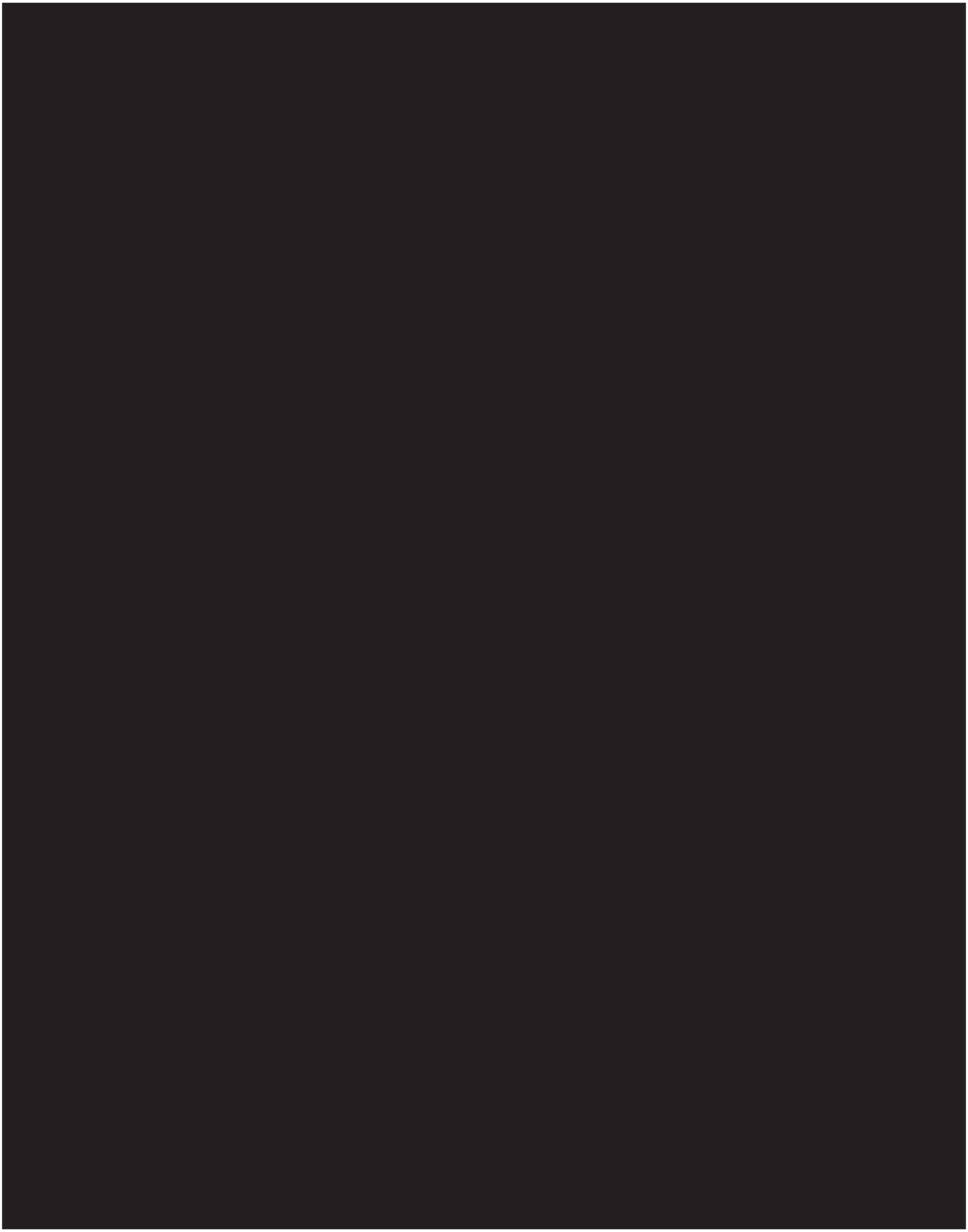


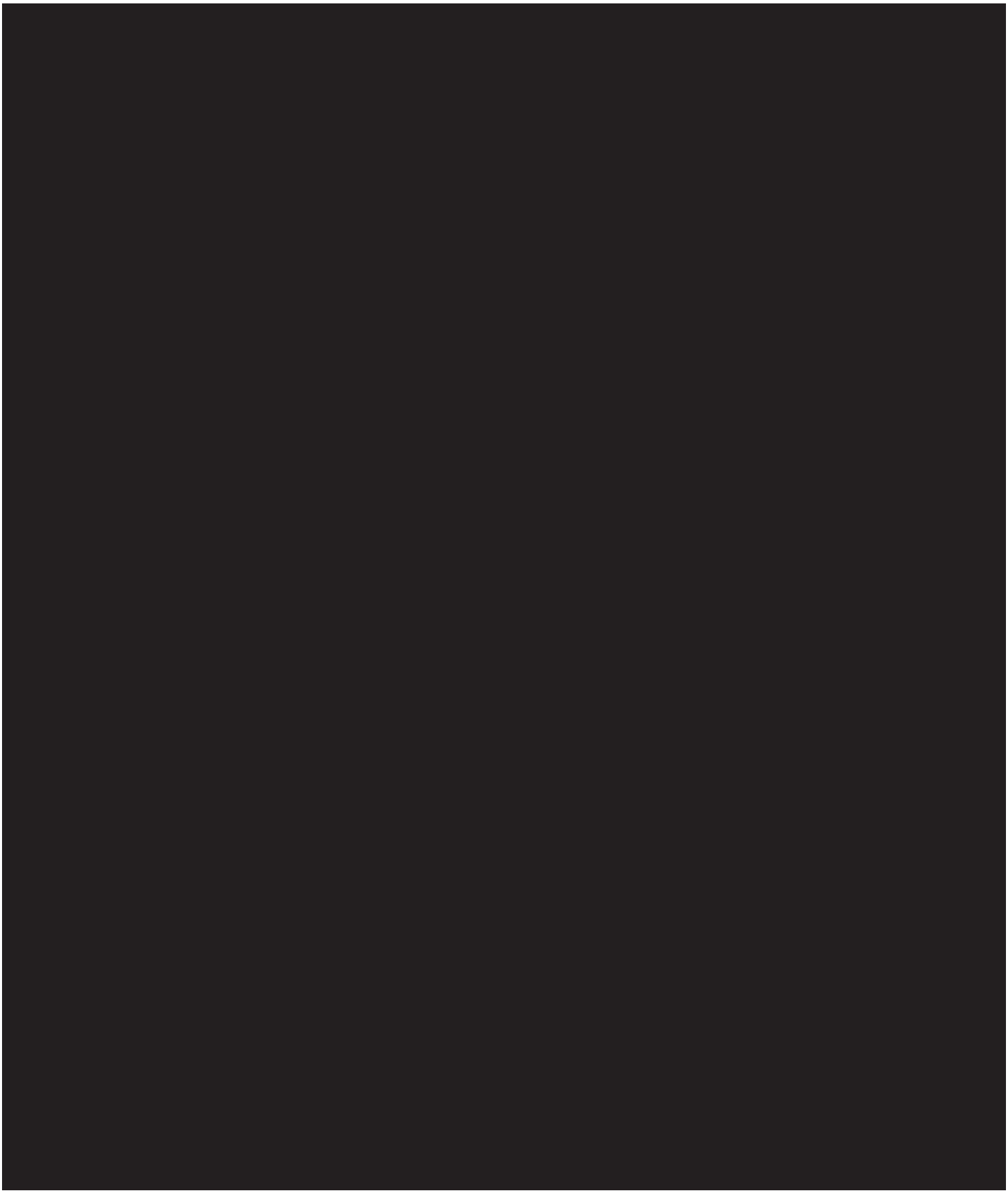
[redacted]



[redacted]







17.2.3 Refraction Protocol

Refraction Procedure

Subjective Refraction

Follow the steps outlined below to complete subjective refraction:

1. Level the phoropter with the floor utilizing the bubble on top (ensure the subject does not tilt his/her head).

2. Adjust the phoropter's interpupillary distance to equal that of the subject's interpupillary distance.

3. Occlude the eye not tested.

4. Set up the optical powers. Begin by using the subject's data from the objective refraction (retinoscope). Dial in the sphere power, cylinder power, and cylinder axis.

5. Perform the subjective refraction assessment completing the four steps outlined below.

    a. Determine the initial spherical adjustment

    b. Determine the cylinder axis

    c. Determine the cylinder power

    d. Complete the final sphere adjustment

NOTE: These steps are further outlined in the following sub-sections.

Spherical Adjustment

Determine the initial spherical adjustment as described below.

