Johnson & Johnson Vision Care
7500 Centurion Parkway
Jacksonville, FL 32256

Clinical Study Protocol

Evaluation of a Novel Toric Multifocal Contact Lens in Hyperopic Presbyopes

Protocol Number CR-5903

Version 3.0 Amendment 2

Date 01 March 2017

Key Words:

Daily Disposables
Etafilcon-A
Astigmatism
Multifocal
Dispensing
Presbyopia
Hyperopia

Distribution:

Mr. Ron Clark

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1.1 PROTOCOL TITLE, NUMBER, DATE

TITLE: Evaluation of a Novel Toric Multifocal Contact Lens in Hyperopic Presbyopes

PROTOCOL NUMBER: CR-5903

VERSION: 3.0 Amendment 2

DATE: 01 March 2017

1.2 NAME AND ADDRESS OF SPONSOR

Johnson & Johnson Vision Care

7500 Centurion Parkway, Jacksonville, FL 32256

1.3 AUTHORIZED SIGNATURES

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations, ICH guidelines, and the Declaration of Helsinki.

Author:	**See Electronic Signature Report** Name: Thomas R. Karkkainen, OD, MS, FAAO Title: Sr. Principal Research Optometrist	DATE
Biostatistician:	**See Electronic Signature Report** Name: [redacted] Title: Biostatistician III	DATE
Clinical Data Manager:	**See Electronic Signature Report** Name: [redacted] Title: Clinical Project Manager-Data and Systems	DATE
Clinical Operations:	**See Electronic Signature Report** Name: [redacted] Title: Clinical Operations Manager	DATE
Management/Approver:	**See Electronic Signature Report** Name: [redacted] Title: Presbyopia Platform Sr. Manager	DATE

[redacted]

1.4 MEDICAL MONITOR AND MEDICAL MONTIOR PLAN

NAME: Thomas R. Karkkainen, OD, MS, FAAO

TITLE: Sr. Principal Research Optometrist

ADDRESS: 7500 Centurion Parkway, Jacksonville, Florida 32256

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[redacted]

The Medical Monitor should be notified by the clinical site in writing and by telephone within 24 hours of learning of a Serious Adverse Event. The Medical Monitor may be contacted during business hours for adverse event questions. General study related questions should be directed towards your assigned clinical research associate.

1.5 INVESTIGATOR(S) SIGNATURE PAGE

The Principal Investigator is responsible for ensuring that all study site personnel, including sub-investigators and other staff members, adhere to all ICH regulations and GCP guidelines regarding clinical trials during and after study completion.

I have read and understand the protocol specified above and agree on its content. I agree to conduct this study according to this protocol and GCP and ICH guidelines, the Declaration of Helsinki, and the pertinent individual country laws/regulations and to comply with its obligations, subject to ethical and safety considerations. I shall not disclose the information contained in this protocol or any results obtained from this study without written authorization.

Principal Investigator: _____ _____

Signature Date

_____

Name (Printed)

Institution Name: _____

[redacted]

1.6 ESTIMATED REPORT DATE

The clinical study report will be completed approximately 60 days following database lock.

1.7 CHANGE HISTORY

Document Change History			
Version	**Originator**	**Description of Change(s)**	**Date**
1.0	Tom Karkkainen	Final Protocol	14 December 2016
2.0	Tom Karkkainen	Section 2.1 Added additional CPs for lens builds Section 15.1 Updated Publication	24 January 2017
3.0	Tom Karkkainen	Section 2.1 Added additional CPs for lens builds. Title Page-removed dispensing on title in section 1.1 and 1.8 to match Title Page. Section 1.3-added approver to manager. Section 2.1-removed build numbers 16CP1277, 16CP1278 and 16CP1279 from axis 70. Moved 16CP1298 from axis 70 to axis 110. Added 17CP1018 and 16CP1298 to axes 160 and 16CP1298 180. Section 16.2-Updated title for CTP-2006 Throughout document-changed JJVCI to JJVC	01 March 2017

1.8 PROTOCOL SYNOPSIS

Protocol Number and Title: CR-5903 Evaluation of a Novel Toric Multifocal Contact Lens in Hyperopic Presbyopes
Sponsor: JJVC, 7500 Centurion Parkway, Jacksonville, FL 32256
Investigational Products: Investigational Toric Multifocal Contact Lens for Presbyopia
Ancillary Supplies: ETDRS Light Box, Near Guillon-Poling Charts, Near Lamps, Guillon-Poling Chart Holder, Pupillometer, Rewetting drops, saline solution for final lens storage, and lens cases.
Randomization and Dispensing: Single Arm,(Non- Randomized) Dispensing trial
Microbiology or Other Testing Laboratory: Not Applicable
Phase or Type of Study: Feasibility

Primary Objective: To evaluate the subjective feedback of a multifocal contact lens in a population of presbyopes with hyperopia.

Secondary Objectives:

1 – Evaluate the fit of the toric multifocal lens.

2 – Evaluate the ocular physiological response of the toric multifocal lens.

Study Design: This is a single-masked, single-arm, dispensing feasibility study. There will be three study visits. Visit 1 will include baseline measurements and screening to ensure eligibility. Eligible subjects will be fit in study lenses and dispensed for 6-8 days. At Visit 2 additional measurements will be performed and it will be determined if lens optimization is required and lenses dispensed for an additional 6-8 days. At Visit 3 the primary endpoint data used for analysis will be collected. The lenses will be worn as a daily disposable.

Sample Size: A total of approximately 60 eligible subjects will be enrolled into the study with 48 subjects targeted to complete. An attempt will be made to evenly distribute the subjects across the following ADD groups and ATR & WTR.

Distribution of the 48 Completed Hyperopes will be 24 ATR and 24 WTR

+0.75 to +1.50 ADD		+1.75 to +2.50 ADD	
ATR	WTR	ATR	WTR
≈12	≈12	≈12	≈12

Screening: Healthy male and female volunteers (from 40 to 70 years of age) with a need for presbyopic correction in both eyes will be screened as per criteria outlined below.

Qualification, Dispensing and Follow-Up Procedures:

Screening: Subjects will complete informed consent. Demographics and medical history will be reviewed and baseline measurements completed. Subjects must meet all of the study inclusion criteria to continue in the study.

Investigational Products: The study lenses are Investigational (etafilcon A) Multifocal Contact Lens for Presbyopia

Study Dispensing Procedures: The study procedures are as outline below in the time and events schedule. Subjects that obtain acceptable subjective vision and meet minimum measured distance visual acuity of 20/30 OU will be dispensed lenses for a total of 12-16 days of wear. The subject will have visual performance and subjective assessment of vision and comfort recorded with the lenses in addition to other clinical measures.

Eligibility Criteria:

Potential subjects must satisfy all of the following Inclusion criteria to be enrolled in the study:

1. The subject must read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form.
2. The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol.
3. Healthy adult males or females that are at least 40 years of age and no more than 70 years of age.
4. The subject must either be wearing a presbyopic contact lens correction (e.g., reading spectacles over contact lenses, multifocal or monovision contact lenses, etc.) or if not respond positively to at least one symptom on the "Presbyopic Symptoms Questionnaire".(Appendix B)
5. The subject is a current soft spherical or toric contact lens wearer (defined as a minimum of 6 hours of wear per day at least two days of the week for a minimum of 1 month prior to the study).
6. The subject's distance spherical component of their refraction must be in the range +1.25D to +3.75D in each eye.
7. The subject's refractive cylinder must be -1.00D to -1.50D in each eye.
8. The subject's refractive cylinder axis must be 90° ± 30° or 180° ± 30° in each eye.
9. The subject's ADD power must be in the range of +0.75D to +2.50D in each eye.
10. The subject must have best corrected visual acuity of $20/20^{-3}$ or better in each eye.
11. The subject must have a wearable pair of spectacles if required for their distance vision.

Subjects meeting any of the following Exclusion Criteria will not be eligible to participate in the study:

1. Ocular or systemic allergies or disease, or use of medication which might interfere with contact lens wear.
2. Pregnancy or lactation.
3. Currently diagnosed with diabetes.
4. Infectious diseases (e.g. hepatitis, tuberculosis) or an immune-suppressive disease (e.g. HIV).
5. Clinically significant (grade 3 or 4) corneal edema, corneal vascularization, corneal staining, tarsal abnormalities or bulbar injection, or any other corneal or ocular abnormalities which would contraindicate contact lens wear.
6. Entropion, ectropion, extrusions, chalazia, recurrent styes, dry eye, glaucoma, history of recurrent corneal erosions.
7. Any previous, or planned, ocular or intraocular surgery (e.g., radial keratotomy, PRK, LASIK, lid procedures, cataract surgery, retinal surgery, etc.).
8. A history of amblyopia, strabismus or binocular vision abnormality.
9. Any ocular infection or inflammation.
10. Any ocular abnormality that may interfere with contact lens wear.
11. Use of any ocular medication, with the exception of rewetting drops.
12. History of herpetic keratitis.
13. Participation in any contact lens or lens care product clinical trial within 30 days prior to study enrollment.

Stopping Rules: The occurrence of one or more Serious Unanticipated Adverse Device Effect (SUADE), or any SAE where relationship to study agent cannot be ruled out, may result in stopping further dispensing investigational product. In the event of a UADE or SAE, the Sponsor Medical Monitor may unmask the treatment regimen of subject(s) and may discuss this with the Investigator before any further subjects are enrolled.
Clinical Safety: Assessments by the Investigator will occur at all post-screening study visits and will include review of medical history, concomitant medications, visual acuity and biomicroscopy.

2.1 NAME AND DESCRIPTION OF INVESTIGATIONAL PRODUCTS

The following contact lenses will be used in this study:

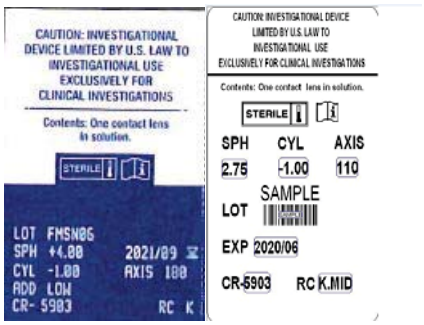
LENSES	
Design / Description	Investigational Toric Multifocal Contact Lens for Presbyopia
Manufacturer	Johnson & Johnson® Vision Care, Inc.
Nominal Distance Sphere Powers (D)	+1.00D to +4.00D in 0.25D steps
Nominal Distance Cylinder Powers (D) **Hyperopic Lenses**	-1.00D Cylinder Axes 20°, 70°, 90° 110°, 160°, 180°,
Nominal ADD Powers (D)	LOW, MID, HIGH
Nominal Base Curve and Diameter (mm)	8.5/14.5
Material	etafilcon A with PVP

Test Lens System Clinical Build Numbers			
Add	**70° Axis**	**90° Axis**	**110° Axis**
Low	PRB 227	PRB 229	PRB 231
Mid	PRB 247	PRB 249	PRB 251
High	PRB 267	PRB 269	PRB 271
[redacted]	[redacted]	[redacted]	[redacted]

Test Lens System Clinical Build Numbers			
Add	**20° Axis**	**160° Axis**	**180° Axis**
Low	PRB 222	PRB 236	PRB 220
Mid	PRB 242	PRB 256	PRB 240
High	PRB 262	PRB 276	PRB 260
[redacted]	[redacted]	[redacted]	[redacted]

*Over-label protocol (16CP1218-HIGH ADD, 16CP1219-MID ADD and 16CP1220-LOW ADD)

Labels: Below are examples of the investigational labels used for this study:



2.2 SUMMARY OF FINDINGS FROM NONCLINICAL STUDIES

See Investigator Brochure

2.3 SUMMARY OF KNOWN RISKS AND BENEFITS TO HUMAN SUBJECTS

See Investigator Brochure

2.4 DESCRIPTION OF TRIAL TREATMENTS

The test lens trial treatment will consist of the Investigational Toric Multifocal (ITM) lenses being fit in both eyes. The study lens system will be worn for approximately 12-16 days with a 6-8 day optimization visit.

2.5 STATEMENT OF COMPLIANCE TO PROTOCOL, GCP, AND APPLICABLE REGULATORY GUIDELINES

This trial will be conducted in compliance with the protocol, the International Conference on Harmonization Good Clinical Practice E6 (ICH-GCP), the Declaration of Helsinki, and all applicable regulatory requirements.

2.6 DESCRIPTION OF POPULATION TO BE STUDIED, ENROLLMENT TARGETS, AND STUDY DURATION

The population to be studied will consist of Presbyopic Astigmats who have hyperopia and are adapted contact lens wearers currently wearing contact lenses. Approximately 60 subjects will be enrolled with a minimum of 48 subjects targeted to complete. The enrollment and study is estimated to last for approximately one month.

Distribution of the 48 Completed Hyperopes will be approximately 24 Against the Rule (ATR) and approximately 24 With the Rule (WTR)

+0.75 to +1.50 ADD		+1.75 to +2.50 ADD	
ATR	WTR	ATR	WTR
≈12	≈12	≈12	≈12

2.7 RELEVANT LITERATURE REFERENCES AND PRIOR DATA

See Investigator Brochure

3.1 DESCRIPTION OF OBJECTIVES AND PURPOSE

To evaluate the clinical performance of contact lenses in hyperopic subjects who are habitual soft contact lens wearers. The primary endpoint is as follows will be the subjective responses.

4.1 PRIMARY AND SECONDARY ENDPOINTS

The primary endpoint is overall quality of vision assessed using the Contact Lens User Evaluation questionnaire (CLUE™). CLUE is a validated Patient Reported Outcome (PRO) questionnaire developed to measure general and throughout the day comfort/vision, as well as symptoms of discomfort/poor vision, lens handling and packaging. Derived CLUE scores using Item Response Theory (IRT) follow a normal distribution with a population average score of 60 (SD 20), where higher scores indicate a more favorable/positive response. A 5 point increase in an average CLUE score translates into 10% shift in the distribution of scores for population of soft contact lens wearers.

The following one (1) primary hypothesis will be tested throughout this investigation. The primary hypothesis must be met to satisfy the objective of the study.

Primary Study Hypothesis	
1	After 12 to 16 days of wear, the CLUE vision score of the test lens will be non-inferior to subjects' habitual lens using a margin of -5 points.

4.2 INCLUSION CRITERIA

Potential subjects must satisfy all of the following criteria to be enrolled in the study:

1. The subject must read, understand, and sign the STATEMENT OF INFORMED CONSENT and receive a fully executed copy of the form.
2. The subject must appear able and willing to adhere to the instructions set forth in this clinical protocol.
3. Healthy adult males or females that are at least 40 years of age and no more than 70 years of age.
4. The subject must either be wearing a presbyopic contact lens correction (e.g., reading spectacles over contact lenses, multifocal or monovision contact lenses, etc.) or if not respond positively to at least one symptom on the "Presbyopic Symptoms Questionnaire".(Appendix B)
5. The subject is a current soft spherical or toric contact lens wearer (defined as a minimum of 6 hours of wear per day at least two days of the week for a minimum of 1 month prior to the study).
6. The subject's refractive spherical component must be between +1.25 D to +3.75D in each eye.
7. The subject's refractive cylinder must be -1.00D to -1.50D in each eye.
8. The subject's refractive cylinder axis must be 90°±30° or 180°±30° in each eye.
9. The subject's ADD power must be in the range of +0.75 D to +2.50 D in each eye.
10. The subject must have best corrected distance visual acuity of $20/20^{-3}$ or better in each eye.
11. The subject must have a wearable pair of spectacles if required for their distance vision.

4.3 EXCLUSION CRITERIA

Potential subjects who meet any of the following criteria will be excluded from participating in the study:

1. Ocular or systemic allergies or disease, or use of medication which might interfere with contact lens wear.
2. Pregnancy or lactation.
3. Currently diagnosed with diabetes.
4. Infectious diseases (e.g. hepatitis, tuberculosis) or an immune-suppressive disease (e.g. HIV).
5. Clinically significant (grade 3 or 4) corneal edema, corneal vascularization, corneal staining, tarsal abnormalities or bulbar injection, or any other corneal or ocular abnormalities which would contraindicate contact lens wear.
6. Entropion, ectropion, extrusions, chalazia, recurrent styes, dry eye, glaucoma, history of recurrent corneal erosions.
7. Any previous, or planned, ocular or intraocular surgery (e.g.radial keratotomy, PRK, LASIK, lid procedures, cataract surgery, retinal surgery, etc.).
8. A history of amblyopia, strabismus or binocular vision abnormality.
9. Any ocular infection or inflammation.
10. Any ocular abnormality that may interfere with contact lens wear.
11. Use of any ocular medication, with the exception of rewetting drops.
12. History of herpetic keratitis.
13. Participation in any contact lens or lens care product clinical trial within 30 days prior to study enrollment.

4.4 STUDY DESIGN, TIME AND EVENT SCHEDULE, FLOWCHART

The study is a bilateral, single masked, single-arm, 3-visit dispensing study. Subjects will wear the study lens system for approximately 12-16 days.

4.4.1 TIME AND EVENT SCHEDULE

Visit 1 (Day 0)

Statement of Informed Consent
Demographics
Medical History/Concomitant Medications
Current Contact Lens Brand/Modality/Type of Correction
Contact Lens History
Wear Time with Habitual Lenses
Screening Eligibility
Baseline PRO Questionnaire and CLDEQ-8
Ocular Symptoms
Distance and Near Entrance Visual Acuity
Visual Performance
Binocular Over-Refraction
Lens Removal
Pupillometry
Keratometry
Subjective Refraction and Distance Visual Acuity
Add Determination
Ocular Dominance
Near Add Refinement
Near Visual Acuity
Biomicroscopy
Baseline Eligibility
Lens Selection
Right Lens Insertion
Lens Damage
1 Minute Rotation Measurement
3 Minute Rotation Measurement
Left Lens Insertion
Lens Damage
1 Minute Rotation Measurement
3 Minute Rotation Measurement
15 Minute Settling Time
Toric Fit Assessment
Subjective Lens Fit Assessment
Visual Satisfaction
Study Lens Distance and Near Visual Acuity
Distance Over-refraction and Distance Visual Acuity
Modification (if required)
PRO Post-Fit Questionnaire
Manual Misrotation Base Nasal (Right Eye Only)
Manual Misrotation Base Temporal (Right Eye Only)
Manual Misrotation Base Nasal (Left Eye Only)
Manual Misrotation Base Temporal (Left Eye Only)
Distance and Near Exit Visual Acuity
Dispensing Criteria

Patient Instructions
Scheduling for Follow-up 6-8 days

<u>VISIT 2 (6-8 Days after Visit 1)</u>
Confirm Medical History
Wear Time
Compliance
PRO Questionnaire
Ocular Symptoms
Subjective Acceptance
Entrance Distance and Near Visual Acuity
Toric Fit Assessment
Subjective Lens Fit Assessment
Distance Over-Refraction and Distance Visual Acuity
Lens Optimization (if needed)
Lens Selection (if needed)
Lens Insertion (if needed)
Lens Damage (if needed)
1 Minute Rotation Measurement (if needed)
3 Minute Rotation Measurement (if needed)
15 Minute Settling Time (if needed)
Toric Fit Assessment (if needed)
Subjective Lens Fit Assessment (if needed)
Visual Satisfaction (if needed)
Study Lens Distance and Near Visual Acuity (if needed)
Distance Over-Refraction and Distance Visual Acuity (if needed)
Additional Optimization (if needed)
Unworn Lens Collection (if lenses are optimized)
Lens Removal
Biomicroscopy
Insertion of Study Lenses
PRO Post-Fit Questionnaires
Distance and Near Exit Visual Acuity
Dispensing Criteria
Patient Instructions
Scheduling for Follow-up 6-8 day

<u>Visit 3 (6-8 days from Visit 2)</u>
Confirm Medical History
Wear Time
Compliance
Unworn Lens Collection
PRO Questionnaires and CLDEQ 8
Ocular Symptoms
Subjective Acceptance
Distance and Near Entrance Visual Acuity
Distance Over-refraction and Distance Visual Acuity
Toric Fitting Assessment
Subjective Lens Fit Assessment
Visual Performance
Questionnaires
Lens Removal and Storage
Biomicroscopy

Subject Interview (PRA only)
Final Evaluation

4.5 RANDOMIZATION AND MASKING

This study is single masked (subject masked), single-arm, dispensing clinical trial. Due to the nature of the study randomization is not required.

This is a single masked study; investigators are not able to be masked due to the differences in the test articles (number of lenses) and fitting guide. Subjects will be masked to the identities of the study lenses.
The lens assignment will be performed at the fitting visit following subject enrollment. The following must occur prior to lens assignment:

- Informed consent must be obtained
- The subject must meet all of the inclusion / exclusion criteria
- The subject history and baseline information must be collected

The following procedures will be followed:

- Subjects will not be aware of the identity of the study lenses.
- Investigators and technical personnel involved in the data collection will not be masked as to the identity of the study lenses.

4.6 WEAR AND REPLACEMENT SCHEDULES, INCLUDING FORM, PACKAGING AND LABELING

Wear Schedule: Daily Disposable

Replacement Schedule: Daily

Test Article Packaging Description: Blister packs

Labeling: Investigational label for all study lenses

4.7 DETAILED STUDY PROCEDURES

4.7.1 SEQUENCE OF EVENTS

Subjects must report to the initial visit wearing their habitual contact lenses, in order to accurately assess baseline PRO performance. If the subject is not wearing their lenses they must be rescheduled. Subjects must also bring their readers if used over their contact lenses for reading to be worn when conducting the logMAR acuity at Baseline. **If subjects do not bring their reading glasses (if required) they must be rescheduled.**

Visit 1: Screening			
Step	**Descriptor**	**Details**	**Appendix**
1	Statement of Informed Consent	Each subject must read, understand, and sign the Statement of Informed Consent before being enrolled into the study. The Principal Investigator or his/her designee conducting the informed consent discussion must also sign the consent form. **NOTE:** The subject must be provided a signed copy of this document.	
2	Demographics	Age, gender, ethnicity and race.	
3	Medical History/ Concomitant Medications	Questions regarding the subjects' medical history and concomitant medications	
4	Current Contact Lens Brand Modality	Record the brand of their current contact lens, lens parameters, modality (i.e. daily wear, extended wear, etc.) and cleaning regiment if the subject is a current contact lens wearer.	
5	Contact Lens History	Record the subject's contact lens correction type (i.e. monovision, multifocal, sphere with readers, etc.) if the subject is a current contact lens wearer.	
6	Wear time and Comfortable Wear time with Habitual lenses	Record the subjects wear time and comfortable wear time with their habitual contact lenses if the subject is a current contact lens wearer.	
7	Eligibility	All responses to Inclusion Criteria questions must be answered "yes," and all responses to Exclusion Criteria questions must be answered "no" for the subject to be considered eligible.	

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Visit 1: Treatment1-Baseline1			
Step	**Descriptor**	**Details**	**Appendix**
1	Baseline Questionnaires and CLDEQ-8	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of their habitual correction using the PRO questions.	Section 16.1
2	Ocular Symptoms	If the subject reports ocular symptoms with their habitual contact lenses they will be recorded in the Subject Reported Ocular Symptom Questionnaire.	[redacted]

[redacted]

3	Distance and Near Entrance Visual Acuity	Distance and near visual acuity will be measured for each eye with the subject's habitual contact lenses in place. Standard examination room Snellen (or equivalent) charts will be used for distance vision. For near measures use the ETDRS 2000 Series Chart 1 or Chart 2. **Note:** The acuity will be recorded to the nearest letter OD, OS and OU.	[redacted]
4	Visual Performance Distance (3M) Intermediate (64cm) Near (40cm) (***Subjects will wear their Habitual Contact Lenses and readers for near if required)***	Visual performance will be recorded OD, OS and OU for the following: **Distance, Bright Illuminance** *ETDRS Charts* 3M-HC#1, HC#2, HC#3 and LC#1, LC#2 and LC#3 **Near, Bright Illuminance** *Reduced Guillon-Poling charts* High Contrast and Low Contrast Intermediate (64cm) and Near (40cm). **Distance, Dim Illuminance (with *Distance* goggles)** *ETDRS Charts* 3M-HC#4, HC#5, HC#6 **Near, Dim Illuminance (with *Near* goggles)** *Reduced Guillon-Poling charts* High Contrast Intermediate (64cm) and Near (40cm). **Note:** **The room illuminance must be between 7.3 and 7.9 EV.** **Distance, HC-1 Chart luminance Acceptable EV Range 10.5-10.7.** **Guillon-Poling, Near Chart luminance Acceptable EV Range 10.8-11.1.** **Do not use the Mesopic filter for Dim luminance (Dim luminance will be simulated by using the goggles)**	[redacted]
5	Binocular Distance Over- refraction and Distance Visual Acuity	Perform a binocular over-refraction over the subject's habitual contact lenses and record the OD and OS results and distance visual acuity.	Appendix D
6	Lens Removal	Have the subject remove their habitual lenses and store in an approved storage solution.	
7	Pupillometry	The pupil measurements will be performed OD and OS under bright illumination (7.3-7.9 EV) and dark illumination (≤0 EV) using a Neuroptic Pupillometer or similar instrument. The room illuminance will be measured for each condition using the Sekonic lightmeter or similar instrument.	[redacted]
8	Keratometry	Keratometry will be performed OD and OS and the steep and flat dioptric power and corresponding meridians recorded.	[redacted]

[redacted]

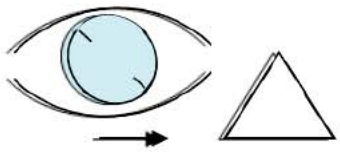
9	Subjective Refraction and Distance Visual Acuity	An optimal, binocular balanced distance sphero-cylindrical refraction will be performed. Record the refraction and distance visual acuity to the nearest letter. ***Note**: Best distance visual acuity with sphero-cylindrical refraction must be at least 20/20-3 in each eye for the subject to enroll in the study.*	[redacted]
10	Near ADD Determination	The near reading addition will be determined using the binocular crossed cylinder technique at 40 cm followed by optimization in a trial frame in step 12 below.	[redacted]
11	Ocular Dominance	Determine the distance ocular dominance with the best distance correction in place using a +1.00 blur test. If the results are equivocal use the sighting dominance test to determine the dominant eye used for the study.	Appendix C
12	ADD Refinement	Place the BCC result in the trial frame and refine the near prescription with trial lenses (or flippers) under binocular conditions.	[redacted]
13	Near Visual Acuity	Using the ETDRS 2000 Series Chart 1 or 2 near card placed at 40 cm. Record the near visual acuity OD, OS and OU at 40 cm.	[redacted]
14	Biomicroscopy	Perform biomicroscopy OD and OS. Slit Lamp Classification Scales will be used to grade the findings. For the conjunctival redness [redacted] 0.5 unit increments will be used in the grading. Corneal Staining Assessment [redacted] will be graded in 1.0 increments.	[redacted]
15	Eligibility	Determine whether the subject is eligible to participate in the study based on the examination findings. If so, proceed to fitting. If not, complete the final evaluation and discharge the subject.	

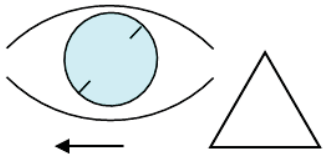
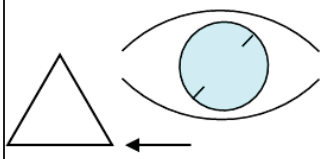
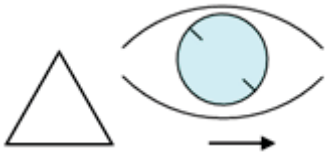
Visit 1: Treatment1 – Assignment1-1			
Step	**Descriptor**	**Details**	**Appendix**
1	Study Lens Selection	Select the lens pair power, and axis based on the Subject's Refraction and Fitting Guide for each eye. Record the test lens parameters (power and lot number).	Appendix E (Fitting Guide)

Visit 1: Treatment1-Fitting1			
Step	Descriptor	Details	Appendix
1	Right lens insertion	Subjects will insert the right lens themselves. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. Damaged lenses will be stored in labeled vial with sterile saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor. Complete the Quality Product Complaint form.	
2	Timed settling for right lens	The investigator will start a stopwatch as soon as the right lens is inserted. **Note: All lenses in this study have scribe marks at 6 o'clock and 12 o'clock positions and rotation measurements are made relative to a vertical reference line.** **Record base nasal or base temporal rotation to the nearest degree.** At one (1) minute after insertion: Record: 1. The rotational position to the nearest degree At three (3) minutes after insertion: Record: 1. The rotational position to the nearest degree	
3	Left lens insertion	The subject will insert the left lens themselves. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. Damaged lenses will be stored in labeled vial with sterile saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor. Complete the Quality Product Complaint form.	
4	Timed settling for left lens	The investigator will start a stopwatch as soon as the left lens is inserted. **Note: All lenses in this study have scribe marks at 6 o'clock and 12 o'clock positions and rotation measurements are made relative to a vertical reference line.** **Record base nasal or base temporal rotation to the nearest degree.** At one (1) minute after insertion: Record: 1. The rotational position to the nearest degree At three (3) minutes after insertion: Record: 1. The rotational position to the nearest degree	
5	Lens settling	Allow lenses to settle at least 15 minutes.	

6	Toric Fit Evaluation	After lens settling, record: • The rotational position to the nearest degree • Lens stability with blink • Lens stability with eye versions • Toric fit acceptable or unacceptable Toric lens fit will be unacceptable if lenses rotated more than 40 degrees, or lens stability is worse than 5 degrees movement with blink. If toric fit is unacceptable, remove the lenses, perform biomicroscopy and proceed to final evaluation.	[redacted]
7	Lens Fit Assessment	Lens fit will be assessed in primary gaze, upgaze & Josephson push up test. An unacceptable lens fit will be any one or more of the following: • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • Presence of unacceptable movement (excessive or insufficient) in all three movement categories (primary gaze, upgaze, and push-up). *If either lens is deemed unacceptable, the subject will be discontinued from the study. Perform a slit-lamp evaluation and complete the Final Evaluation*	[redacted]
8	Determine Visual Satisfaction	Determine if the subject's vision is acceptable with the lenses. Allow the subject to look down a hallway or out of a window for distance vision assessments, and for them to read a book, magazine or similar for near vision.	
9	Distance and Near Visual Acuity	Distance and near Snellen visual acuity will be measured for each eye with the study contact lenses in place. For near measures use the ETDRS 2000 Series Chart 1 or 2. The acuity will be recorded to the nearest letter OD, OS and OU.	[redacted]
10	Over-refraction	Perform a distance spherical over-refraction OD and OS using loose lenses outside of the phoropter under ambient room illumination. The distance over- refraction may also be refined under binocular conditions. Record the results. The results of the distance over-refraction may also be checked for the impact on near vision under monocular and/or binocular conditions.	

[redacted]

11	Lens modification (if needed)	If the subject reports unsatisfactory vision, or is unable to obtain 20/30 distance visual acuity OU with the lenses then a modification must be attempted. If the subject reports satisfactory vision with the lenses a modification is not required however at the Investigators discretion and based upon their findings on the measured visual acuity and/or over- refraction the investigator may make a modification. Select the reason(s) for lens change (select all that apply): • The settled lens rotation is such that one of the other available lens cylinder axis would be better (use LARS rule to determine the replacement lens cylinder axis) • Power Modification needed • Unsatisfactory Vision • Other (specify reason) If one or both lenses are modified, repeat steps 1 through 10 for one or both eyes as appropriate. A maximum of two lens modifications are allowed. **Note: If the subject does not obtain an acceptable visual response (subjective or objective) and a Distance Visual Acuity of 20/30 OU, remove the lenses, complete the slit-lamp exam and Final Evaluation**	
12	PRO Questionnaire	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of the study lenses using the PRO questionnaire. **Note: Subject's Must respond to the Questionnaire in the KIOSK using their User Name and Password**	Section 16.1
13	Manual misrotation (**base nasal**, right lens only)	The investigator will manually misrotate the right lens past 45° **(base nasally) from the settled rotational position.** As the lens begins to rotate back toward the correct position, the investigator will start a stop watch as soon as the lens is **exactly 45 degrees misrotated from its earlier settled**  The investigator will then measure and record the lens rotation at 15 seconds, 30 seconds, 1 minute, 2 minutes and 3 minutes following the start of the stop watch.	

14	Manual misrotation (**base temporal**, right lens only)	The investigator will manually misrotate the right lens past 45˚ **(base temporally) from the settled rotational position**. As the lens begins to rotate back toward the correct position, the investigator will start a stop watch as soon as the lens is **exactly 45 degrees misrotated from its earlier settled position.**  The investigator will then measure and record the lens rotation at 15 seconds, 30 seconds, 1 minute, 2 minutes and 3 minutes following the start of the stop watch.	
15	Manual misrotation (**base nasal**, left lens only)	The investigator will manually misrotate the left lens past 45˚ **(base nasally) from the settled rotational position.** As the lens begins to rotate back toward the correct position, the investigator will start a stop watch as soon as the lens is **exactly 45 degrees misrotated from its earlier settled position**.  The investigator will then measure and record the lens rotation at 15 seconds, 30 seconds, 1 minute, 2 minutes and 3 minutes following the start of the stop watch.	
16	Manual misrotation (**base temporal**, left lens only)	The investigator will manually misrotate the left lens past 45˚ **(base temporally) from the settled rotational position.** As the lens begins to rotate back toward the correct position, the investigator will start a stop watch as soon as the lens is **exactly 45 degrees misrotated from its earlier settled position**.  The investigator will then measure and record the lens rotation at 15 seconds, 30 seconds, 1 minute, 2 minutes and 3 minutes following the start of the stop watch.	

Visit 1:Treatment1- Dispense1			
Step	Descriptor	Details	/Appendix
1	Distance and Near Exit Visual Acuity	Distance and near Snellen visual acuity will be measured for each eye with the study contact lenses in place. For near measures use the ETDRS 2000 Series Chart 1 or Chart 2. The acuity will be recorded to the nearest letter OD, OS and OU. **Note: The distance visual acuity must be at least 20/30 OU for the lenses to be dispensed.**	[redacted]
2	Dispensing Criteria	The lenses will be dispensed for 6 to 8 days. • Distance Snellen acuity equal to or better than 20/30 OU • Subject must indicate that the vision is acceptable. • Subject must indicate that the comfort of the lenses is acceptable. • Lenses must have an acceptable toric and general lens fit.	
3	Patient Instructions	Instruct the Subject the following: • The lenses will be worn on a daily wear basis and discarded at the end of each day. • Only enough lenses will be dispensed to the subject to wear for the required number of days until their follow-up visit. No additional lenses will be dispensed. • A new lens will be opened and worn each day. • No cleaning or disinfecting solutions will be used. If determined necessary by the Investigator sterile non-preserved rewetting drops may be dispensed to be used as needed for dryness. • Subjects will be instructed to wear lenses for a minimum of 6 hours a day, every day during the study. • Subjects will be instructed to wear their glasses when not wearing the study lenses. • A patient instruction booklet will be provided. **Note: In the event a lens is lost or damaged, the subject will return to the investigator site for replacement. As much as reasonably possible, a damaged lens should be returned to the investigational site and then returned to the Sponsor. If lens damage is present, complete the Product Quality Complaint Form. The lens will be stored in labeled vial with sterile saline, and returned to the Sponsor.**	
4	Follow-up	The subject will be scheduled to return for their follow-up appointment in 7±1 day.	

