UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

Current Report

Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 27, 2023

RESPIRERX PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

Delaware	**1-16467**	**33-0303583**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S Employer Identification No.)**

126 Valley Road, Suite C **Glen Rock, New Jersey** **(Address of principal executive offices)**	**07452** **(Zip Code)**

Registrant's telephone number, including area code: (201) 444-4947

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
N/A	N/A	N/A

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On February 27, 2023, ResolutionRx Ltd ("ResolutionRx"), an unlisted public Australian Company (Australian Company Number or ACN: 664 925 651, Australian Business Number or ABN: 17 664 925 651) and a wholly owned subsidiary of RespireRx Pharmaceuticals Inc. (OTC: RSPI) ("RespireRx") entered into a Services Agreement ("Agreement") with iNGENu CRO Pty Ltd (Australian Company Number or ACN: 656 400 056) ("iNGENu") for clinical research and other related services. Under the Agreement, ResolutionRx will be required to make a US$50,000 deposit with iNGENu within 30 days of the rendering of the first invoice by iNGENu which invoice is anticipated to be received within a few days of the signing of the Agreement. The deposit is to be applied to the final research and development budget of approximately US$16.5 million, which has been agreed by the parties and which deposit shall be credited against the first invoice. Under the Agreement, iNGENu is expected to provide full-service contract research organization ("CRO") clinical and related services, including regulatory, compliance, GMP (good manufacturing practices) manufacturing services in addition to human pharmacokinetic, pharmacodynamic and pivotal human efficacy and safety studies of dronabinol for the treatment of obstructive sleep apnea.

The press release dated March 1, 2023 announcing the entry by ResolutionRx into the Agreement, is attached as Exhibit 99.1 to this Current Report on Form 8-K.

A partially redacted copy of the ResolutionRx and iNGENu CRO Agreement is attached as Exhibit 99.2 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

A list of exhibits that are furnished and filed as part of this report is set forth in the Exhibit Index, which follows, and is incorporated herein by reference.

EXHIBIT INDEX

Exhibit Number	Exhibit Description
99.1*	Press Release dated March 1, 2023
99.2*	ResolutionRx Ltd and iNGENu CRO Pty Ltd Services Agreement dated 27 Februay 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Furnished herewith.

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 1, 2023

RESPIRERX PHARMACEUTICALS INC.
(Registrant)

By: */s/ Jeff E. Margolis*
Jeff E. Margolis
SVP, CFO, Secretary and Treasurer

Exhibit 99.1

ResolutionRx Ltd and RespireRx Pharmaceuticals Inc. Announce ResolutionRx's Entry into a Services Agreement with iNGENu CRO Pty Ltd

Glen Rock, N.J., March 1, 2023/Globe Newswire – ResolutionRx Ltd ("ResolutionRx"), an unlisted public Australian company, (Australian Company Number or ACN: 664 925 651, Australian Business Number or ABN: 17 664 925 651) and a wholly-owned subsidiary of RespireRx Pharmaceuticals Inc. (OTC: RSPI) ("RespireRx") are pleased to jointly announce that on February 27, 2023, ResolutionRx entered into a services agreement ("Services Agreement") for clinical research and other related services with iNGENu CRO Pty Ltd ("iNGENu"), a contract research organization ("CRO") with headquarters in Melbourne, Australia. Collectively, ResolutionRx and RespireRx are leaders in the discovery and development of innovative and revolutionary treatments to combat diseases caused by disruption of neuronal signaling. iNGENu is a bespoke contract research organization focused on cannabinoid and psychedelic clinical research.

This press release contains forward looking statements. Please carefully read the sections below entitled "*Not a Securities Offering"* and "*Cautionary Note Regarding Forward-Looking Statements."*

Under the Services Agreement, iNGENu will act as a full-service CRO in support of ResolutionRx's research and development ("R&D") program, which is developing a proprietary formulation of dronabinol for the treatment of obstructive sleep apnea and anorexia. iNGENu will be responsible for conducting laboratory experiments to determine a final optimum dronabinol formulation, scaling up and manufacturing the chosen formulation for clinical use, preparing and submitting regulatory documents and designing and conducting clinical trials, including pharmacokinetic/pharmacodynamic, safety and pivotal efficacy studies.

Under the Services Agreement, ResolutionRx will be required to make a US$50,000 deposit with iNGENu within 30 days of the rendering of the first invoice by iNGENu, which invoice is anticipated to be received within the next few days. The deposit is to be applied to the final research and development budget of approximately US$16.5 million, which has now been agreed and which deposit shall be credited against the first invoice.

The entry into this Services Agreement is one step in a series of transactions some of which have been completed, some of which are in process and others which are anticipated to be completed in the near future:

Completed

- Formation of ResolutionRx as an Australian subsidiary of RespireRx, and all that was required in the formation process, including, among other things, the establishment of a board of directors, the appointment of officers and the engagement of accountants, as well as the opening of both Australian dollar and US dollar bank accounts.
- Entry into the Services Agreement with iNGENu.
- Entry into a letter of intent and term sheet with Radium Capital ("Radium") for a series of debt financings of the Australian Research and Development Tax Incentive ("R&DTI"), a tax credit or rebate available for the component of R&D activities that are qualified core and supporting activities. In the case of ResolutionRx, this is anticipated to be a 43.5% tax rebate, with up to, and at the discretion of ResolutionRx, 80% of which would be financed by Radium and collateralized by the rebate.
- Engagement of Australian counsel subject to the execution of an engagement agreement.

In Process

- Sub-licensing and licensing or otherwise making available certain dronabinol assets by RespireRx to ResolutionRx.
- ResolutionRx's financing of the first iNGENu research and development invoice by Radium or otherwise.
- Obtaining an independent valuation report of the assets contributed to ResolutionRx.
- If consummated, of which no assurance can be provided, an equity or equity-linked financing of approximately US$3 million, which is approximately 18% of the total research and development budget.

- Due diligence with one or more Australian fund-raising agents or advisors to raise additional unlisted finance in Australia, the completion of which cannot be assured, to support the balance of the anticipated R&D expenditures as well as non-R&D expenses, overhead and working capital.

Anticipated

- ResolutionRx's commencement of research and development activities in Australia, with iNGENu as the CRO, including, but not limited to initial manufacturing and bench testing of at least one new formulation of dronabinol, scale up of manufacturing for clinical grade materials for the new formulation for the anticipated initial pharmacokinetic/pharmacodynamic study and regulatory matters.
- Hiring of a limited number of ResolutionRx employees and/or consultants in Australia.
- ResolutionRx's formal engagement of counsel.
- ResolutionRx's engagement of independent auditors.
- ResolutionRx's formal engagement of placement agent for a contemplated offering in Australia, the completion of which cannot be assured.
- ResolutionRx's execution of a term sheet with respect to the approximate US$3 million financing described above, the completion of which cannot be assured.
- ResolutionRx's formal application for registration for the R&DTI.
- Additional R&DTI financings with Radium.
- Filing in Australia for Overseas Finding(s) to enable access to the R&DTI for qualified research and development activities taking place outside of Australia.
- Early preparation for a ResolutionRx initial public offering in Australia, and possibly other international markets at an appropriate future date.

