Study Protocol

A Clinical Study Comparing Postoperative Outcomes Between the TECNIS Intraocular Lens

NCT Number: NCT05396599

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A Clinical Study Comparing Postoperative Outcomes Between the TECNIS [redacted] Intraocular Lens [redacted]

PROTOCOL NUMBER: JJSV201EYST

SPONSOR: Johnson & Johnson Surgical Vision, Inc.
31 Technology Drive, Suite 200
Irvine, CA 92618

Investigator Agreement

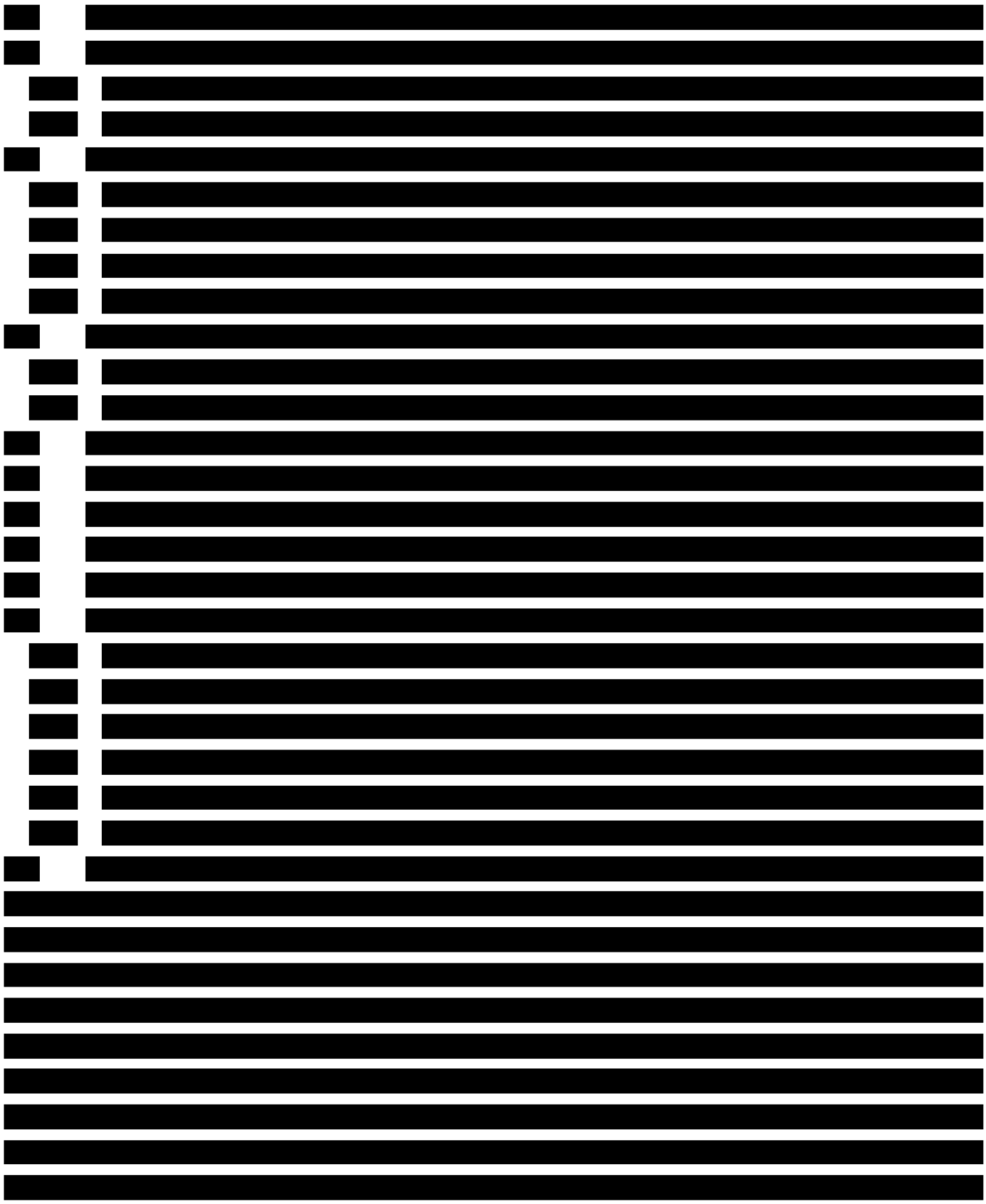
As an Investigator, I agree to:

- Implement and conduct this study diligently and in strict compliance with this agreement; the protocol; Good Clinical Practices; ISO 14155 and all other applicable regulations; conditions of approval imposed by the reviewing Independent Ethics Committee/ Institutional Review Board (IEC/IRB); and other regulatory authorities; and all other applicable laws and regulations.
- Supervise all testing of the device where human subjects are involved.
- Ensure that the requirements for obtaining informed consent are met.
- Obtain authorization for use/disclosure of health information
- Maintain all information supplied by Johnson & Johnson Surgical Vision in confidence and, when this information is submitted to an IEC/IRB, or any other group, it will be submitted with a designation that the material is confidential.

I have read this protocol in its entirety and I agree to all aspects.

Investigator Printed Name	Signature	Date
Sub-Investigator Printed Name	Signature	Date
Sub-Investigator Printed Name	Signature	Date
Sub-Investigator Printed Name	Signature	Date

TABLE OF CONTENTS



PERSONNEL AND FACILITIES

SPONSOR

Johnson & Johnson Surgical Vision, Inc. (JJSV)
31 Technology Drive, Suite 200
Irvine, CA 92618

SPONSOR PERSONNEL

[redacted]

EMERGENCY TELEPHONE NUMBERS

[redacted]

Protocol Change History

Version	Section(s)	Page(s)	Description of Change(s)	Rationale for Change(s)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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[redacted]

1. SYNOPSIS

PROTOCOL

A Clinical Study Comparing Postoperative Outcomes Between the TECNIS [redacted] Intraocular Lens [redacted]

Protocol Number: JJSV201EYST

STUDY PRODUCTS

TECNIS Eyhance® Toric II IOL with TECNIS Simplicity Delivery System (Model Series DIU, test lens #1), TECNIS Synergy® Toric II Intraocular Lens with TECNIS Simplicity Delivery System (Model Series DFW, test lens #2), and TECNIS Toric 1-Piece IOL (Model Series ZCT, control lens)

STUDY OBJECTIVE

The purpose of this clinical study is to compare the performance outcomes of eyes implanted with the TECNIS Eyhance® Toric II IOL and the TECNIS Synergy® Toric II IOL to the TECNIS Toric 1-Piece IOL (control) [redacted]

CLINICAL HYPOTHESIS

[redacted]

OVERALL STUDY DESIGN

Structure: Prospective, multi-center, three-arm, randomized, controlled study

Number of sites: Up to 20 sites located in North America [redacted]

[redacted]

Indication:

TEST #1: The TECNIS Simplicity Delivery System is used to fold and assist in inserting the TECNIS Eyhance Toric II IOLs that are indicated for primary implantation for the visual correction of aphakia and for reduction of refractive astigmatism in adult patients with greater than or equal to 1 diopter of preoperative corneal astigmatism, in whom a cataractous lens has been removed. The lens is intended for capsular bag placement only.

TEST #2: The TECNIS Simplicity Delivery System is used to fold and assist in inserting the TECNIS Synergy Toric II IOLs that are indicated for primary implantation for the visual correction of aphakia and for reduction of refractive astigmatism in adult patients with

greater than or equal to 1 diopter of preoperative corneal astigmatism, in whom a cataractous lens has been removed. Compared to an aspheric monofocal lens, the TECNIS Synergy IOLs mitigate the effects of presbyopia by providing improved visual acuity at intermediate and near distances to reduce eyeglass wear, while maintaining comparable distance visual acuity. The lens is intended for capsular bag placement only.

CONTROL: The TECNIS Toric 1-Piece IOLs are indicated for the visual correction of aphakia and pre-existing corneal astigmatism of one diopter or greater in adult patients with or without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire improved uncorrected distance vision, reduction in residual refractive cylinder and increased spectacle independence for distance vision. The device is intended to be placed in the capsular bag.

Administration: Subjects will be randomized to a treatment group (masked) in ratio 1:1:1. The refractive target will be emmetropia for each eye enrolled in the study. Surgeons will perform standardized, small-incision, cataract surgery and implant the study lenses using a JJSV-validated insertion system qualified for use with the lens to be implanted.

[redacted]

STUDY POPULATION

Condition: Unilateral or bilateral cataracts and corneal astigmatism for which implantation with a toric intraocular lens is planned for one or both eyes.

[redacted]

Enrollment Criteria

Eligible subjects will be enrolled based on surgeon's determination of meeting the minimum study criteria in one or both eyes:

Inclusion Criteria

1. Male or female at least 22 years of age
2. Have a cataract in one or both eyes, with planned phacoemulsification and intraocular lens implantation with a toric intraocular lens
3. Regular corneal astigmatism and predicted postoperative residual astigmatism of less than 1.00 D after implantation with a toric intraocular lens in the study eye(s)
4. Availability, willingness and sufficient cognitive awareness to understand the purpose of the examination procedures and comply with postoperative visits
5. Signed informed consent and HIPAA authorization or equivalent documentation necessary to comply with applicable privacy laws pertaining to medical treatment in the governing countries.

Exclusion Criteria

1. Best-corrected distance visual acuity better than 20/40 Snellen (0.3 logMAR)
2. Potential visual acuity estimated to be worse than 20/32 Snellen (0.2 logMAR)
3. Prior corneal refractive (LASIK, LASEK, RK, PRK, etc.) or intraocular surgery, Including prophylactic peripheral iridotomies and peripheral laser retinal repairs
4. Corneal abnormalities such as stromal, epithelial or endothelial dystrophies (e.g., any observed guttata) that are predicted to cause visual acuity losses to a level worse than 20/30 Snellen during the study
5. Pupil abnormalities (non-reactive, fixed pupils, or abnormally shaped pupils) or unable to dilate to visualize IOL axis (approximately 6.0 mm)
6. Inability to achieve keratometric stability for contact lens wearers (as defined in Section 10.3 Preoperative Procedures)
7. Recent ocular trauma or ocular surgery that is not resolved/stable or may affect visual outcomes or increase risk to the subject
8. Use of systemic or ocular medications that may affect vision
9. Prior, current, or anticipated use during the course of the 6-month study of tamsulosin or silodosin (e.g., Flomax, Flomaxtra, Rapaflo) that may, in the opinion of the investigator, confound the outcome or increase the risk to the subject (e.g., poor dilation or a lack of adequate iris structure to perform standard cataract surgery)
10. Poorly controlled diabetes
11. Acute, chronic, or uncontrolled systemic or ocular disease or illness that, in the opinion of the investigator, would increase the operative risk or confound the outcome(s) of the study (e.g., immunocompromised, connective tissue disease, suspected glaucoma, glaucomatous changes in the fundus or visual field, ocular inflammation, etc.). Note: controlled ocular hypertension without glaucomatous changes (optic nerve cupping and visual field loss) is acceptable.

12. Pregnancy, planned pregnancy, presently lactating, or another condition associated with hormonal fluctuation that could lead to refractive changes
13. Concurrent participation or participation in any other clinical study within 30 days prior to the preoperative visit
14. Any other systemic or ocular disease that, in the opinion of the investigator, may affect the patient's eligibility for the study, affect visual acuity or may require surgical intervention during the study (e.g., macular degeneration, cystoid macular edema, diabetic retinopathy, etc.).

NOTE: *Physicians considering enrollment of a patient with one or more of the conditions listed under the warning or precaution in the device labeling should weigh the potential risk/benefit ratio before enrollment in this study.*

EVALUATION CRITERIA:

Rotational stability of the TECNIS Eyhance Toric II IOL and TECNIS Synergy Toric II IOL are considered the main performance outcome for this study and will be evaluated by measuring the IOL misalignment at postoperative follow-up visits. [redacted]

The primary endpoint is the percentage of eyes with rotational stability of the IOL, where rotational stability is defined as a change in IOL axis ≤10° at a postoperative [redacted]

Safety outcomes include [redacted] adverse event rates.

[redacted]

[redacted]

STUDY VISITS AND PROCEDURES:

Subject eligibility will be assessed at the preoperative visit by the investigators according to the product labeling and study inclusion/exclusion criteria. Written consent must be provided by each patient who agrees to participate in the study prior to undergoing any study-specific procedures. This will include designation as to whether one or both eyes are to be included in the study. Those subjects who meet the inclusion/exclusion criteria for at least one eye and agree to participate in the study will be randomized to the test or control group for implantation in one or both eyes.

[redacted]

2. BACKGROUND/INTRODUCTION

Approximately one-third of patients presenting for cataract surgery are likely to have at least 1.0 D of corneal astigmatism.[1] Patients with astigmatism that desire spectacle independence after cataract surgery will need a method to eliminate or reduce corneal cylinder. Kessel et al.,

[1] Hoffmann PC, Hütz WW. Analysis of biometry and prevalence data for corneal astigmatism in 23,239 eyes. J Cataract Refract Surg. 2010;36(9):1479-1485.

compared the two most commonly available options to reduce astigmatism and noted that the most effective way to reduce astigmatism is by implanting a toric IOL.[2]

Test lens #1 in this study, TECNIS Eyhance Toric II IOL Model series DIU, has been commercially available worldwide as a lens that provides patients with both intermediate and distance (far) vision and reduced spectacle dependence. The lens is intended to compensate for corneal spherical aberration and corneal astigmatism, in addition to providing intermediate and distance vision and reduced spectacle dependence.

Test lens #2 in this study, TECNIS Synergy Toric II IOL has been commercially available worldwide as a lens that compensates for corneal spherical aberrations and corneal astigmatism, in addition to providing near, intermediate and distance vision and reduced spectacle dependence.

The control lens in this study, TECNIS Toric 1-Piece Model ZCT Series IOLs, was developed as an extension of the 1-piece, foldable, acrylic, ultraviolet-absorbing, posterior chamber IOL family, designed to treat aphakia and provide distance vision while compensating for pre-existing corneal astigmatism.

This prospective, randomized, controlled clinical study is being conducted in a post-market format in North America [redacted]

3. CLINICAL HYPOTHESIS

[redacted]

4. STUDY DESIGN

This is a prospective, multi-center, masked, three-arm, randomized clinical study of the TECNIS Eyhance Toric II IOL (test #1) and TECNIS Synergy Toric II (test #2) compared to the TECNIS Toric 1-Piece IOL (control). [redacted]

[2] Kessel L, Andresen J, Tendal B, Erngaard D, Flesner P, Hjortdal J. Toric Intraocular Lenses in the Correction of Astigmatism During Cataract Surgery: A Systematic Review and Meta-analysis. Ophthalmology. 2016;123(2):275-286.