1. Direct the subject's attention to the lowest line they can read on the visual acuity (VA) chart.

2. Add +0.25 Diopter Sphere (DS).

3. Ask the subject if his/her vision is: better, worse, or no different.

    a. If the subject reports that their vision is worse with the +0.25 DS lens, then do not add it. For example, if the subject has -1.0 DS in the phoropter and the letters look blurry with the addition of the +0.25 D lens, then the sphere power should remain at -1.0 DS in the phoropter. Go to Step 4 below in this section.

    b. If the subject reports that their vision improves or remains the same with additional plus power, then adjust the spherical power by +0.25 DS. For example, if the subject has -1.0 DS in the phoropter and letters look clearer with the addition of the +0.25 DS lens, then the new sphere power will be set to -0.75 DS in the phoropter.

c. Using the same approach, continue adding plus lens power in +0.25 DS increments. Stop at the most plus lens that does not blur the subject's VA. d. It would be a good check to measure the visual acuity to confirm that the above steps have not inadvertently worsened the visual acuity.

4. Add -0.25 DS.

a. If the subject reports that their vision is worse or remains the same with a -0.25 DS lens, then do not add it. For example, if the subject has -1.0 DS in the phoropter and letters look blurry or remain the same with the addition of the -0.25 DS lens, then the sphere power should remain at -1.00 DS in the phoropter. Proceed to Cylinder Axis Adjustment.

b. If the subject reports that their vision improves with additional minus lens power, then adjust the spherical power by -0.25 DS. For example, if the subject has -1.0 DS in the phoropter and letters look clearer with the addition of the -0.25 D lens, then the new sphere power will be set to -1.25 DS in the phoropter.

c. Using the same approach, add further minus lenses in -0.25 DS increments only as long as the VA improves. Stop at the least minus lens that provides the best VA.

NOTE: It is important to avoid over-minusing the refraction. The goal is to provide the least amount of minus power that would result in the best VA.

Cylinder Axis Adjustment

1. Ensure the best sphere correction is in place based on the endpoint from the previous section.

2. For refining cylinder axis and power a ±0.25 diopter cylinder (DC) Jackson cross cylinder is recommended.

3. Direct the subject's attention to a line of letters one or two rows above the present visual acuity that the subject can see with the sphere power. A letter "O" or "C" is recommended.

4. Pivot the Jackson cross cylinder into position.

NOTE: Where applicable (i.e., phoropter), the cross cylinder will click into place, and when the cylinder axis is moved, the cross cylinder will move the same amount. The cross cylinder may cause a slight blur or distortion of the image.

5. Instruct the subject to look at the VA line of interest. Point to the line if necessary.

6. Instruct the subject that you are going to show them two lenses and both may be slightly blurred. The subject must tell you which of the two is clearer or whether both look the same.

7. As the cross cylinder is flipped, identify the image of the VA chart for the subject as "#1" and then "#2".

8. Change the lens as the images are identified.

9. Move slowly. Subjects are making an effort to differentiate small differences in image quality, and they may get frustrated if they feel rushed.

10. Upon identification of the clear image, look for the position of the white dots, and rotate the axis 10° towards the white dot. This is known as, “chasing the white dots”.

11. Continue to provide choices and chase the white dots until the axis reverses direction.

12. After the axis reverses, chase the white dot in increments of 10°.

13. Refine the axis using 5° increments.

14. Continue to refine the axis until the flip of the cross cylinder results in no difference in clarity between the two images.

15. If the axis moves back and forth over the same 5° or 10°, set the cross cylinder axis to the middle of the range and try to refine.

NOTE: When using a minus-cylinder phoropter, the procedure for determining the axis is changed so that the red dots (not the white dots) are being chased.

Cylinder Power Adjustment

Determine the cylinder power as described below.

1. Continue to direct the subject’s attention to the lowest line the subject can see with the sphere power.

2. Rotate the cross cylinder so that the “P” is aligned with the cylinder axis arrow.

NOTE: The cross cylinder will click into place. At this point the axis will be aligned with either the red or white dots.

3. Instruct the subject that there will again be two choices and that both may be slightly blurred and distorted.

4. Tell the subject he/she will be presented with two choices and that he/she is to choose the image that appears more clear.

5. As the cross cylinder is flipped, identify the image for the subject as “#3” and then “#4”.

6. Change the lens as the images are identified.

7. Move slowly. Subjects are making an effort to differentiate small differences in image quality, and they may get frustrated if they feel rushed.

8. Where the subject prefers the lens choice when the white dots are lined up on the cylinder axis, add +0.25 DC. Conversely if the red dots are lined up on the cylinder axis, add -0.25 DC.