About ResolutionRx Ltd

Pharmaceutical Cannabinoids, Dronabinol. ResolutionRx Ltd., an unlisted public Australian company and a wholly-owned subsidiary of RespireRx Pharmaceuticals Inc., is developing dronabinol, Δ-9-THC, a synthetic version of the naturally occurring substance in the cannabis plant, for the treatment of OSA, a serious respiratory disorder that impacts more than 95 million people in the United States, Australia, Germany and the United Kingdom. It has been linked to increased risk for hypertension, heart failure, depression, and diabetes, with an annual economic cost in the United States alone of $162 billion according to the AASM (American Academy of Sleep Medicine). There are no approved drug treatments for OSA.

Two Phase 2 clinical trials have been completed demonstrating the ability of dronabinol to significantly reduce the symptoms of OSA and, subject to raising sufficient financing (of which no assurance can be provided) and pending the necessity for and, if required, the approval by the Therapeutic Goods Administration (TGA), Australia's equivalent to the FDA, ResolutionRx plans to commence a pharmacokinetic/pharmacodynamic study for a recently discovered and to-be-developed formulation followed by a Phase 3 clinical study for the treatment of OSA with the new formulation. Because dronabinol is already FDA approved for the treatment of AIDS related anorexia and chemotherapy induced nausea and vomiting, ResolutionRx believes that its re-purposing strategy would only require approval by the FDA of a 505(b)(2) new drug application ("NDA"), an efficient regulatory pathway that allows the use of publicly available data. Similar regulatory equivalents to the 505(b)(2) are available in Australia and Europe.

About RespireRx Pharmaceuticals Inc.

RespireRx Pharmaceuticals Inc. is a leader in the discovery and development of medicines for the treatment of psychiatric and neurological disorders, with a focus on treatments that address conditions affecting millions of people, but for which there are few or poor treatment options, including (i) through its ResolutionRx Ltd subsidiary, pharmaceutical cannabinoids, which include dronabinol, a synthetic form of Δ9-tetrahydrocannabinol ("Δ9-THC") that acts upon the nervous system's endogenous cannabinoid receptors and (ii) through its EndeavourRx business unit, neuromodulators, which include AMPAkines and GABAkines, proprietary chemical entities that positively modulate (positive allosteric modulators or "PAMs") AMPA-type glutamate receptors and $GABA_A$ receptors. RespireRx and ResolutionRx are developing a pipeline of re-purposed and new drug products based on their broad patent portfolios for the above two drug platforms including obstructive sleep apnea ("OSA"), attention deficit hyperactivity disorder ("ADHD"), epilepsy, pain, recovery from spinal cord injury ("SCI"), and certain neurological orphan diseases.

RespireRx holds exclusive licenses and owns patents and patent applications or rights thereto for certain families of chemical compounds that claim the chemical structures and their uses in the treatment of a variety of disorders, as well as claims for novel uses of known drugs.

EndeavourRx: Neuromodulators

AMPAkines. Through an extensive translational research effort from the cellular level through Phase 2 clinical trials, RespireRx has developed a family of novel, low impact AMPAkines, including CX717, CX1739 and CX1942 that may have clinical application in the treatment of CNS-driven neurobehavioral and cognitive disorders, spinal cord injury, neurological diseases, and certain orphan indications. RespireRx's lead clinical compounds, CX717 and CX1739, have successfully completed multiple Phase 1 safety trials. Both compounds have also completed Phase 2 proof of concept trials demonstrating target engagement, by antagonizing the ability of opioids to induce respiratory depression.

AMPAkines have demonstrated positive activity in animal models of ADHD, results that have been extended translationally into statistically significant improvement of symptoms observed in a Phase 2 human clinical trial of CX717 in adult patients with ADHD. Statistically significant therapeutic effects were observed within one week. RespireRx believes AMPAkines may represent a novel, non-stimulant treatment for ADHD with a more rapid onset of action than alternative non-stimulants, such as Straterra® (atomoxetine), and without the drawbacks of amphetamine-type stimulants.

In a series of important studies funded by grants from the National Institutes of Health and published in a number of peer reviewed articles, Dr. David Fuller (University of Florida), a long-time RespireRx collaborator, has demonstrated the ability of CX1739 and CX717, RespireRx's lead AMPAkines, to improve motor nerve activity and muscle function in animal models of spinal cord injury (SCI).

GABAkines. Under a License Agreement with the University of Wisconsin-Milwaukee Research Foundation, Inc. ("UWMRF"), RespireRx has licensed rights to certain selectively acting GABAkines because of their ability to selectively amplify inhibitory neurotransmission at a highly specific, subset of $GABA_A$ receptors, thus producing a unique efficacy profile with reduced side effects. Preclinical studies have documented their efficacy in a broad array of animal models of interrelated neurological and psychiatric disorders including epilepsy, pain, anxiety, and depression in the absence of or with greatly reduced propensity to produce sedation, motor-impairment, tolerance, dependence and abuse. RespireRx is currently focusing on developing KRM-II-81 for the treatment of epilepsy and pain.

KRM-II-81 has displayed a high degree of anti-convulsant activity in a broad range of preclinical studies, including in treatment resistant and pharmaco-resistant models. Not only was KRM-II-81 highly effective in these models, but pharmaco-resistance or tolerance did not develop to its anti-convulsant properties. These latter results are particularly important because pharmaco-resistance occurs when medications that once controlled seizures lose efficacy as a result of chronic use and it is a principal reason some epileptic patients require brain surgery to control their seizures. In support of its potential clinical efficacy, translational studies have demonstrated the ability of KRM-II-81 to dramatically reduce epileptiform electrical activity when administered in situ to brain slices excised from treatment resistant epileptic patients undergoing surgery.

In addition, KRM-II-81 has displayed a high degree of analgesic activity in a broad range of preclinical studies. In intact animal models of pain, the analgesic efficacy of KRM-II-81 was comparable to or greater than commonly used analgesics. At the same time, KRM-II-81 did not display side effects such as sedation and motor impairment, but even more importantly, it did not produce tolerance, dependence, respiratory depression or behavioral changes indicative of abuse liability, which are produced by opioid narcotics and are at the heart of the opioid epidemic.

Additional information about RespireRx and the matters discussed herein can be obtained on RespireRx's web-site at www.RespireRx.com or in its filings with the Securities and Exchange Commission at www.sec.gov.

Not a Securities Offering or Solicitation

This communication shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sales of securities in any jurisdiction in which such offer, solicitation or sale of securities would be unlawful before registration or qualification under the laws of such jurisdiction.

Cautionary Note Regarding Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and RespireRx intends that such forward-looking statements be subject to the safe harbor created thereby. These might include statements regarding RespireRx's future plans, targets, estimates, assumptions, financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about research and development efforts, including, but not limited to, preclinical and clinical research design, execution, timing, costs and results, future product demand, supply, manufacturing, costs, marketing and pricing factors.

In some cases, forward-looking statements may be identified by words including "assumes," "could," "ongoing," "potential," "predicts," "projects," "should," "will," "would," "anticipates," "believes," "intends," "estimates," "expects," "plans," "contemplates," "targets," "continues," "budgets," "may," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words, and such statements may include, but are not limited to, statements regarding (i) future research plans, expenditures and results, (ii) potential collaborative arrangements, (iii) the potential utility of RespireRx's product candidates, (iv) reorganization plans, and (v) the need for, and availability of, additional financing. Forward-looking statements are based on information available at the time the statements are made and involve known and unknown risks, uncertainties and other factors that may cause RespireRx's results, levels of activity, performance or achievements to be materially different from the information expressed or implied by the forward-looking statements in this press release.