5. ACRONYMS

The following acronyms are used throughout this protocol:

ADE: adverse device effect
AK: astigmatic keratotomy
BCDVA: best-corrected distance visual acuity
BSS: balanced salt solution
CRF: case report form
DCNVA: distance-corrected near visual acuity
EDC: electronic data capture
IEC: Independent Ethics Committee
IRB: Independent Review Board
IOP: intraocular pressure
LASEK: laser epithelial keratomileusis
LASIK: laser-assisted in-situ keratomileusis
LRI: limbal relaxing incisions
OCCI: opposite clear corneal incisions
PRK: photorefractive keratectomy
SAE: serious adverse events
UADE: unanticipated adverse device effect
UCDVA: uncorrected distance visual acuity
UCNVA: uncorrected near visual acuity
USADE: unanticipated serious adverse device effect

6. STUDY OBJECTIVES AND ENDPOINTS

The purpose of this clinical study is to compare safety and effectiveness outcomes between the TECNIS Eyhance Toric II IOL, Model series DIU (test #1), and the TECNIS Synergy Toric II IOL, Model series DFW (test #2), respectively, to the TECNIS Toric 1-Piece IOL Model series ZCT (control), [redacted]. Each test IOL will be individually compared to the control IOL. Rotational stability is the primary outcome [redacted]

6.1 EFFECTIVENESS ENDPOINTS

Primary Endpoint

The primary endpoint is the percentage of eyes with rotational stability of the IOL at postoperative 6 months (i.e., misalignment ≤10° [redacted] relative to baseline).

Other Effectiveness Endpoints

[redacted]

[redacted]

6.2 SAFETY AND OTHER ENDPOINTS

- [redacted]
- Adverse event rates, including IOL repositioning and/or IOL exchange primarily due to IOL misalignment

7. STUDY PRODUCT

7.1 TECNIS EYHANCE TORIC II IOL (TEST LENS #1)

The TECNIS Eyhance Toric II IOLs, Model series DIU, are ultraviolet light-absorbing posterior chamber intraocular lenses that are designed to slightly extend the depth of focus compared to a monofocal IOL and compensate for corneal astigmatism.

The TECNIS Eyhance Toric II IOLs are designed to be positioned in the lens capsule to replace the optical function of the natural crystalline lens. The lens compensates for corneal spherical aberrations and corneal astigmatism. The benefits of aspheric compensation for corneal spherical aberrations are contingent upon full refractive correction of sphere and cylinder. Accommodation

will not be restored. The IOL contains a squared posterior edge that provides a 360-degree barrier. The edge of the optic has a frosted design to reduce potential edge glare effects. In addition, compared to the TECNIS Toric 1-Piece IOL (Model Series ZCT), the haptics of the TECNIS Eyhance Toric II IOL have a squared and frosted design. The anteriorly located cylinder axis marks denote the meridian with the lowest power and is to be aligned with the steep corneal meridian.

INDICATION

The TECNIS Simplicity Delivery System is used to fold and assist in inserting the TECNIS Eyhance Toric II IOLs that are indicated for primary implantation for the visual correction of aphakia and for reduction of refractive astigmatism in adult patients with greater than or equal to 1 diopter of preoperative corneal astigmatism, in whom a cataractous lens has been removed. The lens is intended for capsular bag placement only.

7.2 TECNIS SYNERGY TORIC II IOL (TEST LENS #2)

The TECNIS Synergy Toric II IOLs, Model series DFW, are ultraviolet light-absorbing posterior chamber intraocular lenses that are intended to mitigate the effects of presbyopia and provide a continuous range of high-quality vision by extending the depth of focus. In addition, the IOLs compensate for corneal astigmatism.

The TECNIS Synergy Toric II IOLs are designed to be positioned in the lens capsule to replace the optical function of the natural crystalline lens. The TECNIS Synergy Toric II IOL is a one-piece, foldable, posterior chamber lens with an overall diameter of 13.0 mm and an optic diameter of 6.0 mm. It incorporates a proprietary toric-aspheric optic design on the anterior surface that compensates for corneal spherical aberration and a diffractive posterior surface designed to compensate for the eye's chromatic aberrations and to extend the range of vision, improve intermediate and near visual acuities, and reduce how often patients wear glasses or contact lenses.

The anteriorly located cylinder axis marks in the toric-aspheric optic denote the meridian with the lowest power and is to be aligned with the steep corneal meridian. In addition, the haptics of the TECNIS Synergy Toric II IOL have a squared and frosted design. The squared posterior edge of the aspheric and toric-aspheric anterior optic is designed to provide a 360-degree barrier and has a frosted design to reduce potential edge glare effects. TECNIS Synergy Toric II IOLs are designed to have pupil-independent lens performance in any lighting condition.

INDICATION

The TECNIS Simplicity Delivery System is used to fold and assist in inserting the TECNIS Synergy Toric II IOLs that are indicated for primary implantation for the visual correction of aphakia and for reduction of refractive astigmatism in adult patients with greater than or equal to 1 diopter of preoperative corneal astigmatism, in whom a cataractous lens has been removed. Compared to an aspheric monofocal lens, the TECNIS Synergy IOLs mitigate the effects of presbyopia by providing improved visual acuity at intermediate and near distances to reduce

eyeglass wear, while maintaining comparable distance visual acuity. The lens is intended for capsular bag placement only.

7.3 TECNIS TORIC 1-PIECE IOL (CONTROL LENS)

The TECNIS Toric 1-Piece IOLs, Model ZCT Series, are 1-piece, toric, foldable, acrylic, ultraviolet-absorbing, posterior chamber IOLs. The lenses are designed to correct aphakia and provide distance vision while compensating for pre-existing corneal astigmatism.

INDICATION

The TECNIS Toric 1-piece posterior chamber lenses are indicated for the visual correction of aphakia and pre-existing corneal astigmatism of one diopter or greater in adult patients with or without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire improved uncorrected distance vision, reduction in residual refractive cylinder and increased spectacle independence for distance vision. The device is intended to be placed in the capsular bag.

7.4 IMPLANTATION SYSTEMS

The TECNIS Simplicity Delivery System [redacted]

or any other insertion system qualified for use by JJSV.

8. STUDY POPULATION

All study subjects will be enrolled from the normal cataract population at investigative sites in North America. [redacted]

After determining eligibility and completing lens calculations, subjects will undergo unilateral or bilateral primary cataract extraction and implantation with an intraocular lens. Subjects will be implanted in one or both eyes, in accordance with the study inclusion and exclusion criteria. Eligibility criteria may not be waived by the investigator. [redacted]

8.1 INCLUSION CRITERIA

1. Male or female patients at least 22 years of age
2. Have a cataract in one or both eyes, with planned phacoemulsification and intraocular lens implantation with a toric presbyopia-correcting intraocular lens

3. Regular corneal astigmatism and predicted postoperative residual astigmatism of less than 1.00 D after implantation with a toric intraocular in the study eye(s)
4. Availability, willingness and sufficient cognitive awareness to understand the purpose of the examination procedures and comply with study visits
5. Signed informed consent and HIPAA authorization or equivalent documentation necessary to comply with applicable privacy laws pertaining to medical treatment in the governing countries.

8.2 EXCLUSION CRITERIA

1. Best-corrected distance visual acuity better than 20/40 Snellen (0.3 logMAR)
2. Potential visual acuity estimated to be worse than 20/32 Snellen (0.2 logMAR)
3. Prior corneal refractive (LASIK, LASEK, RK, PRK, etc.) or intraocular surgery, Including prophylactic peripheral iridotomies and peripheral laser retinal repairs
4. Corneal abnormalities such as stromal, epithelial or endothelial dystrophies (e.g., any observed guttata) that are predicted to cause visual acuity losses to a level worse than 20/30 Snellen during the study
5. Pupil abnormalities (non-reactive, fixed pupils, or abnormally shaped pupils) or unable to dilate to visualize IOL axis (approximately 6.0 mm)
6. Inability to achieve keratometric stability for contact lens wearers (as defined in Section 10.3 Preoperative Procedures)
7. Recent ocular trauma or ocular surgery that is not resolved/stable or may affect visual outcomes or increase risk to the subject
8. Use of systemic or ocular medications that may affect vision
9. Prior, current, or anticipated use during the course of the 6-month study of tamsulosin or silodosin (e.g., Flomax, Flomaxtra, Rapaflo) that may, in the opinion of the investigator, confound the outcome or increase the risk to the subject (e.g., poor dilation or a lack of adequate iris structure to perform standard cataract surgery)
10. Poorly controlled diabetes
11. Acute, chronic, or uncontrolled systemic or ocular disease or illness that, in the opinion of the investigator, would increase the operative risk or confound the outcome(s) of the study (e.g., immunocompromised, connective tissue disease, suspected glaucoma, glaucomatous changes in the fundus or visual field, ocular inflammation, etc.). Note: controlled ocular hypertension without glaucomatous changes (optic nerve cupping and visual field loss) is acceptable.
12. Pregnancy, planned pregnancy, presently lactating, or another condition associated with hormonal fluctuation that could lead to refractive changes
13. Concurrent participation or participation in any other clinical study within 30 days prior to the preoperative visit
14. Any other systemic or ocular disease that, in the opinion of the investigator, may affect the patient's eligibility for the study, affect visual acuity or may require surgical intervention during the study (e.g., macular degeneration, cystoid macular edema, diabetic retinopathy, etc.).

[redacted]

9. INVESTIGATOR SELECTION

9.1 INVESTIGATOR QUALIFICATIONS

JJSV will select ophthalmic surgeons who have completed a residency in ophthalmology (or its documented equivalent) and are licensed to practice medicine and perform surgery at his/her investigative site. Study site must have one designated principal investigator and may have additional implanting sub-investigators.

[redacted]

9.2 INVESTIGATOR OBLIGATIONS

Investigators are required to fulfill the following obligations:

- Conduct the study in accordance with the relevant and current protocol and all legal requirements for clinical trials including ISO 14155 and Good Clinical Practice (GCP). Investigator will only make changes to a protocol after notifying and obtaining approval from JJSV and the Independent Ethics Committee/Institutional Review Board (IEC/IRB) except when necessary to protect the safety, rights or welfare of subjects.
- Personally conduct and supervise the study.
- Maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.
- Be responsible for protecting the rights, safety and welfare of subjects under the investigator's care.
- Maintain confidentiality as required by applicable laws and regulations.
- Obtain IEC/IRB approval and written informed consent from any subject prior to their participation in a study-specific activity.
- Document in each subject's case history that informed consent was obtained prior to participation in the study.
- Report to JJSV and the reviewing IEC/IRB any adverse experiences that occur during the study in accordance with applicable laws and regulations.
- Maintain adequate and accurate records in accordance with applicable laws and regulations and make available all study documents and subject medical records for inspection by either JJSV, duly authorized regulatory agencies.

- Submit progress reports on the investigation to JJSV and the reviewing IEC/IRB at regular intervals, but no less often than yearly.
- Ensure the IEC/IRB that is responsible for initial and continuing review of the study complies with applicable laws and regulations.
- Report all changes in research activity and all unanticipated problems involving risks to patients to the IEC/IRB and JJSV.
- Provide sufficient accurate financial information to JJSV to allow JJSV to submit complete and accurate certification or disclosure statements. Promptly update this information if any relevant changes occur during the investigation or for up to one year following completion of the study.
- Comply with all other obligations of clinical investigators and requirements according to all applicable regulations and all conditions of approval imposed by the reviewing IEC/IRB.
- Ensure that all associates, colleagues and employees assisting in the conduct of the study are adequately informed about the protocol, the investigational device, their study-related duties and functions and agree to fulfill their obligations in meeting the above commitments.

Investigators shall provide adequate time and resources to conduct and report on the study. The Investigator, or delegate, shall notify JJSV of any change in the conduct of the study including changes in study personnel assigned to the study project or maintenance of study records, etc.

9.3 INVESTIGATOR APPROVAL

It is the responsibility of the investigator to obtain prospective approval of the study protocol, protocol amendments or changes, ICF and other relevant documents (e.g., advertisements) from the IEC/IRB. All correspondence with the IEC/IRB should be retained in the Investigator Study Files/Notebook. Copies of IEC/IRB submissions and approvals should be forwarded to JJSV. Study sites will obtain IEC/IRB approvals and fulfill any other site-specific regulatory requirements.

10. EXPERIMENTAL PLAN

10.1 OVERVIEW

This study will be conducted in accordance with U.S. Code of Federal Regulations the Declaration of Helsinki, ISO 14155:2020 and all other applicable laws and regulations. The study will not begin until IRB/IEC approval has been obtained.

This study will be a prospective, three-arm, randomized, controlled clinical study conducted at up to 20 study sites located in North America. [redacted] After informed consent is obtained and all eligibility criteria are confirmed as being met, the subject (one or both eyes) may be enrolled and randomized to a treatment group.

For subjects with both eyes eligible, the investigator will choose which eye to operate on first at his/her discretion and standard clinical practice (e.g., the eye with the worse cataract, poorer best corrected distance vision and/or more severe optical/visual complaints); both eyes will be implanted with the same lens model. [redacted]

The study visits and procedures will include procedures that are study-specific or part of normal clinical practice, [redacted] The operative visit procedures for the study will be standard procedures for cataract surgery and IOL implantation.

Key postoperative assessments include IOL axis measurement [redacted]

10.2 VISIT SCHEDULE

The study visit schedule for all study subjects is outlined in **TABLE 1**.

Each subject is intended to have unilateral or bilateral cataract surgery with the lens model assigned by randomization. [redacted] Unscheduled visits may be conducted as necessary at the discretion of the investigator for medically indicated follow-up.

TABLE 1: Visit Schedule

[redacted]

10.3 PREOPERATIVE PROCEDURES

All subjects enrolled in the study must sign the current IEC/IRB-approved ICF and meet the eligibility criteria. The ICF must be signed before any study-specific examinations are performed, and this must be documented in the source documents.