Subjects must report to the visit wearing the study lenses

Visit 2: Treatment1 – FollowUp1			
Step	**Descriptor**	**Details**	**Appendix**
1	Concomitant and Medical History Review	Confirm if there have been any changes in concomitant medications or health status since the last visit.	
2	Wear Time	Record the average hours the subject has worn the study lenses and the comfortable wear time.	
3	Compliance	Record compliance with the required wear time. Subjects must have worn lenses for at least 6 hours per day. ***Note:*** *To be counted as a day of wear at this visit the Subject must have worn the study lenses for 6 hours prior to the visit.*	
4	PRO Questionnaires	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of the study lenses using the PRO questionnaire. Note: **Subject's Must respond to the Questionnaire in the KIOSK using their User Name and Password**	Section 16.1
5	Ocular Symptoms	If the subject reports ocular symptoms with the study lenses they will be recorded in the Subject Reported Ocular Symptom Questionnaire.	[redacted]
6	Subjective Acceptance	Record whether the subjects distance and near vision with the lenses is acceptable.	
7	Distance and Near Entrance Visual Acuity	Distance and near Snellen visual acuity will be measured for each eye with the study contact lenses in place. Standard examination room Snellen (or equivalent) charts will be used for distance vision. For near measures use the ETDRS 2000 Series Chart 1 or Chart 2. **Note:** The acuity will be recorded to the nearest letter OD, OS and OU.	[redacted]
8	Toric Fit Evaluation	Record the toric fit of the study lenses : • The rotational position to the nearest degree • Lens stability with blink • Lens stability with eye versions • Toric fit acceptable or unacceptable Toric lens fit will be unacceptable if lenses rotated more than 40 degrees, or lens stability is worse than 5 degrees movement with blink. If toric fit is unacceptable, remove the lenses, perform biomicroscopy and proceed to final evaluation.	[redacted]

[redacted]

9	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). An unacceptable lens fit will be any one or more of the following: • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • Presence of unacceptable movement (excessive or insufficient) in <u>all three</u> movement categories (primary gaze, upgaze, and push-up). *If either lens is deemed unacceptable, the subject will be discontinued from the study. Perform a slit-lamp evaluation and complete the Final Evaluation.*	[redacted]
10	Distance Over-refraction and Distance Visual Acuity	Perform a distance spherical over-refraction OD and OS using loose lenses outside of the phoropter under ambient room illumination. The distance over-refraction may also be refined under binocular conditions. Record the results and distance visual acuity OD and OS. The results of the distance over-refraction may also be checked for the impact on near vision under monocular and/or binocular conditions.	
11	Determination of Lens Optimization	If the subjects vision is unacceptable for at least one distance or the Investigator determines that the visual acuity or over-refraction are not acceptable then a lens modification must be made. Up to *two* attempts at changes are permitted if necessary, in order to achieve an acceptable distance and near binocular performance for the subject. Follow the fitting guide allowing for at least 15 minutes of settling time between lens changes.	Appendix E (Fitting Guide)

[redacted]

Visit 2: Treatment1 – Optimization (If needed)			
Step	**Descriptor**	**Details**	**Appendix**
1	Lens Optimization *(if needed)*	Select the reason(s) for lens change (select all that apply): • The settled lens rotation is such that one of the other available lens cylinder axis would be better (use LARS rule to determine the replacement lens cylinder axis) • Power Modification needed • Unsatisfactory Vision • Other (specify reason)	
2	Lens Selection	Select the lens power, based on the Fitting Guide for each eye needing optimization. Record the test lens parameters (power and lot number).	Appendix E (Fitting Guide)
3	Lens insertion *(Repeat steps 2-4 for each eye being optimized)*	Subjects will insert the lens themselves. If the lens is uncomfortable, inspect for damage and remove, reinsert or replace as necessary. Damaged lenses will be stored in labeled vial with sterile saline, and clearly differentiated from the other worn lenses that will be shipped back to the Sponsor. Complete the Quality Product Complaint form.	
4	Timed settling *(Repeat steps 2-4 for each eye being optimized)*	The investigator will start a stopwatch as soon as the lens is inserted. **Note: All lenses in this study have scribe marks at 6 o'clock and 12 o'clock positions and rotation measurements are made relative to a vertical reference line. Record base nasal or base temporal rotation to the nearest degree.** <u>At one (1) minute after insertion:</u> Record: 1. The rotational position to the nearest degree <u>At three (3) minutes after insertion:</u> Record: 1. The rotational position to the nearest degree	
5	Lens settling	Allow lenses to settle at least 15 minutes.	

6	Toric Fit Evaluation	After lens settling, record: • The rotational position to the nearest degree • Lens stability with blink • Lens stability with eye versions • Toric fit acceptable or unacceptable Toric lens fit will be unacceptable if lenses rotated more than 40 degrees, or lens stability is worse than 5 degrees movement with blink. If toric fit is unacceptable, remove the lenses, perform biomicroscopy and proceed to final evaluation.	[redacted]
7	Lens Fit Assessment	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). An unacceptable lens fit will be any one or more of the following: • presence of limbal exposure (appearance of clear cornea) in any gaze • presence of edge lift • Presence of unacceptable movement (excessive or insufficient) in <u>all three</u> movement categories (primary gaze, upgaze, and push-up). *If either lens is deemed unacceptable, the subject will be discontinued from the study. Perform a slit-lamp evaluation and complete the Final Evaluation.*	[redacted]
8	Determine Visual Satisfaction	Determine if the subject's vision is acceptable with the lenses. Allow the subject to look down a hallway or out of a window for distance vision assessments, and for them to read a book, magazine or similar for near vision.	
9	Distance and Near Visual Acuity	Distance and near Snellen visual acuity will be measured for each eye with the study contact lenses in place. For near measures use the ETDRS 2000 Series Chart 1 or Chart 2. **Note:** The acuity will be recorded to the nearest letter OD, OS and OU.	[redacted]
10	Over-refraction	Perform a distance spherical over-refraction OD and OS using loose lenses outside of the phoropter under ambient room illumination. The distance over-refraction may also be refined under binocular conditions. Record the results. The results of the distance over-refraction may also be checked for the impact on near vision under monocular and/or binocular conditions.	

[redacted]

11	Additional Optimization (if needed)	Repeat steps 1-10 if an additional optimization is needed. Note: Two total attempts at optimization are permitted.	Appendix E (Fitting Guide)
12	Collection of unworn lenses	Collect unworn lenses returned by the subject when lens power has been optimized *If lens power was not changed allow the subject to use the unworn lenses dispensed at Visit 1 and dispense enough lenses of the same power to last the subject until their next visit.*	
13	Lens Removal	The **optimized study lenses** will be removed and discarded. If the lenses **were not modified** also remove and discard the lenses.	
14	Biomicroscopy	Perform biomicroscopy OD and OS. Slit Lamp Classification Scales will be used to grade the findings. For the conjunctival redness [redacted]) 0.5 unit increments will be used in the grading. Corneal Staining Assessment ([redacted] will be graded in 1.0 increments.	[redacted]
15	Insertion of Study Lenses	Provide the subject with a new set of lenses that match the distance and ADD power of the lenses that were discarded in step 13 above. **Note: For lens accountability in EDC, add this new set of lenses to the total number dispensed on the Dispensing form.**	
16	PRO Questionnaires	The subject will complete the PRO post-fit questionnaire. **Note: Subject's Must respond to the Questionnaire in the KIOSK using their User Name and Password.**	Section 16.1

Visit 2: Treatment1 – Dispense2			
Step	**Descriptor**	**Details**	**Appendix**
1	Distance and Near Exit Visual Acuity	Distance and near Snellen visual acuity will be measured for each eye with the study contact lenses in place. For near measures use the ETDRS 2000 Series Chart 1 or 2. The acuity will be recorded to the nearest letter OD, OS and OU. **Note: The distance visual acuity must be at least 20/30 OU for the lenses to be dispensed.**	[redacted]
2	Dispensing Criteria	The lenses will be dispensed for 6-8 days. • Distance Snellen acuity equal to or better than 20/30 OU • Subject must indicate that the vision is acceptable. • Subject must indicate that the comfort of the lenses is acceptable. • Lenses must have an acceptable toric and general lens fit.	
3	Patient Instructions	Instruct the Subject the following: • The lenses will be worn on a daily wear basis and discarded at the end of each day. • Only enough lenses will be dispensed to the subject to wear for the required number of days until their follow-up visit. No additional lenses will be dispensed. • A new lens will be opened and worn each day. • No cleaning or disinfecting solutions will be used. If determined necessary by the Investigator sterile non-preserved rewetting drops may be dispensed to be used as needed for dryness. • Subjects will be instructed to wear lenses for a minimum of 6 hours a day, every day during the study. • Subjects will be instructed to wear their glasses when not wearing the study lenses. **Note: In the event a lens is lost or damaged, the subject will return to the investigator site for replacement. As much as reasonably possible, a damaged lens should be returned to the investigational site and then returned to the Sponsor. If lens damage is present, complete the Product Quality Complaint Form. The lens will be stored in labeled vial with sterile saline, and returned to the Sponsor.**	
4	Follow-up	The subject will be scheduled to return for their follow-up appointment in 7±1 day.	

[redacted]

Subjects must report to the visit wearing the study lenses

Visit 3: Treatment1 – FollowUp2			
Step	**Descriptor**	**Details**	**Appendix**
1	Concomitant Medication and Medical History Review	Confirm if there have been any changes in concomitant medications or health status since the last visit.	
2	Wear Time	Record the average hours the subject has worn the study lenses and the comfortable wear time.	
3	Compliance	Record compliance with the required wear time. Subjects must have worn lenses for at least 6 hours per day. ***Note: To be counted as a day of wear at this visit the Subject must have worn the study lenses for 6 hours prior to the visit.***	
4	Collection of Unworn lenses	If there are any unworn study lenses collect them from the subject.	
5	PRO Questionnaires and CLDEQ 8	The subject will evaluate the vision characteristics, comfort characteristics, handling characteristics, and visual symptoms of the study lenses using the PRO questionnaires. ***Note: Subject's Must respond to the Questionnaire in the KIOSK using their User Name and Password***	Section 16.1
6	Ocular Symptoms	If the subject reports ocular symptoms with the study lenses they will be recorded in the Subject Reported Ocular Symptom Questionnaire.	[redacted]
7	Subjective Acceptance	Record whether the subjects distance and near vision with the lenses is acceptable.	
8	Distance and Near Entrance Visual Acuity	Distance and near Snellen visual acuity will be measured for each eye with the study contact lenses in place. For near measures use the ETDRS 2000 Series Chart 1 or Chart 2. ***Note: The acuity will be recorded to the nearest letter OD, OS and OU.***	
9	Binocular Distance Over-refraction and Distance Visual Acuity	Perform a binocular over-refraction and record the OD and OS results and distance visual acuity. ***Note: No lens changes are allowed based on the over-refraction.***	Appendix D

[redacted]

10	Toric Fitting Assessment	Record the toric fit of the study lenses: • The rotational position to the nearest degree • Lens stability with blink • Lens stability with eye versions • Toric fit acceptable or unacceptable Toric lens fit will be unacceptable if lenses rotated more than 40 degrees, or lens stability is worse than 5 degrees movement with blink.	[redacted]
11	Lens Fit Assessment:	Evaluate and grade lens centration, primary gaze movement, upgaze movement and tightness (push-up test). An unacceptable lens fit will be any one or more of the following: • Presence of limbal exposure (appearance of clear cornea) any gaze • Presence of edge lift • Presence of unacceptable movement (excessive or insufficient) in all three movement categories (primary gaze, upgaze, and push-up).	[redacted]
12	Visual Performance Distance (3M) Intermediate (64cm) Near (40cm)	Visual performance will be recorded OD, OS, and OU for the following: **Distance, Bright Illuminance** *ETDRS Charts* 3M-HC#1, HC#2, HC#3 and LC#1, LC#2 and LC#3 **Near, Bright Illuminance** *Reduced Guillon-Poling charts* High Contrast and Low Contrast Intermediate (64cm) and Near (40cm). **Distance, Dim Illuminance (with *Distance* goggles)** *ETDRS Charts* 3M-HC#4, HC#5, HC#6 **Near, Dim Illuminance (with *Near* goggles)** *Reduced Guillon-Poling charts* High Contrast Intermediate (64cm) and Near (40cm). **Note:** **The room illuminance must be between 7.3 and 7.9 EV.** **Distance, HC-1 Chart luminance Acceptable EV Range 10.5-10.7.** **Guillon-Poling, Near Chart luminance Acceptable EV Range 10.8-11.1.** **Do not use the Mesopic filter for Dim luminance (Dim luminance will be simulated by using the goggles)**	[redacted]

[redacted]

13	Questionnaires	The subject will answer the product concept questions. **Note: Subject's Must respond to the Questionnaire in the KIOSK using their User Name and Password**	
14	Lens Removal	Have the Subject remove the study lenses and save in sterile saline in glass labeled vials, detailing the study number, subject number, subject global ID, date, eye the lens was worn on, and time of lens wear (in hours).	
15	Biomicroscopy	Perform biomicroscopy OD and OS. Slit Lamp Classification Scales will be used to grade the findings. For the conjunctival redness in CTP 2002 0.5 unit increments will be used in the grading. Corneal Staining Assessment [redacted] will be graded in 1.0 increments.	[redacted]

Step	Descriptor	Final Evaluation	Appendix
1	Distance Subjective Sphero-cylindrical Refraction and Distance Exit Visual Acuity	An optimal, binocular balanced distance sphero-cylindrical refraction will be performed. Record the refraction and distance visual acuity to the nearest letter.	[redacted]
2	Subject Interviews (PRA clinic only)	Subjects at the PRA clinic will be interviewed with regards to their experience with the study lenses.	Section 16.1
3	Subject Disposition	Indicate the subject completed the study successfully or not. For subjects who discontinue, indicate the reason.	

4.8 DISCONTINUATION CRITERIA

Johnson & Johnson Vision Care, Inc. reserves the right to terminate the study at any time for any reason. Additionally, the IRB/IEC reserves the right to terminate the study if an unreasonable risk is determined. The study may be terminated by the Principal Investigator or Medical Monitor due to specific clinical observations, if in their opinion it would be unwise to continue.

Johnson & Johnson Vision Care, Inc. will evaluate all adverse events. If it is determined that an adverse event presents an unreasonable risk, the investigation, or that part of the investigation presenting the risk, will be terminated, as soon as possible.

Should the study be terminated (either prematurely or as scheduled), the Investigator will notify the Institutional Review Board (IRB), and Regulatory Authority as required by local regulatory requirements.

4.9 ACCOUNTABILITY PROCEDURES FOR INVESTIGATIONAL PRODUCT AND CONTROL

Johnson & Johnson Vision Care, Inc. will provide the Investigator with sufficient quantities of study articles and supplies to complete the investigation. The Investigator is asked to retain all lens shipment documentation for the test article accountability records. The Investigator may provide the subject additional lenses in the event a lens is damaged or lost between visits.

Test articles must be kept in a locked storage cabinet, accessible only to those assigned by the Investigator for dispensing. All investigational products must be accounted. This includes 1) what was dispensed for the subject to wear out of the office or issued for the subject to replace appropriately between visits, 2) what was returned to the Investigator unused, and 3) the number and reason for unplanned replacements. The Investigator may delegate this activity to an authorized study site staff member on the Delegation Log.

The Investigator will collect all unused test articles from the subjects at the end of the subject's participation. Following final reconciliation of test articles, the Investigator will package and return all unused study articles to JJVC.

Reference APPENDIX A: TEST ARTICLE ACCOUNTABILITY IN THE EDC SYSTEM for additional instructions.

4.10 PROCEDURES FOR MAINTAINING AND BREAKING RANDOMIZATION CODES

The study lenses will be labeled using lens codes. It is not possible to mask the subjects as to the prescription type (i.e. astigmatism, spherical, multifocal) however the partial masking will occur as the subjects will not be informed of the identity of the test lens. The study lens mask shall not be broken unless information concerning the lens type is necessary for the urgent medical treatment of a subject. The Sponsor should be notified before the mask is broken.

As the study is a single ARM study there is no randomization.

4.11 REPORTING PRODUCT QUALITY COMPLAINTS

A Product Quality Complaint (PQC) refers to any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of test articles after they have been released for clinical trial use. A PQC is associated with any investigational product (i.e. product manufactured or supplied specifically for a clinical trial).

Complaint Handling

Once site personnel have become aware that a PQC has occurred, it shall then be recorded in the EDC system, which triggers an automatic email notification to the appropriate COM/CRA and Clinical QA representative. In cases where the EDC system in use is not configured to send automatic notifications, then the COM/CRA is responsible for notifying Clinical QA upon discovery that a PQC has occurred.

Upon receipt of the EDC notification the COM/CRA shall complete the applicable sections of the Product Quality Complaint Form [redacted]

For each complaint, the following minimum information shall be recorded by the CRA/COM on the Product Quality Complaint Form [redacted]

- Date the complaint was received/recorded in the EDC System (Date of Sponsor Awareness)
- Who received the complaint
- Study number
- Investigational site information (contact name, site ID, telephone number)
- Lot number(s)
- Unique Subject Identifier(s)
- Indication of who first observed complaint (site personnel or subject)
- OD/OS indication, along with whether or not the lens was inserted
- Any related AE number if applicable
- Detailed complaint description (scheduled/unscheduled visit, wear time, symptoms, resolution of symptoms, etc.)
- Eye Care Provider objective (slit lamp) findings if applicable
- Confirmation of product availability for return (and tracking information, if available), or rationale if product is not available for return [redacted]

Clinical QA will assign a unique number to the PQC. Complaint numbering is assigned as follows:

RDTC-XX-001, where RDTC = R&D Technical Complaint, XX = last two digits of the current year, 001 = sequential numbering starting with 001.

5.1 WITHDRAWAL CRITERIA

A subject will be withdrawn from the study for any of the following reasons:

- Lost to follow-up
- Withdrawal of consent
- Death
- Discontinuation of study treatment as a result of the investigator's clinical judgment that for safety reasons (e.g., adverse event) it is in the best interest of the subject to stop treatment.
- The subject becomes pregnant.

For discontinued subjects, the Investigator will:

- Update the enrollment log to document reason for discontinuation
- Complete the "last" Follow-up Visit form (scheduled or unscheduled)
- Complete the Final Evaluation form, indicating the reason that the subject was discontinued from the study
- Record the spherocylindrical refraction with best corrected distance visual acuity
- Collect used study lenses and test articles (worn or brought to the visit) from the subject and return to JJVC
- Collect all unused study lenses and test articles from the subject and return to JJVC

Subjects becoming pregnant during the study will be discontinued. Once discontinued, pregnant participants and their fetuses will not be monitored for study related purposes. At the Investigators' discretion, the study

participant may be followed by the Investigator through delivery. However, this data will not be collected as part of the clinical study database. Pregnant participants are not discontinued from contact lens or solution related studies for safety concerns, but due to general concerns relating to pregnancy and contact lens use. Specifically, pregnant women are discontinued due to fluctuations in refractive error and/or visual acuity that occur secondary to systemic hormonal changes, and not due to unforeseen health risks to the mother or fetus.

In cases where a subject is lost to follow-up, every possible effort must be made to contact the subject and determine the reason for discontinuation / withdrawal. The measures taken to follow up must be documented including two written attempts and a certified letter as the final attempt.

6.1 PRESTUDY AND CONCOMITANT THERAPY

Concomitant medications will be documented during screening and during the study. Disallowed medications for this study include: use of medications that contraindicate contact lens wear. Concomitant therapies that are disallowed include: therapies in which contact lens wear is contraindicated.

6.2 MONITORING TREATMENT COMPLIANCE

Johnson & Johnson Vision Care, Inc. representatives or designees will monitor the study in a manner consistent with ICH GCP E6. The study monitors will maintain close contact with the Principal Investigator and the Investigator's designated staff. The monitor's responsibilities will include:

- Ensuring that the investigation is being conducted according to the protocol
- Ensuring the rights and wellbeing of subjects are protected
- Ensuring that protocol deviations are documented with corrective action plans, as applicable
- Ensuring that the site has sufficient test article and supplies
- Clarifying questions regarding the study
- Resolving study issues or problems that may arise
- Reviewing the study records to ensure completeness and accuracy
- Study and subject source document records reviewed will include:
- The Information and Consent Form per 21CFR Parts 50 and 56 and the HIPAA documents
- Source documentation including consenting and HIPAA process, medical history, concomitant medications, and adverse event information as applicable. The source document should be initialed and dated by the study investigator/s.
- Investigational product shipping, dispensing, accountability, and return/destruction records
- Study related Regulatory documents as per ICH E3 section 8

Monitoring for this study will be specified in the monitoring plan which will be provided separately.

6.3 UNSCHEDULED VISITS

If, during the investigation, a subject experiences any investigational device-related difficulties and/or problems requiring an unscheduled visit to the clinic, the following information will be collected at a minimum:

- Chief complaint prompting the visit. If the reason is an adverse event, the applicable eCRF for the adverse event should be completed and source documentation completed as appropriate.
- Date and time of the visit and all procedures completed at the unscheduled visit

- Review of adverse event and concomitant medications
- Documentation of any investigational product dispensed or collected from the subject.
- Slit lamp findings (using the Slit Lamp Classification Scale)

If the Investigator withdraws a subject from the study, the final study visit case report forms must be completed indicating the reason(s) why the subject was withdrawn. The subject enrollment log should be completed documenting the date and primary reason for withdrawal and the study CRA notified.

Any investigational device-related difficulties and/or problems that are ongoing at the time of the final study visit will be followed by the Investigator, within licensure, until they have returned to pre-treatment status, stabilized, or been satisfactorily explained. If further treatment (i.e., beyond licensure) is required, the subject will be referred to the appropriate health care provider.

7.1 EFFICACY PARAMETERS

The efficacy parameter in this study is subjective assessment of quality of vision after wearing the optimized study lenses for 12 to 16 days.

7.2 METHODS FOR ASSESSING, RECORDING, AND ANALYZING EFFICACY

See detailed study procedures section 4.5 and statistics section 9.

8.1 SAFETY PARAMETERS

The following safety parameters will be monitored and evaluated:

- Ocular physiology characteristics
- Lens fitting characteristics
- Adverse events
- Ocular symptoms
- Snellen distance visual acuity
- Reasons for discontinuation
- Reasons for unplanned lens replacement
- Product Quality Complaints

Safety parameters will be tabulated using frequency distribution tables and descriptive statistics. Adverse events will be listed by subject/eye. There will be separate summary tables for adverse events and infiltrative adverse events. Statistical methods for analyzing safety data, if any, are provided in section 9.

8.2 ADVERSE EVENTS

Non-Serious Adverse Events:

All non-serious adverse events, including non-serious adverse device effects, will be reported to the sponsor by the Investigator no later than 2 days from discovery for review by the Medical Monitor.

Serious Adverse Events:

The Investigator will inform the sponsor of all serious adverse events occurring during the study period as soon as possible by e-mail, fax, or telephone, but no later than 24 hours following discovery of the event. The investigator is obligated to pursue and obtain information requested by the Sponsor in addition to that information reported on the CRF. All subjects experiencing a serious adverse event must be followed up and all outcomes must be reported.

When medically necessary, the investigator may break the randomization code to determine the identity of the treatment that the subject received. The Sponsor and study monitor should be notified prior to unmasking the test articles.

In the event of a serious adverse event, the investigator must:

- Notify the Sponsor immediately
- Obtain and maintain in the subject's file all pertinent medical records, information and medical judgment for colleagues who assisted in the treatment and follow-up of the subject
- Provide the Sponsor with a complete case history which includes a statement as to whether the event was or was not related to the use of the investigational test article
- Notify the IRB/IEC as required by the IRB/IEC reporting procedure according to national regulations

Unanticipated (Serious) Adverse Device Effect (UADE):

In the event of an Unanticipated (Serious) Adverse Device Effect (UADE), the Investigator will submit a report of the UADE to the Sponsor and IRB/IEC as soon as possible, but no later than 24 hours after the Investigator first learns of the effect. This report is in addition to the immediate notification mentioned above.

The Sponsor must conduct an evaluation of the UADE and must report the results of the evaluation to FDA, the IRB/IEC and participating investigators within 10 working days after the Sponsor first receives notification of the effect.

8.3 ADVERSE EVENT DEFINITIONS

Adverse Event (AE) – An AE is any untoward (unwanted) medical occurrence in a patient or clinical investigation subject administered a test article whether or not caused by the test article or treatment. An AE can therefore be any unfavorable or unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of the test article whether or not related to the test article.

An AE includes any condition (including a pre-existing condition) that: 1) was not present prior to study treatment, but appeared or reappeared following initiation of study treatment; or 2) was present prior to study treatment, but worsened during study treatment. This would include any condition resulting from concomitant illnesses, reactions to concomitant medications, or progression of disease states. Pregnancy should be documented as an adverse event and should be reported to the clinical monitor and to the Sponsor immediately upon learning of the event

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Serious Adverse Event (SAE) – An SAE is any untoward medical occurrence that:

- Results in death
- Is life threatening
- Requires in-patient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity (i.e., a significant persistent or permanent change, impairment, damage, or disruption to the subject's body)
- Is a congenital anomaly/birth defect, or
- Requires intervention to prevent permanent damage (the use of the investigational product resulting in a condition which requires medical or surgical intervention to preclude permanent impairment of the body structure or a body function). Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in the above definition.

Diagnoses and conditions that are considered Serious Adverse Events include:

- Microbial Keratitis (MK)
- Iritis
- Permanent decrease in best spectacle corrected visual acuity equivalent to 2 acuity lines or greater
- Central Corneal Opacity
- Central Corneal Neovascularization
- Uveitis
- Endophthalmitis
- Hypopyon
- Hyphemia
- Penetration of Bowman's Membrane
- Persistent Epithelial Defect
- Limbal cell Damage leading to Conjunctivalization

Significant Adverse Events – Those events that are usually symptomatic and warrant discontinuation (temporary or permanent) of the test article (excluding Serious Adverse Events). Diagnoses and conditions that are considered Significant Adverse Events include the following:

- Contact Lens Induced Peripheral Ulcer (CLPU)
- Significant Infiltrative Events (SIE)
- Superior Epithelial Arcuate Lesions (SEALs)
- Any Temporary Loss of > 2 Lines of BSCVA
- Other grade 3 or higher corneal findings, such as abrasions or edema
- Any corneal event which necessitates temporary lens discontinuation > 2 weeks
- Non-contact lens related corneal events - e.g. EKC (Epidemic Keratoconjunctivitis)
- Asymptomatic Corneal Scar

Non-Significant Adverse Events – Those conditions that are usually asymptomatic and usually do not warrant discontinuation (temporary or permanent) of the test article. However, the Investigator may choose to treat as a precautionary measure. Diagnoses and conditions that are considered Non-Significant Adverse Events include the following:

- Non-significant Infiltrative Event
- Contact Lens Papillary Conjunctivitis
- Superficial Punctate Keratitis
- Conjunctivitis: Bacterial, Viral, Allergic
- Blepharitis
- Meibomianitis
- Contact Dermatitis
- Localized Allergic Reactions
- Any corneal event not explicitly defined as serious or significant adverse event, which necessitates temporary lens discontinuation < 2 weeks

Adverse Device Effect (ADE) – A sub-set of AEs, and include only those adverse events that are cause by or related to the investigational device or study procedure.

Unanticipated Adverse Device Effect (UADE) – Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, the test article, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan, investigator's brochure or protocol, or any other unanticipated serious problem associated with the test article that relates to the rights, safety and welfare of subjects.

Causality Assessment – A determination of the relationship between an adverse event and the test article. The test article relationship for each adverse event should be determined by the investigator using these explanations:

- Not Related- An adverse event that is not related to the use of the test article.
- Doubtful – An adverse event for which an alternative explanation is more likely, e.g. concomitant treatment, concomitant disease(s), or the relationship of time suggests that a causal relationship is not likely.
- Possible – An adverse event that might be due to the use of the test article. An alternative explanation, e.g. concomitant treatment, concomitant disease(s), is inconclusive. The relationship in time is reasonable. Therefore, the causal relationship cannot be excluded.
- Probable – An adverse event that might be due to the use of the test article. The relationship in time is suggestive (e.g. confirmed by de-challenge). An alternative explanation is less likely, e.g. concomitant treatment or concomitant disease(s).
- Very Likely – An adverse event that is listed as a possible adverse effect (device) or adverse reaction (drug) and cannot be reasonably explained by an alternative explanation, e.g. concomitant treatment of concomitant disease(s). The relationship in time is very suggestive, e.g. it is confirmed by de-challenge and re-challenge.

Severity Assessment – A qualitative assessment of the degree of intensity of an adverse event as determined by the investigator or reported to him/her by the subject. The assessment of severity is made irrespective of test article relationship or seriousness of the event and should be evaluated according to the following scale:

- Mild – Event is noticeable to the subject, but is easily tolerated and does not interfere with the subject's daily activities.
- Moderate – Event is bothersome, possible requiring additional therapy, and may interfere with the subject's daily activities.
- Severe – Event is intolerable, necessitates additional therapy or alteration of therapy and interferes with the subject's daily activities.

8.4 METHODS FOR ASSESSING, RECORDING, AND ANALYZING SAFETY

The recording and documenting of adverse events (ocular and non-ocular) begin when the subjects are exposed to the test article or study treatment. Adverse events reported before the use of test article or start of study treatment should be recorded as medical history. Untoward medical events reported after the subject's exit from the study will be recorded as adverse events at the discretion of the Investigator.

All adverse events observed by the Investigator; reported by the subject spontaneously; or in response to direct questioning; will be recorded in the source document. Such documentation will include a description of the adverse event, time of onset, duration of event, treatment regimen instituted, any referral to another health care provider (if needed), any new concomitant medications, outcome, ocular damage (if any), and likely etiology. Best Corrected Visual Acuity (BCVA) should be recorded prior to the report of an adverse event (as part of the baseline evaluation), upon report of the subject's report of the adverse event, and after the adverse event has resolved. All adverse events will be followed in accordance with licensing requirements.

All adverse events will be documented in the appropriate section of the subject's Case Report Form (CRF).

In conjunction with the medical monitor, the Investigator will evaluate adverse events to ensure the events are categorized correctly. Elements of categorization will include:

Seriousness (see definition in Section 8.3)

Expectedness – i.e. if the event was unexpected or unanticipated in that it was not previously identified in nature, severity, or degree of incidence (see definition in Section 8.3)

Causality or Relatedness – i.e. the relationship between the test article and the adverse event (not related; doubtful; possible; probable; very likely - see definition in Section 8.3)

Adverse Event Intensity or Classification – Adverse event intensity is used to assess the degree of intensity of the adverse event (mild, moderate, severe for all events). In addition adverse event Classification is used to assess the severity of ocular adverse events (AE not requiring treatment, non-significant or significant see definition in Section 7.4).

Outcome – Fatal, not resolved, resolved, resolved with sequelae, resolving and unknown.

Actions Taken – None, temporarily discontinued, permanently discontinued, other action taken

Upon finding an adverse event, the Principal Investigator will document the condition on the follow-up visit worksheet source document and in the CRF's using photos or drawings (where appropriate) that detail size, location, and depth. He will also complete the Adverse Event Classification (AEC) Discovery form / eCRF. In addition, if an infiltrate(s) is present, he will complete the Corneal Infiltrate Assessment Form / eCRF. Where necessary, a culture of the corneal lesion will be collected to determine if the infection is microbial in nature. If cultures are collected, a source document note should be completed specifying the date of culture collection and laboratory utilized. An eCRF documenting this should be completed in a comment or unscheduled visit.

Complete description of all adverse events must be available in the source documents. All Adverse Events including local and systemic reactions not meeting the criteria for "serious adverse events" should be captured on the appropriate case report form or electronic data system. Information to be recorded, based on above assessment criteria, includes date site notified, event description, date and time of onset, investigator assessment of severity, relationship to Study Agent(s)/Intervention(s), and time of resolution/stabilization of the event. All adverse events occurring while on study must be documented appropriately regardless of relationship. Define a timeframe for CRF completion and entry of the adverse event information into the database, as applicable.

Any medical condition that is present at the time that the subject is screened should be considered as baseline and not recorded as an AE. However, if the condition deteriorates at any time during the study it should be recorded and reported as an AE.

Changes in the severity of an AE should be documented to allow an assessment of the duration of the event at each level of intensity to be performed. Adverse events characterized as intermittent require documentation of the onset and duration of each episode. Changes in the assessment of relationship to the Study Agent(s)/Interventions should also be clearly documented.

The investigator will notify the Sponsor of an adverse event by e-mail, facsimile, or telephone as soon as possible and no later than 24 hours from discovery for a serious / significant adverse event, and 2 days from discovery for a non-significant adverse event. In addition, a written report will be submitted by the Principal Investigator to the IRB/IEC according to their requirements (Section 1212.3). Such a report should comment whether or not the adverse event was considered to be related to the test article.

8.5 ADVERSE EVENTS FOLLOW-UP

It is the Investigator's responsibility to maintain documentation of each reported adverse event. All adverse events will be followed in accordance with applicable licensing requirements. Such documentation will include the following:

- Adverse Event (Diagnosis not symptom)
- Detailed drawings or photographs, when appropriate
- Date and time of onset
- Date and time of resolution
- Adverse event intensity and classification, as applicable
- Treatment regimen instituted, including concomitant medications prescribed, in accordance with applicable licensing requirements
- Any referral to another health care provider if needed
- Outcome, ocular damage (if any)
- Likely etiology.

- Best corrected visual acuity at the discovery of the event and upon conclusion of the event

In addition, if an infiltrate(s) is present, the Investigator will complete the Corneal Infiltrate Assessment Form / eCRF.

Photographs or video recordings may be collected at the Investigator's discretion for purposes of documenting adverse event findings.

Visual acuity (best corrected) should be recorded prior to the report of an adverse event (as part of the Baseline Evaluation), upon the subject's report of the adverse event, and after the adverse event has resolved.

Subjects who present with adverse events should be followed by the Investigator, within licensure, until all signs and symptoms have returned to pre-treatment status, stabilized, or been satisfactorily resolved. If further treatment (i.e. beyond licensure) is required, the patient will be referred to the appropriate health care provider. The Investigator should use his/her clinical judgment as to whether or not a subject (eye) reporting with an adverse event should continue in the study. If a subject is discontinued from the study, it will be the responsibility of the Investigator to record the reason for discontinuation. The investigator will also complete the Adverse Event Classification (AEC) Outcome form / eCRF. Any subjects with ongoing adverse events related to the test article as of the final study visit date should be followed to resolution of the adverse event or until referral to an appropriate health care provider, as recommended by the Investigator.

9.1 STATISTICAL METHODS TO BE EMPLOYED

All data summaries and statistical analyses will be performed using the SAS software Version 9.4 (SAS Institute, Cary, NC). Throughout the analysis of data, the results for each subject/eye will be used when available for summarization and statistical analysis. Unscheduled visits will be summarized separately and will be excluded from the statistical analysis.

Summary tables (Descriptive statistics and/or frequency tables) will be provided for all baseline variables, efficacy variables and safety variables as appropriate. Continuous variables will be summarized with descriptive statistics (n, mean, standard deviation (SD), median, minimum and maximum). Frequency count and percentage of subjects or eyes within each category will be provided for categorical data.

Summaries will be presented by study lens type and will be performed separately by completion status (Completed or Non Completed). All analyses will be conducted on all subjects who completed the study (see section 9.7).

Primary Endpoint:

Overall quality of vision scores will be analyzed using a linear mixed model. The model will include the experimental design factors: time point (baseline/follow-up) as fixed effects. Other baseline characteristics known of importance such as age, gender, and/or add power will be included as fixed covariates when appropriate. Site will be included as random covariates when appropriate. The covariance between residual errors from the same subject across time points will be selected based on the finite-sample corrected Akaike's Information Criterion (Keselman et al. 1998). Covariance structures considered may include: Homogenous compound symmetry (CS) and Unstructured covariance structure (UN). The structure that returns the lowest Akaike Information Criteria Corrected (AICC) will be selected as the structure that best fit the data.

Comparisons between the time points will be carried out using 95% confidence intervals constructed of least-square means (LSM) differences (follow-up minus baseline) from the linear mixed model. The non-inferiority of the

test lens relative to the control will be concluded if the lower confidence limit of LSM difference is above the non-inferiority margin -5. The superiority will be established if the lower confidence limit is above 0.

In all models, the Kenward and Roger method (Kenward and Roger, 1997) will be used for the calculation of the denominator of degrees of freedom.

9.2 NUMBER OF SUBJECTS BY SITE AND JUSTIFICATION FOR SAMPLE SIZE

Approximately 60 eligible subjects will be enrolled and approximately 48 subjects are targeted to complete the study. Data from historical study CR 5758 and CR 5765 were used as the bench mark for sample size calculation because it tested the same population with the same study design and test article.

Using the POWER procedure in SAS 9.4, below is the summary of sample size required based on the different assumptions of the true difference. Each study hypothesis is tested with at least 90% of statistical power and 2-sided type I error of 0.05.

Several scenarios were listed in the table below to allow variations in the upcoming clinical trial:

Difference (FU-Baseline)	Standard Deviation	# of subjects needed	Power
2	19	65	0.9
3	19	50	0.9
4	19	40	0.9

9.3 LEVEL OF STATISTICAL SIGNIFICANCE

All planned analysis for this study will be conducted with an overall type I error rate of 5%.