9. Define the choices to the subjects on each flip.

10. For each 0.5 DC of change in cylinder power, change the sphere power by 0.25 D in the opposite direction. For example, if you add -0.5 DC, then add +0.25 DS before comparing the lens positions.

Final Sphere Adjustment

1. Following cylinder testing, fog the eye by +1.00 DS and decrease the fog in 0.25 diopter steps (or adding -0.25 DS lenses) to achieve the endpoint of maximum plus sphere or least minus sphere that allows the subject to read the most letters possible on the threshold visual acuity line (ie, the best visual acuity).

- As a guideline, once the best possible visual acuity is achieved, if a +0.25 diopter sphere is added to the endpoint sphere, the subject should lose the ability to read some or all of the letters. Be careful not to over minus the subject.
- For example: If the subject states that his/her visual acuity (VA) seems better but he/she read fewer letters, he/she has been over-minused. Similarly, if he/she reports that the letters seem smaller and darker but he/she read the same letters or fewer letters, he/she has been over-minused.

2. As a final check, add +1.50 DS and record the visual acuity. If visual acuity with the addition of +1.50 is better than 20/40 the patient may be over-minused and the above Step 1 should be repeated. Record the final refraction. Record refraction results with sphere, cylinder and axis readings.

NOTE: If no cylinder correction is required, cylinder should be recorded as 0 and axis left blank in the Electronic Data Capture (EDC) system.

Example: Recording a refraction with no cylinder -0.50 0.0 -Sphere + Cylinder x Axis. Once this step is completed, occlude the tested eye, and repeat the above procedure on the fellow eye.

17.2.4 logMAR Visual Acuity

A. General Instructions

Measure VA prior to IOP measurement, the administration of eye drops to dilate or anesthetize the eye, or any examination requiring contact with the eye. Test VA at all distances (i.e., distance and intermediate) use a stringent version of the "ETDRSFast" method (Camparini 2001, Tong 2002) as outlined below.

1. Provide vision correction as required by protocol.
2. Seat subject in front of the chart ensuring he/she is in the appropriate distance from the chart, with eye level approximately aligned to the middle of the chart.
3. Provide preliminary instructions to the subject.
    a. Inform the subject that his/her distance/intermediate/near vision will be assessed.
    b. Tell the subject that the chart has letters only, no numbers or other symbols.
    c. Explain that he/she should read slowly when responding (i.e., about one letter per second) to achieve best identification of each letter, and that he/she should not proceed to the next letter until definite response has been given.
4. Use an occluder as required.
    a. For monocular assessments, occlude the contralateral eye. Use a Sponsor provided ETDRS chart, alternating between charts so as to reduce memorization.
    b. For binocular assessment, complete all monocular assessments prior to commencement, and use a Sponsor provided ETDRS chart, alternating between charts so as to reduce memorization.
5. Identify the starting row.
    a. Ask subject to read the first letter of each line beginning at the top left of the chart, working downward toward progressively smaller letters.
    b. When the subject misidentifies the first letter on a line, move the subject up 1 line (ie, toward larger letters), and have him/her read every letter on that row.
    c. If 1 or more errors are made when reading the row, move the subject up one line and try again.
    d. Repeat the above process until zero errors are made on a row.
    e. Identify the row in which no errors were made, as the starting row of the test.
    f. Score the starting row as described in Section C, below.

6. Instructions on identifying the starting line in two unique scenarios are described below.

   a. All letters read: If the subject correctly identifies the first letter of every row in the chart, identify the second from bottom line as the starting row of the test.

   b. No letters read: For distance assessment, if no letters can be read, move the chart to a distance of 2 m, increase add to +0.50 D from the manifest refraction, and perform assessment at this distance (2 m). If no letters can be read at the 2 m distance, move the chart to a distance of 1 m and increase add to +1.00 D from the manifest refraction. Perform the test at this distance (1 m). If no letters can be read test subject for count finger (CF), hand motion (HM), light perception (LP), or no light perception (NLP), and document accordingly.

      For near and intermediate assessments, if no letters can be read, enter the worst possible logMAR value (eg, 1.4 logMAR) as the subject score. In addition, assess subject for count finger (CF), hand motion (HM), light perception (LP), or no light perception (NLP), and document accordingly.

7. Proceed with the test. Score the assessment as described below in Section C below.

   a. Move the subject down one line from the starting row (toward the smaller letters).

   b. Request subject to call out each letter on the line.