An Authorization for Use/Disclosure of Health Information Form (HIPAA authorization) or similar medical treatment privacy law documentation must also be signed. The preoperative procedures

will follow the normal clinical practice. [redacted]

Preoperative testing: to be performed for each enrolled eye includes the following:

POTENTIAL POSTOPERATIVE DISTANCE VISUAL ACUITY

The subject must be capable of achieving Snellen 20/32 or better best-corrected distance vision in each eye after cataract extraction and IOL implantation. [redacted]

BEST-CORRECTED DISTANCE VISUAL ACUITY AND MANIFEST REFRACTION

Manifest refraction should be performed on each study eye to obtain monocular BCDVA using logMAR visual acuity charts. Monocular BCDVA must be worse than 20/40 Snellen (0.3 logMAR) to be considered eligible to participate in the study.

KERATOMETRY

Corneal astigmatism is to be measured by keratometry or topography. Predicted postoperative corneal astigmatism, based on measurements by keratometry, should be less than 1.00 D. No irregular astigmatism should be present preoperatively. [redacted]

CONTACT LENS WEAR AND CORNEAL STABILITY

The surgeon should follow their routine procedures to establish keratometric corneal stability in contact lens wearers before surgery.

[redacted]

[redacted]

IOL POWER AND TARGETED REFRACTION

The spherical equivalent lens power, as determined by the investigator's standard biometry methods, [redacted]

[redacted].

ADDITIONAL PREOPERATIVE INFORMATION COLLECTED SHOULD INCLUDE:

- Informed consent
- Subject demographic information
- Planned surgery dates for each enrolled eye
- Ocular history, including presence of ocular pathology for each enrolled eye
- [redacted]
- Any medical findings from a slit lamp exam, dilated fundus exam, intraocular pressure or other assessment.
- Ocular and systemic medications

10.4 SELECTION OF IOL POWER

In order to facilitate IOL selection and axis placement, JJSV provides a web-based proprietary tool, the TECNIS Toric Calculator (www.TecnisToricCalc.com) for the surgeon. [redacted]

[redacted]

10.5 RANDOMIZATION AND MASKING

A randomization list will be created by the JJSV biostatistician for each investigative site. Subjects will be randomized to either the test #1, test #2, or control IOL on a 1:1:1 basis. Randomization will take place after the subject has signed the informed consent document, has met all inclusion and exclusion criteria, and the investigator has documented which eye will be the first implanted (if bilaterally enrolled).

As part of the informed consent process, the investigator or delegate will explain to the subject the requirements of a randomized study and the differences expected between the test and control lenses. Once the investigator has determined that a subject is eligible for inclusion in the study and documented which eye will be implanted first (if bilateral), the site will proceed with the randomization. After notification, the site will open the next sealed randomization envelope in numerical order to determine lens group assignment. The randomization envelope number will be recorded on the Operative Case Report Form.

[redacted]

The subjects and the study technicians performing the postoperative vision tests are to be masked through study completion. [redacted]

[redacted]

[redacted]

10.6 STUDY LENS SUPPLY

[redacted]

10.7 OPERATIVE PROCEDURES

Surgical procedures should be in accordance with each site's routine practice and in accordance with the product labeling. The surgeons should follow the procedures as described in the respective IOL's Directions for Use to ensure appropriate alignment of the IOL axis.

[redacted]

REFERENCE AXIS

Prior to surgery the operative eye should be marked per the surgeon's routine method.

Operative case report forms should include the following information:

INCISION TYPE AND SIZE

The incision may be clear corneal, limbal or scleral tunnel at the discretion of the investigator. Lenses should be inserted per the investigator's standard technique when using the JJSV-qualified implantation system.

BALANCED SALT SOLUTION (BSS) STERILE IRRIGATING SOLUTION

BSS solution should be used as is customary for each investigator and recorded on the case report form.

VISCOELASTIC

Viscoelastic materials should be used as is customary for each investigator and recorded on the case report form (CRF).

IMPLANT INSTRUMENTATION USED

[redacted] IOLs should be folded for implantation and inserted into the capsular bag using the TECNIS Simplicity Delivery System (preloaded).

[redacted] or any other insertion system qualified for use by the JJSV.

BASELINE LENS AXIS

At the end of each case, the axis of lens in its final position should be recorded.

SURGICAL COMPLICATIONS

Should a surgical complication occur, implantation of a study lens will be at the investigator's discretion. The subject should be exited from the study if a non-study lens is implanted as a result of a surgical complication during implantation; however, the eye will be followed until resolution of the complication prior to exiting the subject.

MEDICATIONS

Preoperative, operative and intraoperative medications should be used as is customary for each investigator and recorded in the source document for each subject, as appropriate. [redacted]

TYPE OF CLOSURE

Wound closure is left to the surgeon's discretion and will be recorded on the CRF.

ADDITIONAL OPERATIVE INFORMATION THAT MAY BE COLLECTED:

- Date of surgery
- Operative eye
- Lens power and serial number
- Intended residual spherical equivalent
- Intended residual cylinder
- Surgical complications or other surgical procedures
- Product complaints
- Serious and/or device-related adverse events

10.8 POSTOPERATIVE PROCEDURES

Postoperatively, subjects will be examined according to the schedule in **Section 10.2**, Visit Schedule.

[redacted]

The postoperative CRF will be used to collect postoperative information, as following (not all data are required at every visit):

[redacted]

BIOMICROSCOPIC SLIT-LAMP BASED LENS AXIS ORIENTATION

[redacted] The lens orientation should be measured by the investigator, or other study personnel, by rotating the slit lamp beam to match the IOL axis orientation and reading the axis [redacted]

[redacted]

[redacted]

ADVERSE EVENTS

Subjects should be assessed at each visit for occurrence of and/or change in status of any adverse events, particularly serious and/or device-related adverse events, and secondary surgical interventions. [redacted]

Secondary Surgical Interventions

Secondary surgical interventions due to refractive error and/or medical complications are considered serious adverse events. Secondary surgical interventions that occur under the circumstances below will be considered device-related serious adverse event/device effects:"

- IOL repositioning due to a significant axis misalignment resulting in a visual outcome that is unsatisfactory, providing the axis misalignment is rotationally correctable.
- IOL exchange due to incorrect spherical power resulting in a significant decrease in uncorrected visual acuity.
- IOL exchange due to surgical or postoperative medical complications or adverse events.

If IOL repositioning procedure is required, the investigator should document the IOL position (including axis measurement) prior to repositioning procedures. After repositioning, the eye should be followed through study completion for safety. If a toric IOL is exchanged for a non-toric IOL, the subject should be followed until resolution of the serious adverse event/adverse device effect.

10.9 EXIT OF SUBJECTS

An Exit CRF will be completed for each subject that completes the study or exits the study before completing all scheduled visits.

A subject will be considered a "screen failure" if he/she does not meet the eligibility criteria, consent is withdrawn prior to surgery, implantation in the first eye is aborted due to a surgical complication, or the subject dies prior to first-eye treatment.

[redacted]

Subjects will be "discontinued" from the study if the subject does not undergo surgery; or if both study lenses are removed; or if the subject dies.

If a subject receives at least one study lens, he/she is to be followed according to the study procedures scheduled in **TABLE 1** (**Section 10.2**).

Subjects will be considered “lost-to-follow-up” from the study if there is no information to account for missing data or failing to complete the [redacted] study visit.

If a subject is exited early from the study, the investigator must indicate the reason for study exit on the CRF. In the event of a lens removal or other serious adverse event, the subject may be exited from the study; however, effort must be made by the investigator to follow the subject until resolution of the adverse event before exiting the subject from the study.

10.10 UNSCHEDULED VISITS

During the study period, if a non-protocol-required visit is done for the purpose of medically indicated follow-up for a study eye, data from this visit should be reported using the Unscheduled Visit CRF. The need for unscheduled visits is at the investigator’s discretion. Specific examinations to be performed at unscheduled visits are also at the discretion of the investigator (based on the reason for the unscheduled visit) and data are to be recorded in the appropriate section of the CRF.

[redacted]

Conditions found postoperatively, but previously documented at the preoperative visit, do not trigger an unscheduled visit report. However, if the severity of the condition increases from the preoperative visit, an Unscheduled Visit CRF is needed.

10.11 PROTOCOL DEVIATIONS

Any departure from the protocol procedures represents a protocol deviation. Protocol deviations may be subject-based (e.g., inclusion/exclusion criteria, informed consent deviation, etc.) or procedural-based (e.g., out-of-interval visits, non-compliance with testing procedures, etc.). All protocol deviations will be documented in the Clinical Trial Management System. Any deviation made to protect the life or physical well-being of a subject in an emergency must be reported to JJSV within 5 working days. Protocol deviations will be monitored by the Sponsor, and if the non-

compliance is persistent or egregious, Sponsor may take action, including but not limited to termination of the investigator's participation in the study. The investigator is also responsible for informing the reviewing IEC of protocol non-compliance in accordance with the IEC requirements.

11. ADVERSE EVENTS AND PRODUCT COMPLAINTS

11.1 ADVERSE EVENT DEFINITIONS

Adverse Event (AE)

An adverse event is defined (per ISO 14155) as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether related to the study device.

Serious Adverse Event (SAE)

An adverse event is considered serious (per ISO 14155) if it is an untoward occurrence which may or may not be related to use of the study device that

- is sight- or life-threatening,
- results in death,
- requires inpatient hospitalization or prolongation of hospitalization (a planned hospitalization for a pre-existing condition without a serious deterioration in health is not considered a serious adverse event),
- results in permanent impairment of a body structure or body function,
- necessitates medical or surgical intervention to prevent permanent impairment to a body structure or function, or
- results in fetal distress, fetal death or a congenital abnormality or birth defect including physical or mental impairment

Device-Related Adverse Event/Adverse Device Effect (ADE)

A device-related adverse event is defined as any adverse event that is believed to be definitely, probably, or possibly related to the study device (following the guidelines in Section 11.4, Causal Relationship). A device-related event is also considered an adverse device effect (ADE; following ISO 14155) resulting from the use of the study device that may result from user error, insufficiencies or inadequacies in the instructions for use, deployment, implantation, installation, operation or any malfunction of the device.

Anticipated Study-Specific Serious Adverse Events

The following is a list including, but not limited to, ocular serious adverse events that are anticipated and must be reported to JJSV for this study. Any events that are unlikely but anticipated (i.e., endophthalmitis) will be reported to the FDA and other appropriate regulatory agencies.

- Endophthalmitis/intraocular infection

- Hypopyon
- Hyphema
- IOL dislocation
- Cystoid macular edema
- Pupillary block
- Retinal detachment/tear
- Acute corneal decompensation
- Corneal edema accompanied by BCDVA of 20/40 (0.3 logMAR) or worse at 3 months or later
- Chronic anterior uveitis/iritis that persists at 3 months postoperative
- Raised IOP that persists (i.e., is present at 3 months postoperative or later)
- Toxic anterior segment syndrome
- Visual symptoms requiring secondary surgical intervention (e.g., lens removal)
- Tilt and decentration requiring secondary surgical intervention (e.g., repositioning)
- Residual refractive error resulting in a secondary surgical intervention
- Retained lens material resulting in secondary surgical intervention

NOTE 1: Wound "burps" during the first week after surgery, suture removal, planned blepharoplasty, and Nd:YAG capsulotomy (for PCO) are not considered adverse events for this study.

NOTE 2: Raised IOP requiring treatment, cornea edema, and iritis will only be considered serious if persistent at 3 months or later or sight-threatening at the time of occurrence. Treatment merely to hasten the resolution of such conditions (and not intended to prevent permanent damage to the eye) will not be reported as serious adverse events.

Unanticipated Adverse Device Effect (UADE)/Unanticipated Serious Adverse Device Effect (USADE)

Any UADE (USA 21CFR 812.3(s)) or USADE (ISO 14155) is defined as any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem or death was not previously identified in nature, severity, or degree of incidence in the investigational plan (i.e., this protocol), application (including a supplementary plan or application), or risk assessment, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

Serious Health Threat

A serious health threat (following ISO 14155) is a signal from any adverse event or device deficiency that indicates an imminent risk of death or a serious deterioration in the health in subjects, users or other persons, and that requires prompt remedial action for other subject, users or other persons. This would include events that are of significant and unexpected nature such that they become alarming as a potential serious health hazard or possibility of multiple deaths occurring at short intervals.

11.2 PRODUCT COMPLAINT/DEVICE DEFICIENCY DEFINITION

A product complaint/device deficiency is defined (21 CFR 820.3(b) and ISO 14155) as any alleged deficiency related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device. This may include malfunctions, use error, and inadequacies in labeling. Product complaints can pertain to any marketed JJSV device being used in the study. The investigator is to assess whether the deficiency could have led to a serious adverse event without suitable action or intervention or under less fortunate circumstances.

11.3 ADVERSE EVENT AND COMPLAINT REPORTING REQUIREMENTS

All adverse events and any complaint encountered using any JJSV product, regardless of severity and whether attributed to the study device(s), are to be reported to JJSV and recorded on the case report form corresponding to the visit during which awareness of the event occurred. Adverse events are also to be reported to the reviewing IEC/IRB as per the IEC's reporting requirements. If required, adverse events will be reported to the appropriate regulatory agencies (e.g., FDA/Health Canada) according to all applicable laws and regulations. Specific instructions on notification procedures to JJSV are included in **Appendix I**, Adverse Event Reporting.

Reporting of adverse events shall follow the USA Code of Federal Regulations (21CFR812) for sites in the USA. For sites located outside the USA, reporting of adverse events shall follow ISO 14155 and country-specific guidelines, of which the shortest/strictest timeline requirement for reporting adverse events will be followed. General guidelines are provided below:

Adverse Event Reporting

An adverse event that is not serious or device-related is to be reported to JJSV in a timely manner. Notification of non-serious and non-device related adverse events will occur by recording events on the CRF when noted. Such adverse events are also to be reported to the reviewing IEC/IRB per their reporting requirements.

Complaints/Device Deficiency Reporting

A general product complaint or device deficiency is to be reported to JJSV in a timely manner. Notification of complaints/device deficiencies will occur by recording complaints on the CRF at the visit the complaint occurs (e.g., operative visit) and/or by a phone call/email to JJSV.

[redacted]

Serious and/or Device-Related Adverse Event Reporting

[redacted] SAE/ADE is to be reported to JJSV by phone (and/or email) and by submitting the completed SAE/ADE CRF. Any SAE or device-related AE should also be reported to the investigator's IEC/IRB per their reporting requirements.