9.4 CRITERIA FOR STUDY TERMINATION

In addition to the stopping rules defined in section 9.1, the occurrence of one or more Serious Unanticipated Adverse Device Effect (USADE), or any SAE where the relationship to study agent cannot be ruled out, may result in stopping further dispensing of investigational product. In the event of a USADE or SAE, the Sponsor may unmask the treatment regimen for the subject(s) and may discuss this with the Investigator before any further subjects are enrolled.

The sponsor may determine when a study will be stopped. The principal investigator always has the discretion to initiate stopping the study based on subject safety or if information indicates the study's results may be compromised.

9.5 PROCEDURE FOR ACCOUNTING FOR MISSING, UNUSED, AND SPURIOUS DATA

Missing or spurious values will not be imputed. The count of missing values will be included in the summary tables and listings. If the percent of dropout is higher than 15% a sensitivity analysis will be conducted on all subjects who successfully tried at least one study lens.

9.6 PROCEDURE FOR REPORTING DEVIATIONS FROM STATISTICAL PLAN

The analysis will be conducted according to section 9.1. There are no known reasons for which it is planned to deviate from these analysis methods. If for any reason a change is made, the change will be documented in the study report along with a justification for the change.

9.7 EVALUABLE SUBJECTS

Subjects will be allocated to one of the three mutually exclusive groups:

1. Enrolled, Not Assigned: Subjects were considered to be Enrolled Not Eligible if they are (i) enrolled to the study (i.e. provided informed consent) but failed to satisfy the eligibility criteria (i.e. inclusion/exclusion criteria) or (ii) are not assigned to treatment for any reason.

2. Assigned, Not Completed: Subject are considered to have not completed the study from the study if they (i) were discontinued because of one the reasons described in section 5.1 or (ii) have successfully completed all required visits with a protocol deviation that the study responsible clinician documents as impacting the assessment of the hypotheses

3. Assigned, Completed: Subject are considered to have completed the study if (i) they are eligible, (ii) not discontinued (iii) have successfully completed all required visits without a protocol deviation that the study responsible clinician documents as impacting the assessment of the hypotheses.

10.1 ELECTRONIC CASE REPORT FORM/DATA COLLECTION

The data for this study will be captured on electronic case report forms (eCRFs) using an EDC system when possible. Designated study site personnel will enter study data into the electronic CRFs (eCRFs) using the EDC system. Data collected on equipment that is not possible to be captured in EDC will be formatted to the specification of the JJVC database manager and sent to JJVC for analysis. Data generated from post hoc measurements (e.g. Compositional characteristics of contact lens lipid uptake, Measured tear film protective capability, Measured contact lens surface dehydration rate) will be collected on specific Microsoft Office Excel format worksheets at the clinical site and at the completion of the analysis transferred to JJVC biostatistician for data analysis in such format.

External Data Source: Not Applicable or, if External Data is collected outside of EDC, please enter vendor contact information in this section of the protocol and type of external data collected.

Vendor Name: NA
Vendor Address: NA
Vendor Contact: NA
Phone: NA
Email: NA
Type of Data collected: NA

The CRFs will be reviewed for accuracy and completeness and signed by the investigator. Unless otherwise stated, the eCRFs will be considered the source document. The sponsor or sponsor‘s representatives will be authorized to gain access to the source documentation for the purposes of monitoring and auditing the study.

Edit checks, electronic queries, and audit trails are built into the system to ensure accurate and complete data collection. Data will be transmitted from the investigational site to a secure central database as forms are

completed or updated, ensuring information accuracy, security, and confidentiality. After the final database lock, the Investigator will be provided with Individual Patient Profiles (IPP) including the full audit trail on electronic media in a non-editable format for all of the study data. The IPP should be retained in the study files as a certified copy of the source data for the study.

The content and structure of the CRFs are compliant with ISO14155:2011 [3].

10.2 SOURCE DOCUMENTATION

At a minimum, source documentation should be available for the following to confirm data collected in the CRF: subject identification, eligibility, and study identification; study discussion, provision of and date of informed consent; visit dates; results of safety and efficacy parameters as required by the protocol; a record of all adverse events; follow-up of adverse events; concomitant medication; investigational product receipt / dispensing / return records; study investigational product administration information; date of study completion; reason for early discontinuation of investigational product or withdrawal from the study, if applicable.

The author of an entry in the source documents must be identifiable. Adverse event notes should be reviewed and initialed by the Investigator.

At a minimum, the type and level of detail of source data available for a study subject should be consistent with that commonly recorded at the site as a basis for standard medical care. Specific details required as source data for the study will be reviewed with the investigator before the study and will be described in the monitoring guidelines (or other equivalent documents).

10.3 ACCESS TO SOURCE DATA/DOCUMENT

The Investigator(s) / Institution(s) will permit trial-related monitoring, audits, IRB/IEC review and regulatory inspection(s) by providing direct access to source data / documents. Should the clinical site be contacted for an audit by an IRB/IEC or regulatory authority, JJVC should be contacted and notified in writing within 24 hours.

10.4 CONFIDENTIALITY OF INFORMATION

Information concerning the investigational product and patent application processes, scientific data or other pertinent information is confidential and remains the property of JJVC. The Investigator may use this information for the purposes of the study only. It is understood by the Investigator that JJVC will use information developed in this clinical study in connection with the development of the investigational product and therefore may disclose it as required to other clinical investigators and to regulatory agencies. In order to allow the use of the information derived from this clinical study, the Investigator understands that he/she has an obligation to provide complete test results and all data developed during this study to the Sponsor.

The Investigator may not submit for publication or presentation the results of this study without first receiving written authorization from JJVC. JJVC agrees that, before it publishes any results of the study, it shall provide the Investigator with at least 30 days for review of the pre-publication manuscript prior to the submission of the manuscript to the publisher.

11.1 DATA QUALITY ASSURANCE

Steps to be taken to ensure the accuracy and reliability of data include the selection of qualified investigators and appropriate study sites and review of protocol procedures with the principal investigator. The principal investigator, in turn, must ensure that all sub-investigators and study staff are familiar with the protocol and all study-specific procedures and have appropriate knowledge of the study article.

Guidelines for case report form completion will be provided and reviewed with study personnel before the start of the study. The sponsor, Johnson & Johnson Vision Care, Inc. will review case report forms for accuracy and completeness remotely during the course of the study, during on-site monitoring visits and after transmission to data management. Any data discrepancies will be resolved with the investigator or designee, as appropriate.

Quality Assurance representatives from Johnson & Johnson Vision Care, Inc. may visit study sites to review data produced during the study and to access compliance with applicable regulations pertaining to the conduct of clinical trials. The study sites will provide direct access to study-related source data/documents and reports for the purpose of monitoring and auditing by Johnson & Johnson Vision Care, Inc. and for inspection by local and regulatory authorities.

12.1 STUDY-SPECIFIC DESIGN CONSIDERATIONS

Potential subjects will be fully informed of the risks and requirements of the study and, during the study, subjects will be given any new information that may affect their decision to continue participation. They will be told that their consent to participate in the study is voluntary and may be withdrawn at any time with no reason given and without penalty or loss of benefits to which they would otherwise be entitled. Only subjects who are fully able to understand the risks, benefits, and potential adverse events of the study, and provide their consent voluntarily will be enrolled.

12.2 INVESTIGATOR RESPONSIBILITY

The Investigator is responsible for ensuring that the clinical study is performed in accordance with the protocol, Section 4 of the ICH E6 guidelines on Good Clinical Practice (GCP), and applicable regulatory requirements. GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting studies that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of study subjects are protected, consistent with the principles of the Declaration of Helsinki 64th WMA General Assembly 2013 and that the clinical study data are credible. The Investigator must maintain clinical study files in accordance with Section 8 of the ICH E6 guidelines on Good Clinical Practice (GCP), and applicable regulatory requirements.

12.3 INDEPENDENT ETHICS COMMITTEE OR INSTITUTIONAL REVIEW BOARD (IEC/IRB)

Before the start of the study, the Investigator (or Sponsor when applicable) will provide the IEC/IRB with current and complete copies of the following documents (where applicable):

- final protocol and, if applicable, amendments
- Sponsor-approved informed consent form (and any other written materials to be provided to the subjects)
- Investigator's Brochure (or equivalent information) and amendments
- Sponsor-approved subject recruitment materials

- information on compensation for study-related injuries or payment to subjects for participation in the study, if applicable
- Investigator's curriculum vitae, clinical licenses, or equivalent information (unless not required, as documented by IEC/IRB)
- information regarding funding, name of the Sponsor, institutional affiliations, other potential conflicts of interest, and incentives for subjects
- any other documents that the IEC/IRB requests to fulfill its obligation

This study will be undertaken only after IEC/IRB has given full approval of the final protocol, amendments (if any), the informed consent form, applicable recruiting materials, and subject compensation programs, and the Sponsor has received a copy of this approval. This approval letter must be dated and must clearly identify the documents being approved.

During the study the Investigator (or Sponsor when applicable) will send the following documents to the IEC/IRB for their review and approval, where appropriate:

- protocol amendments
- revision(s) to informed consent form and any other written materials to be provided to subjects if applicable, new or revised subject recruiting materials approved by the Sponsor
- revisions to compensation for study-related injuries or payment to subjects for participation in the study, if applicable
- Investigator's Brochure amendments or new edition(s)
- summaries of the status of the study (at least annually or at intervals stipulated in guidelines of the IEC/IRB)
- reports of adverse events that are serious, unanticipated, and associated with the investigational product, according to the IRB's requirements
- new information that may adversely affect the safety of the subjects or the conduct of the study
- major protocol deviations as required by the IEC/IRB
- report of deaths of subjects under the Investigator's care
- notification if a new investigator is responsible for the study at the site
- any other requirements of the IEC/IRB

For protocol amendments that increase subject risk, the amendment and applicable informed consent form revisions must be submitted promptly to the IEC/IRB for review and approval before implementation of the change(s).

At least once a year, the IEC/IRB will be asked to review and reapprove this clinical study. This request should be documented in writing.

At the end of the study, the Investigator (or Sponsor where required) will notify the IEC/IRB about the study completion. Documentation of this notification must be filed in the study Investigator binder and a copy provided to the CRO or Sponsor as applicable.

12.4 INFORMED CONSENT

Each subject must give written consent according to local requirements after the nature of the study has been fully explained. The consent form must be signed before performance of any study-related activity. The consent form that is used must be approved by both the Sponsor and by the reviewing IEC/IRB. The informed consent should be in accordance with principles that originated in the Declaration of Helsinki, current ICH and GCP guidelines, applicable regulatory requirements, and sponsor policy.

Before entry into the study, the Investigator or an authorized member of the investigational staff must explain to potential subject the aims, methods, reasonably anticipated benefits, and potential hazards of the study, and any discomfort it may entail. Subjects will be informed that their participation is voluntary and that they may withdraw consent to participate at any time. They will be informed that choosing not to participate will not affect the care the subject will receive. Finally, they will be told that the Investigator will maintain a subject identification register for the purposes of long-term follow-up if needed and that their records may be accessed by health authorities and authorized sponsor staff without violating the confidentiality of the subject, to the extent permitted by the applicable law(s) or regulations. By signing the informed consent form the subject is authorizing such access, and agrees to be contacted after study completion, by health authorities and authorized sponsor staff, for the purpose of obtaining consent for additional safety evaluations if needed.

The subject will be given sufficient time to read the informed consent form and the opportunity to ask questions. After this explanation and before entry into the study, consent should be appropriately recorded by means of the subject's dated signature. After having obtained the consent, a copy of the informed consent form must be given to the subject.

In the event additional investigators / sites are added to the protocol, the informed consent will be modified to include the Investigator’s name, address, phone number and 24-hour emergency number.

12.5 PRIVACY OF PERSONAL DATA

The collection, processing and disclosure of personal data and medical information related to the Study Subject, and personal data related to Principal Investigator and any investigational staff (e.g., name, clinic address and phone number, curriculum vitae) is subject to compliance with the Data Protection Act of 1998 and other applicable personal data protection and security laws and regulations. Appropriate measures will be employed to safeguard these data, to maintain the confidentiality of the person’s related health and medical information, to properly inform the concerned persons about the collection and processing of their personal data, to grant them reasonable access to their personal data and to prevent access by unauthorized persons.

All information obtained during the course of the investigation will be regarded as confidential. All personal data gathered in this trial will be treated in strictest confidence by investigators, monitors, Sponsors personnel and independent ethics committee. No data will be disclosed to any third party without the express permission of the subject concerned, with the exception of sponsor personnel (monitor, auditor), independent ethics committee and regulatory organizations in the context of their investigation related activities that, as part of the investigation will have access to the CRFs and source documents.

The collection and processing of personal data from subjects enrolled in this study will be limited to those data that are necessary to investigate the efficacy, safety, quality, and utility of the investigational product(s) used in this study.

These data must be collected and processed with adequate precautions to ensure confidentiality and compliance with applicable data privacy protection laws and regulations.
The Sponsor ensures that the personal data will be:

- processed fairly and lawfully
- collected for specified, explicit, and legitimate purposes and not further processed in a way incompatible with these purposes
- adequate, relevant, and not excessive in relation to said purposes
- accurate and, where necessary, kept current

Explicit consent for the processing of personal data will be obtained from the participating subject before collection of data. Such consent should also address the transfer of the data to other entities and to other countries.

The subject has the right to request through the Investigator access to his personal data and the right to request rectification of any data that are not correct or complete. Reasonable steps should be taken to respond to such a request, taking into consideration the nature of the request, the conditions of the study, and the applicable laws and regulations.

Appropriate technical and organizational measures to protect the personal data against unauthorized disclosures or access, accidental or unlawful destruction, or accidental loss or alteration must be put in place. Sponsor personnel whose responsibilities require access to personal data agree to keep the identity of study subjects confidential

13.1 DATA HANDLING AND RECORD KEEPING

In compliance with the ICH/GCP guidelines, the Investigator / Institution will maintain all CRFs and all source documents that support the data collected from each subject, as well as all study documents as specified in ICH/GCP Section 8, Essential Documents for the Conduct of a Clinical Trial, and all study documents as specified by the applicable regulatory requirement(s). The Investigator / Institution will take measures to prevent accidental or premature destruction of these documents.

Essential documents must be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents will be retained for a longer period if required by the applicable regulatory requirements or by an agreement with the Sponsor. It is the responsibility of the Sponsor to inform the Investigator / Institution as to when these documents no longer need to be retained.

If the responsible Investigator retires, relocates, or for other reasons withdraws from the responsibility of keeping the study records, custody must be transferred to a person who will accept the responsibility. The Sponsor must be notified in writing of the name and address of the new custodian. Under no circumstance shall the Investigator relocate or dispose of any study documents before having obtained written approval from the Sponsor.

If it becomes necessary for the Sponsor or the appropriate regulatory authority to review any documentation relating to this study, the Investigator must permit access to such reports.

If the Investigator has a question regarding retention of study records, he should contact JJVC Research and Development.

14.1 FINANCIAL CONSIDERATIONS

Remuneration for study services and expenses will be set forth in detail in the Investigator's Research Agreement. The Research Agreement will be signed by the Principal Investigator and a Johnson & Johnson Vision Care management representative prior to study initiation.

Case Report Forms will be completed in real time according to the study procedures specified in the study protocol. Case Report Forms should be completed and reviewed and signed as applicable by the Investigator within 3 days of visit completion. Data queries must be addressed with complete responses within 3 days of generation. Johnson & Johnson Vision Care reserves the right to withhold remuneration until these activities are addressed.

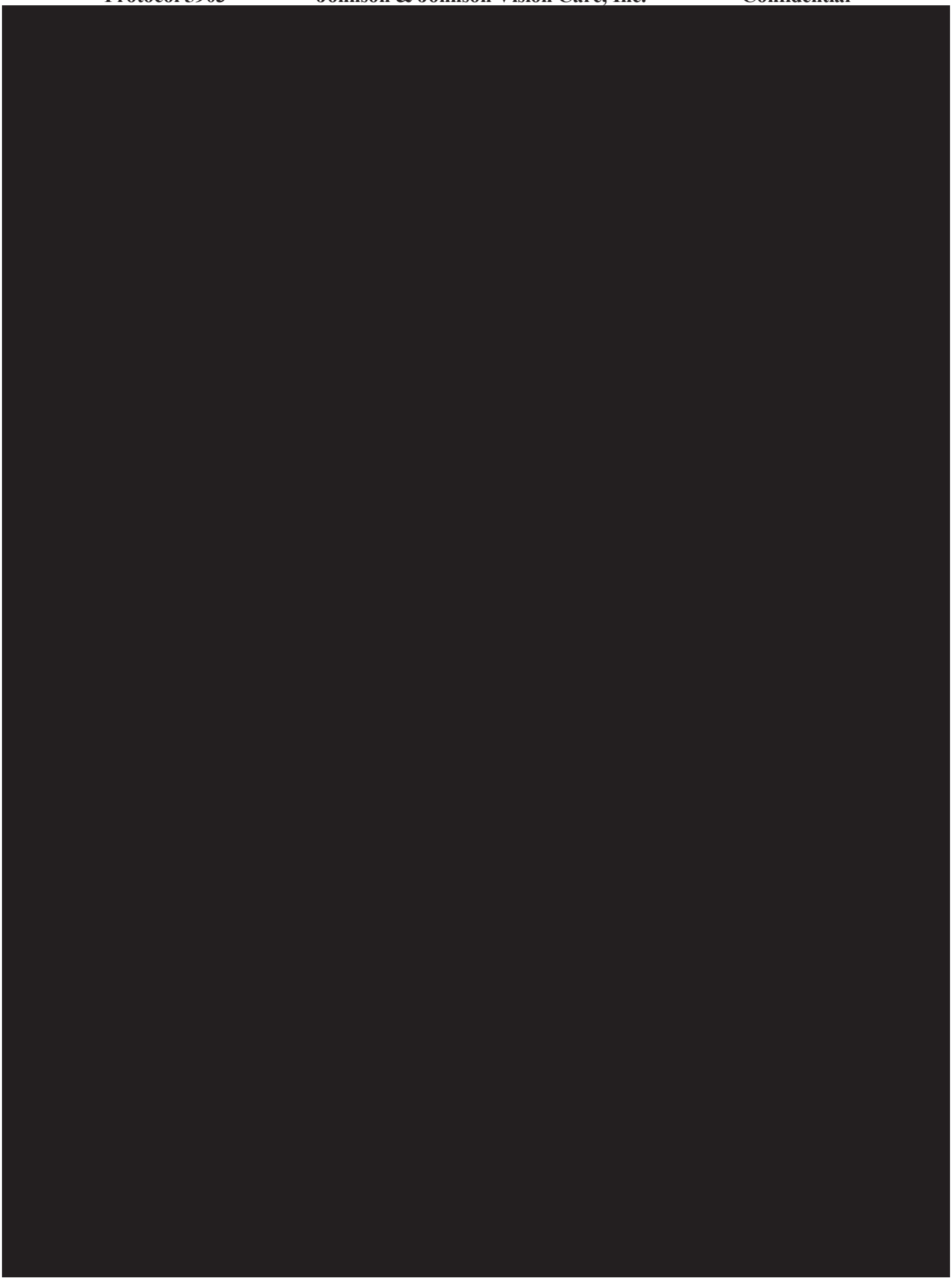
Johnson & Johnson Vision Care reserves the right to withhold remuneration for costs associated with protocol violations such as:

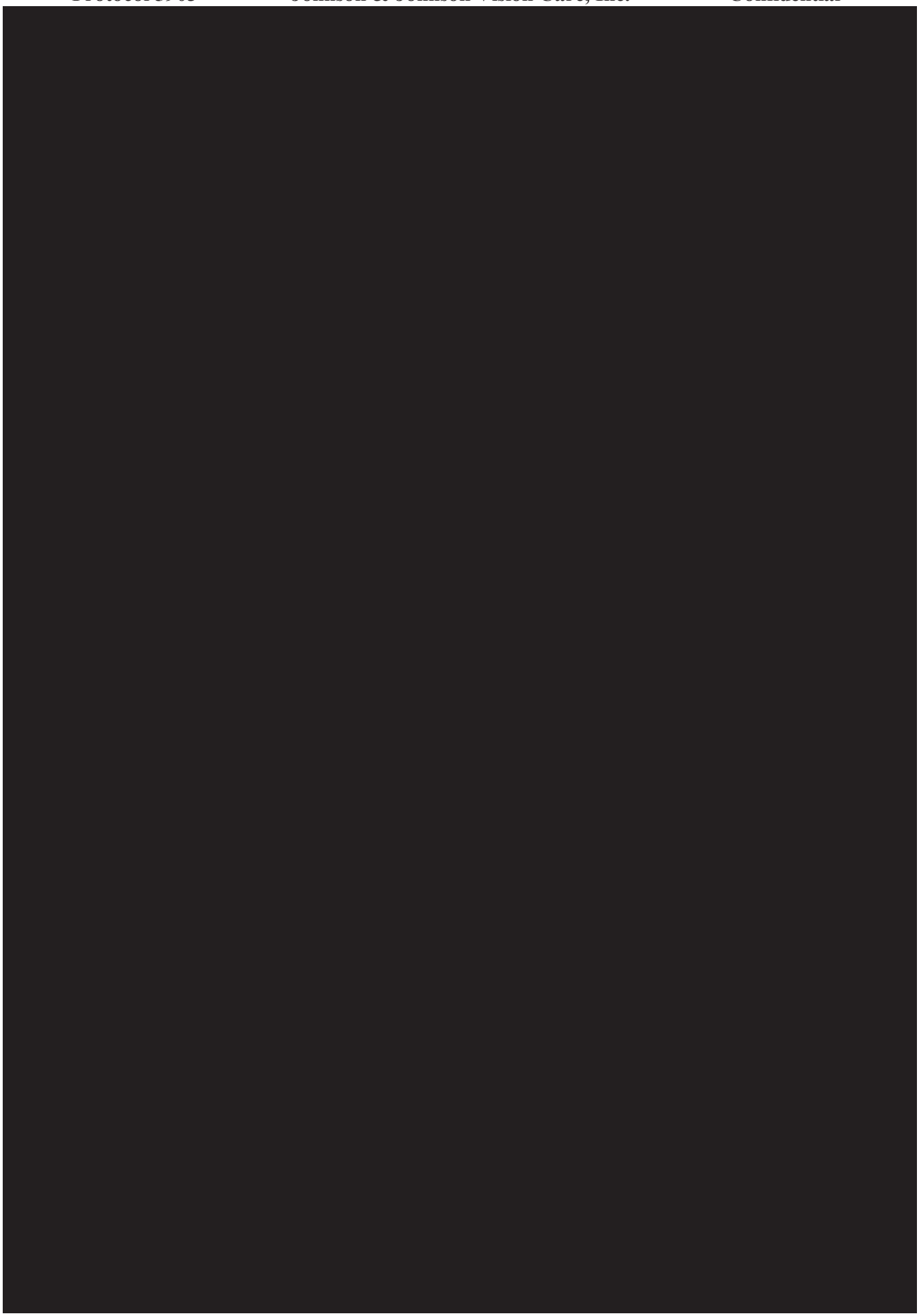
- Continuing an ineligible subject in the study
- Scheduling a study visit outside the subject's acceptable visit range

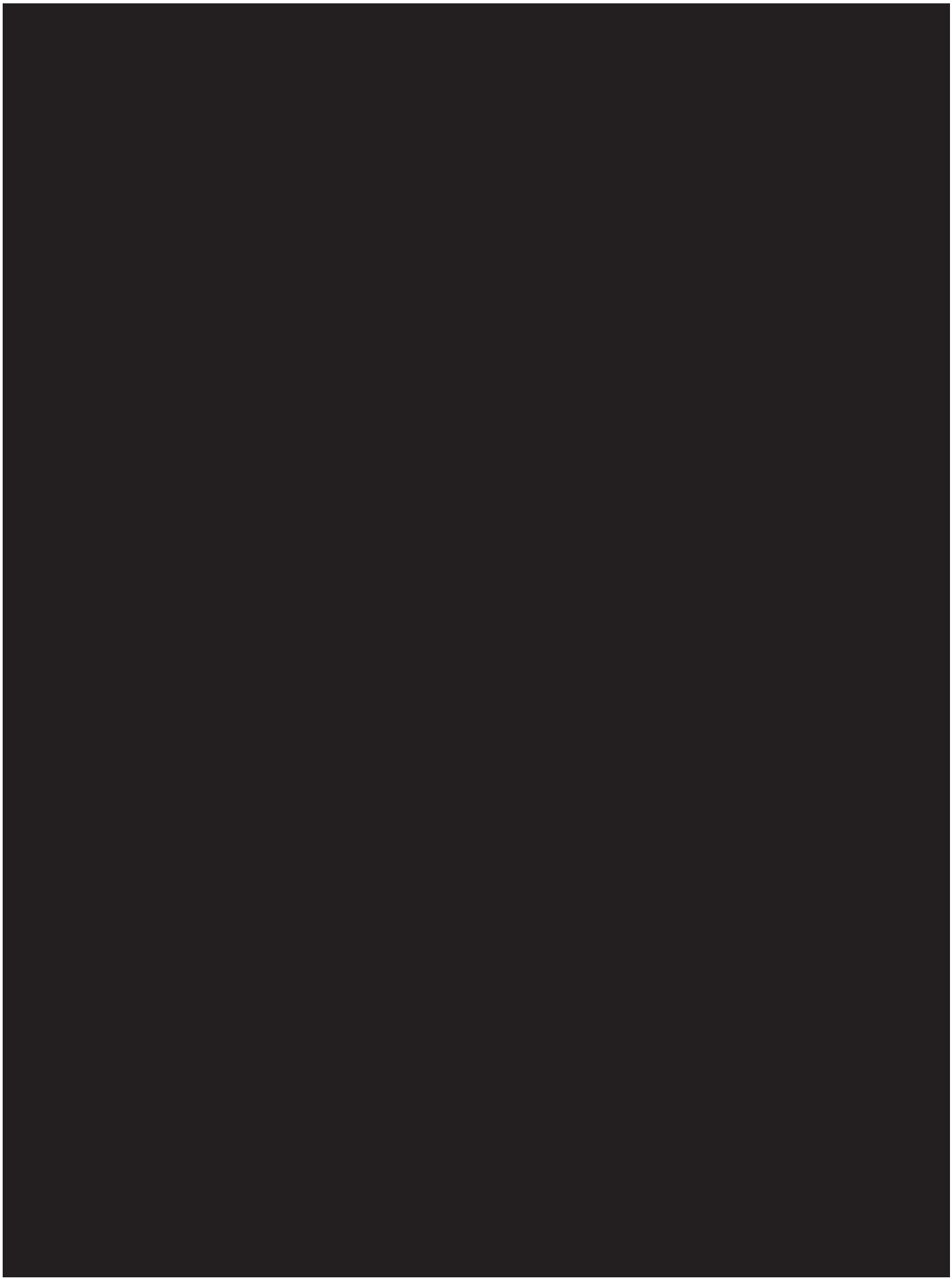
15.1 PUBLICATION

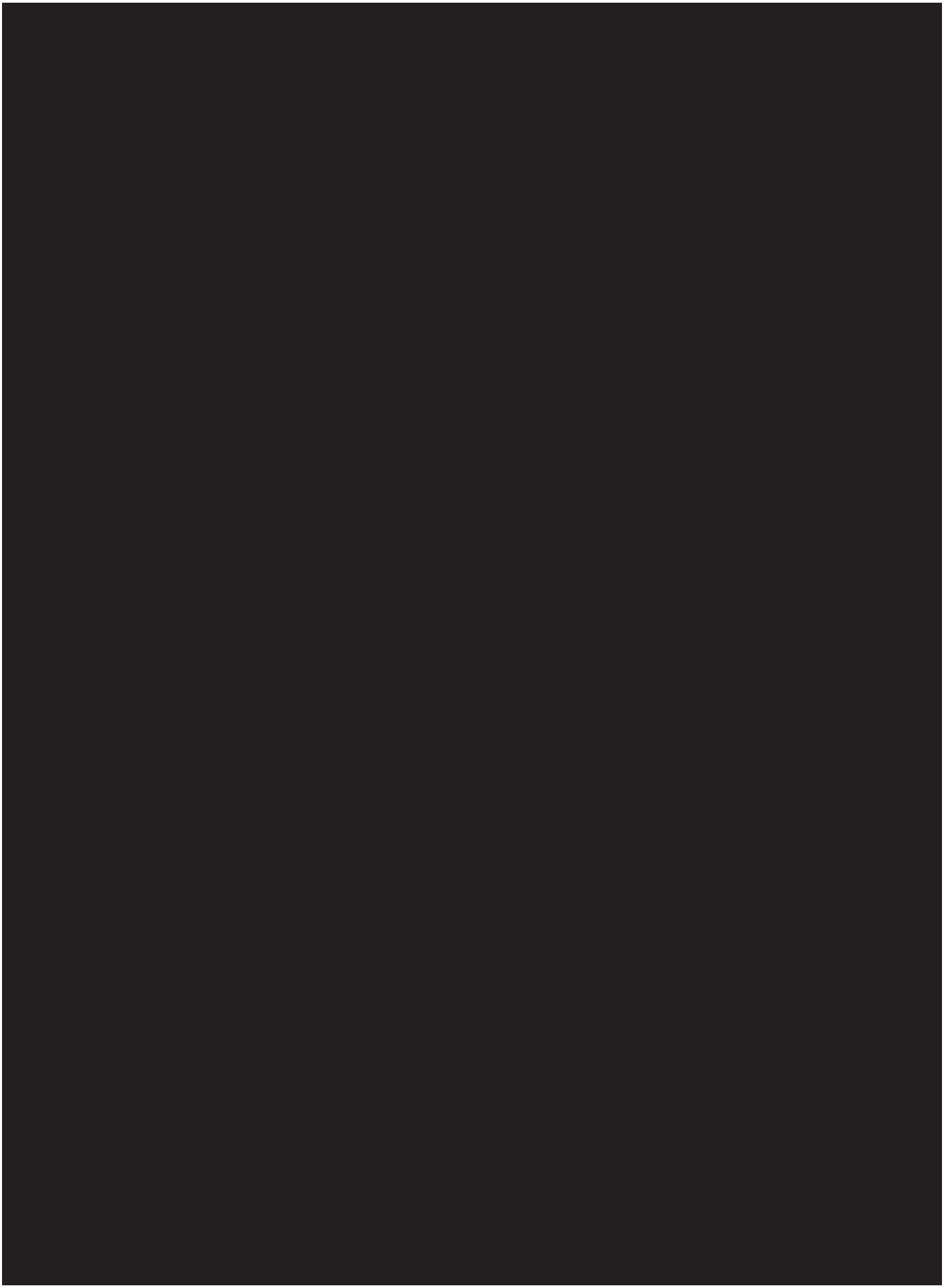
This study will be registered on Clinical Trials.gov.

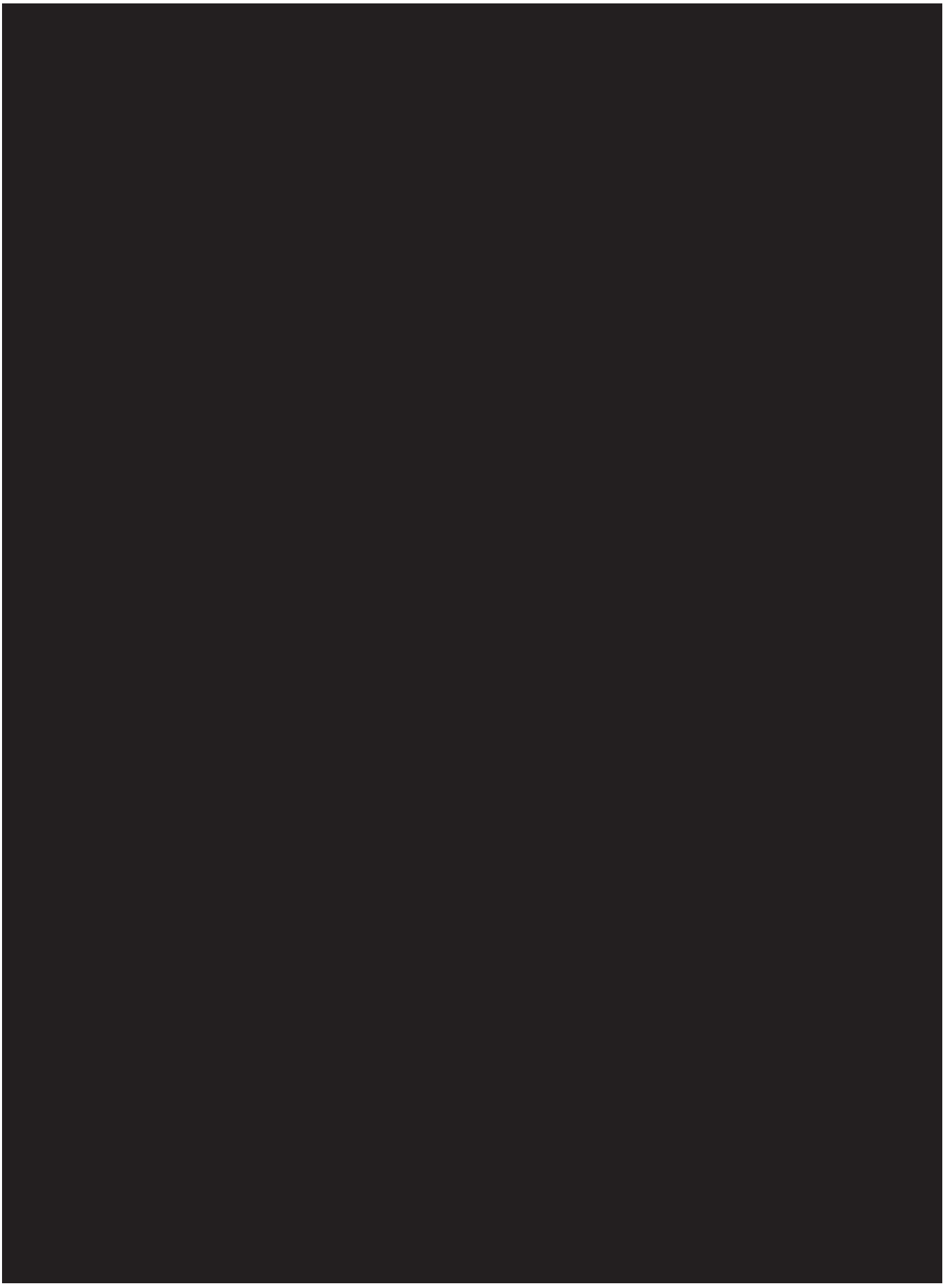
16.1 PATIENT REPORTED OUTCOMES (STUDY QUESTIONNAIRES)