These factors include but are not limited to, regulatory policies or changes thereto, available cash, research and development results, issuance of patents, competition from other similar businesses, interest of third parties in collaborations with RespireRx, and market and general economic factors, and other risk factors disclosed in "Item 1A. Risk Factors" in RespireRx's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as filed with the SEC on April 15, 2022 (the "2021 Form 10-K").

You should read these risk factors and the other cautionary statements made in RespireRx's filings as being applicable to all related forward-looking statements wherever they appear in this press release. RespireRx cannot assure you that the forward-looking statements in this press release will prove to be accurate and therefore prospective investors, as well as potential collaborators and other potential stakeholders, are encouraged not to place undue reliance on forward-looking statements. You should read this press release completely. Other than as required by law, RespireRx undertakes no obligation to update or revise these forward-looking statements, even though RespireRx's situation may change in the future.

RespireRx cautions investors, as well as potential collaborators and other potential stakeholders, not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forward-looking statements and from historical results, due to the risks and uncertainties described in the 2021 Form 10-K and in this press release, as well as others that RespireRx may consider immaterial or does not anticipate at this time. These forward-looking statements are based on assumptions regarding RespireRx's business and technology, which involve judgments with respect to, among other things, future scientific, economic, regulatory and competitive conditions, collaborations with third parties, and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond RespireRx's control. Although RespireRx believes that the expectations reflected in its forward-looking statements are reasonable, it does not know whether its expectations will prove correct. RespireRx's expectations reflected in its forward-looking statements can be affected by inaccurate assumptions that it might make or by known or unknown risks and uncertainties, including those described in the 2021 Form 10-K and in this press release. These risks and uncertainties are not exclusive and further information concerning RespireRx and its business, including factors that potentially could materially affect RespireRx's financial results or condition, may emerge from time to time.

For more information about the risks and uncertainties RespireRx faces, see "Item 1A. Risk Factors" in RespireRx's 2021 Form 10-K. Forward-looking statements speak only as of the date they are made. RespireRx does not undertake and specifically declines any obligation to update any forward-looking statements or to publicly announce the results of any revisions to any statements to reflect new information or future events or developments. RespireRx advises investors, as well as potential collaborators and other potential stakeholders, to consult any further disclosures it may make on related subjects in its annual reports on Form 10-K and other reports that RespireRx files with or furnishes to the SEC.

Company Contact:

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and
Senior Financial Officer and Member of the Board of Directors
ResolutionRx Ltd
GPO Box 939
Adelaide, South Australia 5001
or
Registered office c/- Bentleys (SA) Pty Ltd
Level 5
63 Pirie Street
Adelaide South Australia 5000
(website: under development)

SERVICES AGREEMENT

SCHEDULE

TERM	MEANING
we, us or **our**	**iNGENU CRO Pty Ltd (ACN 656 400 056) ("Us")** Address: Office C2, level 1, 459 Toorak Road, Toorak, 3142 Email: sud.agarwal@ingenucro.com
you or **your**	**ResolutionRx Ltd (ACN 664 925 651) ("You")** Address: C/- Bentleys (SA) Pty Ltd, Level 5, 63 Pirie Street, Adelaide SA 5000 Email: jmargolis@respirerx.com
Currency	All currency amounts are United States dollars ($)
Services	The Services are particularised in the applicable Work Order.
Deposit	The Deposit is particularised in the applicable Work Order.
Expenses	The Expenses are: • as particularised in the applicable Work Order; and • any other disbursements, reasonably and directly incurred by us and approved in advance by you for the purpose of the supply of the Services.
Price	The Price is particularised in the applicable Work Order.
Payment Terms	You must pay us the Price and all Expenses in accordance with the payment terms set out in in each Work Order.
Territory	Worldwide
Required Insurances	At a minimum, you are required to effect and maintain the following insurances for the Term (and for a reasonable period thereafter) and with a reputable insurance provider, claims-based policies for: • clinical trial insurance policy, in the amount no less than $20 million; • a professional indemnity insurance policy, or equivalent, in the amount of no less than $10 million for any one claim; and any and all other insurances required by Law in order for us to provide you with the Services
Term	This Agreement will commence on the Commencement Date and will continue until terminated in accordance with its terms.

EXECUTION

Executed by **iNGENu CRO Pty Ltd (ACN 656 400 056)** in accordance with section 126 of the *Corporations Act 2001* (Cth), by its duly authorised agent:

DocuSigned by: Dr. Sud Agarwal 00981179F44F496...	Dr. Sud Agarwal
Signature	Name (Print)
CEO	27 February 2023
Position (Print)	Date

Executed by **ResolutionRx Ltd (ACN 664 925 651)** in accordance with section 126 of the *Corporations Act 2001* (Cth), by its duly authorised agent:

DocuSigned by: Mr. Jeff Margolis 7CA04D05086D4D0...	Mr. Jeff Margolis
Signature	Name (Print)
Senior Financial Officer and Director	27 February 2023
Position (Print)	Date

TERMS AND CONDITIONS

This Agreement is entered into between us and you, together the **Parties** and each a **Party**.

Background

A. We offer contract research organisation services and our Group Companies (as hereinafter defined) including but not limited to Affiliates are authorised to process, import, export, test and sell cannabis, cannabis related molecules and cannabinoids for medical research in Australia and specialise in clinical and commercial development and contract manufacture of custom cannabinoid formulations;

B. You are a global therapeutic medicinal cannabinoid company that is focused on developing branded cannabinoid-based medicines for the treatment of a variety of medical conditions including but not limited to obstructive sleep apnea, nausea and general anorexia;

C. You have developed the Study Product; and

D. You have engaged us to assist you in the steps required to register the Study Product with the Food and Drug Administration of the United States of America (**FDA**) and other similar Regulatory Authorities in Australia and elsewhere in the world.

1. Services

1.1 In consideration of your payment of the Price, we will provide the Services in accordance with this Agreement, whether ourselves or through our Personnel or our Group Companies. Where required, you agree to sign all relevant agreements with our Group Companies.

1.2 You have requested that we assist you with all steps required to register the Study Product with the FDA and other Regulatory Authorities (where applicable) and assist you in obtaining the Regulatory Approvals and licenses required for the Study Product to be commercialised. We will provide the Services in the following three (3) stages, which will be documented in the relevant Work Orders (Annexures 1-3) and will consist (where applicable) of the following Services:

(a) Stage 1: Manufacturing Supply Services as described in clause 16 and the annexed Work Order 1, including pre-clinical formulation development and the supply of clinical study material;

(b) Stage 2: Regulatory Services as described in clause 17 and the annexed Work Order 2, including drafting and submission of an IND or similar applications with other worldwide Regulatory Authorities;

(c) Stage 3: Clinical Trial Services as described in clause 18 18 and the annexed Work Order 3, including Proof of Concept clinical pharmacokinetic studies in subjects with obstructive sleep apnea, as well as Pivotal Studies and Registration, including Phase 3 Clinical Trials and the drafting and submission of applications to the FDA for an NDA or similar applications with other worldwide Regulatory Authorities.

1.3 You acknowledge and agree that any dates for delivery or for completion of the Services notified by us are estimates only, and we will have no Liability to you for failing to meet any delivery or Milestone date other than as may be described elsewhere is this Agreement or in a Work Order.