Unanticipated Adverse Device Effect (UADE)/Unanticipated Serious Adverse Device Effect (USADE) Reporting

If during the study, a serious adverse event occurs that may reasonably be regarded as device-related and was not previously expected in nature, severity, or degree of incidence, the investigator is to report the SADE/USADE to JJSV [redacted], and to the investigator's IEC/IRB as soon as possible [redacted]

11.4 CAUSAL RELATIONSHIP

The investigator should always be alert to adverse events that may be related to the study device or the use of the study device (i.e., the procedure specific to the initial application of the device). An attempt should be made in every case to determine the causality of the event. The following definitions are to be used as guidelines in determining the relationship between the event and the study device and/or use of the device.

Definitely related:	If the event is associated with the device and/or the use of the device beyond a reasonable doubt, a causal relationship exists between the adverse event and the device and/or the use of the study device.
Probably related:	There is a reasonable possibility of a causal relationship between the adverse event and the device and/or the use of the study device and/or the adverse event cannot be reasonably explained by another cause.
Possibly related:	The adverse event has not been determined to be related to the device and/or the use of the device, but no other cause has been identified and the device and/or the use of the study device cannot be ruled out as a possible cause.
Unlikely to be related:	The possibility of a potential causal relationship between adverse event and the device and/or the use of the device could exist, but the adverse event can be reasonably explained by another cause.
Not related:	There is no possibility of a causal relationship between the adverse event and the device and/or the use of the study device and/or the adverse event can be attributed to another cause.

If an adverse event is believed to be definitely, probably or possibly related to the study device and/or the use of the device, the event will be considered related to the study device and/or the use of the device.

11.5 ADVERSE EVENT FOLLOW-UP

For every adverse event, appropriate measures should be undertaken to treat and/or monitor the subject until resolution occurs. Obtain and maintain in the subject's files all pertinent medical data relating to the event including the subject's medical records, medical reports and/or judgments from colleagues or outside specialists who assisted in the treatment and follow-up of the subject.

[redacted] Any subject who is exited from the study due to a serious and/or device-related adverse event will be followed until the outcome is determined.

12. PROTOCOL CHANGES/AMENDMENTS

If the investigator wishes to modify any procedure and/or the design of the study, he or she must contact and obtain consent from JJSV regarding the proposed changes prior to implementation. Any modifications (including additional data collection) require approval by the governing IEC/IRB prior to implementation.

13. ETHICS REVIEW AND PATIENT WELFARE

13.1 INDEPENDENT ETHICS COMMITTEE/INSTITUTIONAL REVIEW BOARD (IEC/IRB)

It is the responsibility of the investigator to obtain prospective approval of the study protocol, protocol amendments or changes, informed consent forms (ICF), and other relevant documents (e.g., advertisements) from the IEC/IRB. All correspondence with the IEC/IRB should be retained in the Investigator Study Files/Notebook. Copies of IEC submissions and approvals should be forwarded to JJSV.

The investigator is responsible for notifying the IEC/IRB of reportable adverse events as well as any other circumstance in which additional procedures outside the protocol were conducted to eliminate apparent hazards to subjects.

13.2 INFORMED CONSENT

The current version of the IEC/IRB-approved study ICF must be signed by each study subject prior to any study-specific examinations being performed. The IEC/IRB-approved ICF is to be signed and dated by the subject as well as by the person who conducted the informed consent discussion. The signed ICF will be maintained by the investigator as a permanent part of the subject's medical records. A copy of the signed and dated form is to be provided to the subject. The investigator will provide JJSV written acknowledgement on the preoperative case report form that a signed agreement of informed consent has been obtained and is in the investigator's possession for each

subject. As required by 21CFR812 Part G, the site shall document in the patient chart that informed consent was obtained prior to participation in the study for each subject enrolled.

NOTE: *The informed consent process also includes obtaining the subject's signature on an Authorization for Use/Disclosure of Health Information for Research Form or equivalent documentation necessary to comply with applicable privacy laws pertaining to medical treatment in the governing countries.*

NOTE: *The sponsor will secure appropriate insurance for study subjects prior to study start.*

14. DOCUMENTATION

14.1 SOURCE DOCUMENTS

Source documents must be kept for all study subjects. Source documents may include a subject's medical records, hospital charts, clinic charts, the investigator's subject study files, as well as results of any diagnostic tests or procedures such as topographies or laboratory tests with photographs or instrument printouts.

Each site is expected to adhere to the clinic's own standard documentation requirements for medical charts/clinic notes. For the purposes of this clinical study, the medical charts/clinic notes must also include, at a minimum, the following data that will be considered source data and will be reviewed by the Sponsor:

- Subject's name and study identification number
- Subject's contact information
- Study protocol number and the Sponsor name (JJSV)
- A statement that informed consent was obtained prior to participation in the study (including the date)
- Evidence of subject eligibility
- Dates of all subject visits and surgeries throughout the duration of the study
- Implant serial number identification (NOTE: This is masked information, and may only be reviewed by unmasked study staff)
- Concurrent medications
- Corrected and uncorrected distance visual acuity (NOTE: ETDRS visual acuity score cards are considered source documentation and are to be retained by the site in the subject CRF notebooks)
- Manifest refraction
- Occurrence and status of any operative complications, postoperative medical or lens findings and adverse events
- Occurrence and status of any subject complaints, e.g., ocular/visual symptoms
- The date the subject exited the study, and a notation as to whether the subject completed the study or reason for early exit.

14.2 SUBJECT CONFIDENTIALITY

Subjects will be assigned a unique subject number at the time of enrollment as a means of identification on study documents. Subject confidentiality will be maintained by recording only the subject number on the CRFs. Subject names may possibly be disclosed to JJSV or regulatory agencies during inspection of medical records related to the study, but reasonable precautions will be taken to maintain confidentiality of personal information to the extent permitted by applicable laws and regulations.

14.3 CASE REPORT FORM COMPLETION

This study will use an electronic data capture system. All study staff responsible for entering data into the system must complete certification prior to using the system. The investigator is responsible for ensuring that data are properly recorded on each subject's case report forms and related documents. Prior to database lock, the investigator will verify completeness and accuracy of data submitted to the JJSV.

14.4 STUDY SUMMARY

A final investigator's summary will be provided to the reviewing IEC/IRB within 3 months after termination or the completion of the study or the investigator's part of the investigation.

15. [redacted]

[redacted]

15.2 ADMINISTRATIVE MONITORING

Administrative monitoring procedures will ensure that study devices, subjects, and forms can be traced and will allow monitoring of investigator progress and compliance.

Accountability and traceability of study devices will be monitored by trained JJSV personnel.

[redacted]

[redacted]

[redacted]

16. MEDICAL OVERSIGHT

The medical monitor will be available throughout the clinical trial to review study results and to answer any questions from investigators. The medical monitor will review and assess any reports of serious and/or device-related adverse events and discuss these with the reporting investigator(s) as necessary. The medical monitor, as well as any other qualified personnel designated by JJSV, shall also review study reports.

17. PUBLICATIONS

[redacted]

18. RISK ANALYSIS

POTENTIAL RISKS AND RISK MANAGEMENT

RISKS OF THE STUDY LENSES

The risks and benefits of the commercially available TECNIS Eyhance Toric II IOL, TECNIS Synergy Toric II IOL, and the TECNIS Toric 1-Piece IOL are detailed in their respective approved product labeling (i.e., Directions for Use).

GENERAL RISKS OF CATARACT SURGERY AND IOL IMPLANTATION

There are risks and complications associated with cataract surgery and IOL implantation in general. These can include worsening of vision, hemorrhage, loss of corneal clarity, inflammation, infections, retinal detachment, pupil changes, glaucoma, etc. Complications can result in poor vision, loss of vision or loss of the eye.

RISK MANAGEMENT

Subjects will be closely monitored throughout the trial duration. The occurrence of adverse events and complaints will be assessed at each study visit and reported to JJSV according to **Section 11.0**, Adverse Events and Product Complaints. Additionally, JJSV will monitor incoming data following the procedures outlined in **Section 15.0**, Monitoring. The Medical Monitor will ensure subjects are not exposed to additional risks by monitoring serious adverse events, device-related adverse events, and device-deficiencies that could have led to serious adverse events (**Section 16.0**, Medical Oversight).

POTENTIAL BENEFITS

The primary benefit from implantation of either of the study lens models is the correction of aphakia and corneal astigmatism following removal of the natural crystalline lens due to cataract.

CONCLUSION

The hazards/risks associated with either of the study lens models are expected to be acceptable and within those of currently marketed IOLs. These IOLs have been approved for market based on the determination that the potential benefits outweigh the residual risks when the devices are used as intended.

19. RECORDS RETENTION

All study-related correspondence, subject records, consent forms, Authorization for Use/Disclosure of Health Information Forms or similar medical treatment privacy law documentation, records of the distribution and use of all study products, and original case report forms should be maintained by the investigator.

[redacted]

20. TERMINATION OF THE STUDY

The clinical study will be suspended in the event of high levels of complications and/or adverse events that are unexpected in nature and/or severity and evaluated as to causality relative to the study device. The clinical study may be suspended if the Medical Monitor or IEC/IRB, upon review and evaluation of the clinical data, finds unacceptable clinical performance or the level of single or total complications and/or adverse events unacceptable for continuation of the study.

If causality is shown not to be related to the device, the study may be resumed in accordance with the IEC/IRB. The study will be terminated if causality is shown to be related to the study device.

Additionally, the investigator, or JJSV may stop a subject's participation at any time. JJSV may also stop the study at any time for reasons it determines appropriate; however, no suspension of the study would be made to disadvantage the study subjects. Following suspension of the study for any reason, all study subjects who have already received treatment would continue to be followed through completion of the study visit schedule.

21. STATISTICAL METHODS

This section highlights the analyses to be performed for key study endpoints. The detailed analysis plan will be documented in the Statistical Analysis Plan (SAP). Data from the [redacted] postoperative visit will be the key timeframe for rotational stability [redacted] All complications and adverse events will be evaluated at all visits.

Summary statistics include mean, standard deviation, median, minimum, and maximum for continuous variables, and frequency counts and proportions for categorical endpoints. [redacted]

21.1 ANALYSIS POPULATIONS

- [redacted]

- All Implanted Safety population: all subjects randomized and bilaterally or unilaterally implanted with test or control lens and analyzed per treatment received. All eyes will include both study eyes from bilaterally implanted subjects and one study eye from unilaterally implanted subjects.

[redacted]

21.2 Effectiveness Endpoints

All analyses will be based on observed case available data at each study visit with no imputation of missing data, [redacted].

Primary Endpoint

The primary endpoint is the percentage of eyes with rotational stability of the IOL at postoperative [redacted] (i.e., misalignment ≤10° at the [redacted] visit relative to baseline).

[redacted]

For the rotational stability endpoint, the primary analysis population will be All Implanted Safety population. [redacted]

Other Effectiveness Endpoints

All statistical descriptive summaries for all other timepoints will be presented by lens group. [redacted]

[redacted]

21.3 SAFETY AND OTHER ENDPOINTS

ADVERSE EVENTS

The frequency counts and proportion of eyes with medical/lens findings or adverse events will also be reported by lens group.

[redacted]

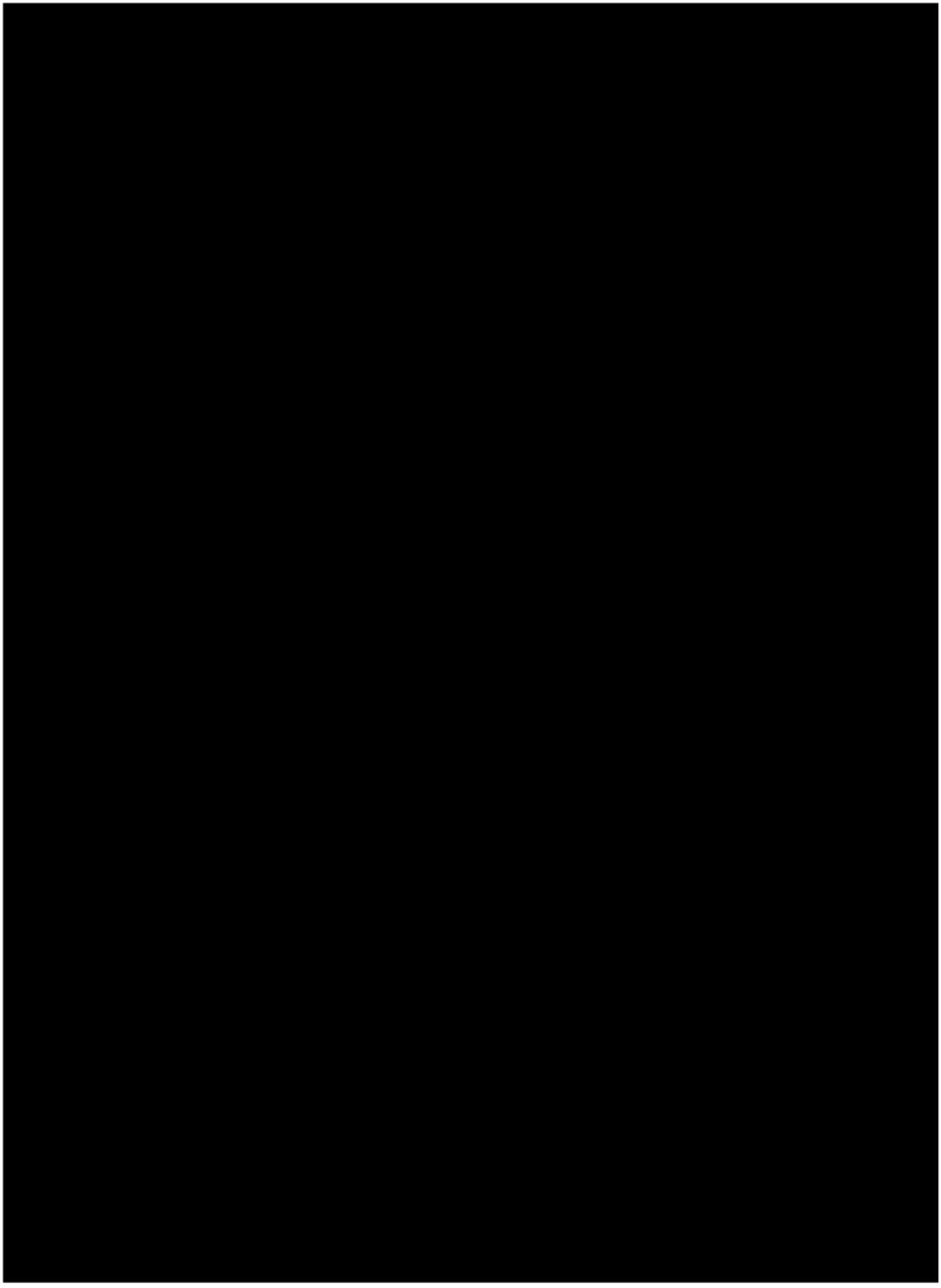
21.4 VISUAL ACUITY CONVENTIONS AND STATISTICS