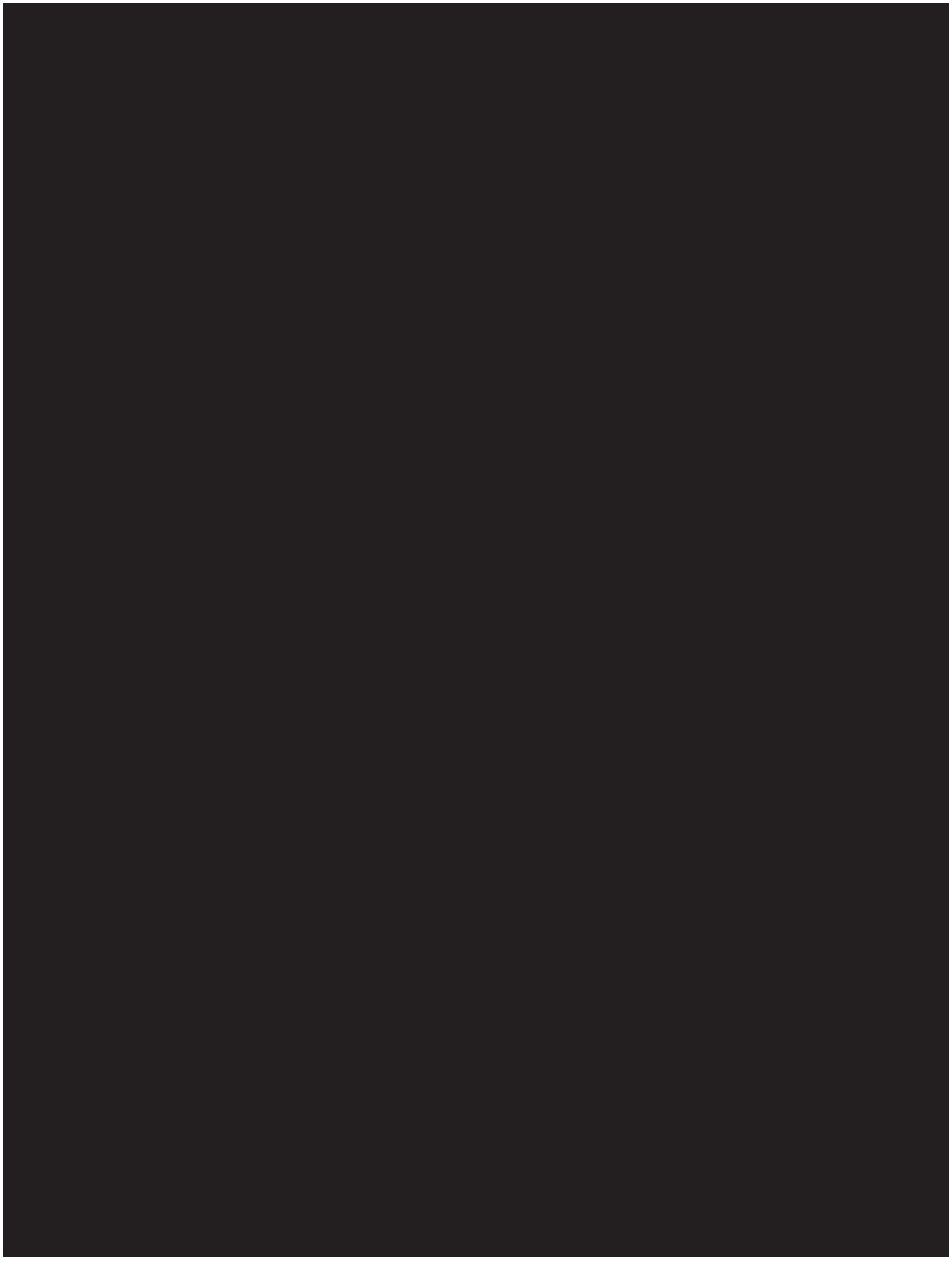


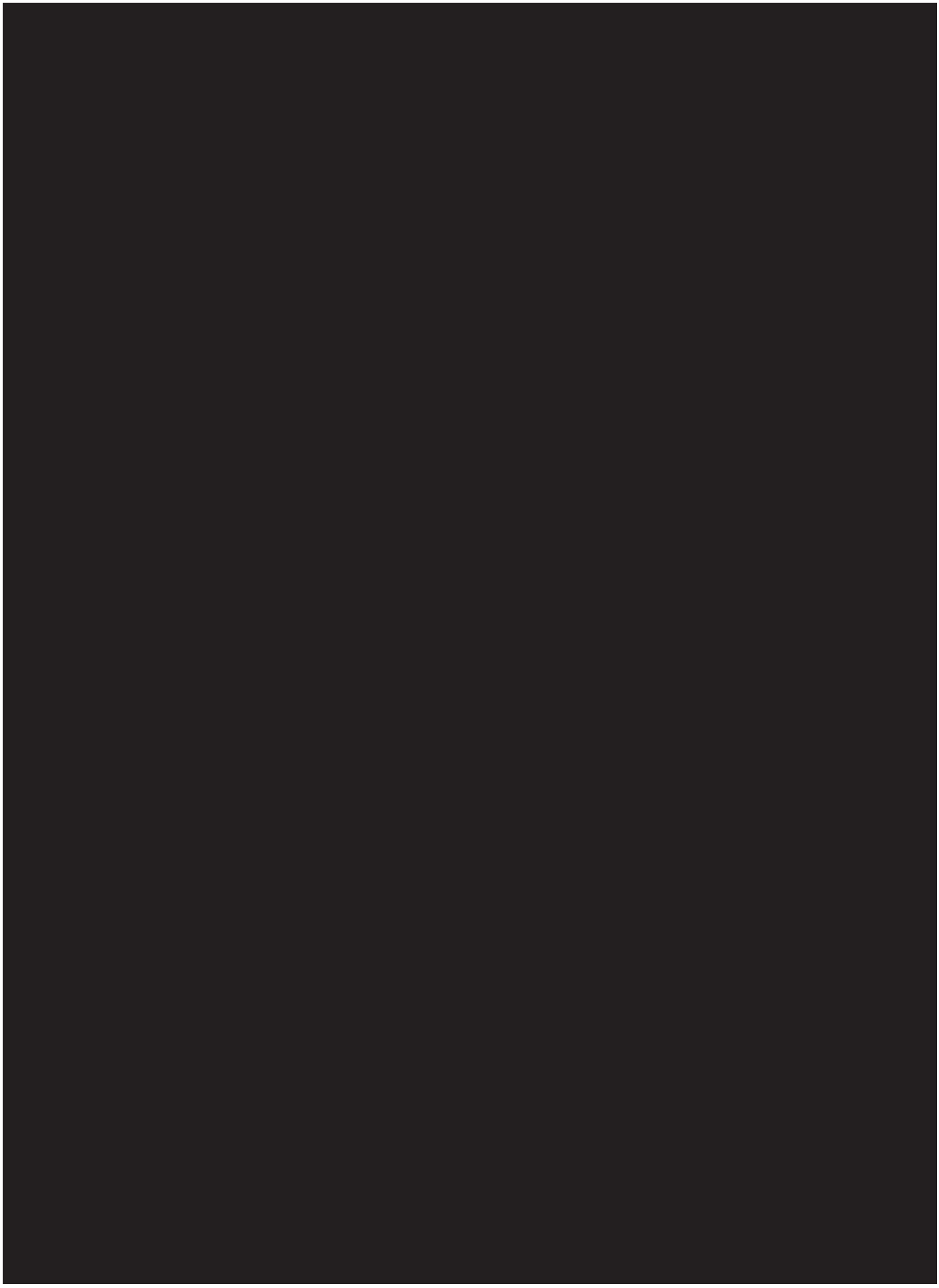


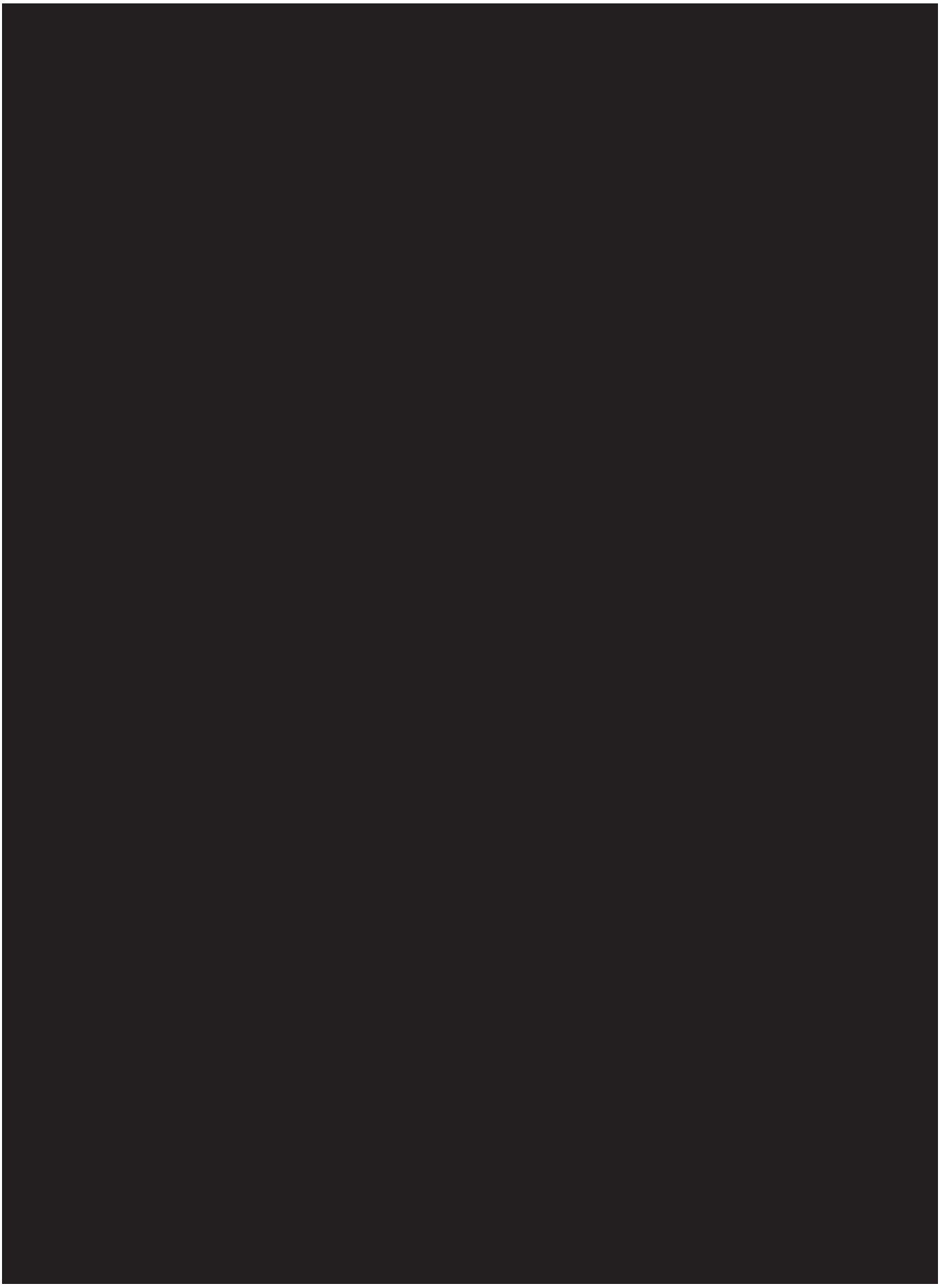


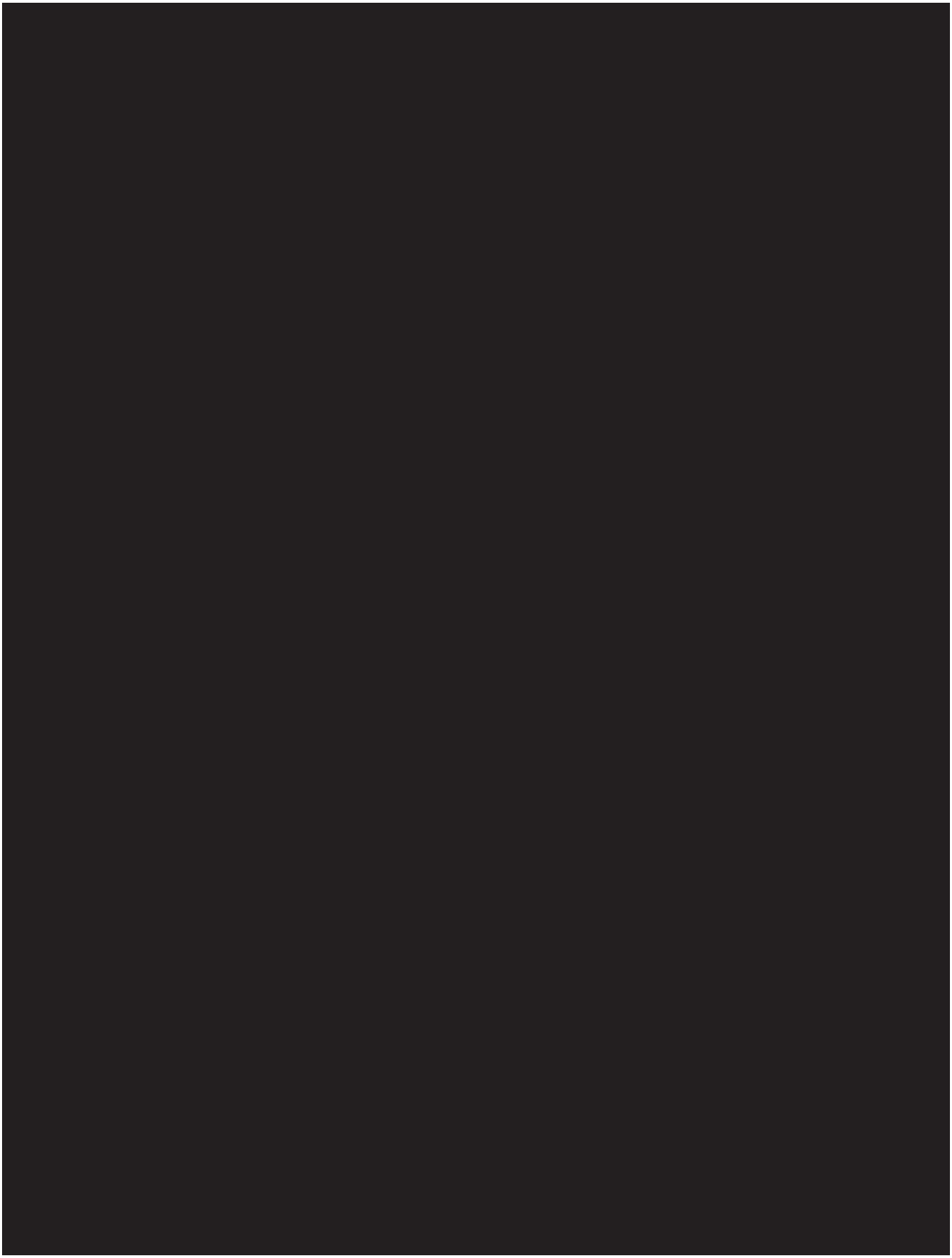


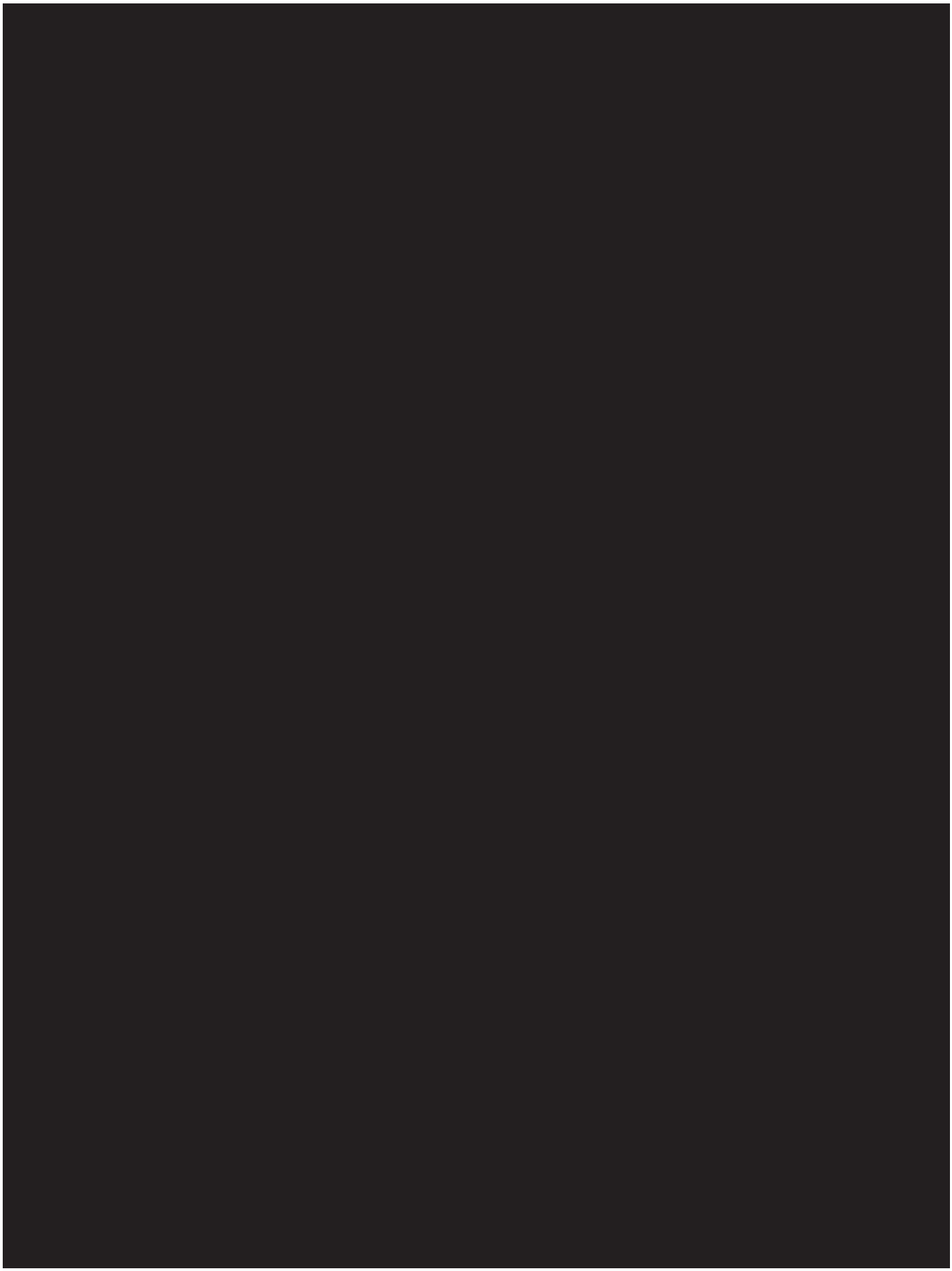


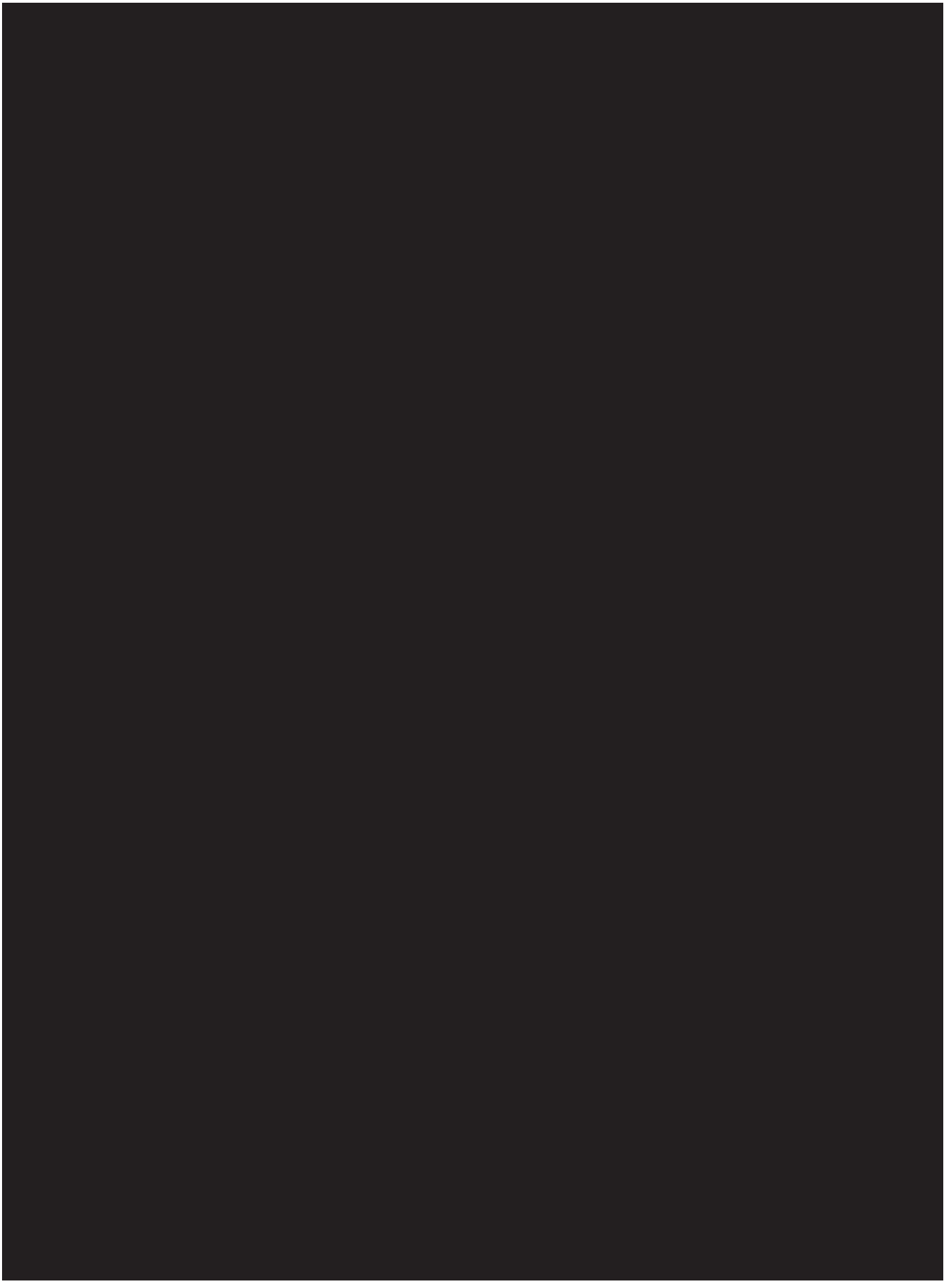


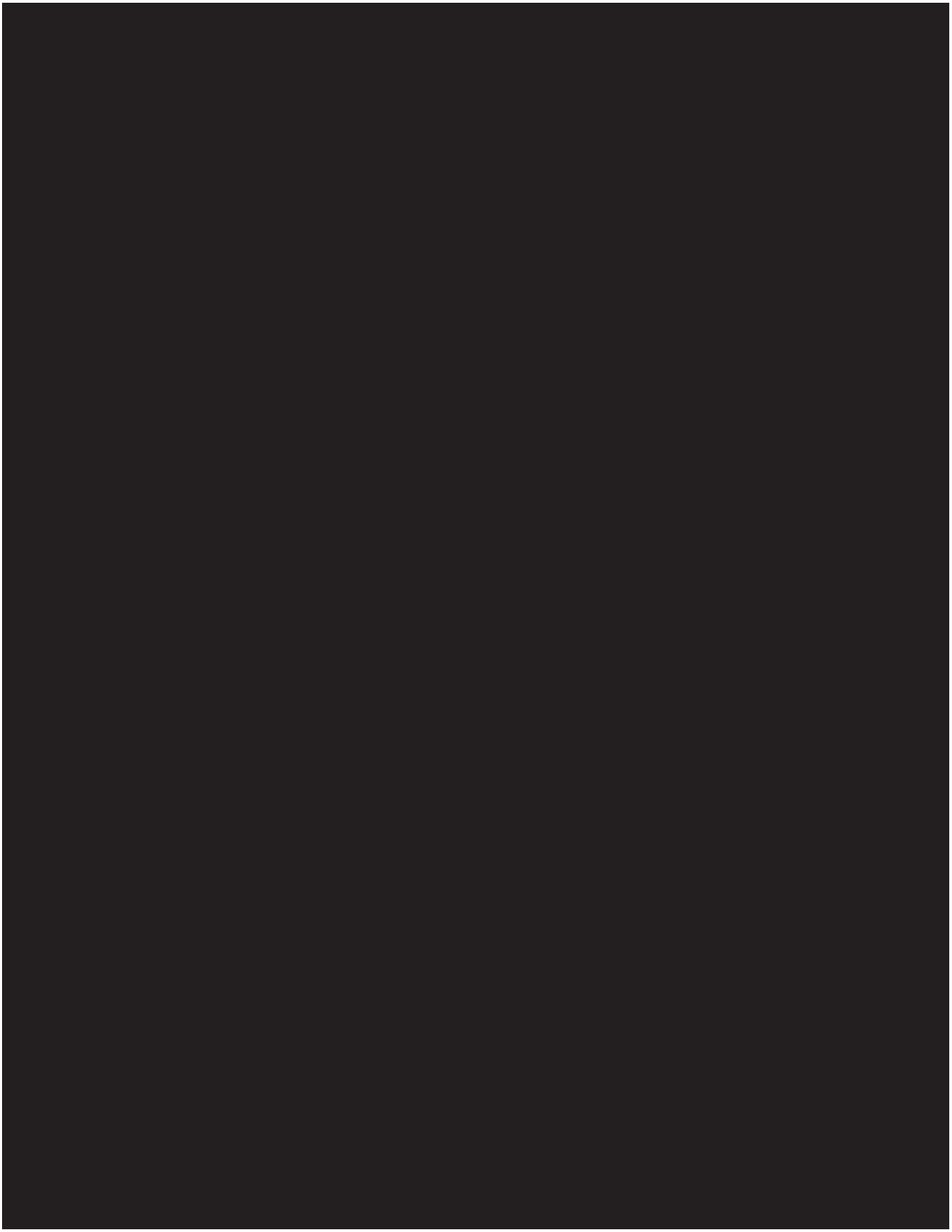


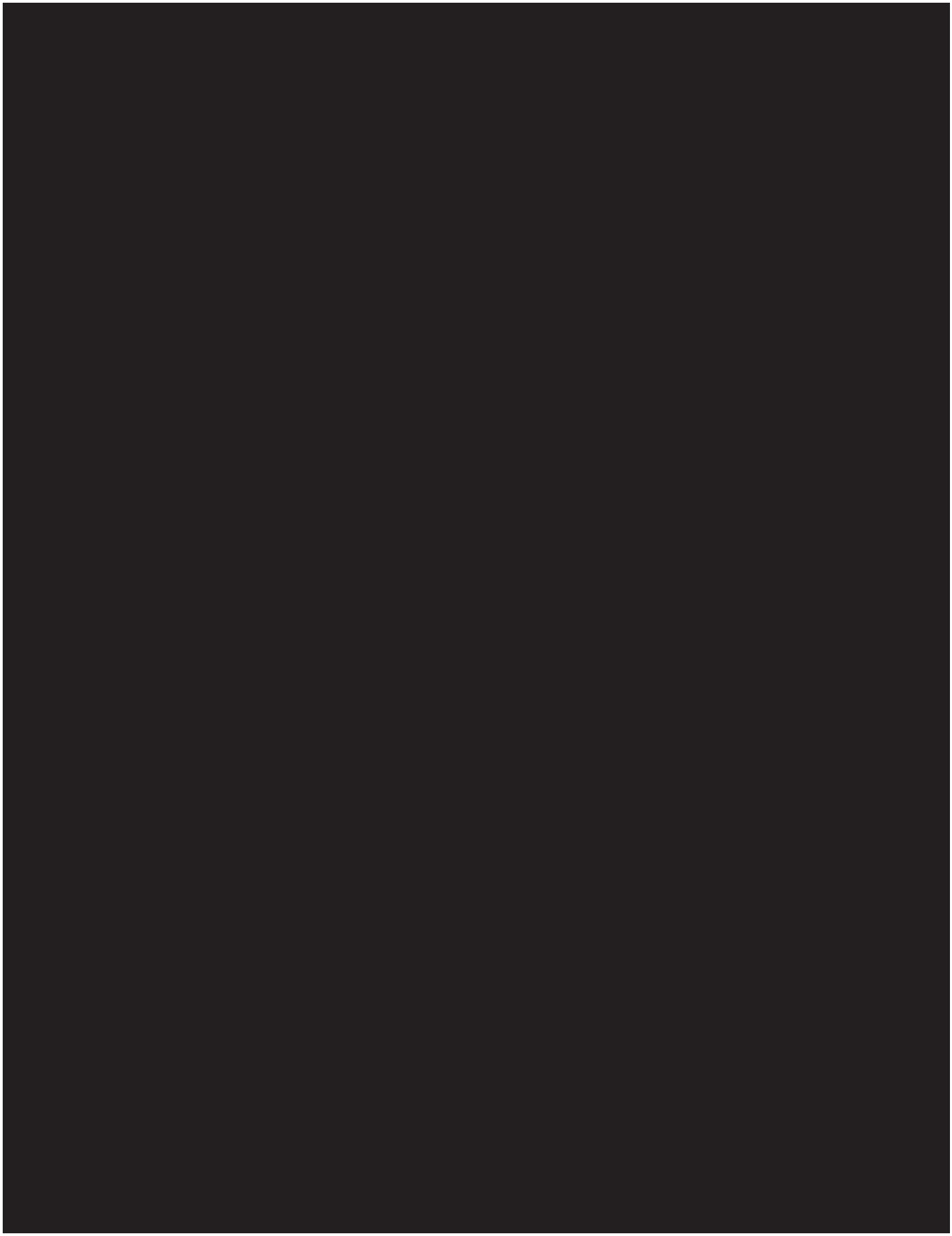


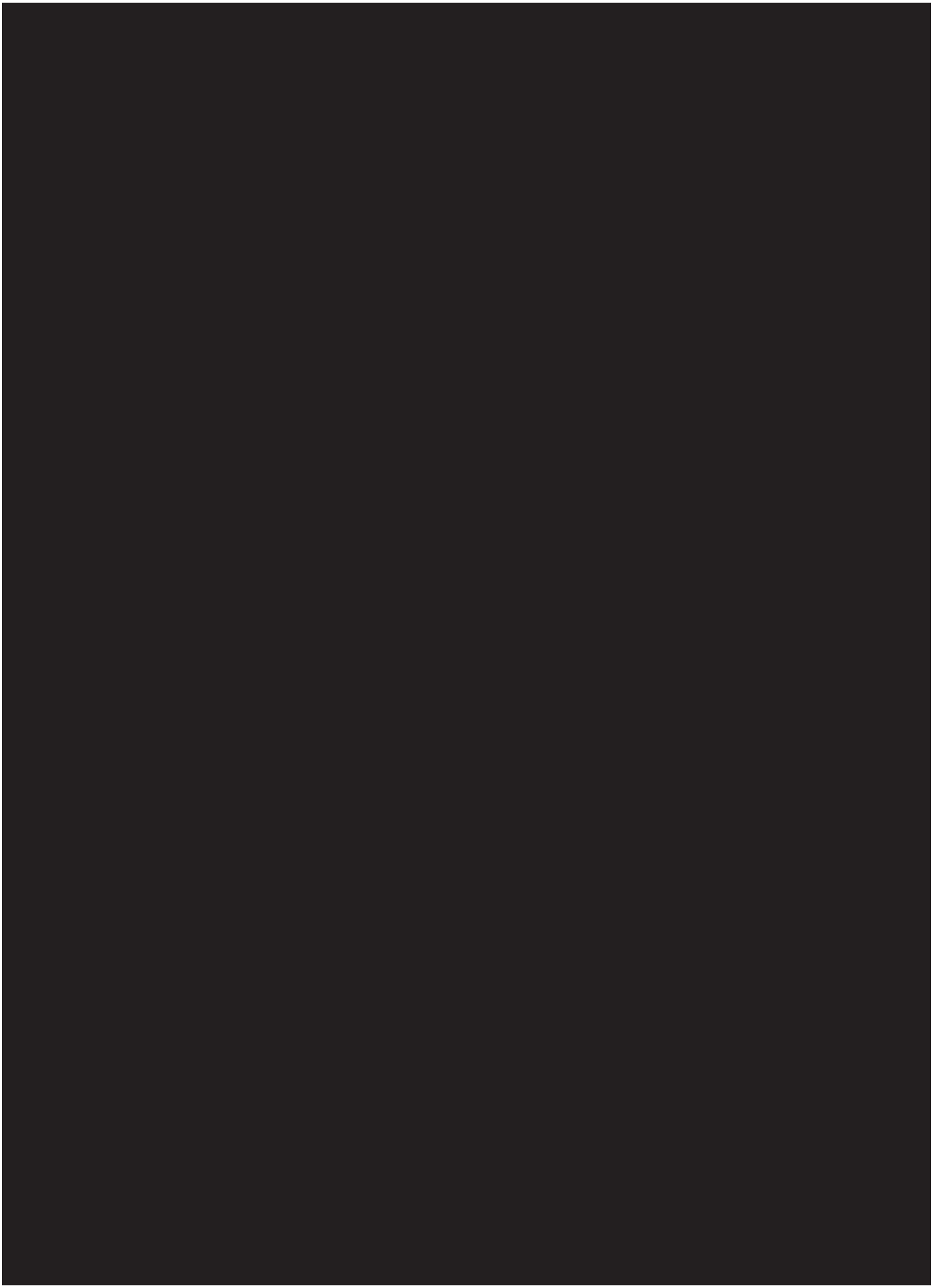


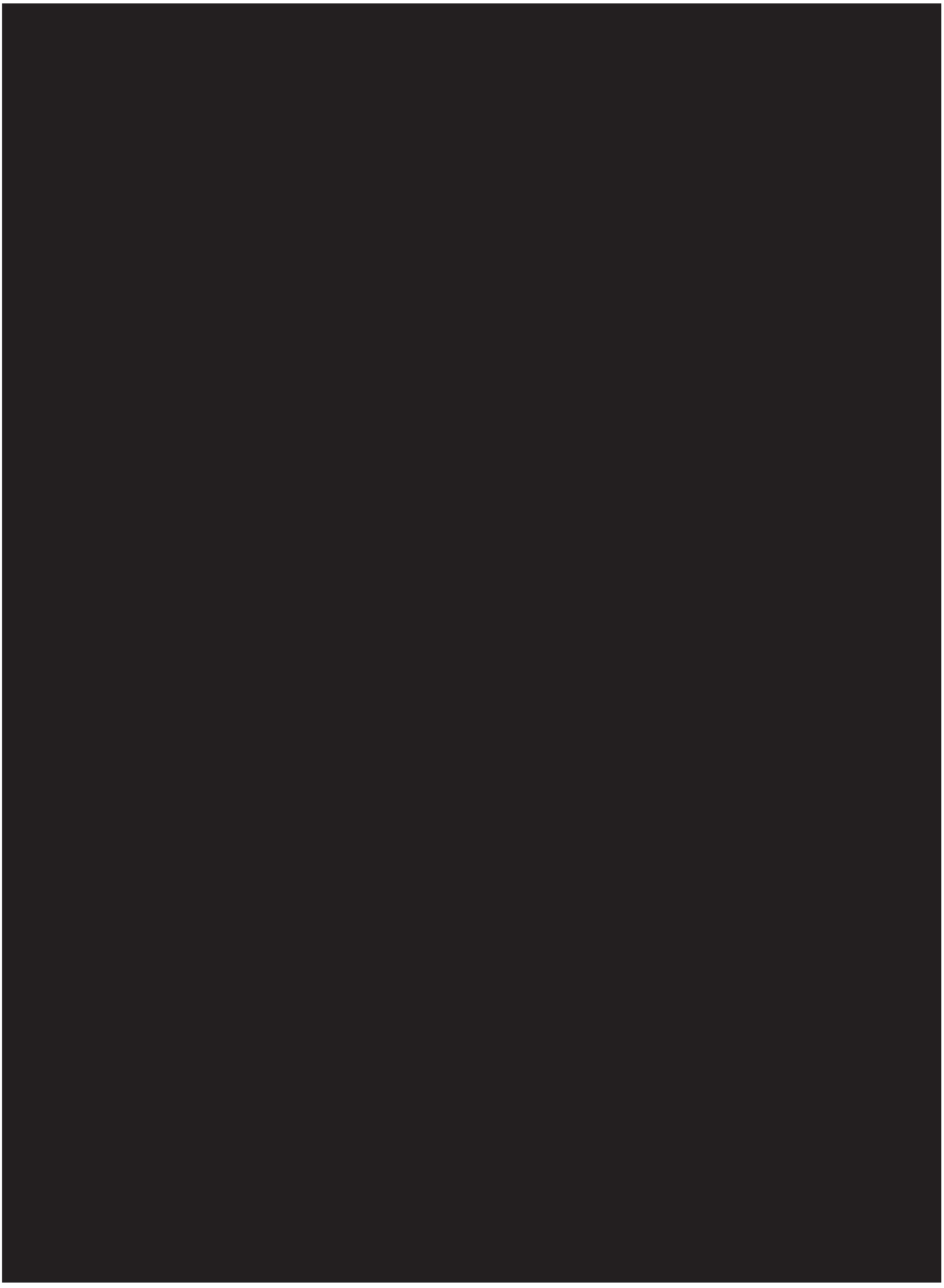


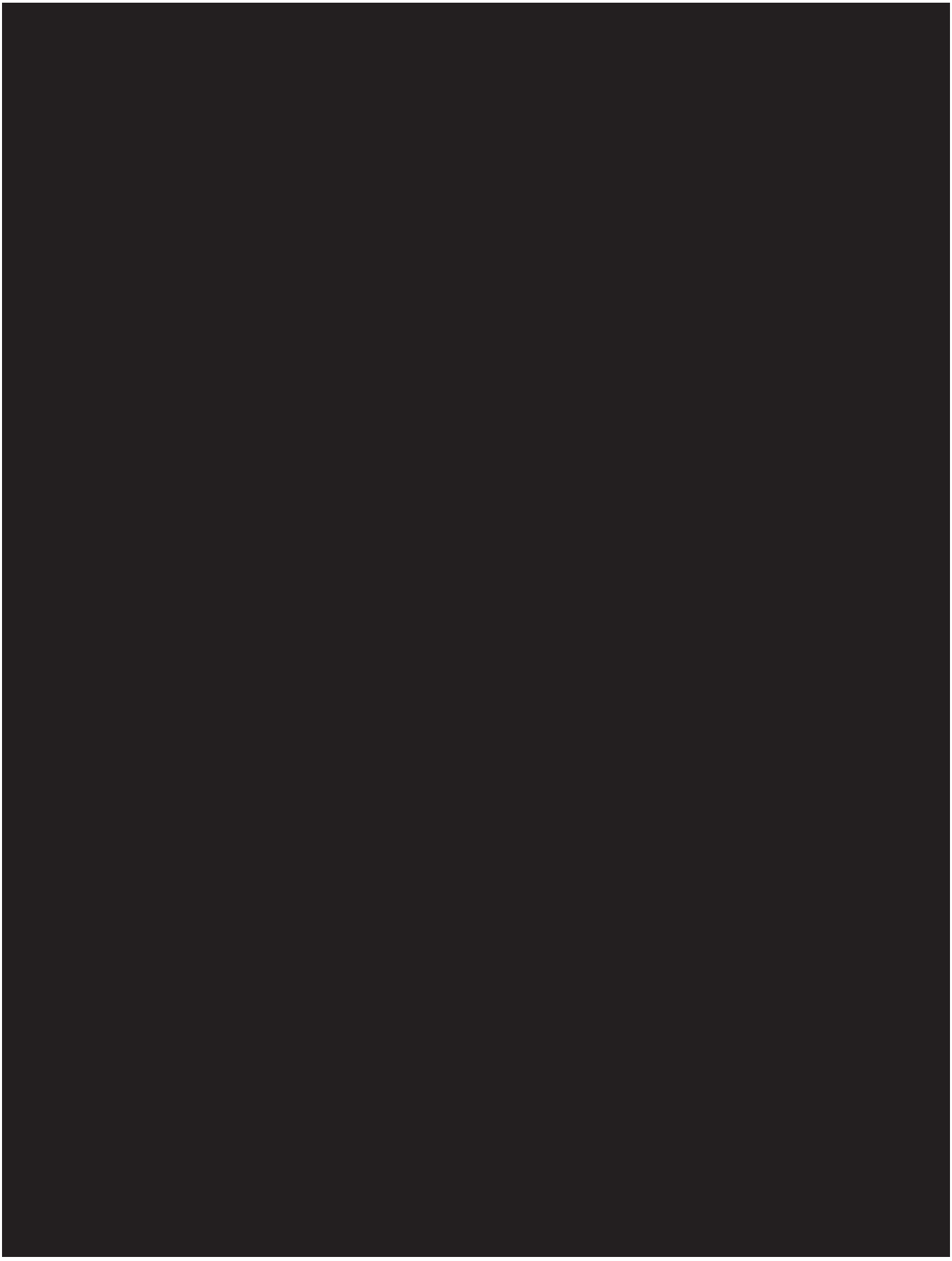


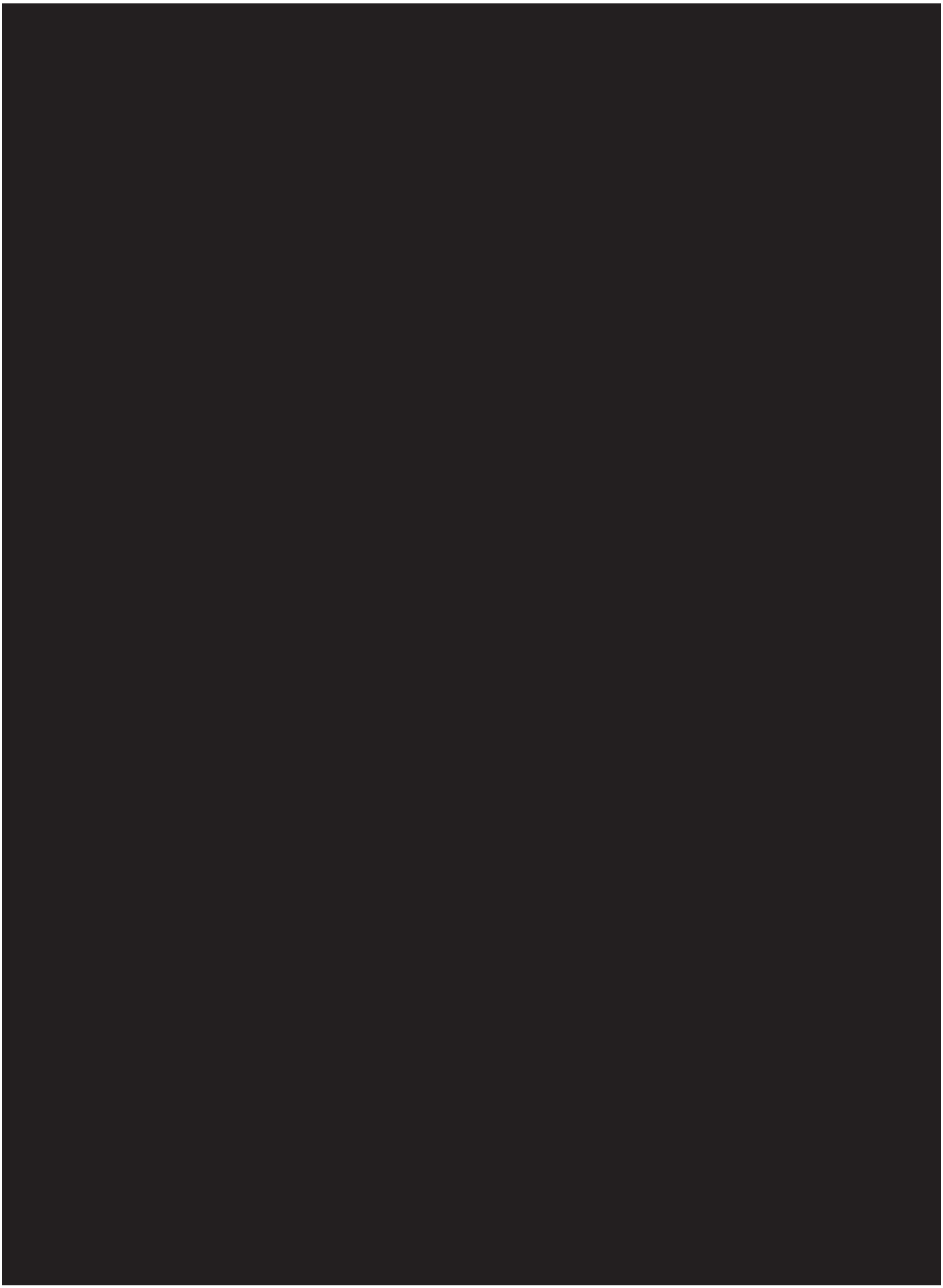


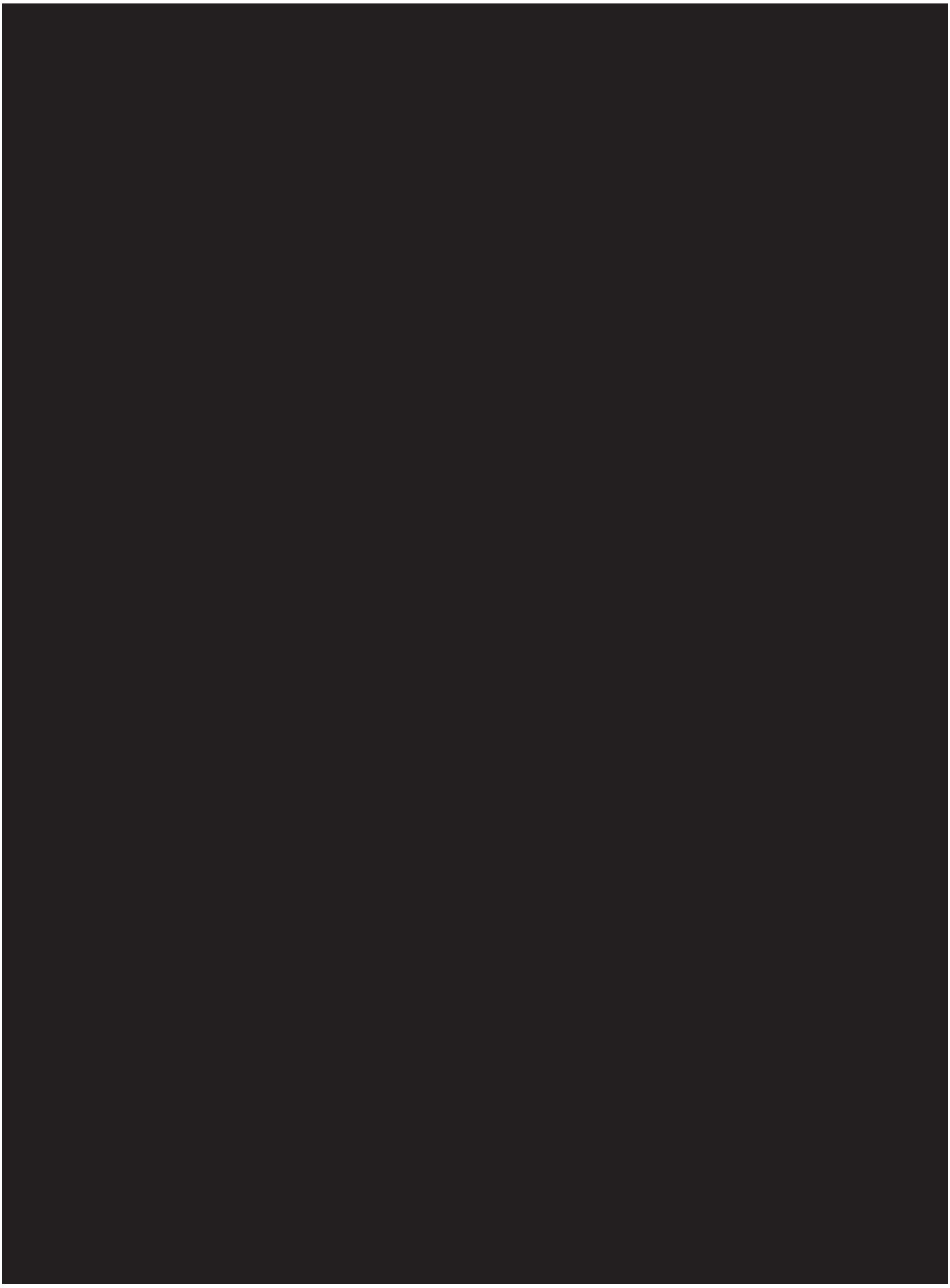


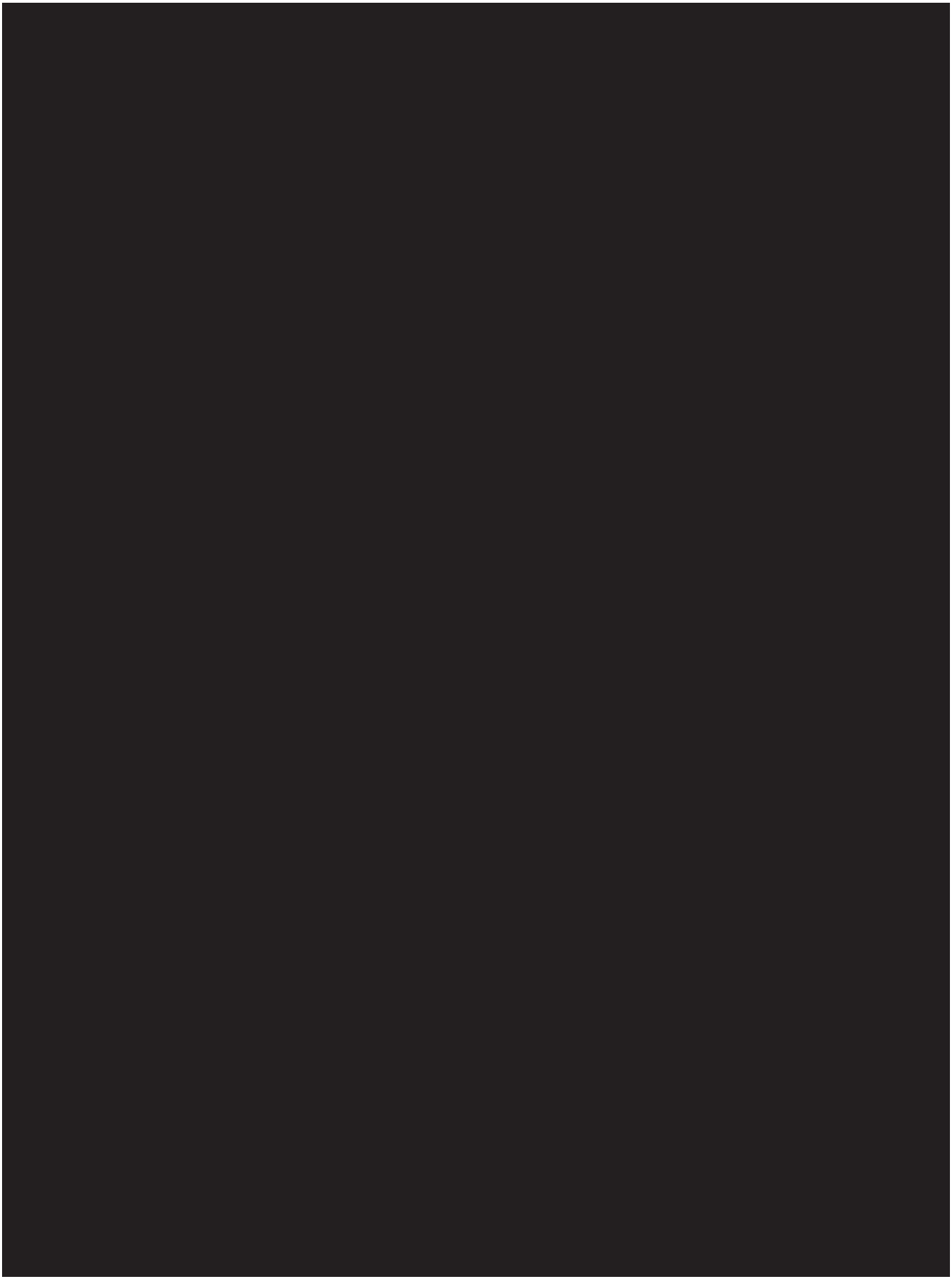


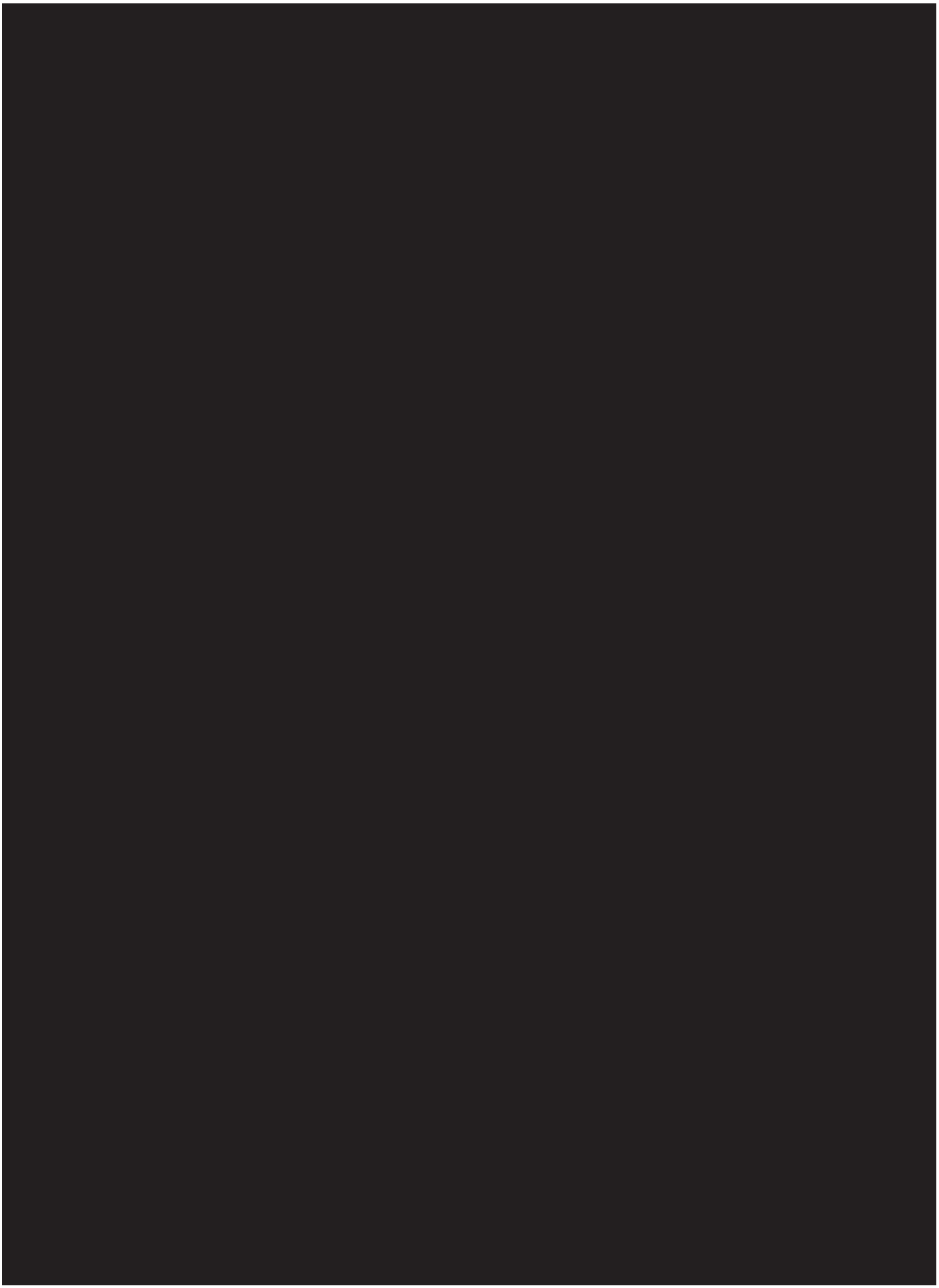


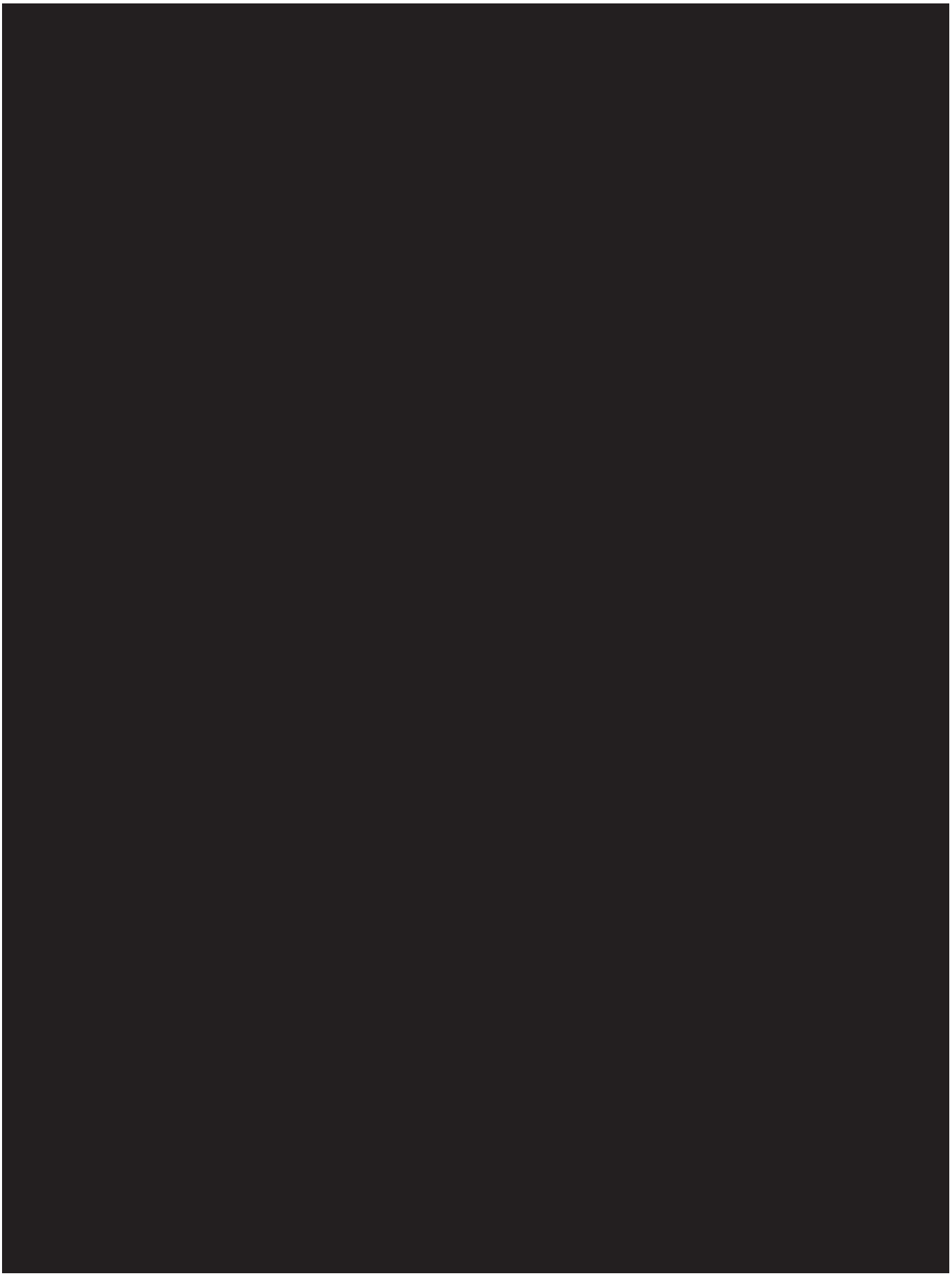


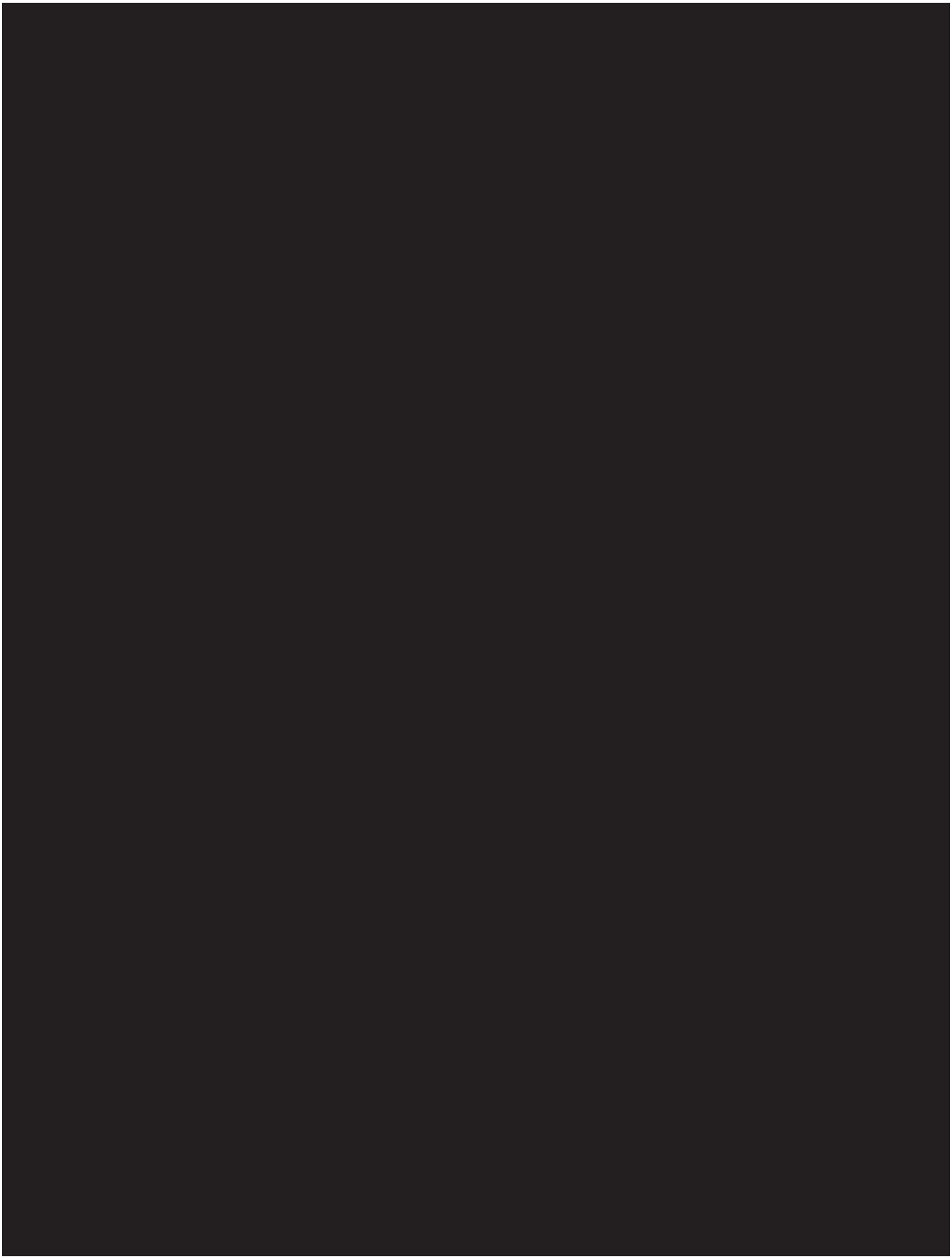


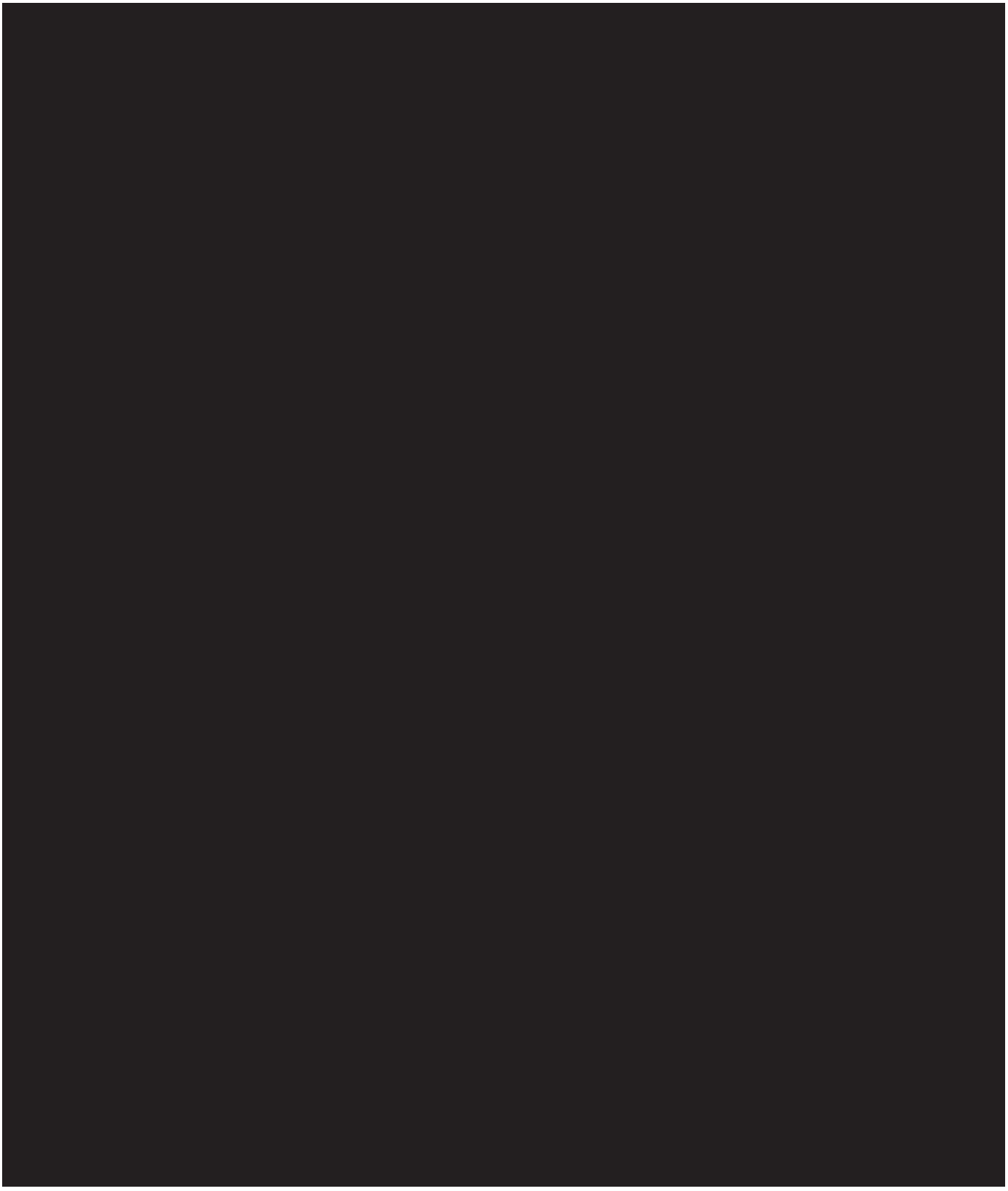


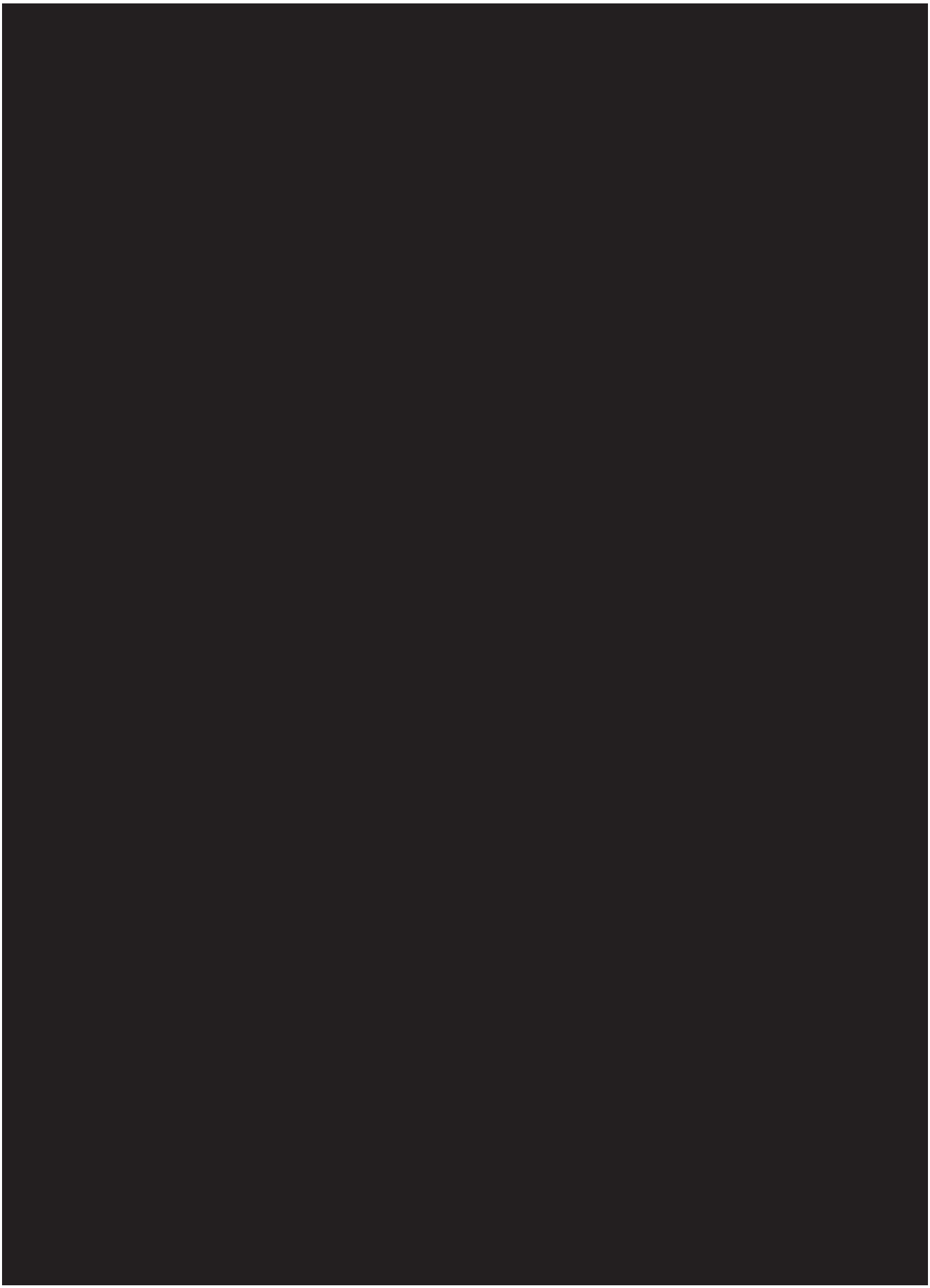


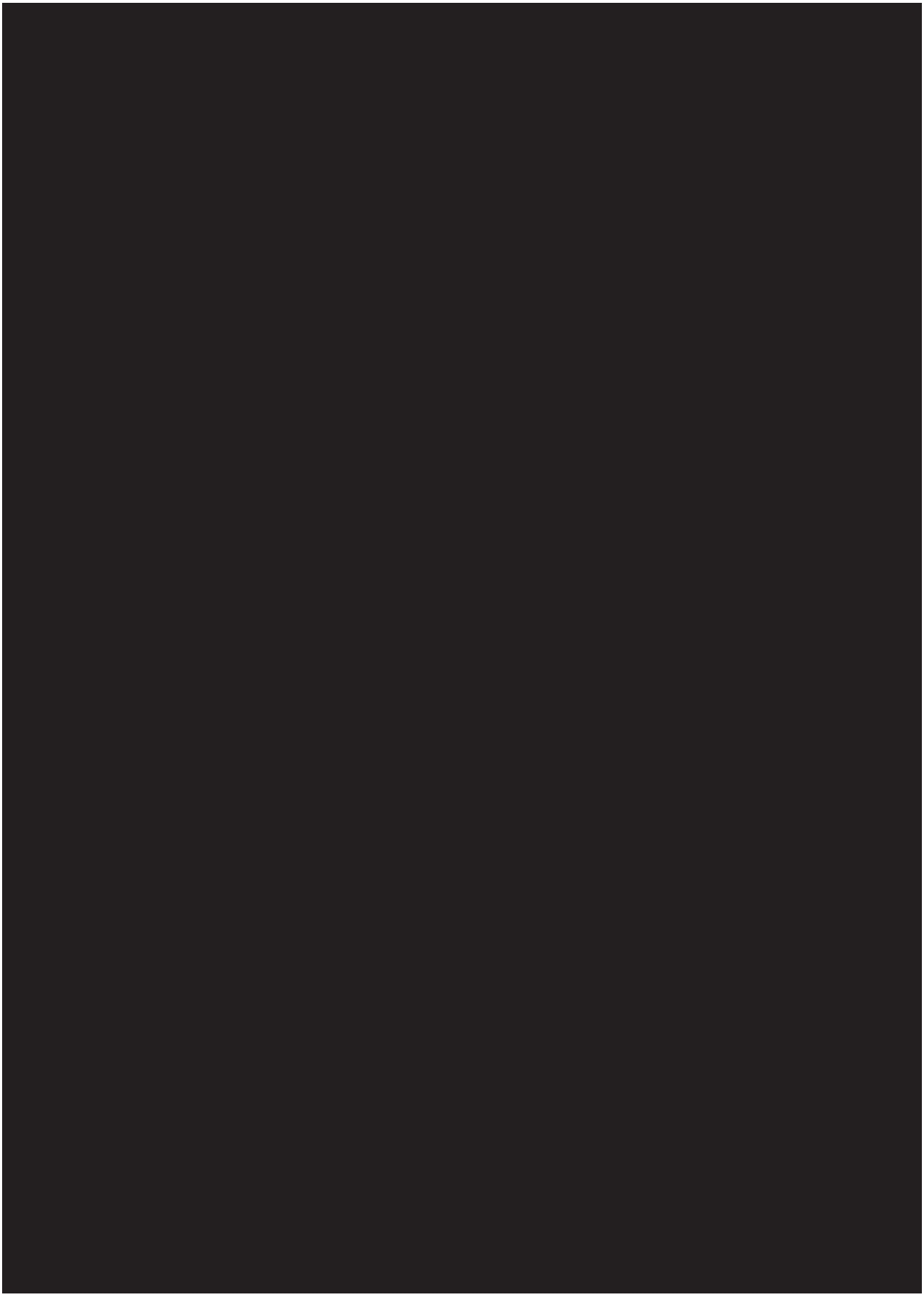


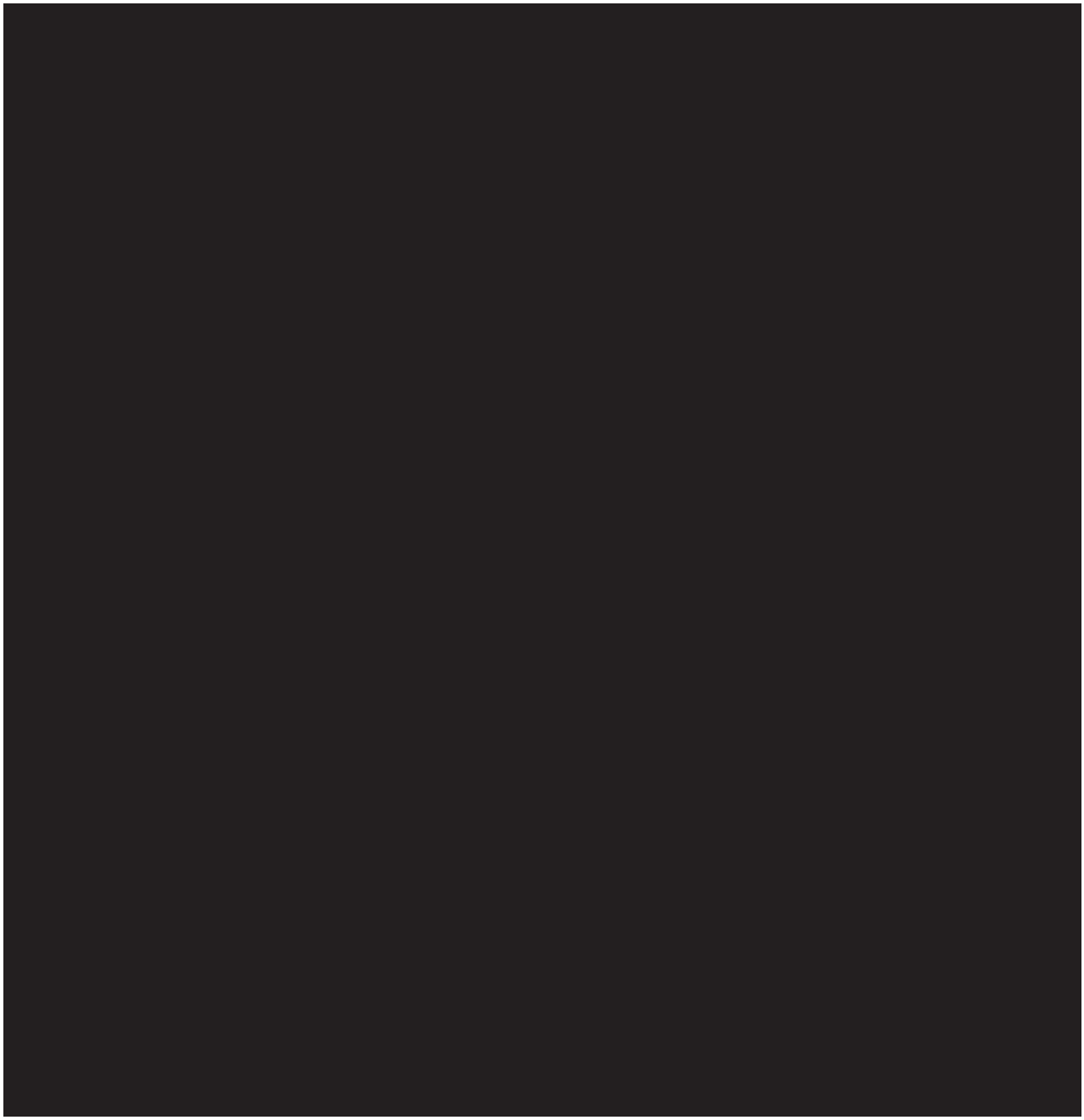


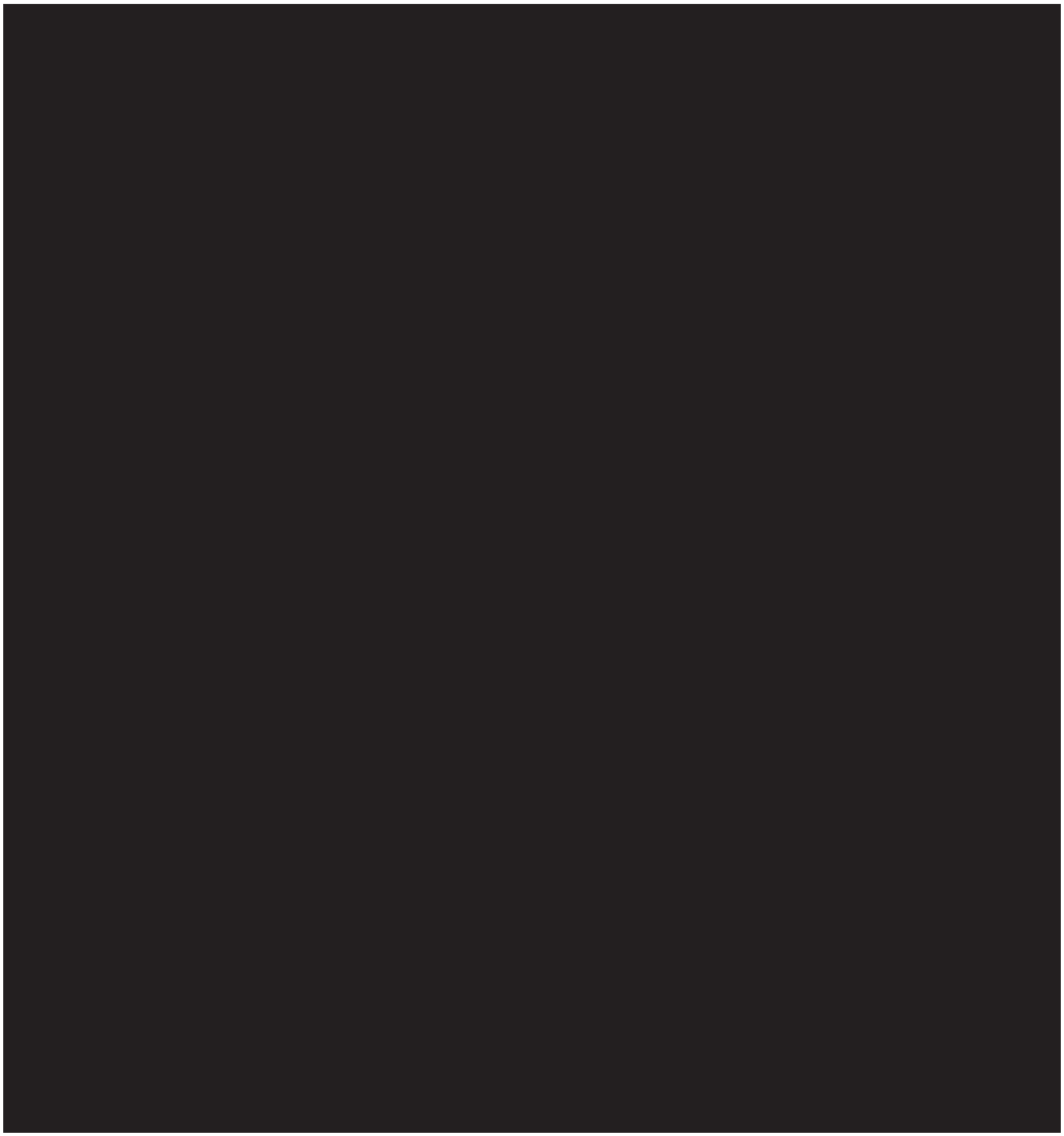


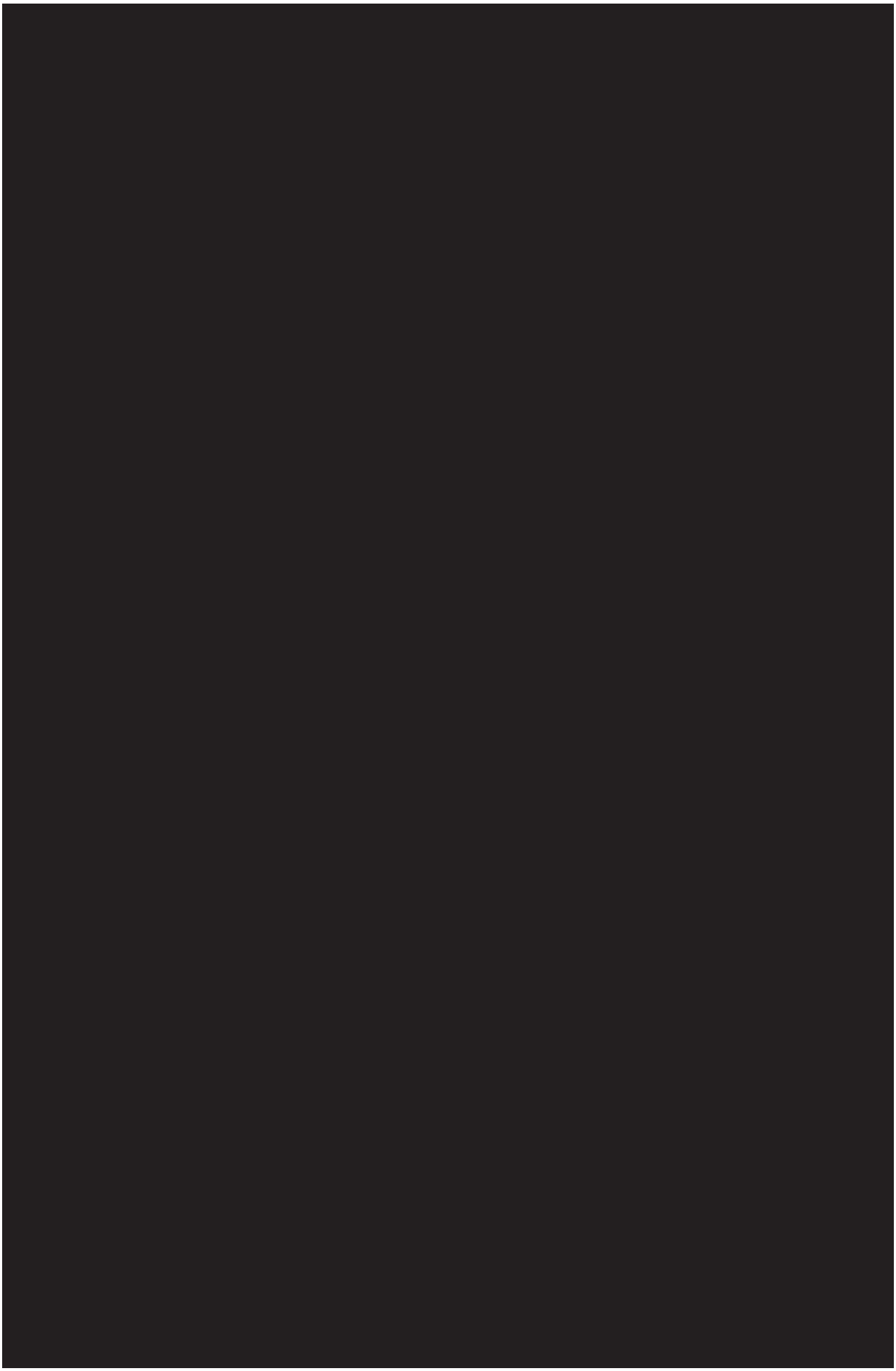


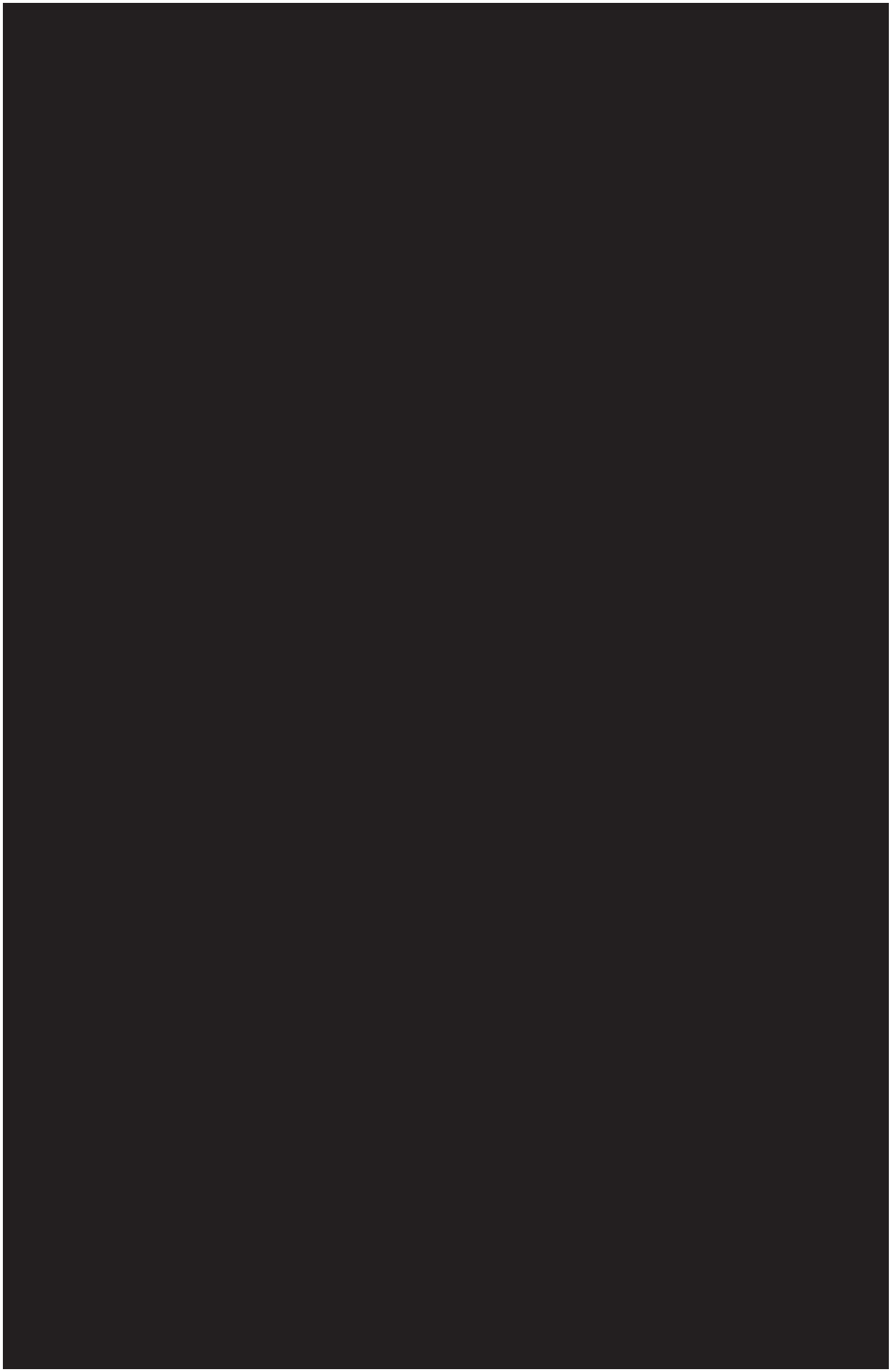


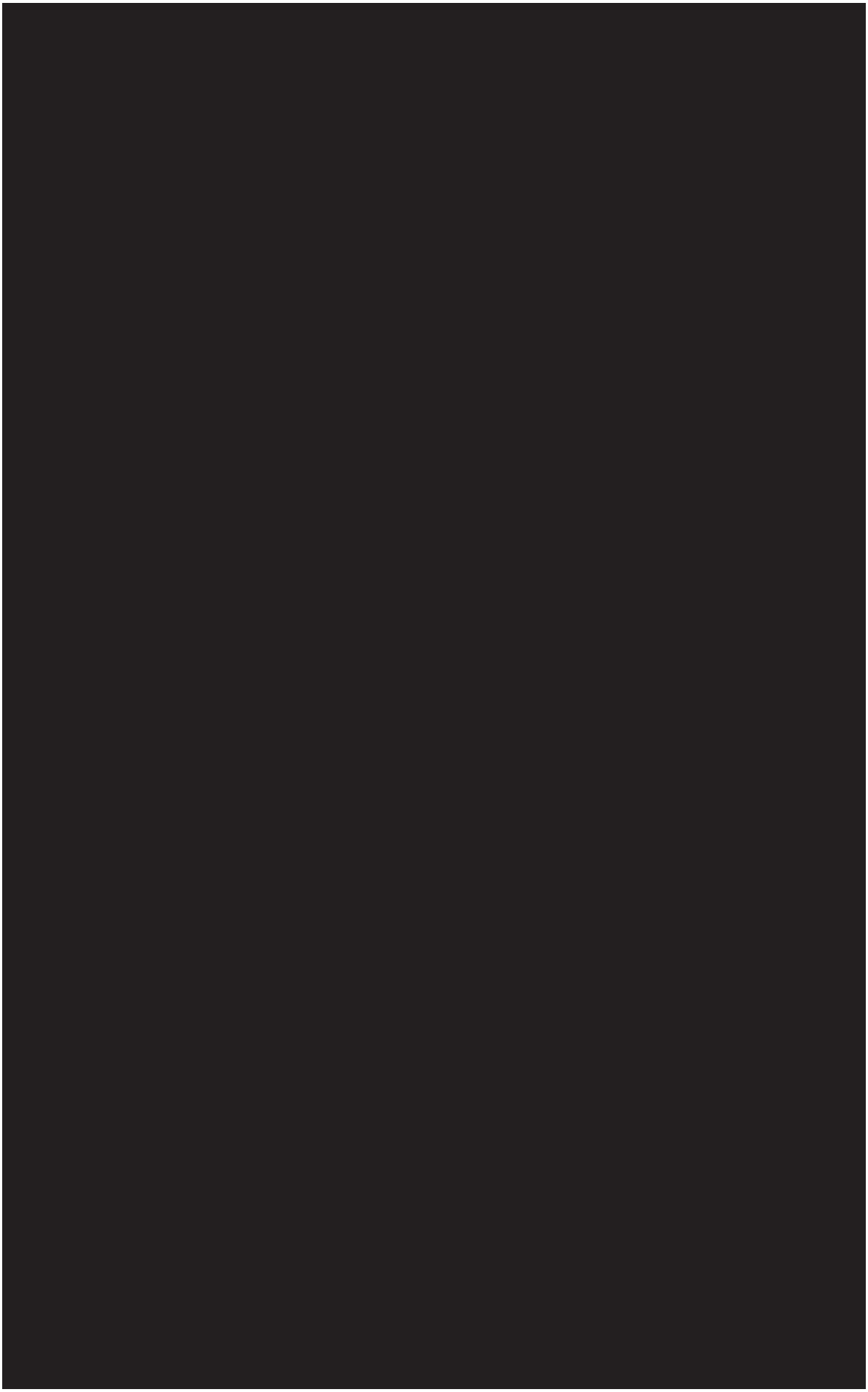


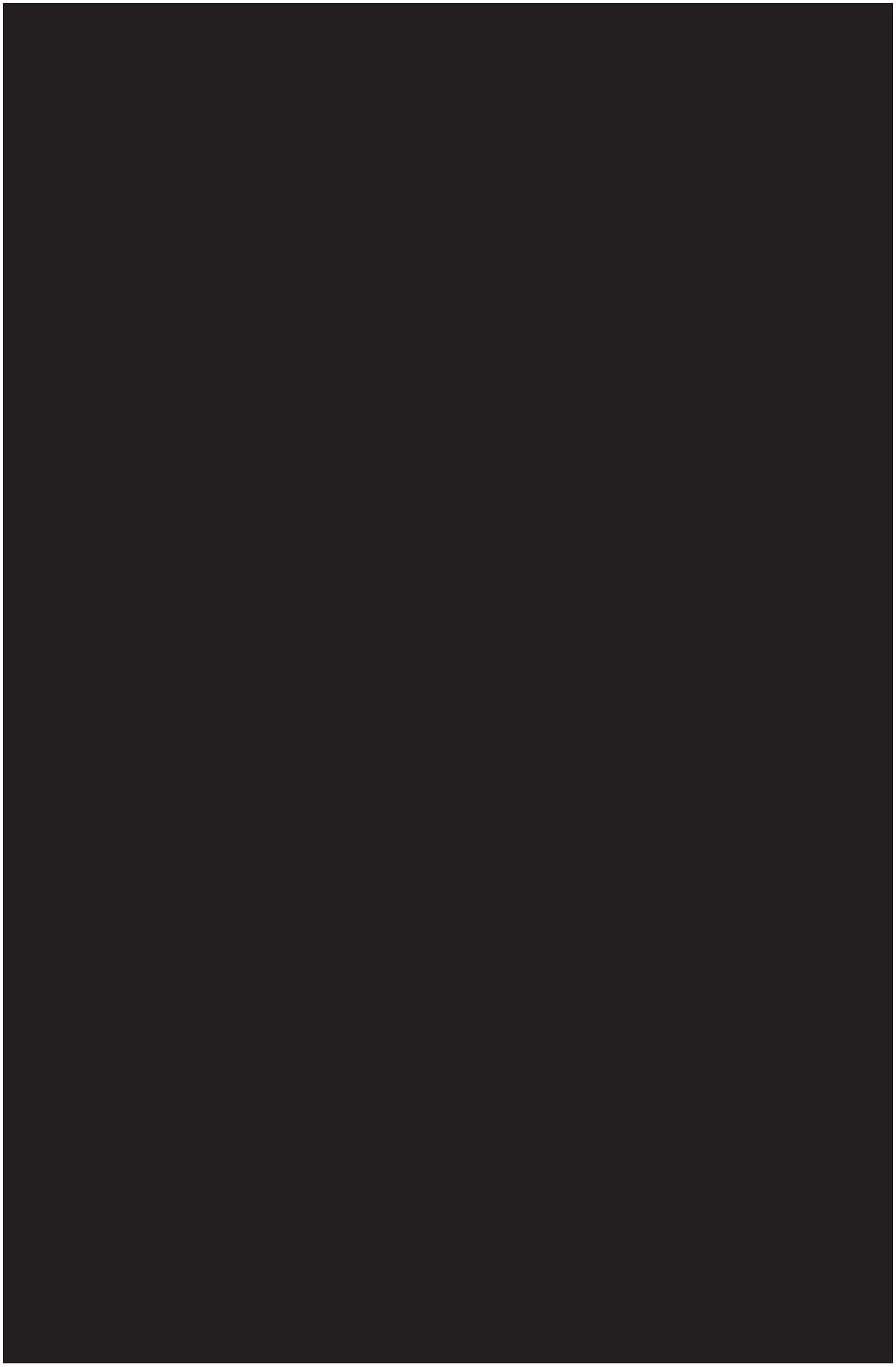


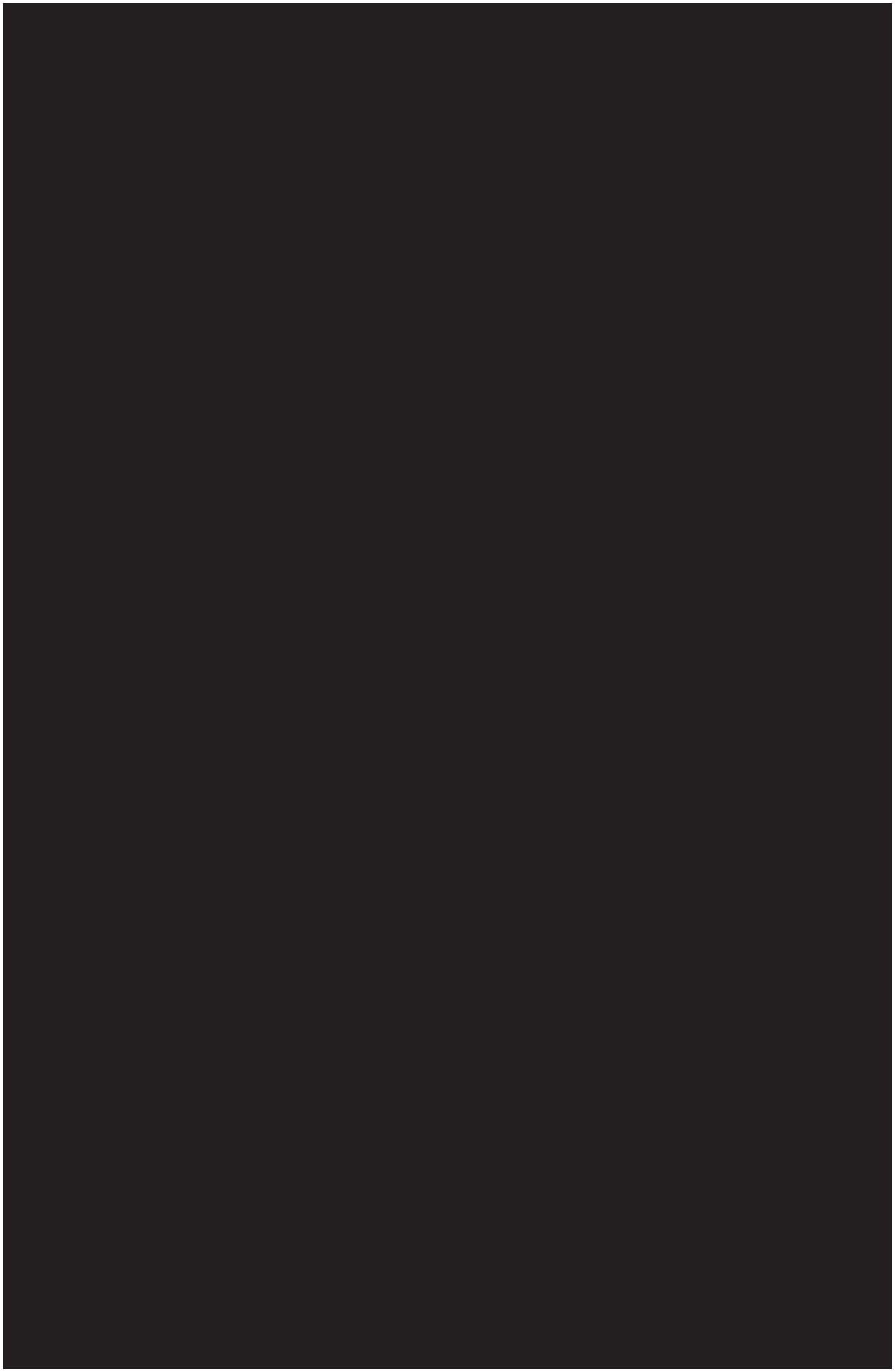












CR-5903 Subject Interview Questions (PRA site only)

1. What are some of the challenges you face with your current vision correct solutions, such as glasses or contact lenses?