1.4 We acknowledge and agree that where (a) we do not meet any delivery or Milestone date and (b) such delay is due to our negligent acts or omissions then (c) the next quarterly payment by you to us shall be delayed until the Milestone has been completed.

1.5 You acknowledge and agree that where the scope, timing and cost of the Services are dependent on the acts and decision of third parties including Regulatory Authorities and Government Agencies (**Third Party Events**):

(a) while it is your responsibility to obtain all necessary approvals from the relevant Regulatory Authorities and Government Agencies, we will assist in the process of obtaining such approvals, if specified in the applicable Work Order;

(b) we cannot guarantee any outcome or that any approval from a Regulatory Authority or Government Agency will be obtained;

(c) we have no control over, and are not responsible for, the decisions of any Regulatory Authority or Government Agencies;

(d) we are not responsible or liable for any changes to the scope, timing or Price of the Services (including the termination or suspension of a Study) which occurs, or needs to occur, as the result of a decision by a Regulatory Authority or Government Agency; and

(e) any decision of a Regulatory Authority or Government Agency in relation to the Study Product or a Study may result in a Variation Event as set out in clause 4.3.

As such, we will not be liable in relation to, and you waive and release us from, any loss or Liability incurred by you in relation to any delay in the performance of the Services due to a Third Party Event.

2. Relationship of the Parties

2.1 Both Parties are independent contractors. Nothing in this Agreement constitutes, or will be deemed to constitute, a relationship of employer and employee between the Parties, a partnership between the Parties or make any Party the agent of the other Party for any purpose.

2.2 Subject to any express provision in this Agreement to the contrary, neither Party has any right or authority to and must not do any act, enter into any contract, make any representation, give any warranty, incur any liability, assume any obligation, whether express or implied, of any kind on behalf of the other Party or bind the other Party in any way.

2.3 Notwithstanding the above, you authorise us to act as your agent, to the extent required by this Agreement, including to provide the Services and to communicate with the FDA and other Regulatory Authorities, on your behalf.

3. Work Orders

3.1 This Agreement constitutes a "standing offer" under which, during the Term, you may engage us to conduct Services under separate Work Orders.

3.2 The details of the Services to be performed under each Work Order are documented in Annexures 1-3 and must be signed by both Parties prior to commencement of the Services.

3.3 Each Work Order is subject to, and will be governed by, this Agreement and any other conditions expressly set out in the Work Order. To the extent of any ambiguity or discrepancy between a Work Order and this Agreement, the terms of the Work Order will prevail unless otherwise specified in the Work Order that this Agreement has precedence.

3.4 You may issue a request for us to provide further Services (beyond those Services that are particularised in the Work Orders in the Annexures) by email (**Order Request**).

3.5 We may, in our discretion, accept or reject an Order Request. If we accept the Order Request, we will provide you with a formal Work Order, and once the Work Order is agreed by both Parties in writing, it will be binding in accordance with the terms of this Agreement and the Work Order.

4. Variations

4.1 You may request a variation or change to the Services set out in a Work Order, including the timing for the supply of the Services (**Variation**), by providing written notice to us, with details of the Variation (**Variation Request**). We will not be obliged to comply with a Variation Request unless we accept the Variation Request in writing. The Parties agree to comply with this Agreement as varied by any Variation Request accepted in writing.

4.2 If we reasonably consider that any instruction or direction from you constitutes a Variation, then we will not be obliged to comply with such instruction or direction unless a Variation Request has been issued and accepted by us in accordance with clause 4.1.

4.3 Where the Services are delayed, varied or changed, or the costs of providing the Services increases (**Variation Event**) and the cause of that Variation Event relates to, or is connected with:

(a) your failure to meet your obligations under this Agreement or a Work Order, or delays caused by you not providing us with the required information requested by us, or failing to sign or execute required documents, you agree to pay us our reasonable additional costs and expenses that we may incur as result of the Variation Event, as a debt due and payable within 30 days.

(b) a Third Party Event or the acts or omissions of a third party (excluding our Personnel) or an event or circumstance beyond a Party's reasonable control, then the Parties agree that:

i. where there is a delay, the delay will not constitute a breach of the applicable Work Order or the Agreement by either Party;

ii. we are entitled to stop providing the Services until the Parties have reached written agreement about new completion dates for the Services and any amendments to the Price which are necessary in view of the delays; and

iii. if you instruct us to continue with the Services, you agree to be responsible for any additional costs incurred by us when performing the Services (including any additional Expenses),

(c) our failure to meet our obligations under this Agreement or a Work Order (where such failure is not due to an event in subclause (a) or (b)), then you will not be obligated to pay additional costs and expenses incurred by us as a result of the Variation Event.

4.4 No variation to this Agreement or a Work Order (including to the Services) will be effective unless agreed in writing by both Parties.

5. Sublicensing and subcontracting

5.1 The Parties will develop an initial approved subcontractor list prior to the commencement of the first Work Order which list may be updated from time to time by mutual consent in writing. With respect to subcontractors not on the approved list, and where the services are less than $150,000 we may subcontract the provision of any part of the Services without your approval, subject to notification to you prior to the commencement of the subcontractor services.

5.2 Any subcontractor engagement by a Party under this Agreement will be subject to a written agreement that is consistent with the terms of this Agreement and will include confidentiality, intellectual property, and compliance provisions at least as restrictive or protective of the sublicensing Party as those set forth in this Agreement.

5.3 Each Party agrees that it will be fully responsible and liable to the other Party for any breach of the terms of this Agreement or applicable Laws by any of its sublicensees or subcontractors.

6. Payment

6.1 In consideration for us providing the Services, you agree to pay us:

(a) the Deposit (if any);

(b) the Price; and

(c) all Expenses (if any);

in accordance with the Payment Terms.

6.2 We will issue you with an invoice which will:

(a) be issued in US dollars (or such other currency as agreed in writing between the Parties);

(b) include our bank and account details to enable EFT payment;

(c) sufficiently describe the Services to which the invoice relates;

(d) be in the form of a valid tax invoice and clearly and separately show the amount of any GST (or other value-added tax) payable, if applicable; and

(e) be issued in accordance with the terms of the Work Order.

6.3 When applicable:

(a) GST (or other value-added tax) is payable on the Price and Expenses and will be clearly shown on our invoices. You agree to pay us an amount equivalent to the GST (or other value-added tax) imposed on these charges; and

(b) If we are required to pay any Sales Tax in relation to the Services supplied under this Agreement, the applicable Sales Tax will be set out in the invoice provided to you and the Price payable by you under this Agreement must be increased by the applicable Sales Tax.

6.4 Where a Work Order specifies that a Deposit is payable, you will not be entitled to any part of the Services until the Deposit has been paid in full.

6.5 If any payment has not been made in accordance with the Payment Terms, we may (at our absolute discretion, and without prejudice to any of our rights or remedies under this Agreement or at law):

(a) after a period of 10 Business Days from the relevant due date, cease providing the Services, and recover, as a debt due and immediately payable from you, our reasonable additional costs of doing so (including all recovery costs); and/or

(b) charge interest at a rate equal to the Reserve Bank of Australia's cash rate, from time to time, plus 2% per annum, calculated daily based on a 365 day year and compounding annually, on any such amounts unpaid after the relevant due date in accordance with the Payment Terms.

6.6 If a Party disputes an invoice or other payment obligation under this Agreement, then that Party must pay the undisputed amount of the invoice or other payment obligation, and the Parties will resolve any disputed invoice amount in accordance with 26.6 (**Disputes**).