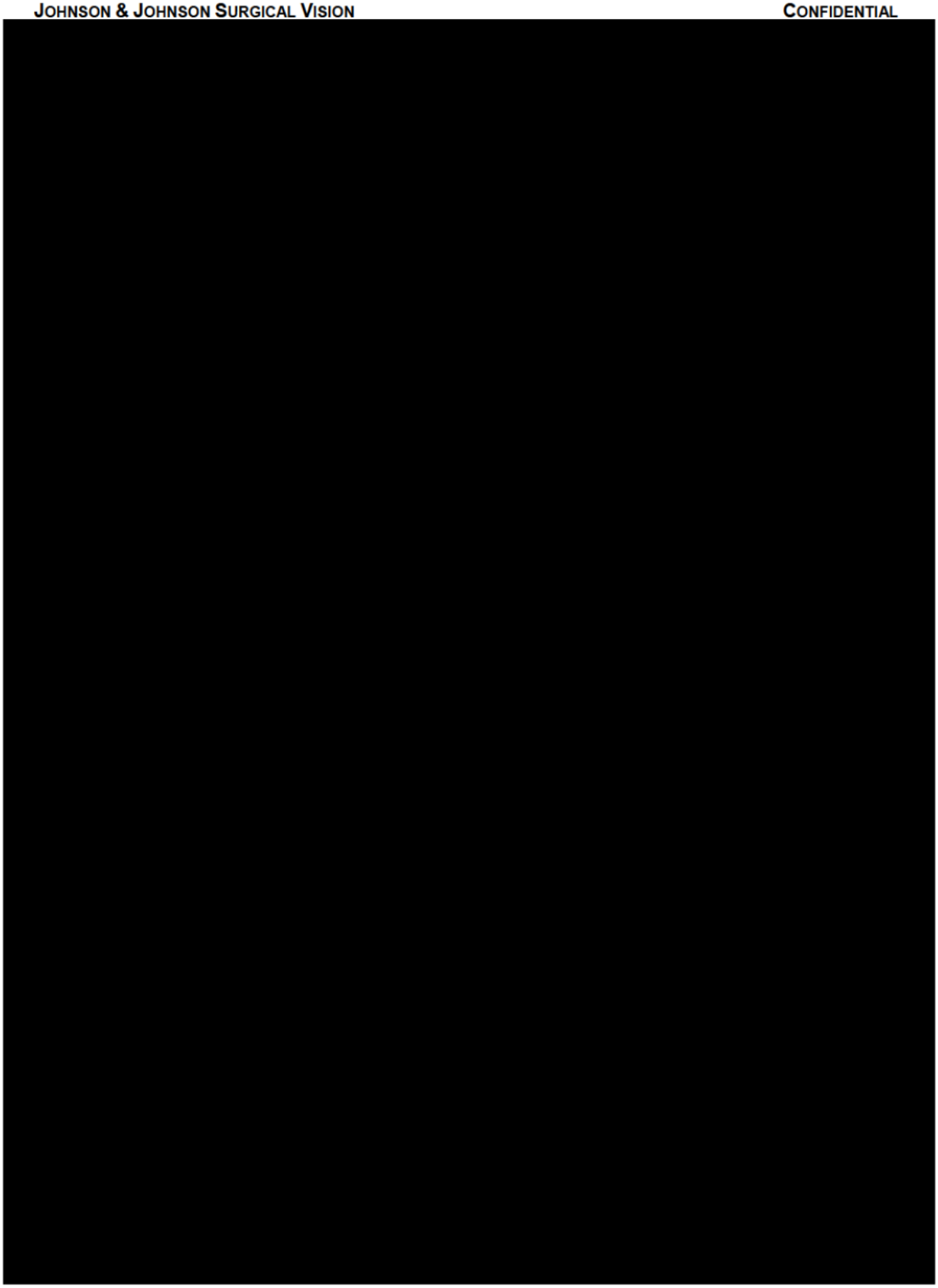
Visual acuity data will be converted to LogMAR values prior to analysis and adjusted for the test distance used if it is not the standard distance for the chart. Summary statistics will include sample size (N), mean, standard deviation (SD), median, minimum (Min), maximum (Max), [redacted] as appropriate [redacted]

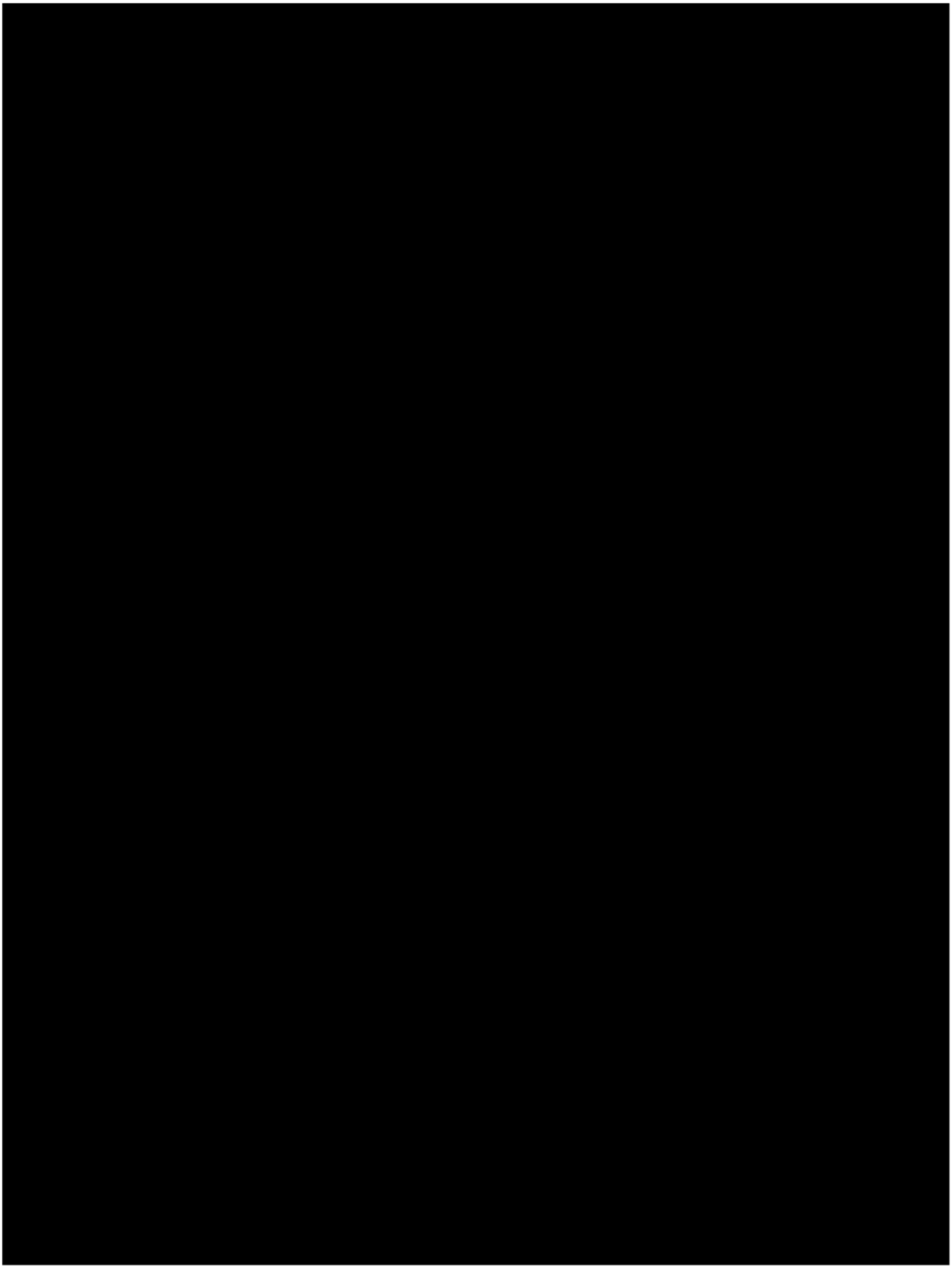
[redacted]

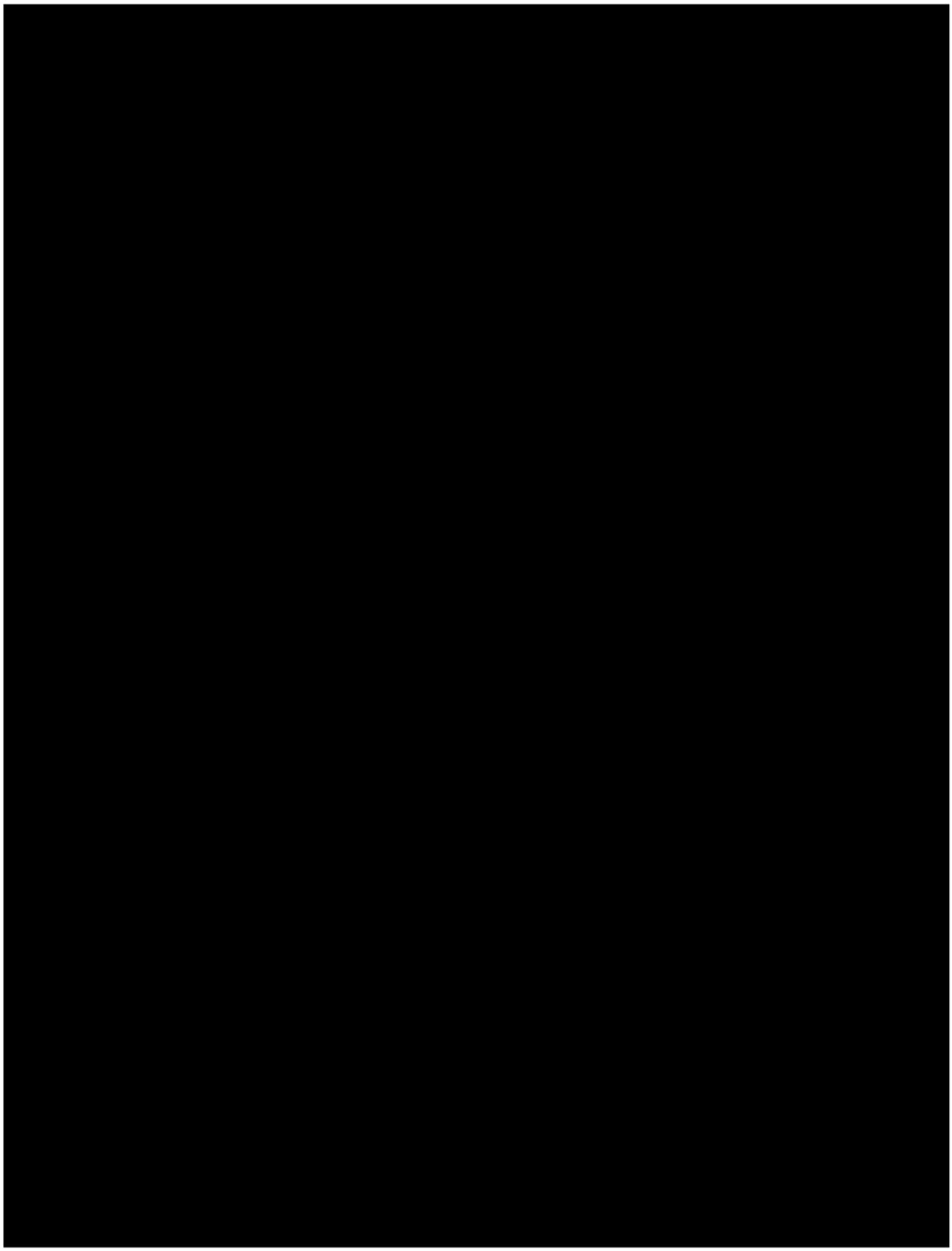
22. FUNDING

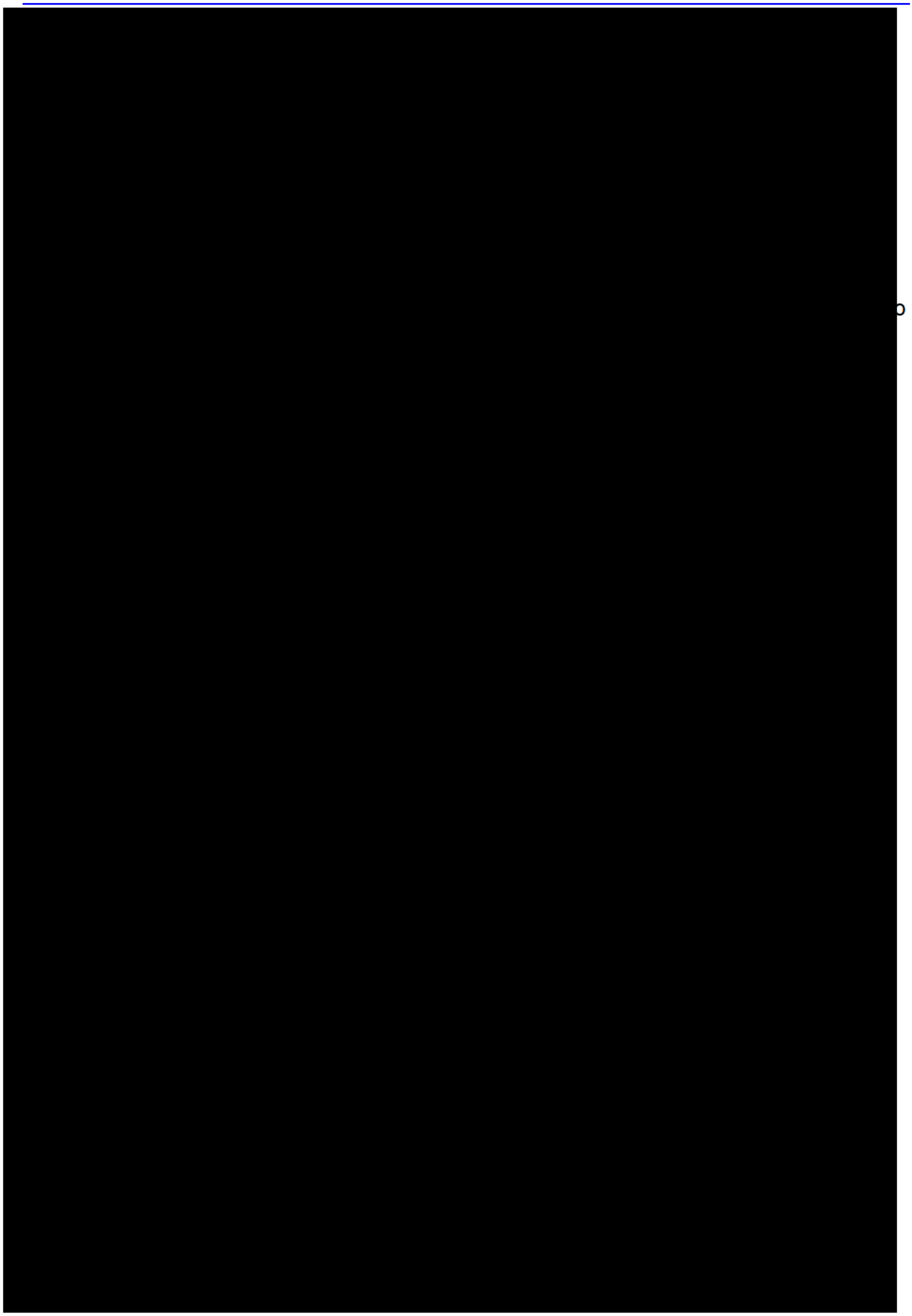
The funding of this clinical trial will be provided by the sponsor, Johnson & Johnson Vision, [redacted].