2. How did the new lens you tried as part of this clinical study compare to your current vision correction solutions?
3. What did you like most about this study lens?
4. Describe a moment when you felt this study lens performed well.
5. How did the study lens feel on your eye?
6. How would this study lens change the vision correction solutions you use today?
7. If you were to buy this study lens, what impact do you think it would have on your contact lens use?
8. Do you have any final remarks about this contact lens that you would like ACUVUE to know?

16.2 CLINICAL TECHNICAL PROCEDURES (CTPS)

- [redacted] LIMBAL & CONJUNCTIVAL (BULBAR) REDNESS (APPENDIX F)
- [redacted] EXPANDED SODIUM FLUORESCEIN CORNEAL STAINING (APPENDIX G)
- [redacted] DETERMINATION OF NEAR ADD (APPENDIX H)
- [redacted] NEAR LOGMAR VISUAL ACUITY MEASUREMENT PROCEDURE (APPENDIX I)
- [redacted] LENS FITTING CHARACTERISTICS (APPENDIX J)
- [redacted] SUBJECT REPORTED OCULAR SYMPTOMS (APPENDIX K)
- [redacted] DETERMINATION OF DISTANCE SPHEROCYLINDRICAL REFRACTIONS (APPENDIX L)
- [redacted] BIOMICROSCOPY SCALE (APPENDIX M)
- [redacted] KERATOMETRY PROCEDURE (APPENDIX N)
- [redacted] DISTANCE AND NEAR VISUAL ACUITY EVALUATION (APPENDIX O)
- [redacted] TORIC FIT EVALUATION (APPENDIX P)
- [redacted] ETDRS DISTANCE VISUAL ACUITY MEASURMENT PROCEDURE (APPENDIX Q)