6.7 A Party has the right to set-off or deduct from any monies payable to the other Party under this Agreement, any amounts which are payable to it by the other Party (whether under this Agreement or otherwise).

7. Conditions precedent

7.1 Our obligation to perform the Services is subject to and conditional on us having received the following, in form and substance reasonably satisfactory to us, on or prior to the Commencement Date:

(a) each Transaction Document duly executed by each party to those documents (other than us);

(b) evidence that all action required under your constitutional documents in connection with your entry into the Transaction Documents has been duly taken;

(c) confirmation that the representations and warranties set out in the Transaction Documents are correct and not misleading as at the Commencement Date; and

(d) confirmation that no Event of Default or Potential Event of Default is continuing as at the Commencement Date.

8. Warranties and Representations

8.1 Each Party represents, warrants and agrees that:

(a) all information and documentation that it provides to the other Party in connection with the Transaction Documents is, to the best of its knowledge, true, correct and complete and does not infringe any third party rights (including any Intellectual Property Rights);

(b) it has taken all necessary corporate action to authorise the entry into and performance of, and to carry out the transactions contemplated by, the Transaction Documents;

(c) no Event of Default or Potential Event of Default is continuing in respect of it;

(d) it is not entering into the Transaction Documents as the trustee of a trust;

(e) no registration, recording or filing of this Agreement, no payment of any tax and no other action is necessary or desirable to ensure the validity and enforceability of its liabilities or rights under this Agreement;

(f) it is not immune from the jurisdiction of any court or any legal process;

(g) its execution and performance of the Transaction Documents and each transaction contemplated by them do not conflict with any law, order, judgment, rule or regulation applicable to you or any document binding on it;

(h) no litigation, arbitration or administrative proceeding is current, pending or to its knowledge threatened which has or the adverse determination of which would be likely to have a Material Adverse Effect;

(i) it has the right to grant all the rights and licenses granted to the other Party under this Agreement;

(j) it is a body corporate duly incorporated and validly existing under the laws of the place of its incorporation;

(k) it will comply with this Agreement and all applicable Laws;

(l) it has full legal capacity, right, authority and power to enter into this Agreement, to perform its obligations under this Agreement, and to carry on its business;

(m) that no Insolvency Event has occurred in respect of it and that it will immediately notify the other Party if it is (or is likely to be) the subject of an Insolvency Event;

(n) that this Agreement constitutes a legal, valid and binding agreement, enforceable in accordance with its terms;

(o) if applicable, it holds a valid ABN which has been advised to the other Party; and

(p) if applicable, it is registered for GST purposes.

8.2 You represent, warrant and agree that:

(a) you will comply with our reasonable requests or requirements;

(b) there are no investigations, inquiries, actions, or other proceedings pending before or, to your knowledge, threatened by any Regulatory Authority or other Governmental Agency in the Territory with respect to the Study Product;

(c) you (and to the extent applicable, your Personnel) will provide us with all documentation, information, instructions, cooperation and access reasonably necessary to enable us to provide the Services;

(d) any information, advice, material, work and services (including the Services) provided by us under this Agreement does not constitute legal, financial, merger, due diligence or risk management advice; and

(e) you must not use, and you must ensure that no person uses, any part of the Services:

(1) to break any Law or infringe any person's rights (including Intellectual Property Rights);

(2) to transmit, publish or communicate material that is defamatory, offensive, abusive, indecent, menacing or unwanted; or

(3) in any way that damages, interferes with or interrupts the supply of the Services.

8.3 We represent, warrant and agree that:

(a) there are no claims pending or, to our knowledge, threatened in writing alleging that our supply of cannabinoid products infringes or would infringe any issued patent of a third party;

(b) we will use reasonable efforts to ensure all of our obligations under this Agreement will be carried out by suitably competent and trained Personnel and in an efficient and professional manner; and

(c) the Services will be provided in accordance with this Agreement.

8.4 Neither Party gives any warranty that any outcome will be achieved, including that Regulatory Approval for the Study Product will be granted, or that outcomes will be commercially valuable, patentable, reliable safe or fit for purpose.

9. Your Obligations

9.1 Prior to our commencement of the Services, you must promptly provide us with:

(a) the formulation of the Study Product as well as all current and relevant information including but not limited to any applicable certificate of analysis, investigator's brochure, Drug Master Files, certificate of Good Manufacturing Practice and Medical Data Sheets, regarding the Study Product (**Study Information**);

(b) any other information reasonably requested by us in order for us to provide the Services; and

(c) the provision of information necessary for you or us to make Regulatory Submissions and Regulatory Materials to achieve Regulatory Approval of the Study Product by the TGA.

9.2 Whilst there are monies outstanding under any Transaction Document, you must:

(a) maintain your corporate existence;

(b) comply with all applicable laws at any time in force and all applicable mandatory requirements of any Government Agency;

(c) duly and punctually pay all taxes assessed, levied or imposed upon you or any secured property owned or held in any capacity by you;

(d) do all things necessary to ensure no Event of Default occurs;

(e) as soon as practicable and in any event within 120 days after the close of each Financial Year, provide to us your audited financial statements for that period;

(f) as soon as practicable and in any event within 45 days after the end of each quarter of each Financial Year, provide to us your quarterly management accounts for that period;

(g) provide to us within 10 days of demand any other information in your possession or under your control in relation to any transaction contemplated by the Transaction Documents and/or your financial affairs and business operations (including your tax affairs);

9.3 You agree to perform all of your Obligations as specified in the relevant Work Order (if any).

10. Reporting Obligations

10.1 You must:

(a) monitor the use of the Study Product in other Clinical Trials and studies, if any, and notify us immediately if a Clinical Trial (using the Study Product) has been terminated or suspended or the Study Product recalled in any jurisdiction; and

(b) you will own and, maintain the global safety database for the Study Product and will be responsible for pharmacovigilance activities throughout the world, including processing of information related to any adverse events for the Study Product received or generated during the Term.

10.2 A Party must notify the other Party of any events:

(c) which may require alteration of the conduct of the Services or a Study;

(d) which may affect the rights, interests, safety or well-being of Study Participants; or

(e) which it is required to report to a Regulatory Authority.

10.3 The Parties must work together to notify all relevant Regulatory Authorities of any events that a Party is required to report under all applicable Laws.

10.4 You must cooperate with us and/or the Reviewing HREC in investigating any event that is required to be reported to the Reviewing HREC arising out of or in connection with a Study.

10.5 If a Party receives any correspondence or inquiry from a Regulatory Authority or Government Agency in relation to the Study Product, it must, to the extent permitted by law:

(a) promptly notify the other Party in writing, and in any event no later than 24 hours after receiving the correspondence or being made aware of the inquiry; and

(b) forward to the other Party copies of any correspondence from any Regulatory Authority or Government Agency relating to any Study.

10.6 Each Party acknowledges that it may not direct the manner in which the other Party fulfils its obligations to permit inspection by Government Agency or Regulatory Authority.

11. Insurance

11.1 The Parties will procure and maintain in full force and effect the Required Insurance.

11.2 Where you are required to obtain clinical trial insurance cover for a Study (either under any applicable Law or as specified in this Agreement), you must ensure that we are named as an insured party under your insurance policy, with respect to the activities including conduct of the Study and the indemnity obligations under this Agreement.

11.3 You must provide us with evidence of insurance by way of a certificate of currency, as requested by us from time to time.