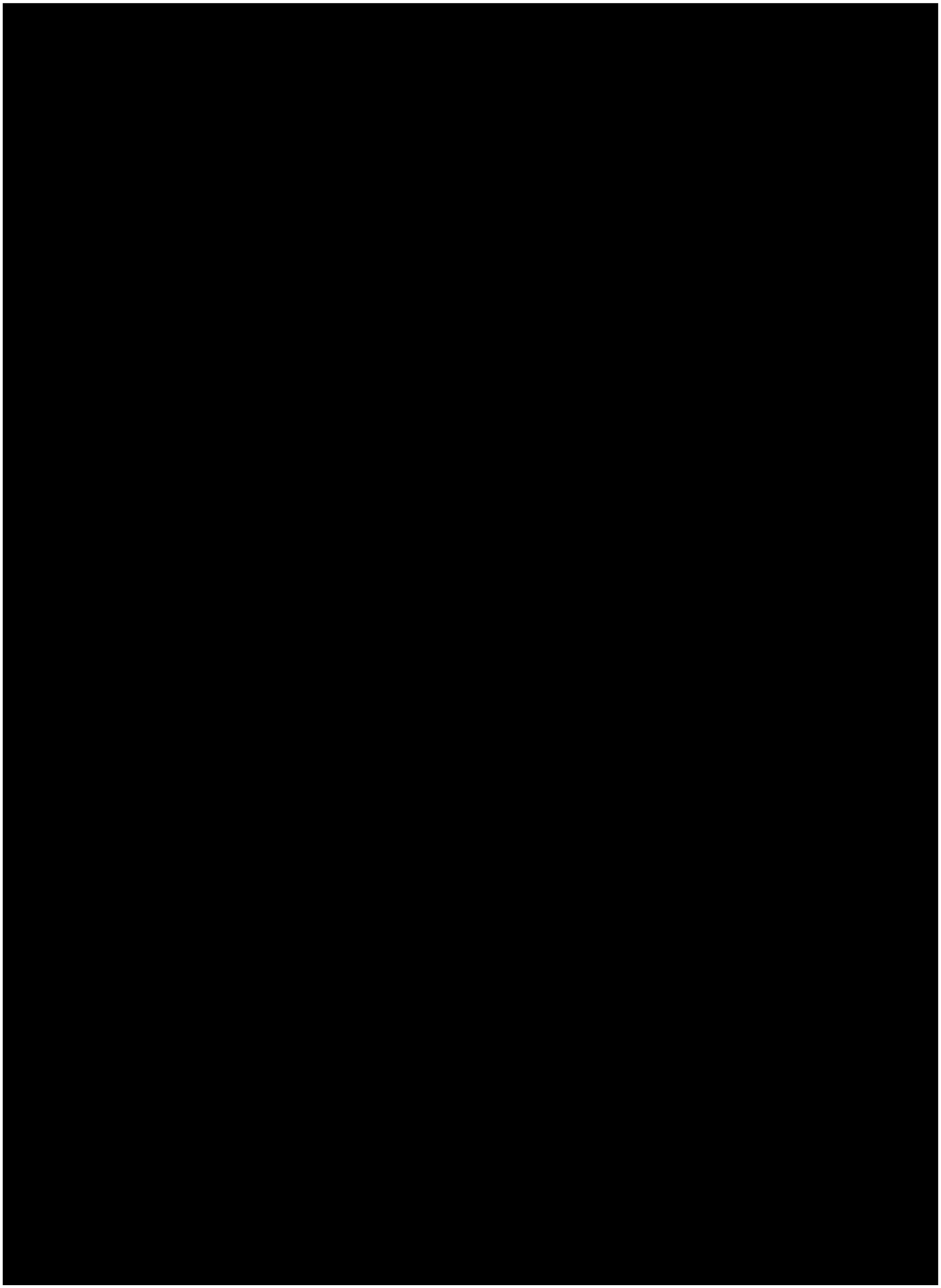


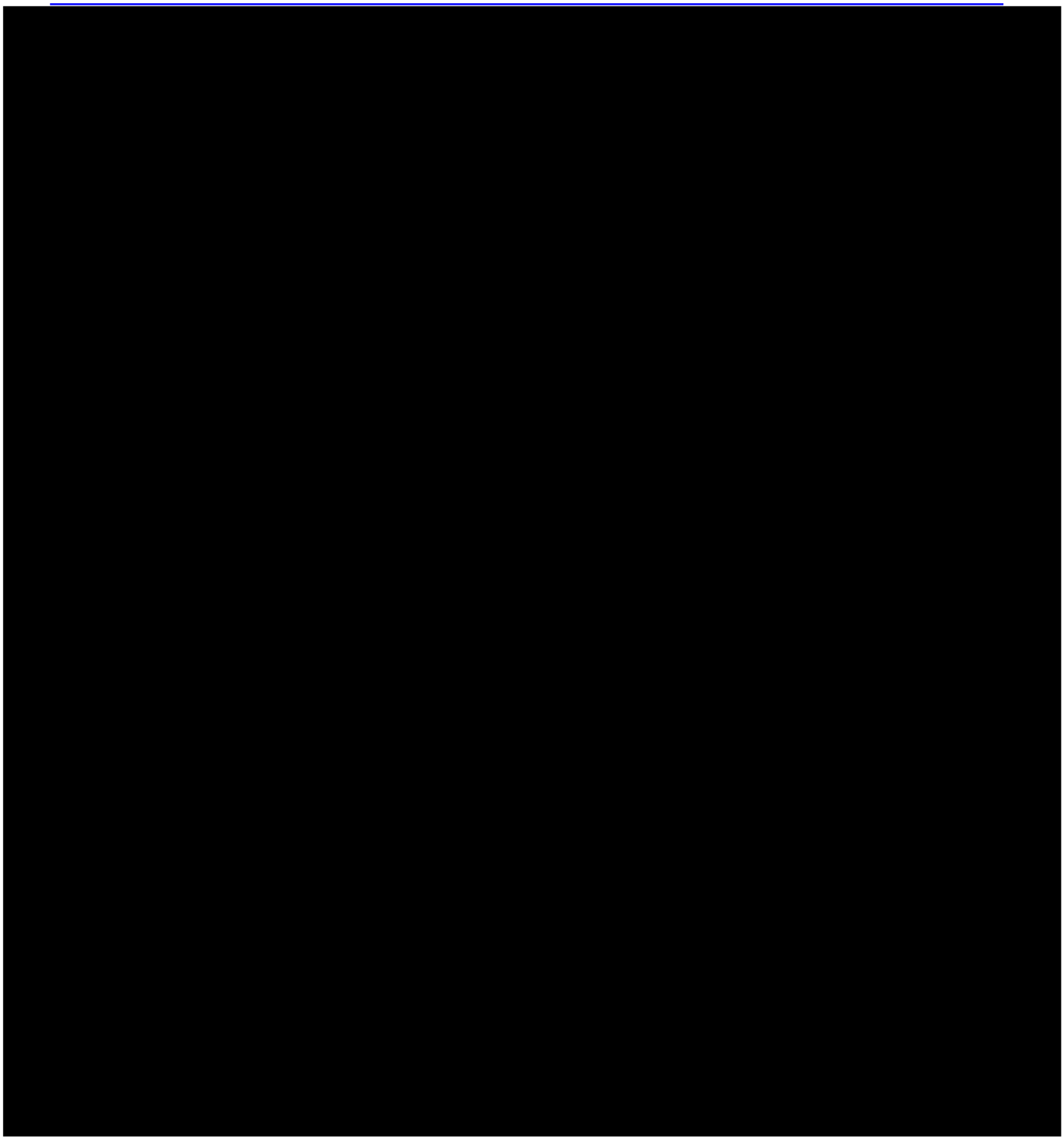


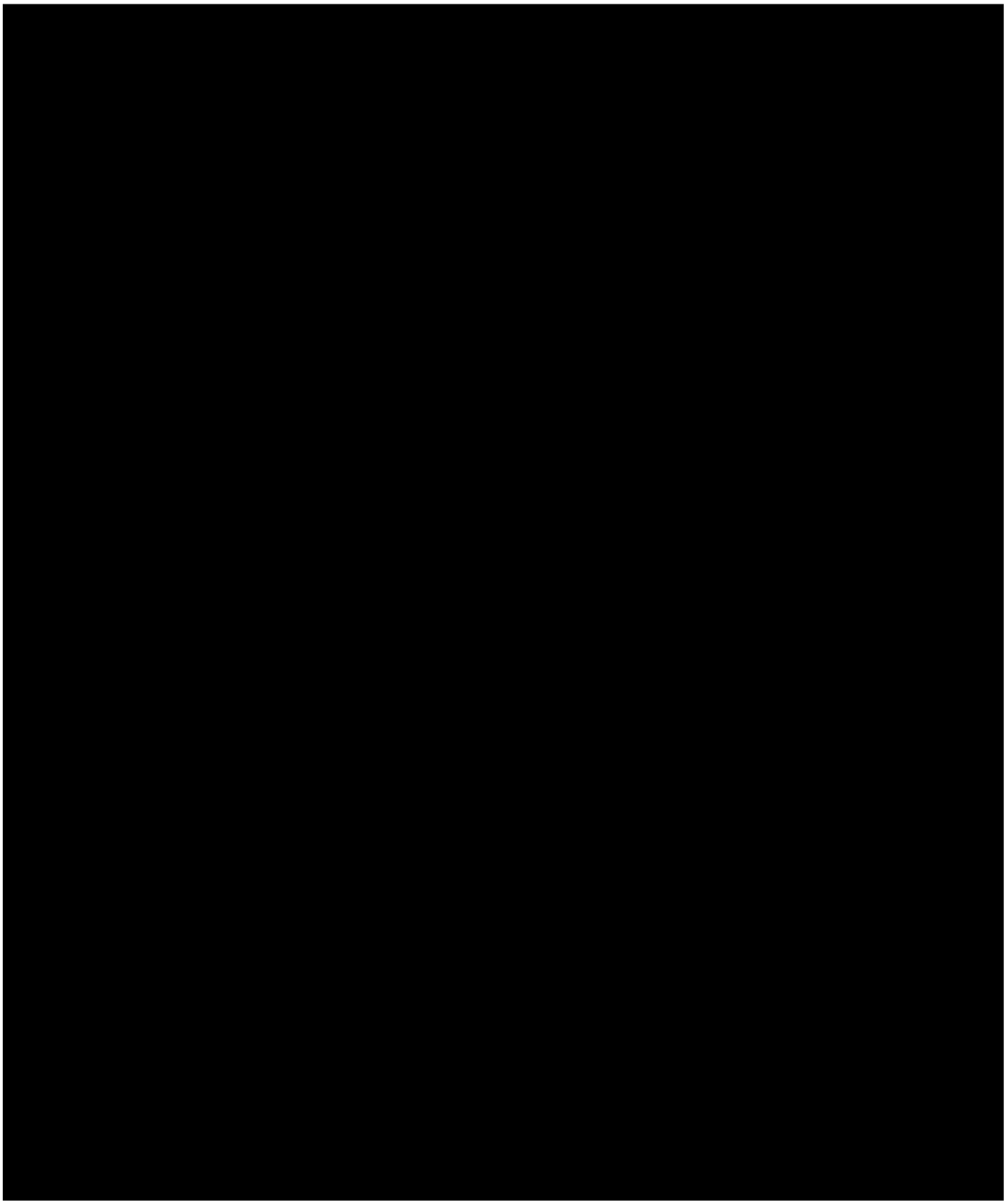


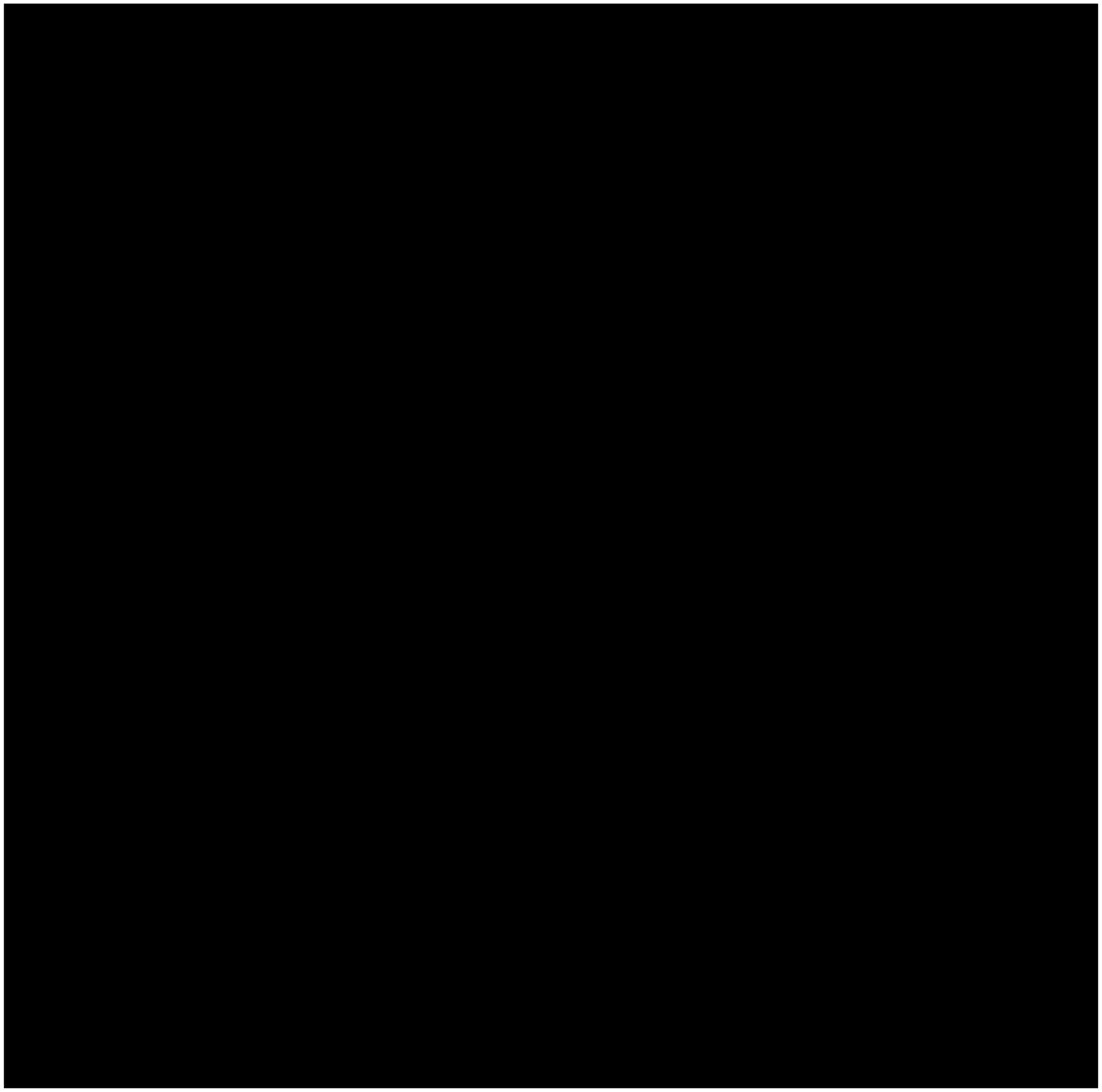