- [redacted] MEASURING PUPIL DIAMETER WITH NEUROPTICS VIP-200 VARIABLE PUPILLOMETER (APPENDIX R)

16.3 PATIENT INSTRUCTION GUIDE

A Patient Instruction Guide will be provided separately.

16.4 PACKAGE INSERT

Not Applicable

17.1 LIST OF ABBREVIATIONS

AE	Adverse Event/Adverse Experience
CFR	Code of Federal Regulations
CIB	Clinical Investigator's Brochure
CRF	Case Report Form
CRO	Contract Research Organization
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
IEC	Independent Ethics Committee
IRB	Institutional Review Board
MedDRA ©	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
OHSR	Office for Human Subjects Research
PHI	Protected Health Information
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SOP	Standard Operating Procedure
UADE	Unanticipated Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect

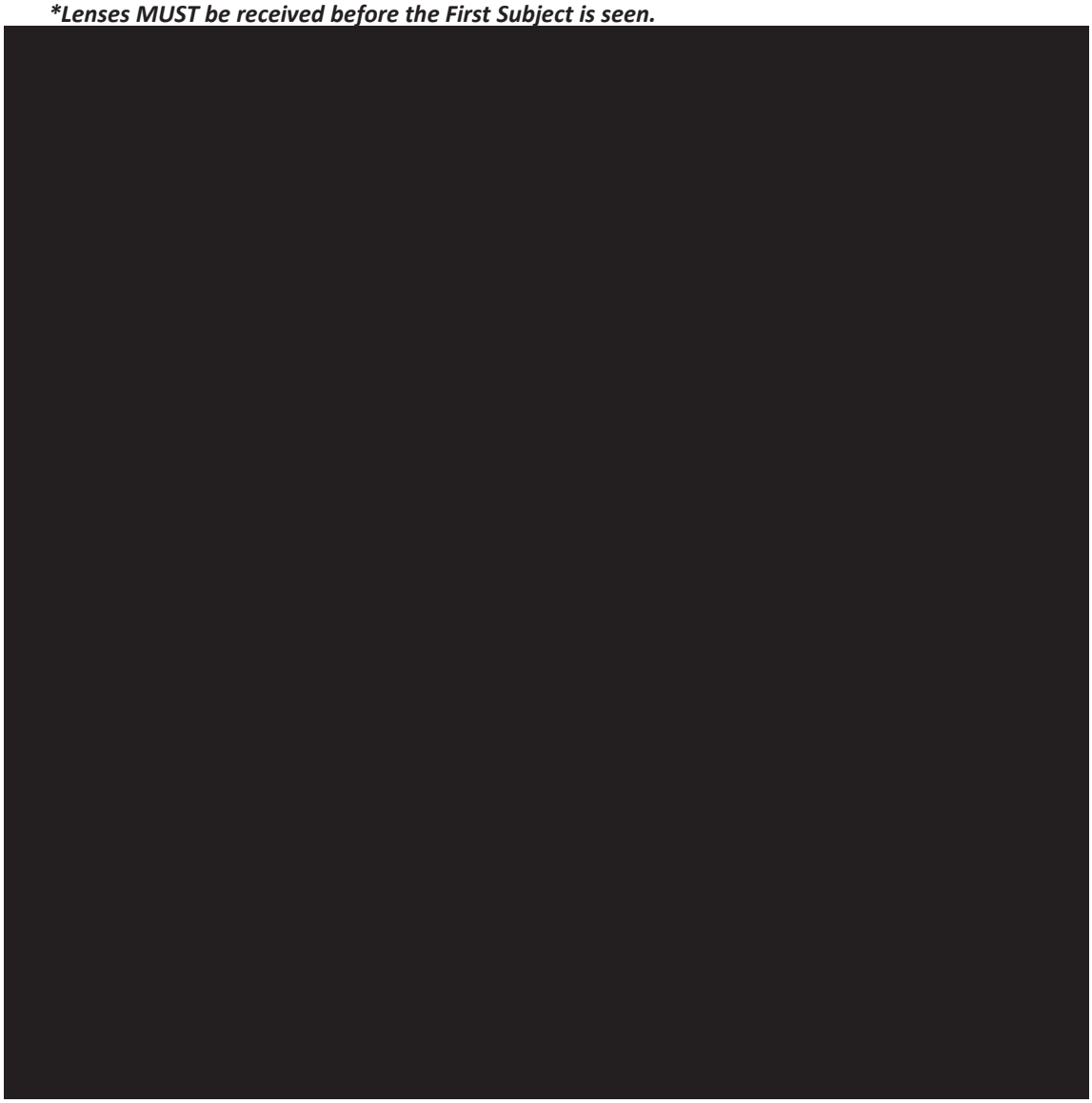
APPENDIX A: TEST ARTICLE ACCOUNTABILITY IN THE EDC SYSTEM

Test Article Accountability in the BioClinica Express EDC 5.4 System

Part 1 – Overall Test Article Accountability

- Once the test article shipped sheet is completed for the shipment the investigational site must log the shipment into the lens depot in the EDC system.

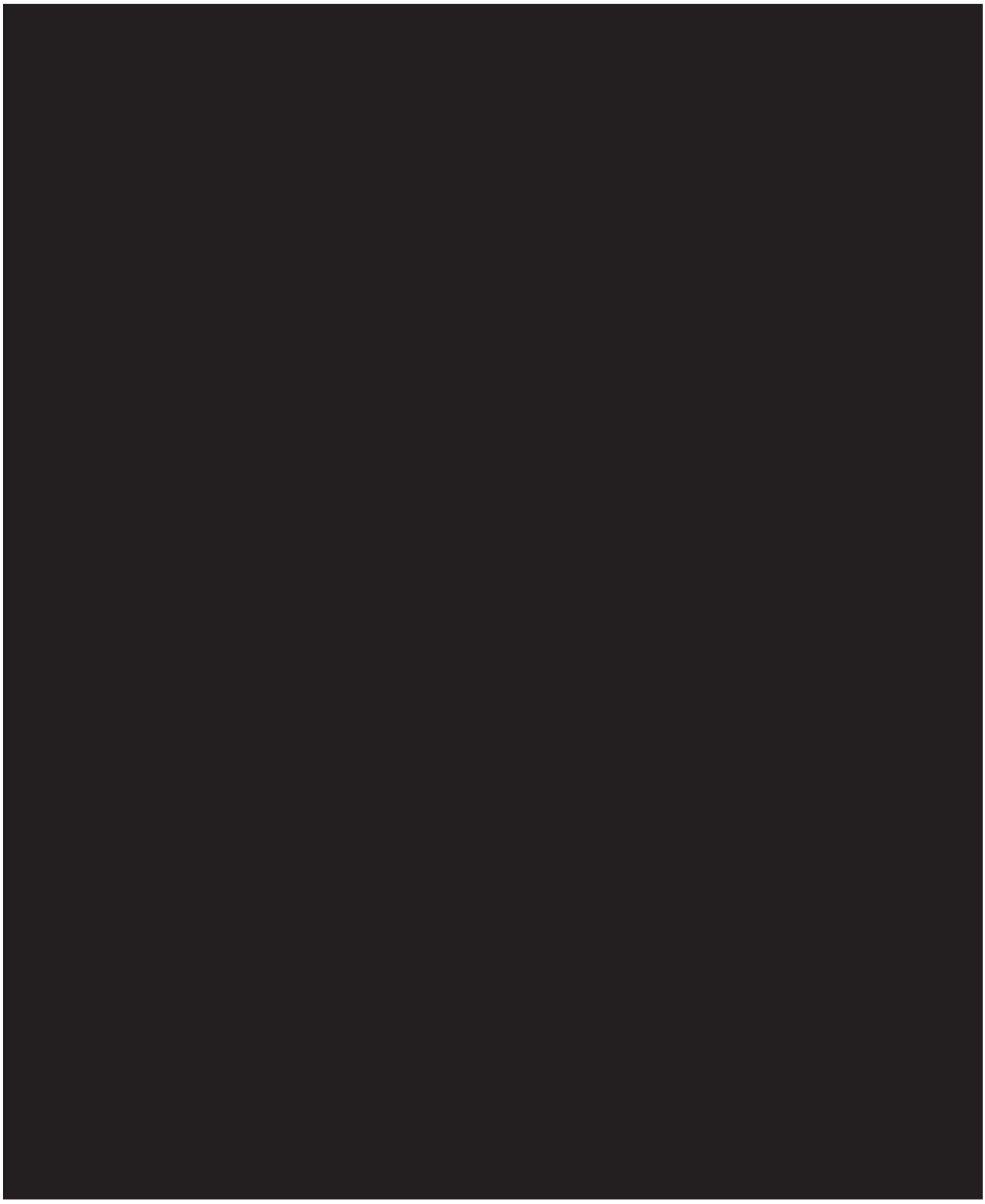
4. Click on to open <u>each form</u> to receive the lenses.
Lenses MUST be received before the First Subject is seen.