12. Record Keeping and Progress Reports

12.1 Both Parties agree to keep full and accurate records as required under all applicable Laws.

12.2 Unless otherwise set out in a Work Order, we agree to provide you with progress reports detailing the status and expectations of all Work Orders at the end of each calendar quarter.

13. Regulatory Inspections

13.1 If, during the Term either Party is subject to an inspection by a Regulatory Authority (**Inspected Party**) which relates to the Study Product, such Party must immediately notify the other Party. The other Party can request that it be present to observe the inspection by providing notice in writing within 5 business days to the Inspected Party. The Inspected Party may accept or deny this request and may negotiate any terms of observation with the other Party.

13.2 The Party being inspected must provide:

(a) the other Party with prompt updates of the inspection, and will disclose a copy of the inspection report to the other Party (which inspection report may be redacted with respect to any information that is unrelated to the Study Product or any information that is the Confidential Information of a third party); and

(b) the other Party with any further material written correspondence with such Regulatory Authority.

13.3 Each Party acknowledges that it may not direct the manner in which the other Party responds or addresses any correspondence from a Regulatory Authority.

14. Compliance with standards and guidelines

14.1 The Parties must comply with the following:

(a) all applicable Laws and requirements of Regulatory Authorities;

(b) the requirements of the TGA in Access to Unapproved Therapeutic Goods – Clinical Trials in Australia (October 2004) or its replacement and any other TGA publication or guideline that relates to clinical investigations, or other such regulations or guidance governing the conduct of clinical research in the jurisdiction of a Study;

(c) the principles that have their origins in the Declaration of Helsinki adopted by the World Medical Association in October 1996 (as accepted by the Australian Government);

(d) the Guideline for Good Clinical Practice developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (**ICH**), being the version in force from time to time or its replacement;

(e) the procedures and practices described in ISO 14155:2011, being the version in force from time to time, or its replacement, of the International Standard ISO14155:2011 'Clinical investigation of medical devices for human subjects - Good clinical practice' developed by the International Organisation for Standardisation; and

(f) the NHMRC Statement and any other relevant NHMRC publication or guideline that relates to clinical trials.

15. Alliance Managers

15.1 Each Party must appoint an appropriately qualified individual to serve as an alliance manager under this Agreement (each, an **Alliance Manager**).

15.2 The Alliance Managers must act as the primary point of contact for any matters arising under this Agreement and will be responsible for ensuring:

(a) clear and responsive communication and the effective exchange of information between the Parties; and

(b) each Party's awareness of and compliance with this Agreement and any applicable Laws.

16. Supply Services

16.1 In consideration for the Price, we will provide you with the Supply Services as set out in the applicable Work Order either ourselves or through our Personnel or a Group Company in accordance with the relevant Work Order.

16.2 You acknowledge and agree that:

(a) we are not a manufacturer and we will subcontract certain Supply Services to a manufacturer as described in clause 5.1;

(b) you will promptly provide us with all relevant specifications, documentation and formulations and any other relevant information (together the **Product Information**) for the Study Product; and

(c) we will not be liable for any Defects in the Study Product or failure of the Study Product to meet Regulatory Requirements where such Defects or failure is due to the Product Information.

16.3 We agree to ensure that the manufacturer is contractually obligated to:

(a) manufacture the Study Product in accordance with all applicable Laws (including GMP and GLP); and

(b) provide all relevant certificates of analysis and documents required to be submitted to a Regulatory Authority.

17. Regulatory Services

17.1 In consideration for the Price, we will provide you with the Regulatory Services as set out in the applicable Work Order either ourselves or through our Personnel or a Group Company in accordance with the relevant Work Order. In the event it becomes necessary to sub-contract certain of these Regulatory Services, we will do so as described in clause 5.1.

17.2 We make no representations, warranties, assurances or guarantees of any kind, whether express or implied, with respect to the Regulatory Services including, without limitation:

(a) any representation or warranty of merchantability, fitness for any particular use or purpose, or non-infringement of Intellectual Property Rights or other third-party rights; and

(b) that you will be able to register the Study Product with the relevant Regulatory Authorities.

17.3 We agree that, provided we have received all payment for the Regulatory Services, we shall as soon as possible after obtaining Regulatory Approvals for the Study Product, assign and transfer to you all Regulatory Approvals, and Regulatory Materials related to the Study Product.

18. Clinical Trial Services

18.1 In consideration for the Price, we will provide all Clinical Trial Services as set out in the applicable Work Order.

18.2 You acknowledge and agree that we may need to subcontract certain Clinical Services to a sub-contractor, in which case we will do so as described in clause 5.1.

18.3 You agree that you are the Local Sponsor for the purposes of any Study and that you must:

(a) enter into all necessary agreements with the relevant Study Sites;

(b) obtain all relevant insurances; and

(c) provide us with your authority to act on your behalf with the Study Sites. A form of authority is found in Annexure 4.

19. Commercial Supply Services

19.1 The Parties will negotiate separately for any agreement in relation to the commercial supply of the Study Product. The existence of such negotiations do not commit either party to enter in a commercial supply agreement nor create any right of first refusal or first negotiation.

20. Intellectual Property

General

20.1 As between the Parties:

(a) we own all Intellectual Property Rights in Our Materials;

(b) you own all Intellectual Property Rights in Your Materials; and

(c) nothing in this Agreement constitutes a transfer or assignment of any Intellectual Property Rights in Our Materials or Your Materials.

20.2 Unless otherwise specified in a Work Order, as between the Parties:

(a) ownership of all Intellectual Property Rights in any Improvements in Your Materials will vest in you upon creation. We agree to execute all documents and do all acts necessary or desirable to assure your title to such Intellectual Property Rights upon payment of the Price in full;

(b) ownership of all Intellectual Property Rights in any Improvements in Our Materials will vest in us upon creation. You agree to execute all documents and do all acts necessary or desirable to assure our title to such Intellectual Property Rights; and

(c) ownership of any New Material will vest in the Party who created it.

20.3 You grant us a non-exclusive, irrevocable, worldwide, non-sublicensable and non-transferable right and licence, to use Your Materials and the Improvements to Your Material and any other information that you provide to us solely for the purpose of performing of our obligations or exercising our rights under this Agreement.

20.4 We grant you a non-exclusive, worldwide, non-sublicensable and non-transferable right and licence, to use Our Materials and Improvements to Our Materials that we provide to you solely for your use and enjoyment of the Services, as contemplated by this Agreement. Subject to clause 26.6, the license may be revoked at any time at our discretion if the Price is not paid in accordance with the Payment terms set out in this Agreement and all applicable Work Orders.

20.5 If you or any of your Personnel have any Moral Rights in any material provided, used or prepared in connection with this Agreement, you agree to (and will procure that your Personnel) consent to our use or infringement of those Moral Rights.

Patent Prosecution

20.6 During the Term, you will have the sole right and discretion (but not the obligation) to file for, prosecute and maintain any Intellectual Property Rights in Your Materials, Improvements to Your Materials and the Study Product in all jurisdictions at your sole cost and expense.

20.7 During the Term, we will have the sole right and discretion (but not the obligation) to file for, prosecute and maintain any Intellectual Property Rights in Our Materials, Improvements to Our Materials in all jurisdictions at our sole cost and expense.