      NOTE: If the subject identifies a character as one of two letters, he/she should be asked to choose one letter and, if necessary, to guess. If the subject reads a number, he or she should be reminded that the chart contains no numbers, and the examiner should then request a letter instead of the number. If the subject changes a response before he/she has read aloud the response after having read the next letter, then the change should not be accepted.

   c If the subject correctly identifies a majority of the letters on a line (ie, ≥3) have him/her should progress to the next smaller line.

   d. Terminate the test when the subject either misidentifies the majority of letters on one row (≥3) or progresses to the smallest row of letters.

      NOTE: All letters must be tried on each line attempted, as letter difficulties vary and the last letter may be the only one read correctly (ISO 8596, 2009).

B. Examiner Conduct

During the test monitor the subject for proper posture, no squinting of the eye under test, and continuous occlusion of the contralateral eye. Do not point to the chart or to specific letters on the chart. Do not comment on the correctness of an answer. Encourage the subject to make a maximum effort to identify each letter, encouraging the subject to guess if needed.

C. Scoring

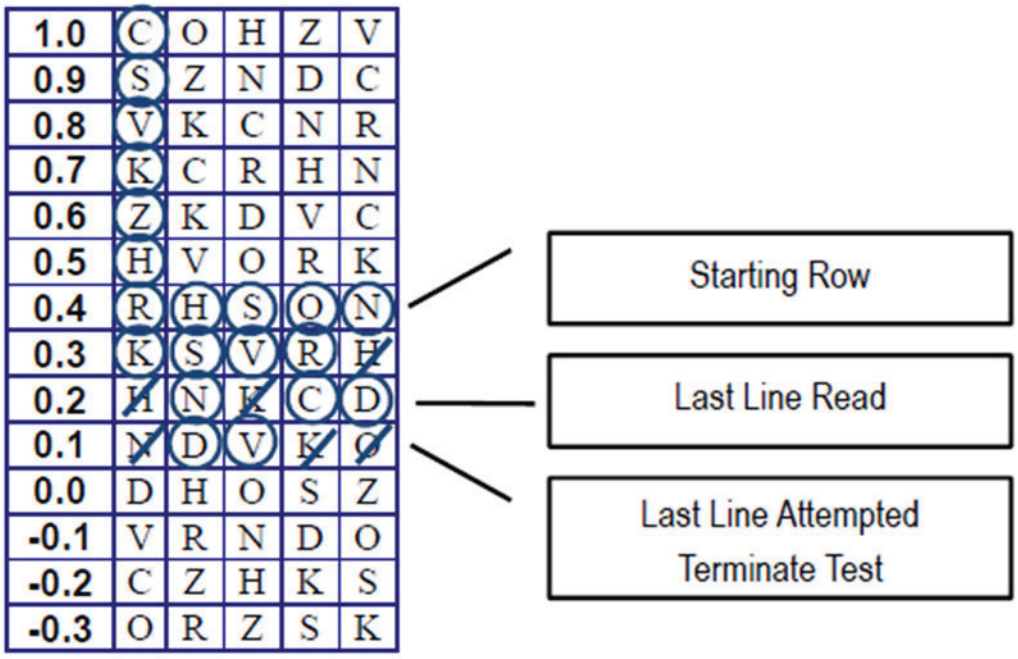
When performing a VA assessment, employ a VA scoring sheet. Begin scoring at the starting row. Mark the letters on the score sheet as follows:

- Circle all letters correctly read;
- Mark through incorrectly read letters; and
- Leave letters not attempted unmarked.

See examples 1 and 2 below.