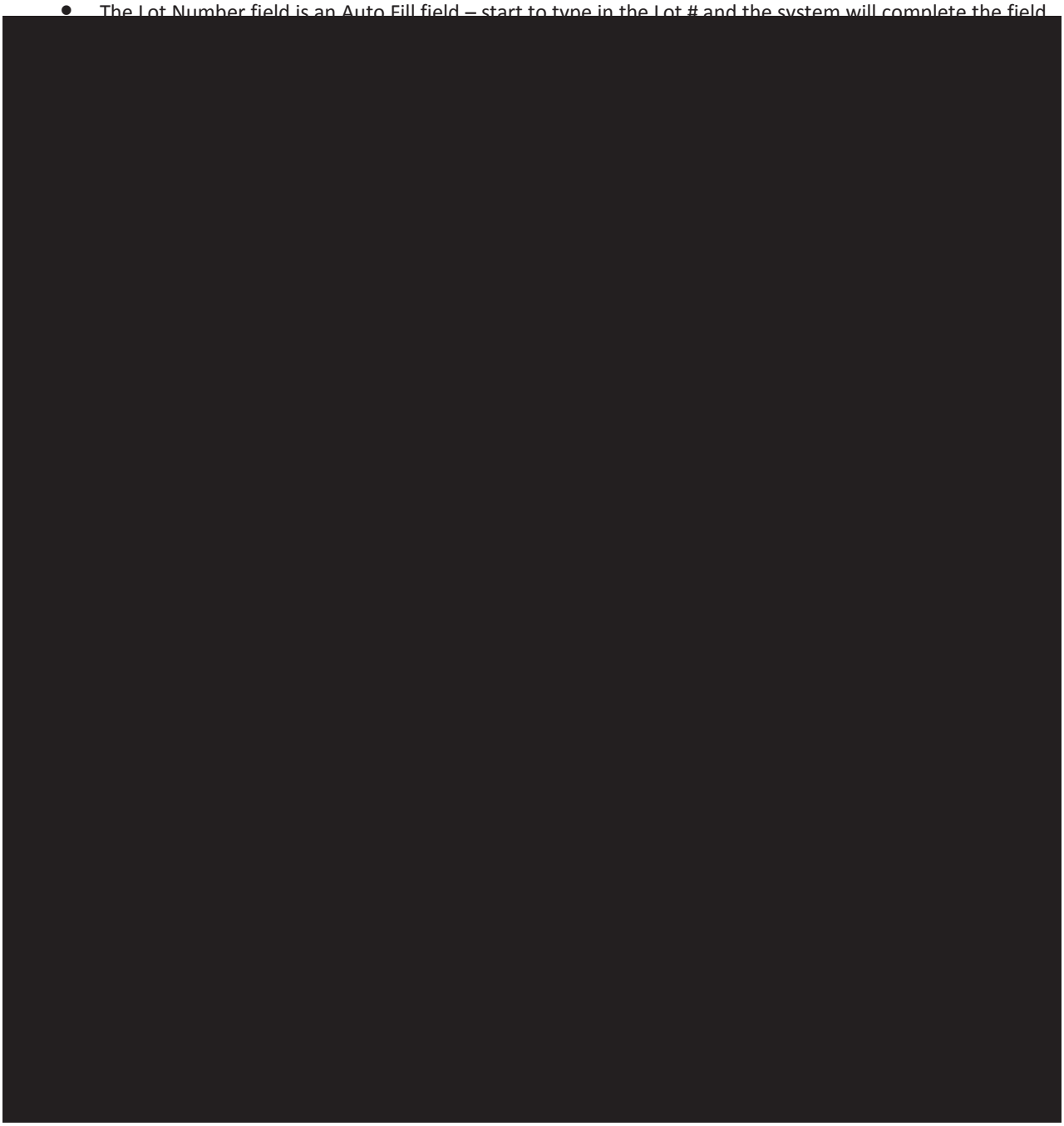
***If <u>Quantity shipped</u> is different from <u>Total Quantity Received</u>, please notify your regional CRA immediately (a query will populate if this occurs to be resolved)**

- At the end of the study you will need to return all unused test article
- At your close out visit your monitor will help you complete a **<u>Test Article Return Worksheet</u>**, documenting how much test article is being returned.
- Once the Test Article Return Worksheet is completed, you will need to enter the quantity of lenses being returned into the lens depot in the EDC system.

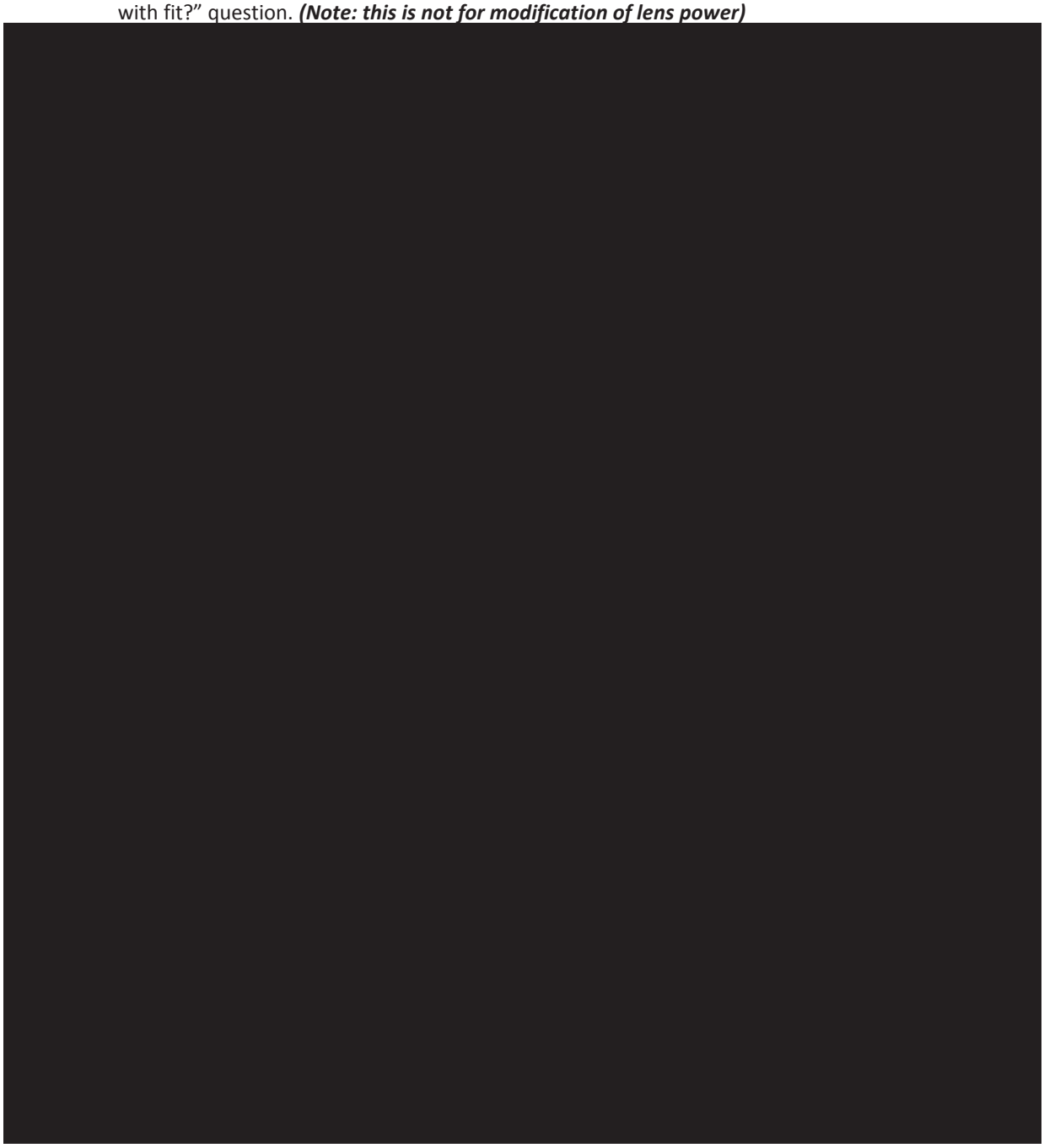
6. Enter <u>Total Quantity Returned</u> after the study is completed and lens accountability has been completed on paper.



- The Lot Number field is an Auto Fill field – start to type in the Lot # and the system will complete the field



- If additional lenses are needed, click “Yes” on the eCRF for the “Are additional lenses needed to proceed with fit?” question. ***(Note: this is not for modification of lens power)***



APPENDIX B: PRESBYOPIC SYMPTOMS

Presbyopic Symptoms Questionnaire

1. Do you notice that you often have to hold things farther away so that you could read them?

2. Do you notice that you often have difficulty focusing on near objects (i.e., experiencing blurry vision when looking at things close-up)?

3. Do you often have headaches or eyestrains, or feel fatigued, when read or conduct other near activities?

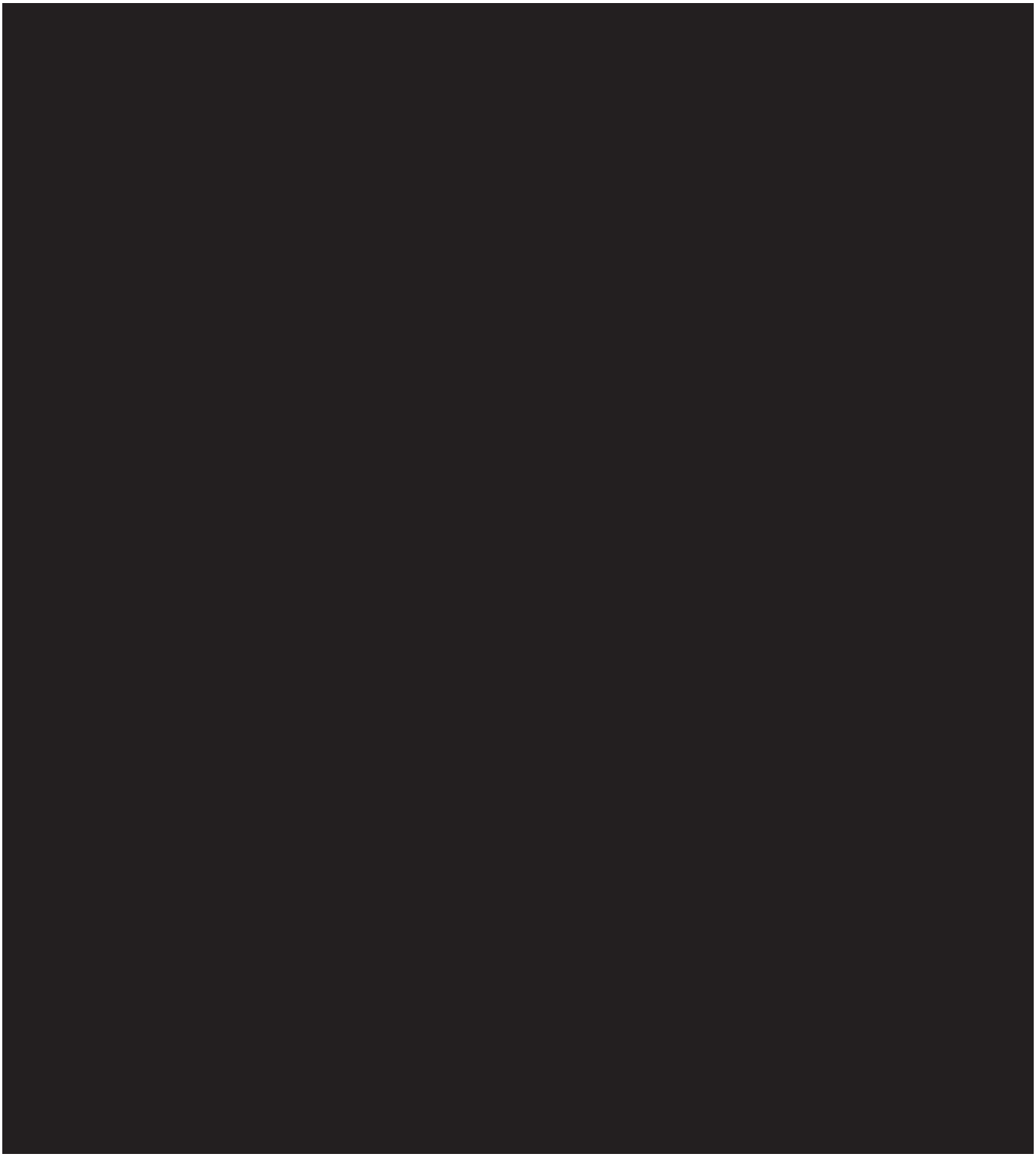
4. Do you often have difficulty reading small or fine prints, such as phone books, medicine bottles or package labels, etc.?

5. Do you often have difficulty reading under dim or low light?

APPENDIX C: OCULAR DOMINANCE

APPENDIX D: BINOCULAR OVER REFRACTION

APPENDIX E: FITTING GUIDE



APPENDIX F: [redacted] LIMBAL & CONJUCTIVAL (BULBAR) REDNESS

[redacted] **Limbal & Conjunctival (Bulbar) Redness**

[redacted]

[redacted]

[redacted]

[redacted]

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[redacted]

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Attachment A Efron Grading Scale for Limbal Redness (0.5 unit increments)

Attachment B Efron Grading Scale for Limbal Redness (1.0 unit increments)

Attachment C Efron Grading Scale for Bulbar Redness (0.5 unit increments)

Attachment D Efron Grading Scale for Bulbar Redness (1.0 unit increments)

Attachment E

APPENDIX G: [redacted] EXPANDED SODIUM FLUORESCEIN CORNEAL STAINING

[redacted]

Expanded Sodium Fluorescein Corneal Staining

[redacted] [redacted]

[redacted]

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[redacted] [redacted]

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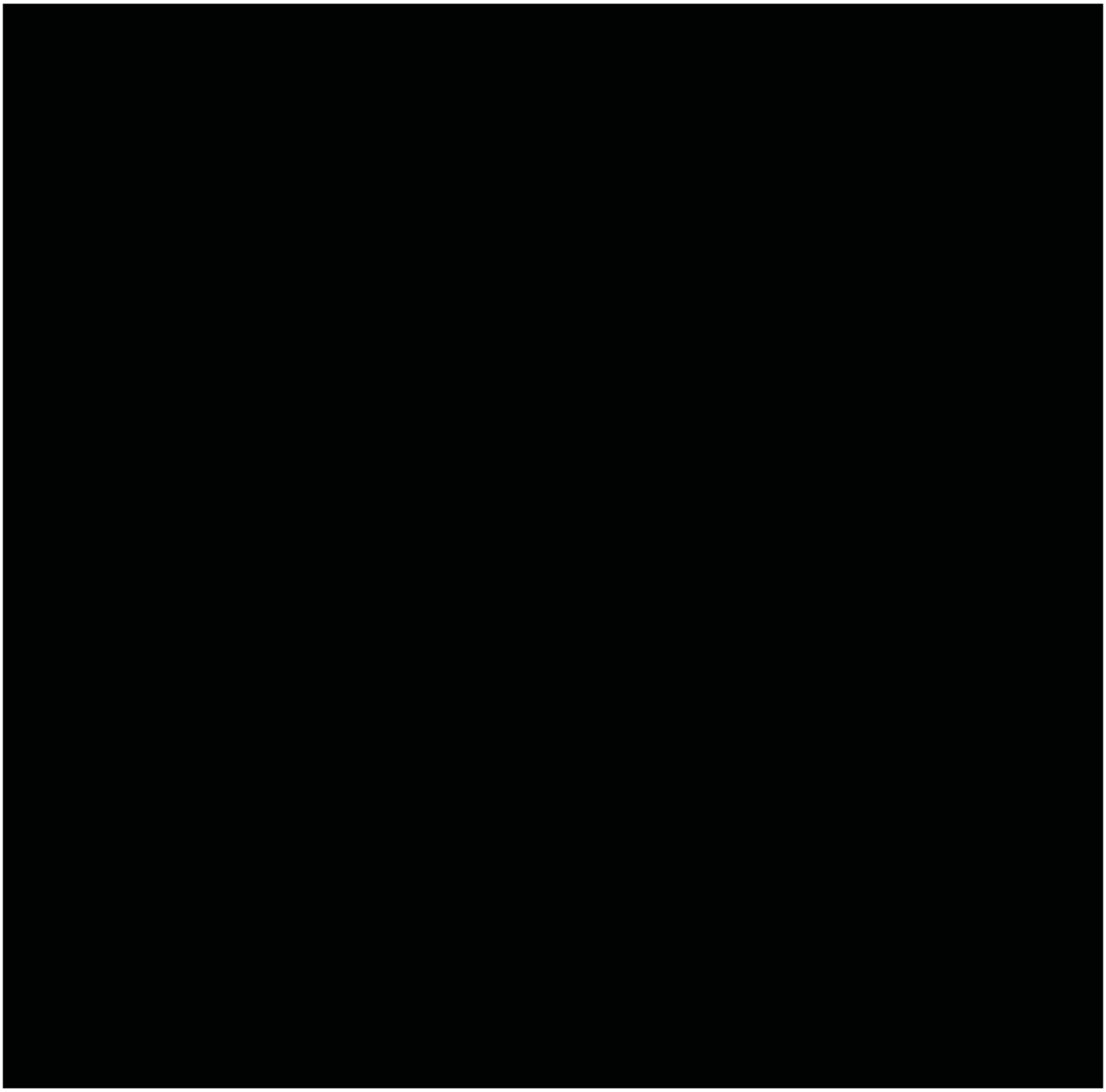


APPENDIX H: [redacted] DETERMINATION OF NEAR ADD

[redacted] **Determination of Near Addition**

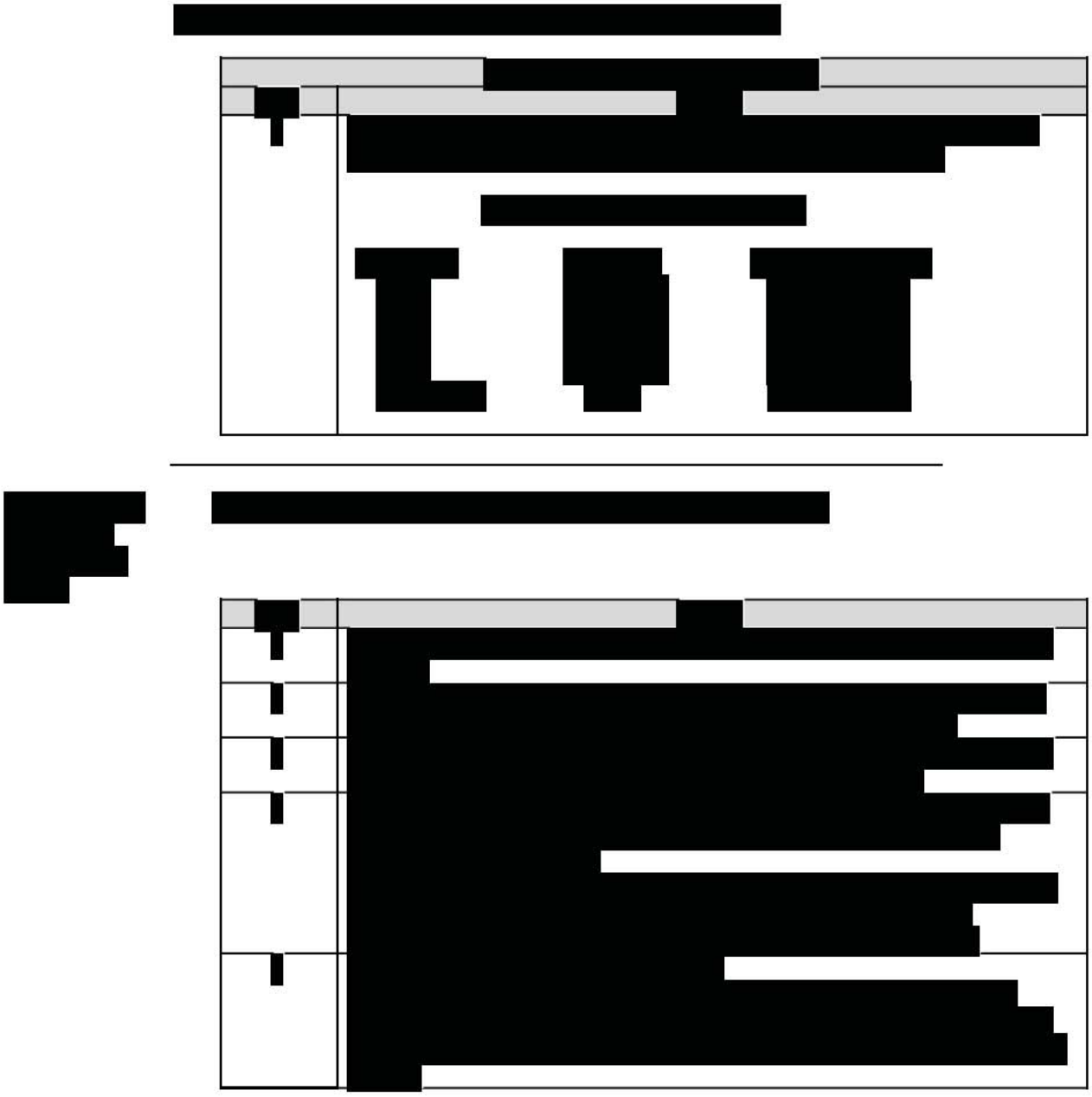
[redacted]

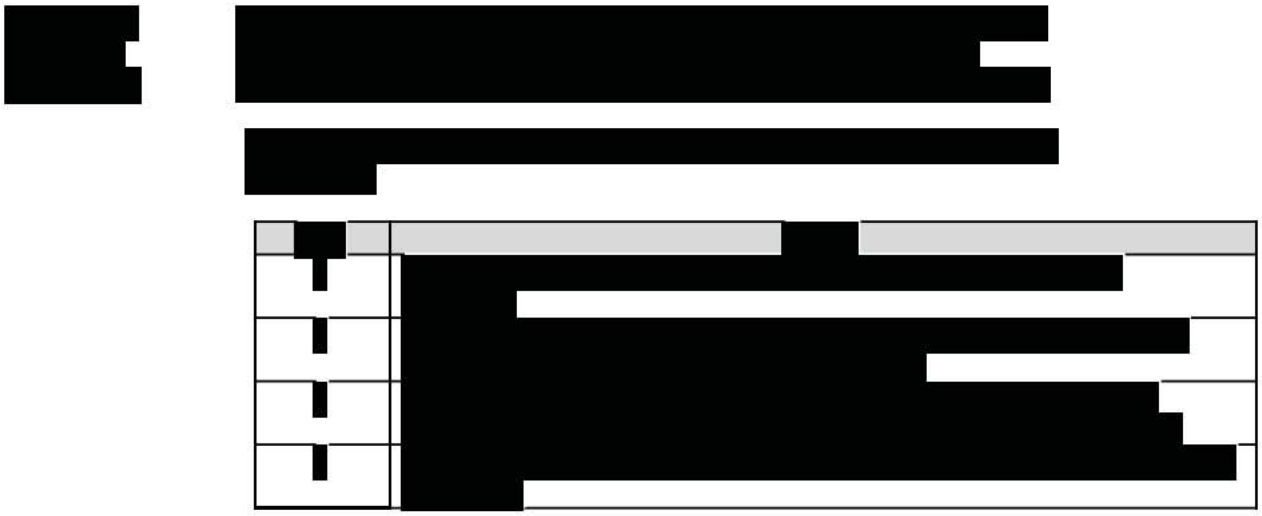
[redacted]

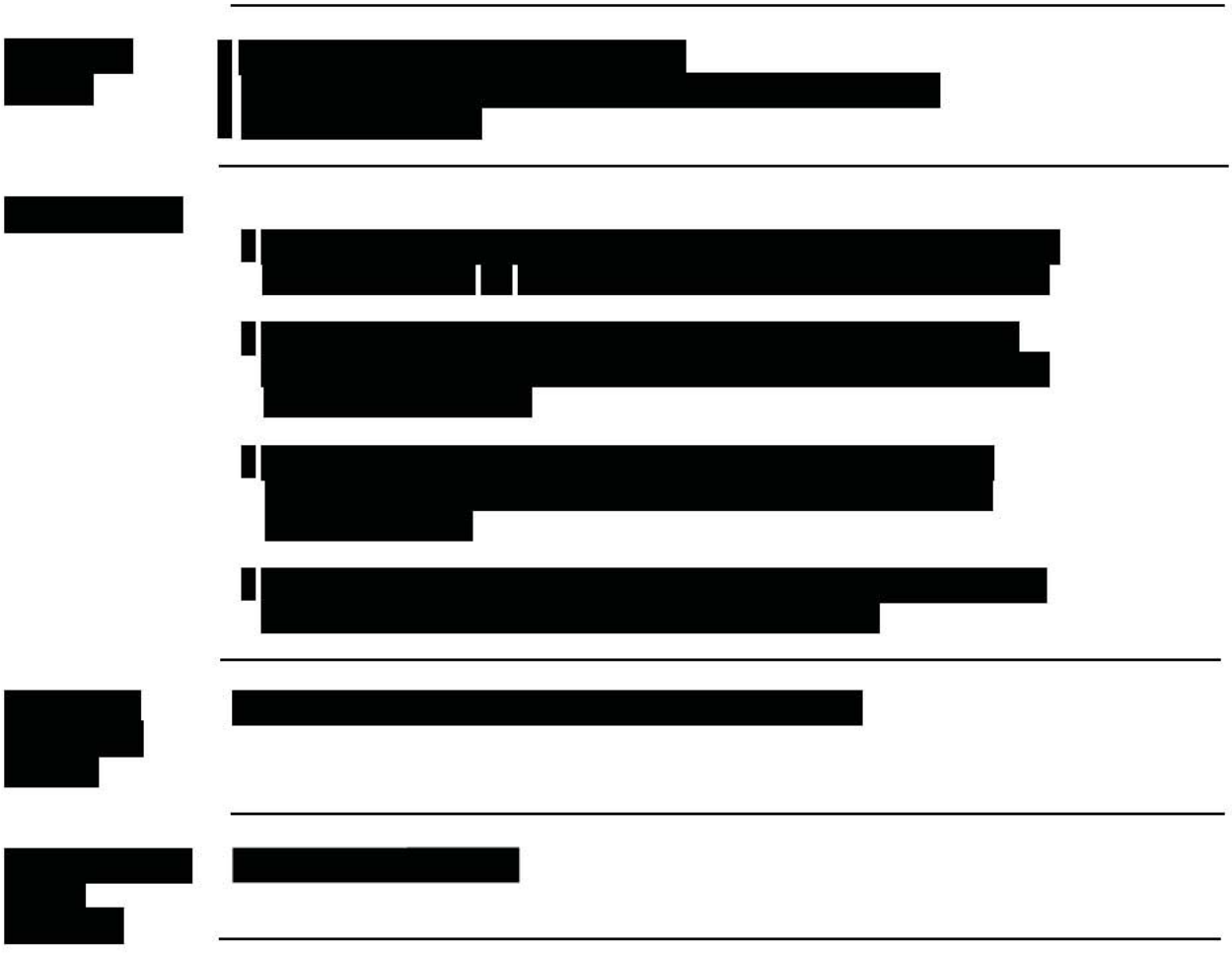
[redacted]

[redacted]

[redacted]







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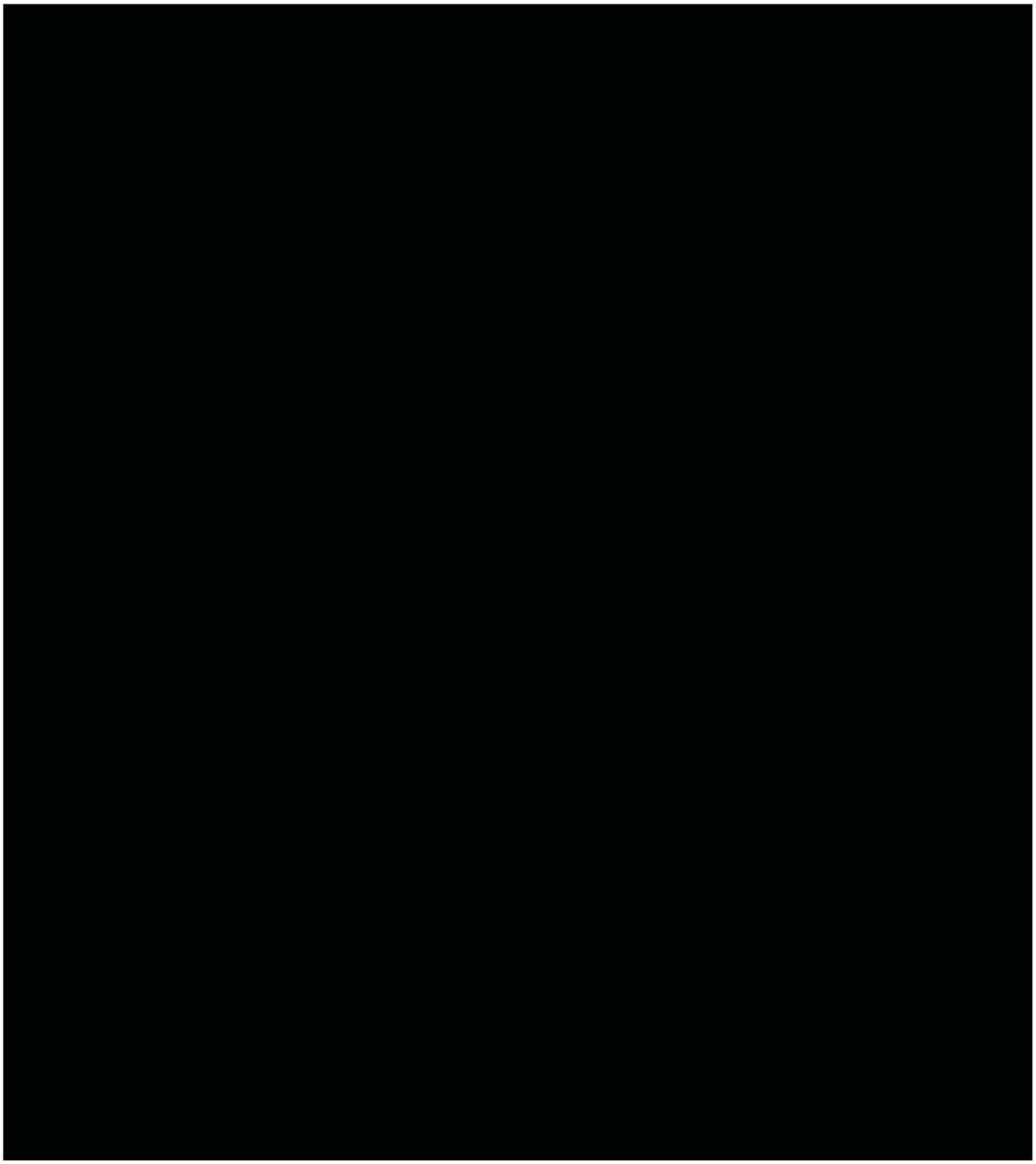

APPENDIX I: [redacted] NEAR LOGMAR VISUAL ACUITY MEASUREMENT PROCEDURE

[redacted] Near LogMAR Visual Acuity Measurement Procedure

[redacted]

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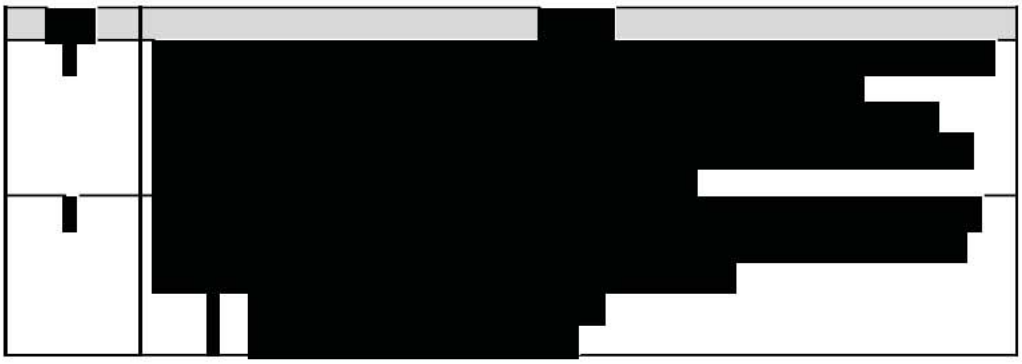
[redacted]

[redacted]