Enforcement of Rights

20.8 If either Party becomes aware of any use of the Study Product that infringes (or that is directed to the development of a product that would infringe) a Party's Intellectual Property Rights in the Territory (**Competing Infringement**),

then the Party becoming aware of such Competing Infringement will give prompt written notice to the other Party regarding such alleged infringement.

20.9 Each Party shall have the exclusive right, but not the obligation, to attempt to resolve any Competing Infringement of its Intellectual Property Rights at its own expense, including the filing of any infringement suits with the counsel of its choice.

20.10 If a third party asserts that it has a right or an interest in any Intellectual Property Right which will be infringed by a Party's activities under this Agreement, or a Party becomes aware of an Intellectual Property Right that might form the basis for such a claim (**Third Party Infringement Claim**), then the Party first obtaining knowledge of such claim or such potential claim will promptly provide the other Party with written notice and the related facts in reasonable detail.

20.11 In addition to the indemnities, provided in clause 23 (Limitations on Liability):

(a) Each Party will notify the other Party as soon as reasonably practicable in writing of a Third Party Infringement Claim against either Party;

(b) Each Party shall have the right to take all reasonable action to defend, manage and settle any Third Party Infringement Claim against it at their cost; however each Party will, upon request of the other Party, in writing, and at the requesting Party's cost, give the other Party, the right to participate in such defence, management and settlement of the Third Party Infringement Claim at its cost;

(c) Each Party:

i. must reasonably take into account the other Party's views in relation to the defence, management and settlement of the Third Party Infringement Claim;

ii. must keep the other Party fully informed of any proposed conduct in respect of the defence and management of the Third Party Infringement claims; and

(d) each Party agrees not to enter into any settlement of a Third Party Infringement claim which includes ot affects the other Party without the other Party's written consent which shall not be unreasonably withheld.

20.12 This clause 20 will survive termination or expiry of this Agreement.

21. Confidential Information

21.1 Each Receiving Party agrees:

(a) not to disclose the Confidential Information of the Disclosing Party to any third party (subject to subclause 21.1(c);

(b) to protect the Confidential Information of the Disclosing Party from any unauthorised disclosure;

(c) to only disclose the Confidential Information to those of its Personnel or Representatives who need to know the Confidential Information in connection with this Agreement, provided those persons keep the Confidential Information confidential in accordance with this clause 21; and

(d) to only use the Confidential Information of the Disclosing Party for the purpose of performing obligations, or exercising rights or remedies, under this Agreement.

21.2 The Receiving Party will be responsible and liable for the acts and omissions of its Representatives in respect of the Confidential Information.

21.3 The obligations in clause 21.1 do not apply to Confidential Information that:

(a) is required to be disclosed in order for the Parties to comply with their obligations under this Agreement;

(b) is authorised in writing to be disclosed by the Disclosing Party;

(c) was rightfully known by the Receiving Party (as shown by its written records) prior to the date of disclosure by the Disclosing Party;

(d) is in the public domain and/or is no longer confidential, except as a result of a breach of this Agreement or other duty of confidence; or

(e) must be disclosed by Law or by a Regulatory Authority, including under subpoena, provided that (to the extent permitted by Law) the Receiving Party has given the Disclosing Party notice prior to disclosure.

Retention of Confidential Information

21.4 The Parties may retain copies of Confidential Information:

(a) if they are required to do so by Law or by a Regulatory Authority;

(b) contained in board papers or board minutes of the relevant Party (to the extent those documents contain only the level of detail consistent with normal practices);

(c) contained in working papers which the relevant Party is required to retain for insurance or risk management purposes, or to comply with any professional standards applicable to the relevant Party (to the extent those documents contain only the level of detail consistent with normal practices) or in accordance with the Relevant Party's practices or policies regarding retention of confidential information provided to such Party;

(d) contained in any advice or report which is prepared by an adviser of the Party for the purpose; and

(e) that is stored electronically on back-up servers under an existing routine data back-up process, if:

I. that Confidential Information is deleted from local hard drives and local media; and

II. no attempt is made to recover it from those servers, unless required by Law or any applicable professional standards.

21.5 Any Confidential Information retained under clause 21.4 remains subject to this Agreement.

Security

21.6 The Receiving Party must:

(a) do all things reasonably necessary to safeguard the confidentiality of the Confidential Information using the highest degree of care to preserve and protect the secrecy, and prevent disclosure, of the Confidential Information (and, in any event, not less than the care a reasonable person would use under similar circumstances);

(b) immediately advise the Disclosing Party in writing of any loss, misappropriation or misuse of the Confidential Information or any suspected, actual or deemed breach of this clause 21 of this Agreement which may come to the Receiving Party's attention; and

(c) provide any assistance reasonably requested by the Disclosing Party in relation to any actions a Disclosing Party takes for any suspected, actual or deemed breach of this clause 21.

21.7 Each Party agrees that monetary damages may not be an adequate remedy for a breach of this clause 21 (Confidential Information). A Party is entitled to seek an injunction, or any other remedy available at law or in equity, at its discretion, to protect itself from a breach (or continuing breach) of this clause 21 (Confidential Information).

21.8 This clause 21 (Confidential Information) will survive the termination of this Agreement.

22. Privacy

22.1 You must comply with and do all things requested by us (acting reasonably) to enable us to comply with all applicable Privacy Laws.

22.2 Without prejudice to the generality of clause 22.1, you must, in relation to any personal information processed in connection with, or received or collected under, this Agreement:

(a) take reasonable steps to protect the information from misuse, interference, loss, unauthorised access, modification and disclosure;

(b) where you disclose any personal information to us you must ensure that you have obtained all necessary consents and authorisations from the individual to whom the personal information relates and you must comply with all relevant Privacy Laws which apply to you; and

(c) comply with any additional obligations which we are obliged to impose upon you from time to time in order to ensure that we comply with any relevant Privacy Laws.

23. Limitations on Liability and Indemnity

23.1 Despite anything to the contrary, to the maximum extent permitted by law, you indemnify us, our Personnel and any of our Group Companies (the **Indemnified**), and hold the Indemnified harmless, from and against any Liability suffered or incurred by us, arising from, or in connection with, any:

(d) grossly negligent or wilful wrongful act or material omission by you or any of your Personnel;

(e) breach by you or any of your Personnel of any material warranty under clause 8 (Warranties and Representations);

(f) property loss or damage or personal injury (including death) caused by you or any of your Personnel or caused to a Study Participant due to the Product Information;

(g) claims made by or on behalf of Study Participants (including their dependants and children injured in utero through the participation of the child's mother or father in a Study) arising out of or relating to the administration and/or use of the Study Product under investigation or any clinical intervention or procedure provided for or required by the Study to which the Study Participants would not have been exposed but for the participation of the Study Participants in the Study;

(h) breach of confidentiality or privacy obligations under this Agreement;

(i) infringement by your or your Personnel of our Intellectual Property Rights;

(j) you or any of your Personnel infringing the rights of any third party (including Intellectual Property Rights);

(k) a claim that our use of the Study Product or the Study Information infringes the rights of any third party (including Intellectual Property Rights); or

(l) breach of any Law by you or any of your Personnel.

23.2 Each Party will indemnify and hold harmless the other Party, against all Liabilities sustained, incurred or suffered by the other Party:

(a) as a result of any breach by such Party of any warranty under clause 8 (Warranties and Representations) of this Agreement; or

(b) as a result of such Party's gross negligence or wilful misconduct.