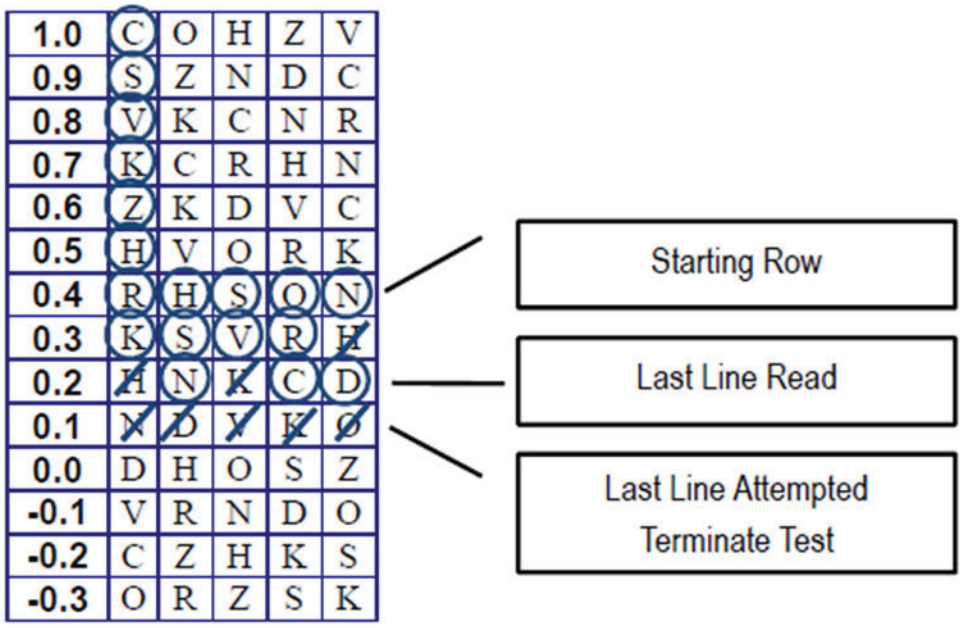
Example 1:

An example of a completed VA score sheet is noted below. In this example, logMAR line 0.4 was identified as the starting row. The subject proceeded to the 0.3 logMAR line and correctly identified 4 of 5 letters. Since this was a majority of the letters in the row, the subject proceeded to the next line (0.2 logMAR). On the 0.2 logMAR line the subject missed 2 of 5 letters, and according to the rules proceeded once more to the 0.1 logMAR line. On the 0.1 logMAR line the subject missed most of the letters (3 of 5); therefore, the test was terminated. The 0.2 logMAR line is identified as the last line read and the 0.1 logMAR line is identified as the last line attempted.



Example 2:

An example of a completed VA score sheet is noted below. In this example, logMAR line 0.4 was identified as the starting row. The subject proceeded to the 0.3 logMAR line and correctly identified 4 of 5 letters. Since this was a majority of the letters in the row, the subject proceeded to the next line (0.2 logMAR). On the 0.2 logMAR line the subject missed 2 of 5 letters, and according to the rules proceeded once more to the 0.1 logMAR line. On the 0.1 logMAR line the subject missed most of the letters (3 of 5); therefore, the test was terminated. The 0.2 logMAR line is identified as the last line read and the 0.1 logMAR line is identified as the last line attempted.



D. LogMAR Value Calculation

To calculate the final logMAR acuity value, follow the below steps.

1. Identify the last line attempted.
2. Locate the logMAR value of the last line attempted.
3. Count the total number of letters missed.
4. Calculate the final logMAR score utilizing the below formula.

$$\underline{\text{Last Line Attempted}} + (0.02 * n) = \text{Score}$$

Where "Last Line Attempted" is given in logMAR and "n" represents the total number of missed letters.

NOTE: An adjustment must be made to the calculation when the chart is placed at a 2 m or 1 m distance. For a 2 m distance, add 0.30 logMAR to the score. For a 1 m distance, add 0.60 logMAR to the score.

Example: Calculation when the test is conducted at the standard 4 m distance. Referring to the previous provided Example 1 from Section C Scoring, the last line attempted is 0.1 logMAR, the number of letters missed (n) is 6. Plugging these values into the formula yields a final score of 0.22 logMAR as demonstrated below.

$$\underset{\text{Last Line Attempted}}{0.10} + (0.02 * \underset{\text{n}}{6}) = \underset{\text{Final Score (logMAR)}}{0.22}$$

Example: Calculation when the test is conducted at a 2 m distance

Using the same example as above, 0.30 logMAR will be added to the score to adjust for the 2 m assessment distance.

$$\underset{\text{Last Line Attempted}}{0.10} + (0.02 * \underset{\text{n}}{6}) \models \underset{\text{Score (logMAR)}}{0.22} \overset{+}{0.3} \underset{\text{Final Score (logMAR)}}{0.52}$$

E. ETDRS Charts

ETDRS Chart R for 13 Feet Good-lite 500013
ETDRS Chart 1 for 13 Feet Good-lite 500014
ETDRS Chart 2 for 13 Feet Good-lite 500015
ETDRS Sloan Intermediate Chart 66cm with Cord Precion Vision 2106-66
ETDRS Sloan Standard Neard 40cm with Cord Precion Vision 2106