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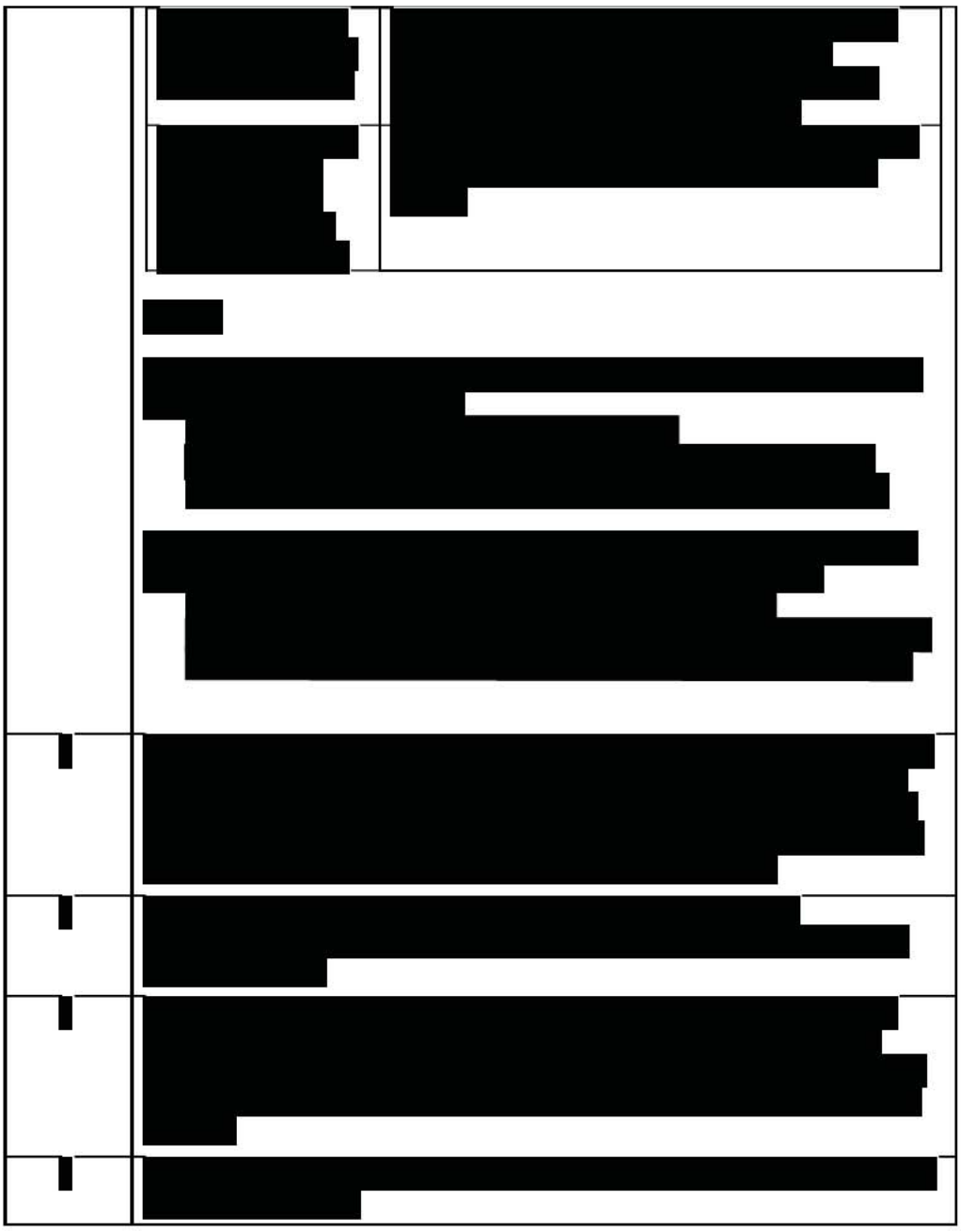
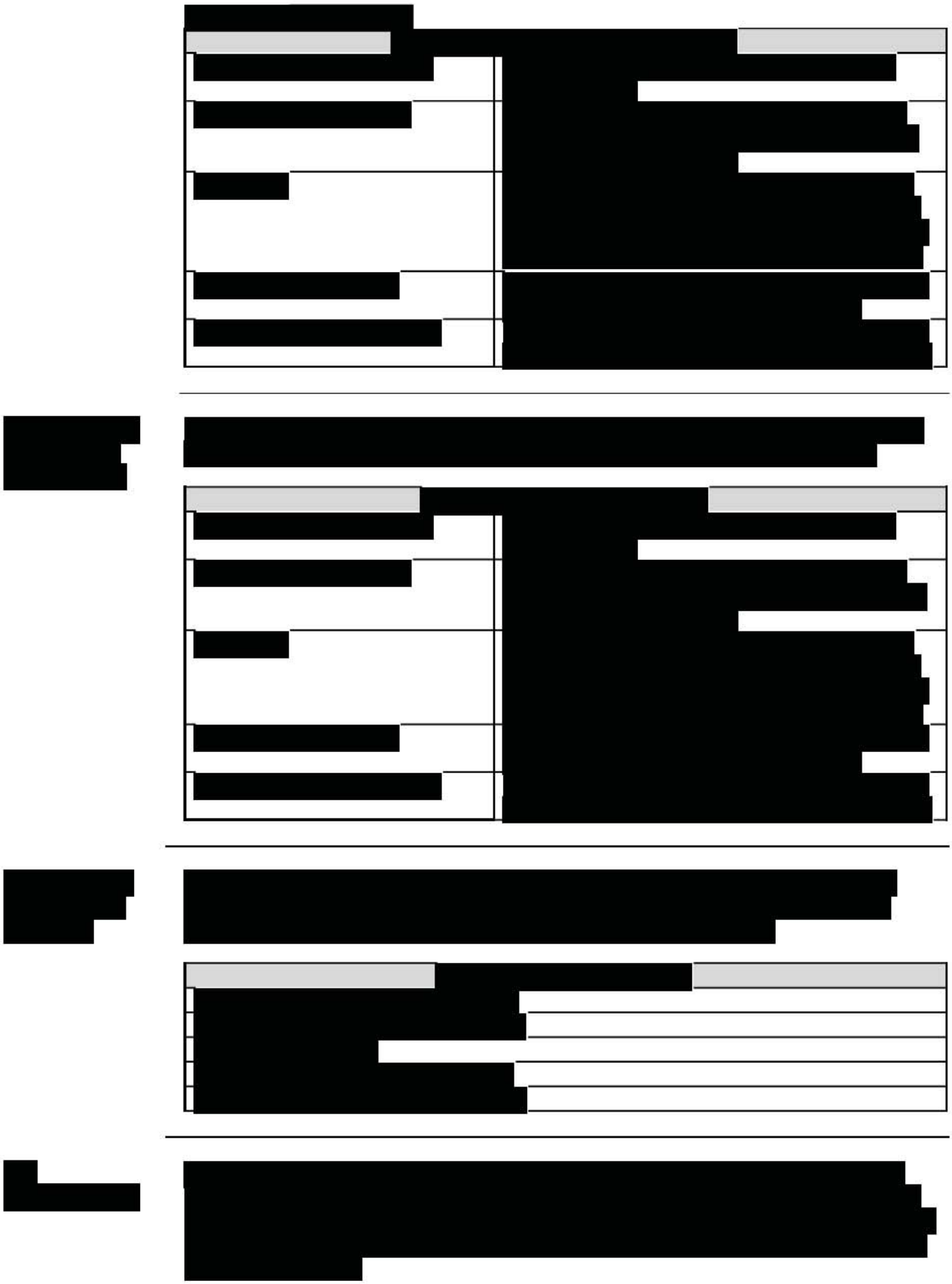
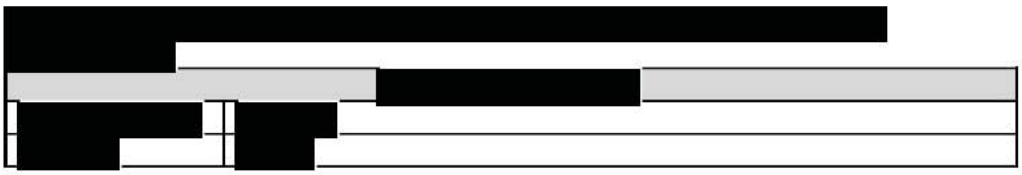


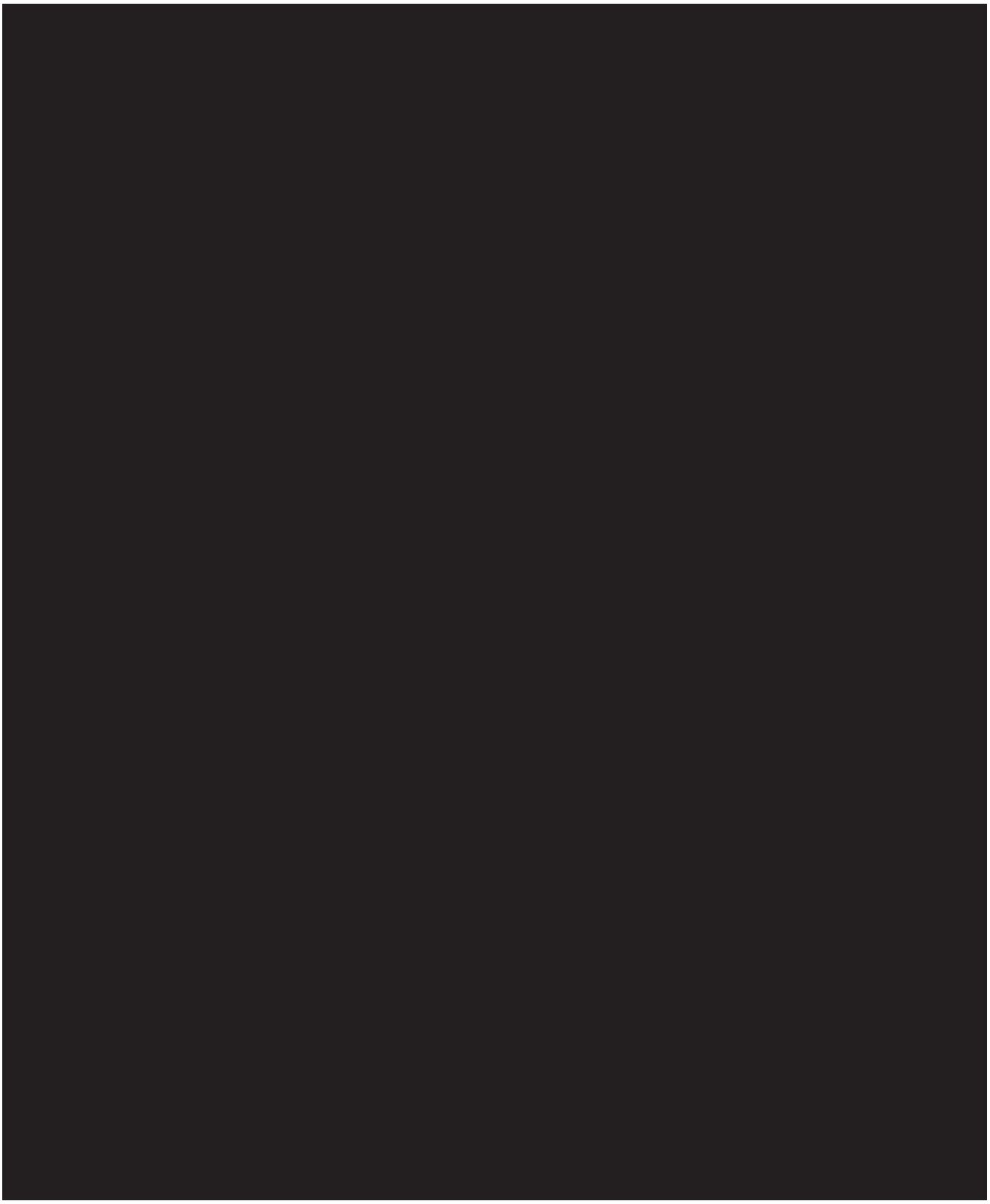
APPENDIX J: [redacted] LENS FITTING CHARACTERISTICS

[redacted] **Lens Fitting Characteristics**

[redacted]







APPENDIX K: [redacted] SUBJECT REPORTED OCULAR SYMPTOMS

[redacted]

Subject Reported Ocular Symptoms/Problems

[redacted] [redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted] [redacted]

[redacted] [redacted]

[redacted] [redacted]

APPENDIX L: [redacted] DETERMINATION OF DISTANCE SPHEROCYLINDRICAL REFRACTIONS

[redacted] **Determination of Distance Spherocylindrical Refractions**

[redacted]

[redacted]

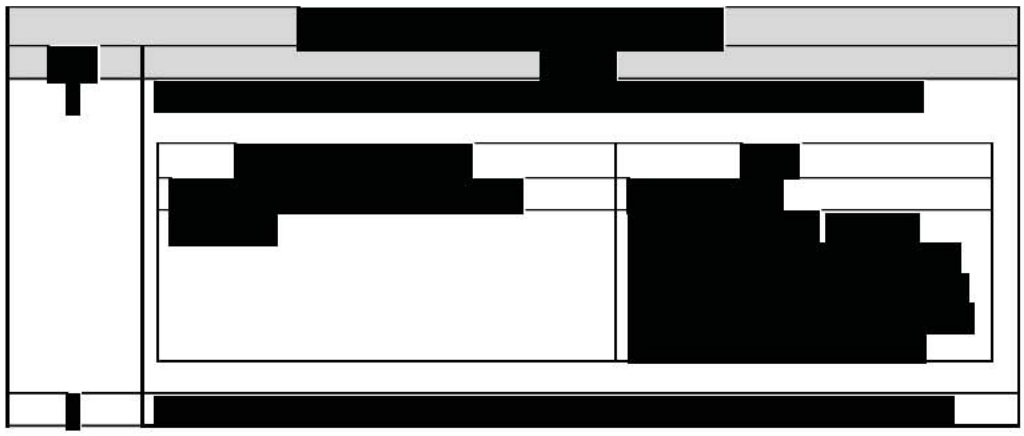
[redacted]

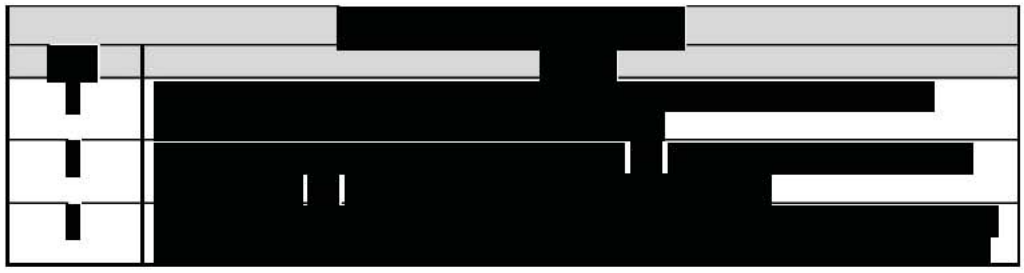
[redacted]

[redacted]

[redacted]

[redacted]





APPENDIX M: [redacted] BIOMICROSCOPY SCALE

[redacted] **Biomicroscopy Scale**

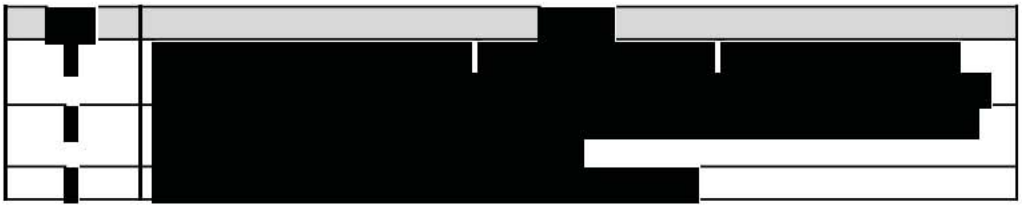
[redacted]

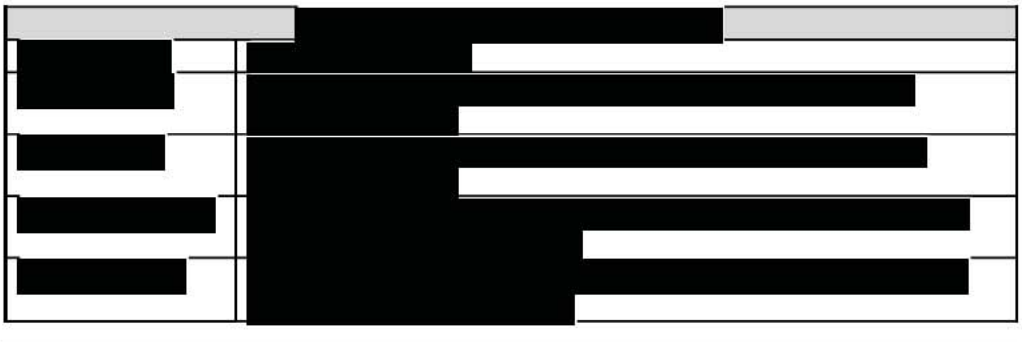
[redacted]

[redacted]

[redacted]

[redacted]





APPENDIX N: [redacted] KERATOMETRY

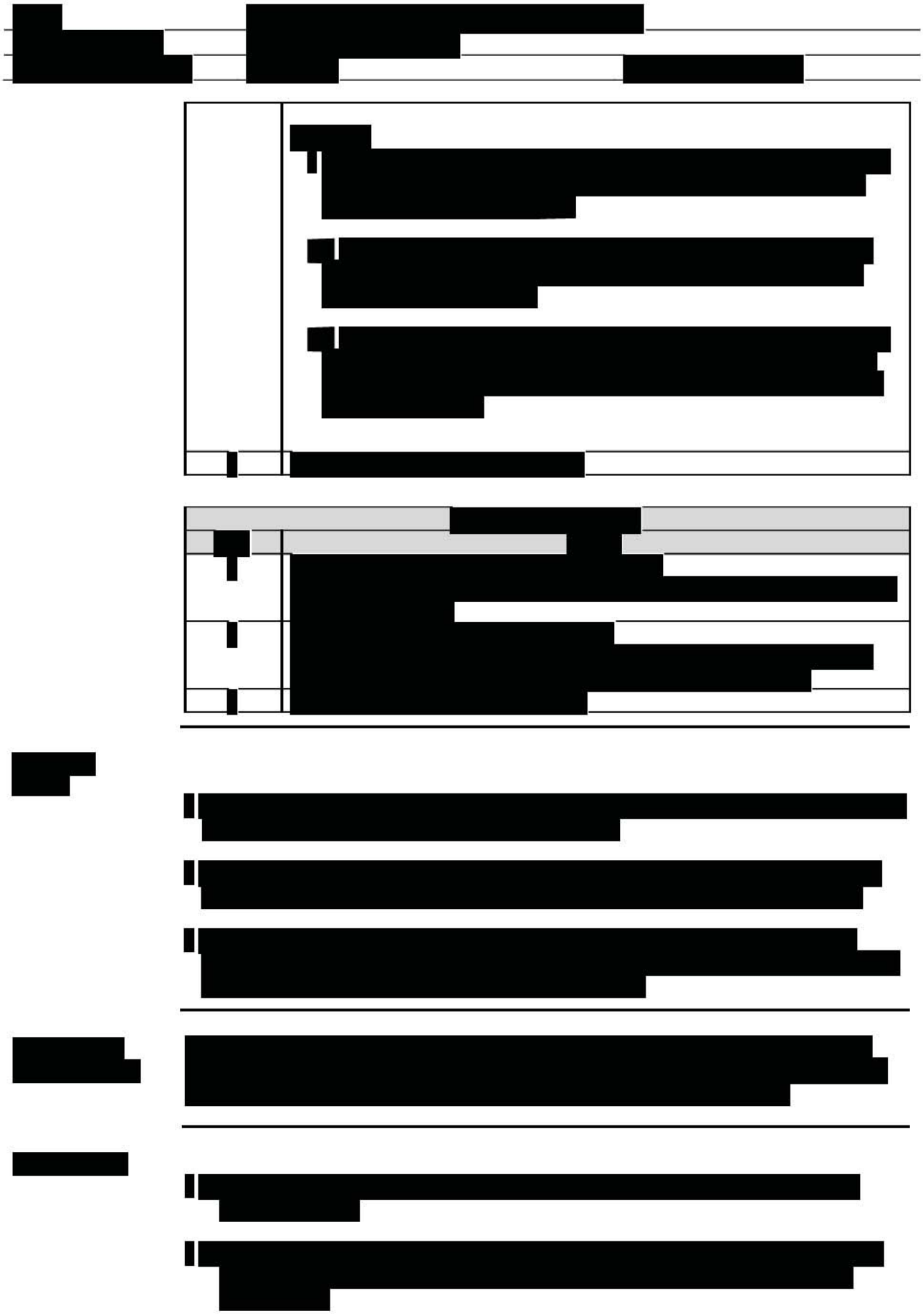
[redacted]

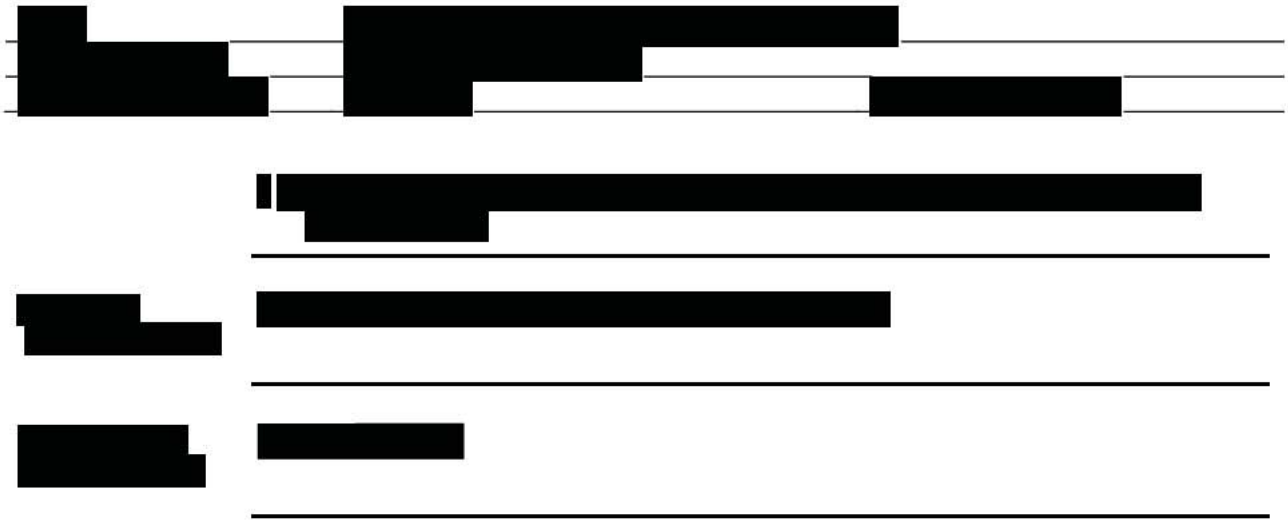
Keratometry Procedure

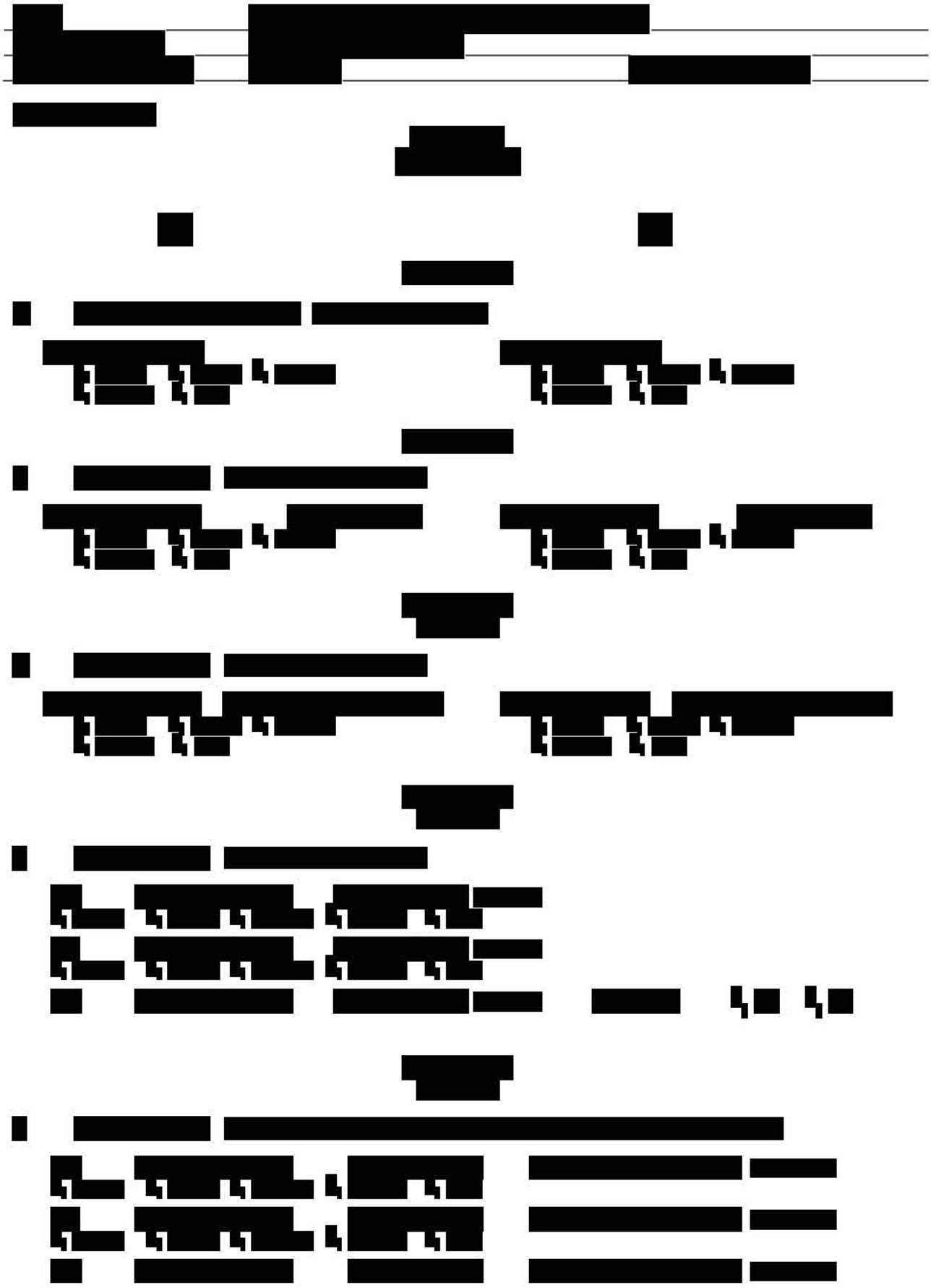
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

APPENDIX O: [redacted] DISTANCE AND NEAR VISUAL ACUITY EVALUATION

[redacted]







APPENDIX P: [redacted] TORIC FIT EVALUATION

[redacted] **Toric Fit Evaluation**

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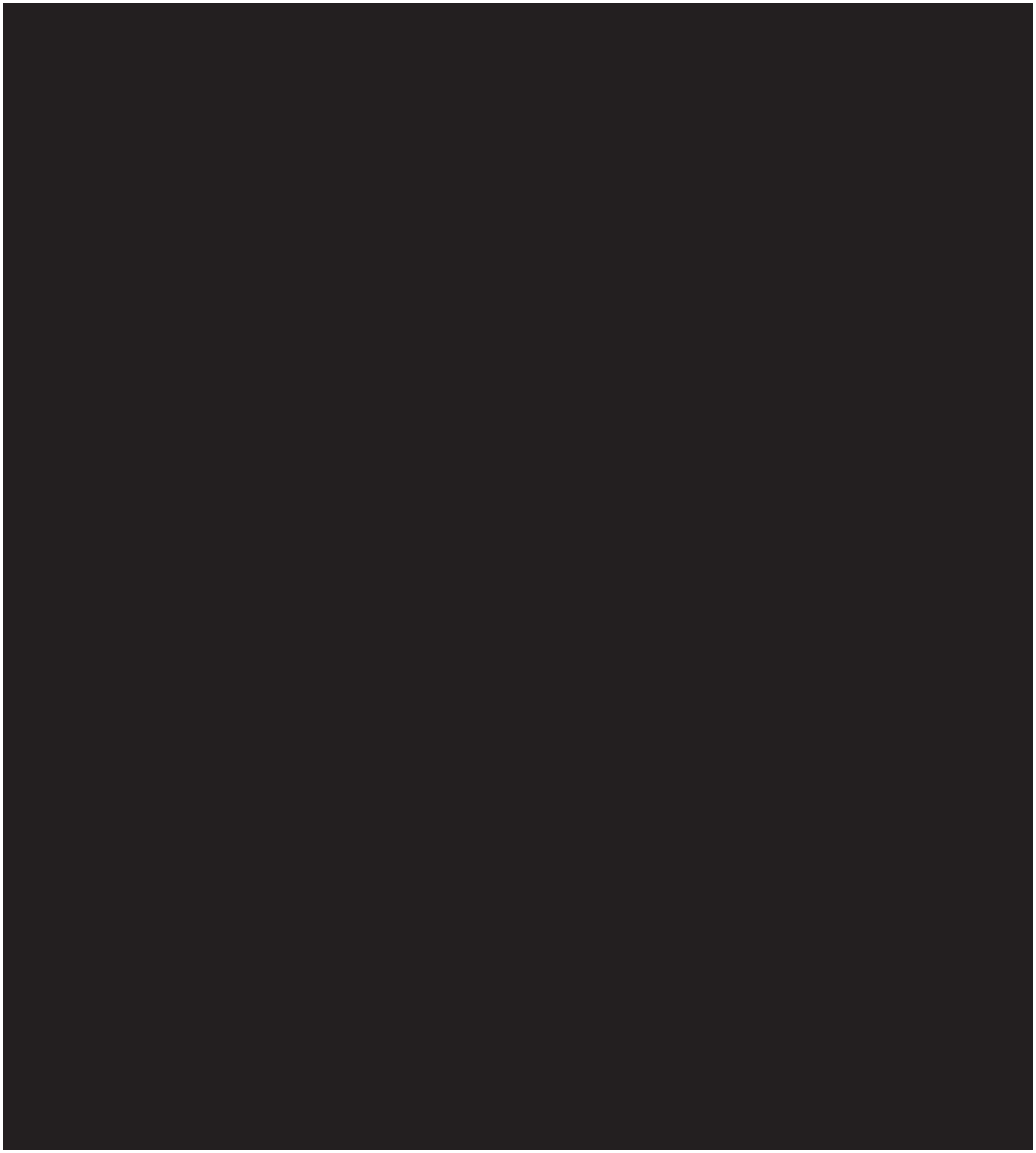
[redacted]

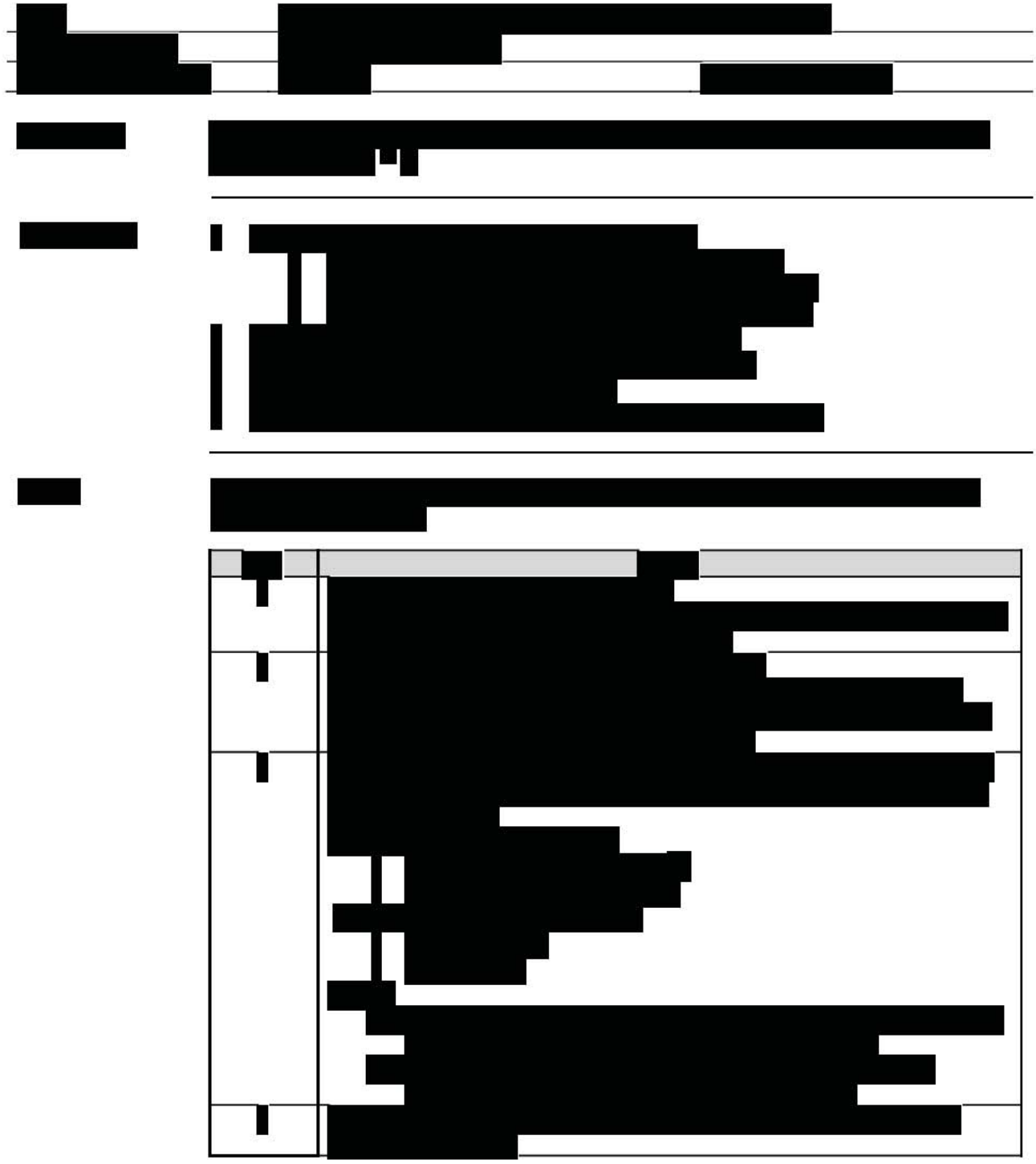
[redacted]

[redacted]

[redacted]



APPENDIX Q [redacted] ETDRS DISTANCE VISUAL ACUITY MEASUREMENT PROCEDURE



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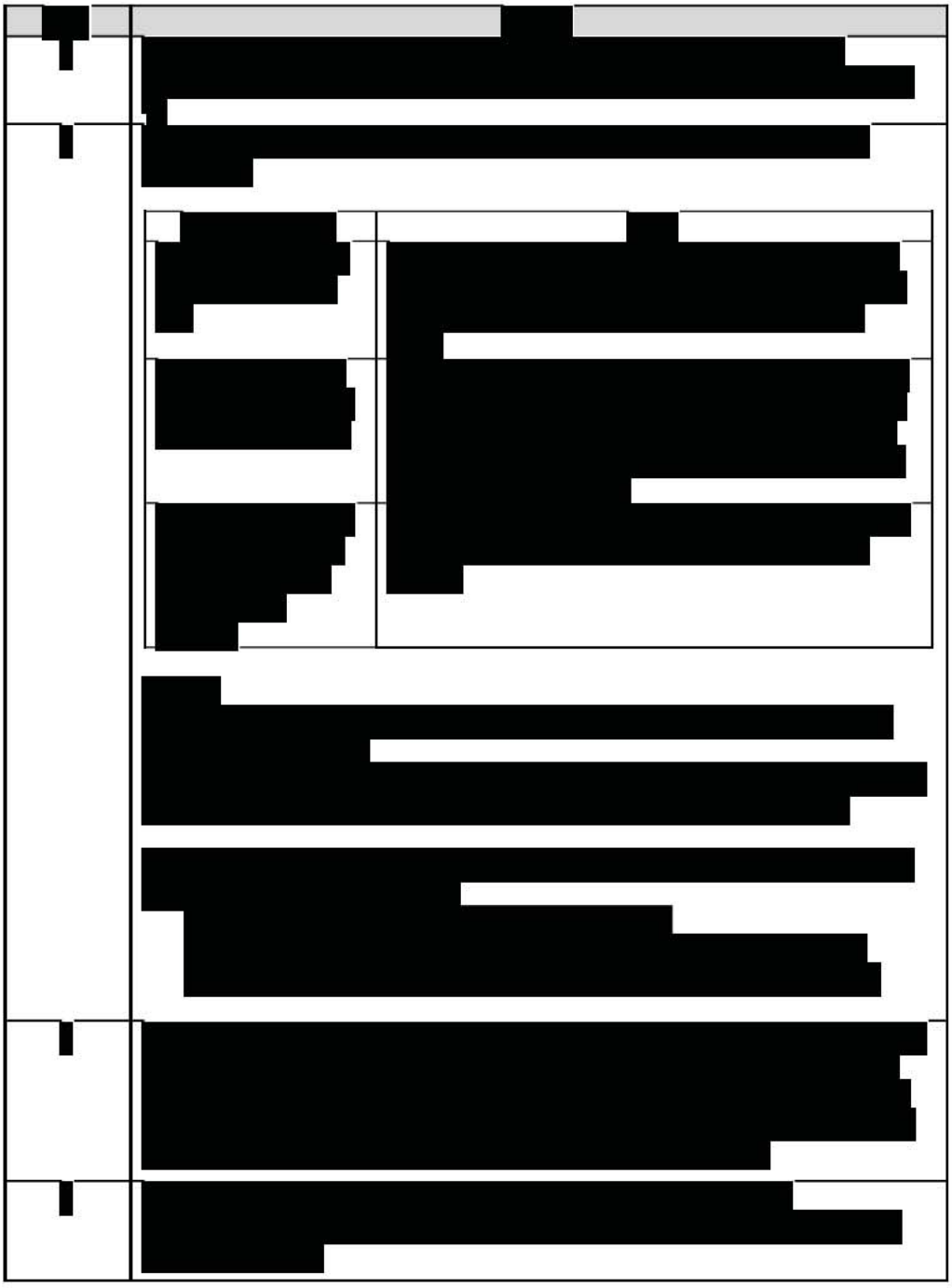

APPENDIX R: [redacted] MEASURING PUPIL DIAMETER WITH NEUROPTICS VIP-200 VARIABLE PUPILLOMETER

[redacted]

Measuring Pupil Diameter with NeurOptics VIP-200 Variable Pupillometer

[redacted]