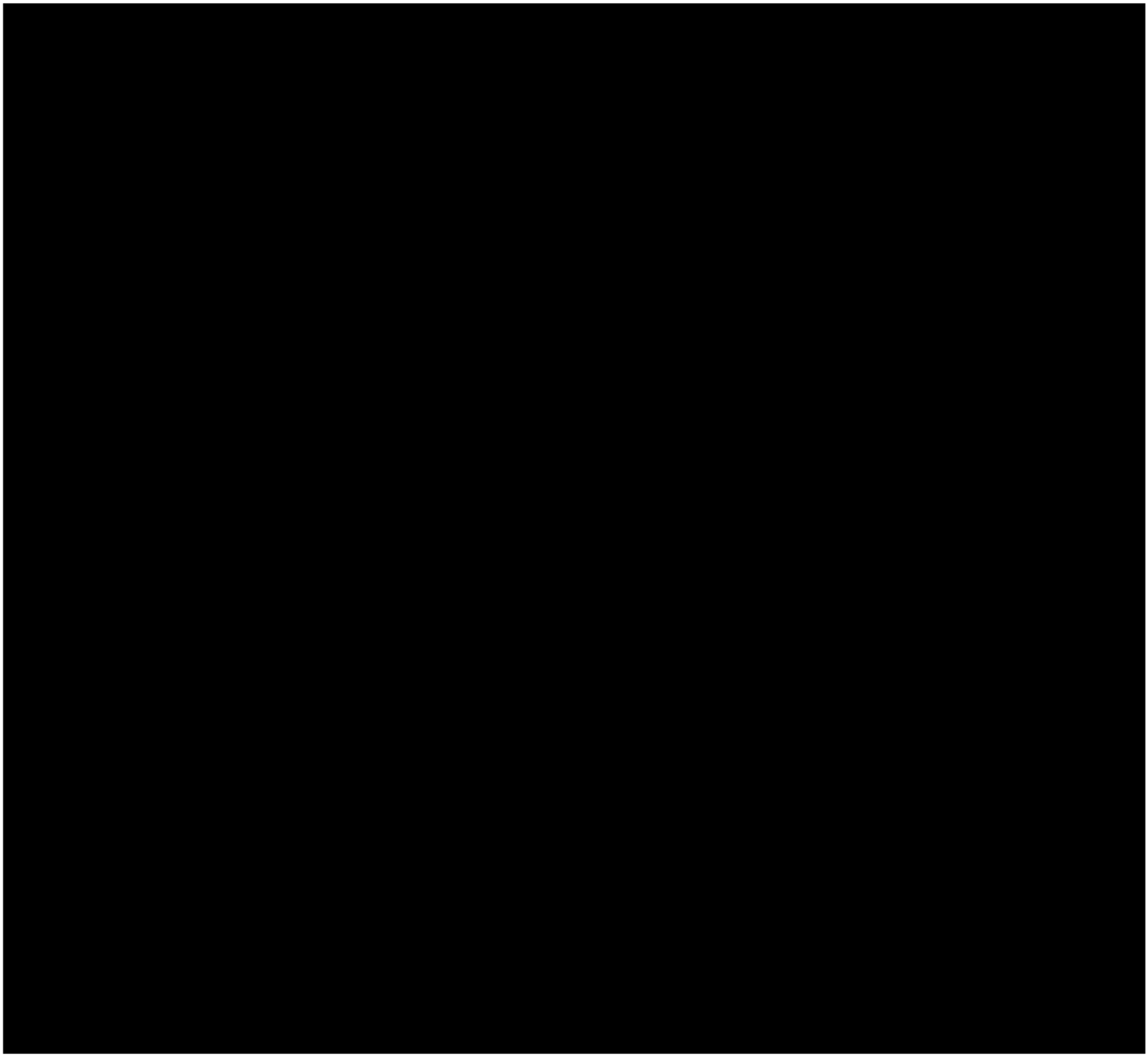


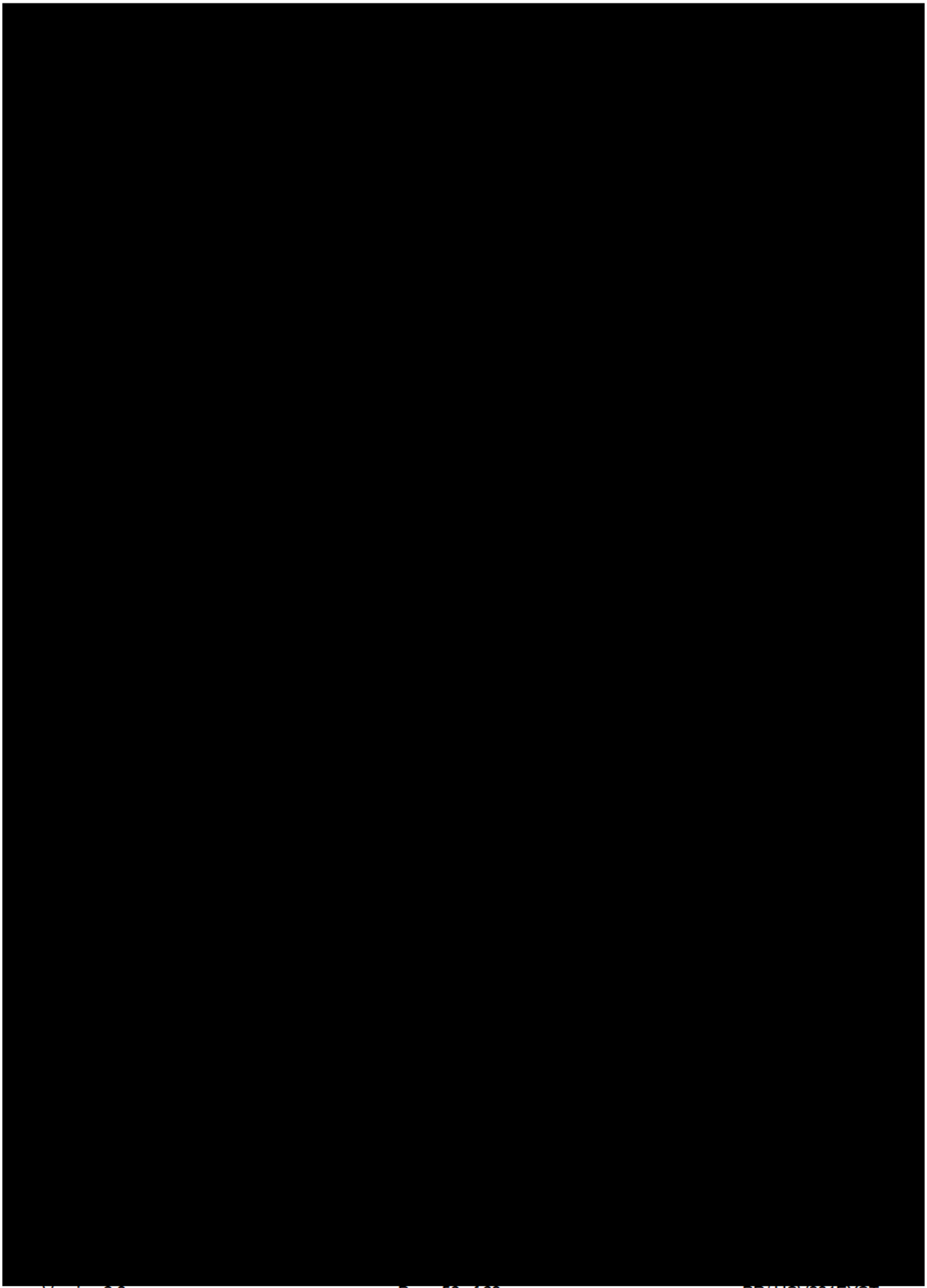


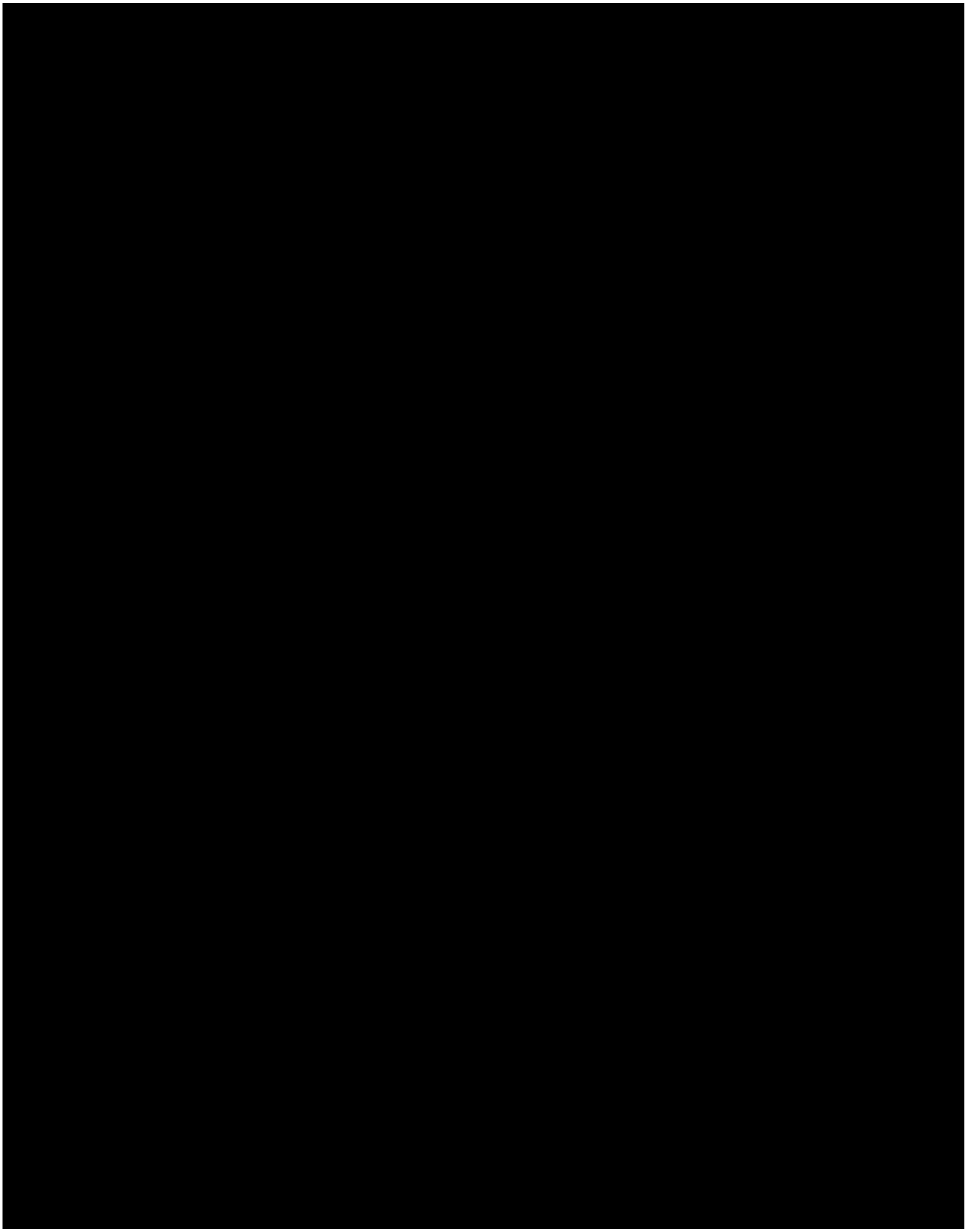


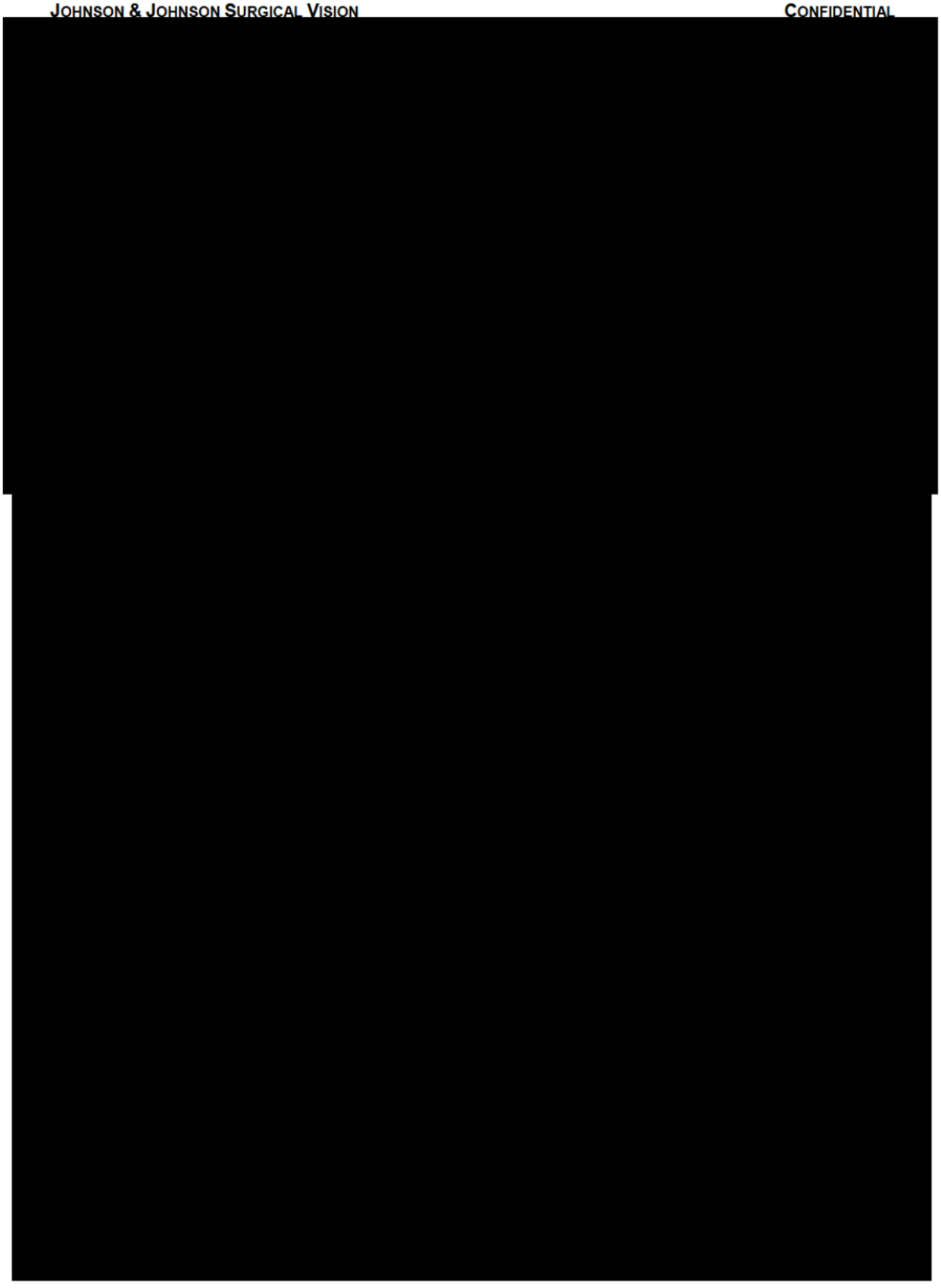


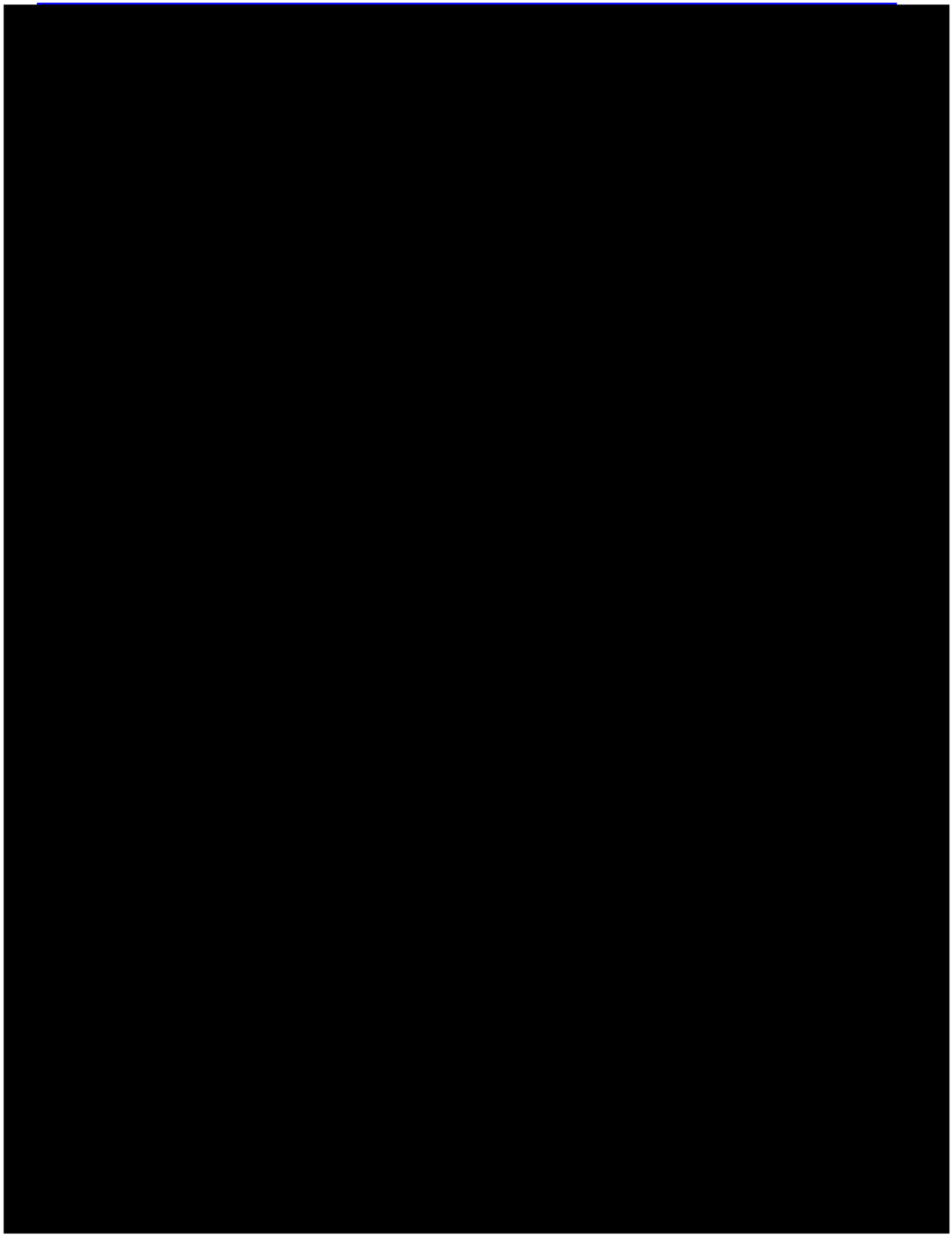


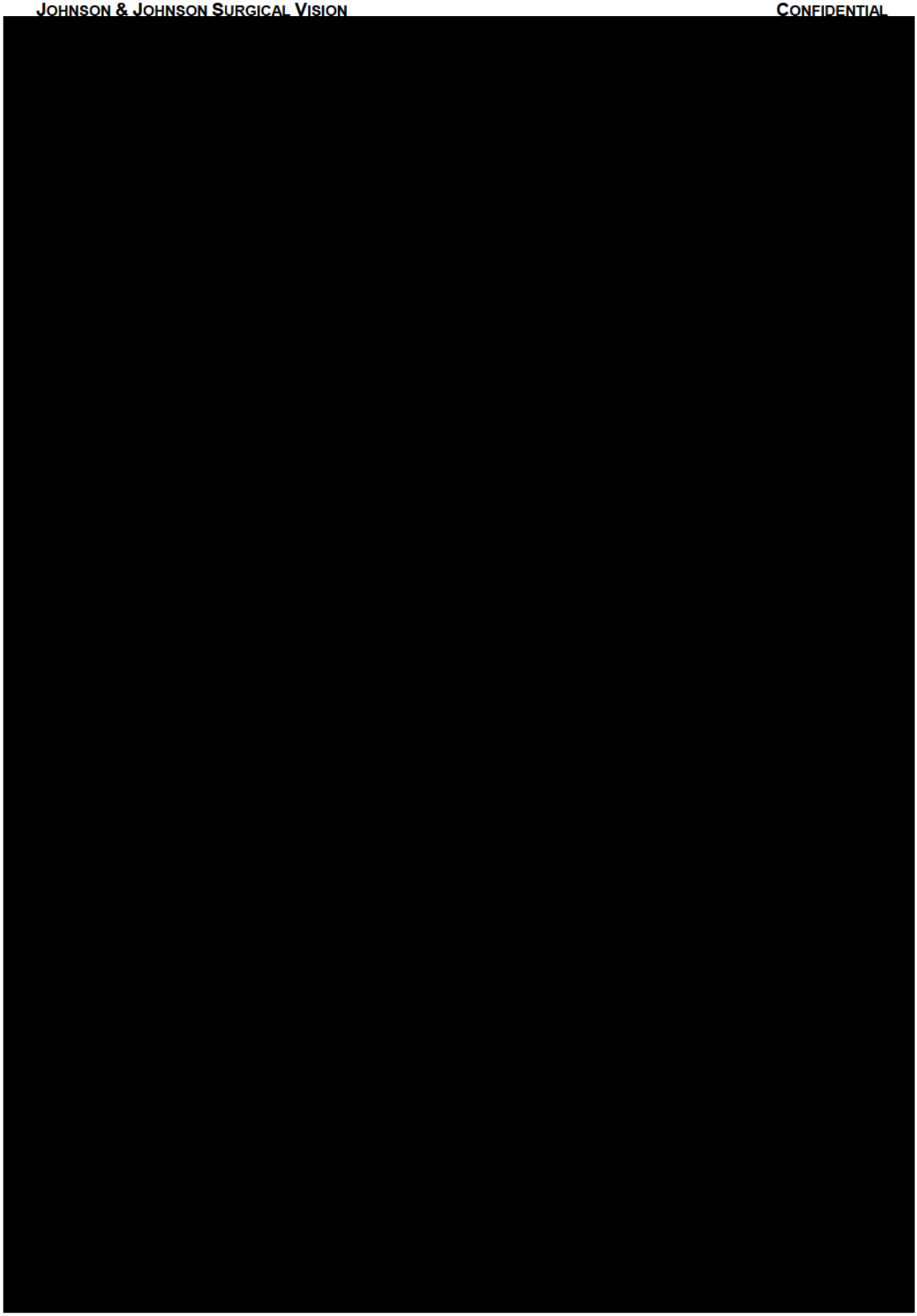


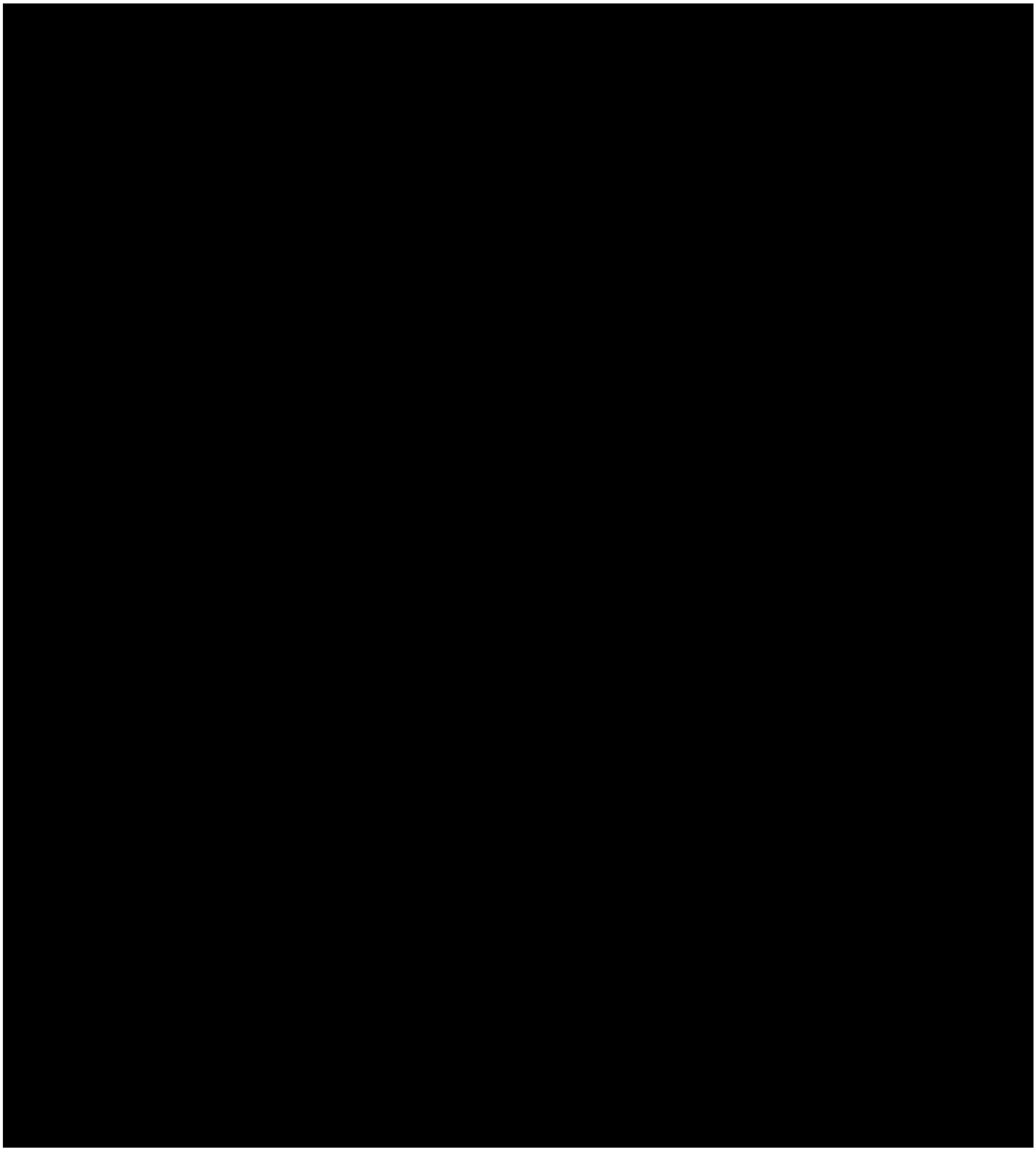












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