23.3 Despite anything to the contrary, to the maximum extent permitted by law:

(a) neither Party will be liable for Consequential Loss;

(b) a Party's liability for any Liability under this Agreement will be reduced proportionately to the extent the relevant Liability was caused or contributed to by the acts or omissions of the other Party (or any of its Personnel), including any failure by that other Party to mitigate its loss; and

(c) our aggregate liability for any Liability arising from or in connection with this Agreement will be limited to the Price paid by you to us in respect of the supply of the relevant Services to which the Liability relates.

23.4 This clause 23 (Limitations on Liability and Indemnity) will survive the termination or expiry of this Agreement.

24. Term and Termination

24.1 This Agreement will operate for the Term.

Termination without cause

24.2 **Termination of this Agreement:** Either Party may terminate this Agreement by giving the other Party 90 days' notice in writing and:

(a) if there are no current Work Orders in force, clause 24.7 shall apply; or

(b) if there are any current Work Orders, then any current Work Orders will continue in accordance with the terms of the Work Order (and this Agreement) until such time as the Work Order is complete or the Work Order is otherwise terminated in accordance with its terms. The Parties may decide to terminate a Work Order at the same time as this Agreement if specified in the Work Order or mutually agreed in writing by the Parties.

24.3 **Termination of a Work Order:** Unless specified otherwise in a Work Order:

(a) either Party may terminate a Work Order in writing by giving the other Party 90 days' notice in writing, unless such Work Order is for, or contains, Clinical Trial Services;

(b) subject to clause 24.6, termination of a Work Order for, or, containing Clinical Trial Services will be set out in the applicable Work Order; and

(c) termination of any Work Order will not terminate this Agreement.

24.4 **Termination by mutual consent:** The Parties can agree to terminate this Agreement or any Work Order at any time by mutual consent evidenced in writing.

Termination for cause

24.5 This Agreement and all Work Orders will terminate immediately upon written notice by a Party (**Non-Defaulting Party**) if:

(a) the other Party (**Defaulting Party**) breaches a material term of this Agreement and that breach has not been remedied within 10 Business Days of the Defaulting Party being notified of the breach by the Non-Defaulting Party; or

(b) (to the extent permitted under the *Corporations Act 2001* (Cth)) any step is taken to enter into any arrangement between the Defaulting Party and its creditors as a group, any step is taken to appoint a receiver, a receiver and manager, a liquidator, a provisional liquidator or like person of the whole or any part of the Defaulting Party's assets or business, the Defaulting Party is bankrupt, or the Defaulting Party is unable to pay its debts as they fall due.

24.6 This Agreement or any Work Order may be terminated by a Party before the end of the Term by written notice to the other Party with immediate effect, if the Study detailed in the Work Order is not continuing for the following reasons:

(a) the Study Product has given rise to unacceptable or serious adverse events;

(b) the Study Product is being shown not to be effective;

(c) the Study Product has been demonstrated to be effective and the Sponsor has determined that further testing is not required; or

(d) a Regulatory Authority requires the suspension or cessation of the study.

Consequences of Termination

24.7 Upon expiry or termination of this Agreement, or any Work Order:

(a) subject to clause 24.2(b), we will immediately cease providing the Services (if any);

(b) you agree that any payments made by you to us are not refundable to you;

(c) you are to pay for all Services provided prior to termination, including Services which have been provided and have not yet been invoiced to you, and all other amounts due and payable under this Agreement;

(d) where a Work Order specifies that payment is due upon completion of a Milestone and that Milestone has not been completed at the date of termination, you agree to pay for all our costs incurred to date toward the uncompleted Milestones and any costs associated with the winding up of a Study and necessary for the continuity of care or safety of the Study Participants;

(e) you agree to promptly return (where possible), or delete or destroy (where not possible to return), any information, documentation or material owned by us that is in your possession or control, subject to any rights you may have to any Intellectual Property in accordance with clause 20 (Intellectual Property) and subject to your documentation retention practices and policies;

(f) if requested by the Disclosing Party, the Receiving Party must destroy or return to the Disclosing Party all of its Confidential Information, except as provided for under clause 21.4;

(g) we will retain your documents (including copies) as required by law or regulatory requirements. Your express or implied agreement to this Agreement constitutes your authority for us to retain or destroy documents in accordance with the statutory periods, or on expiry or termination of this Agreement. and

(h) if required, the Parties will discuss and coordinate the termination of any Study to ensure compliance with all applicable Laws, safety of the Study Participants and if possible, provide continuity of treatment in a safe and efficient manner.

24.8 Where the Agreement is terminated by us under clause 24.5 you also agree to pay us our additional costs, reasonably incurred, and which arise directly from such termination (including recovery fees).

24.9 Where a Work Order is terminated by:

(a) you under clause 24.3 or

(b) under clause 24.4, clause 24.4 or clause 24.6,

you agree that you will pay us all additional costs which we incur due to the termination of the Work Order including:

(a) any costs that we are charged by our Personnel for termination of any subcontracts;

(b) all additional costs that are due to be paid to our Personnel and any third parties as a result of the termination;

(c) all costs associated with the winding up of a Study including all costs due to the Study Sites;

(d) all costs associated with providing continuity of treatment to Study Participants (if applicable); and

(e) any and all costs incurred by us up to the date of Termination in relation to the Services and all costs incurred by us as result of the early termination of the Work Order.

24.10 Termination of this Agreement will not affect any rights or liabilities that a Party has accrued under it.

24.11 This clause 24 will survive the termination or expiry of this Agreement.

25. Events of Default

25.1 Each of the following is an Event of Default:

(a) you not paying any money due for payment by you in accordance with a Transaction Document;

(b) without limiting subclause (a), a Party does not comply with any material obligation under a Transaction Document, and if that default is capable of remedy, it is not remedied within 10 Business Days (or such longer period agreed to by the Parties) of receiving a written notice from the other Party regarding the breach and requiring the breaching Party to remedy the breach;

(c) a representation, warranty or statement made or deemed to be made by a Party under a Transaction Document is untrue or misleading in any material respect and, if the circumstances giving rise to the misrepresentation can be remedied, the breaching Party does not remedy the breach within 10 Business Days of the other Party notifying the breaching Party in writing;

(d) an "event of default" (however described or defined in the relevant Transaction Document) occurs under any Transaction Document;

(e) a Transaction Document is void, voidable or actually unenforceable by either Party;

(f) an authorisation from a Governmental Agency is necessary to enable:

(i) you to comply with your obligations under a Transaction Document; or

(ii) us to exercise our rights under a Transaction Document,

is withheld or ceases to be in full force and effect;

(g) an event or series of events, including any adverse change in either Party's property or financial condition, occurs which has or is likely to have a Material Adverse Effect;

(h) any loan or other financial accommodation of yours in excess of $500,000 becomes due for payment or capable of being declared due for payment before its stated maturity other than by the exercise of an option of yours to pay it before maturity;

(i) an investigation is adjudicated by a Government Agency with respect to a Party's affairs, which has a Material Adverse Effect;

(j) either Party ceases or threatens to cease carrying on its business or a substantial part of its business or dispose of or threaten to dispose of all or substantially all of its assets; and

(k) an Insolvency Event occurs.

25.2 Upon the occurrence of an Event of Default by you, or if an Event of Default is continuing, we may do any one or more of the following, with or without notice to you:

(a) make any amount due to us under this Agreement immediately due for payment; and

25.3 Nothing in this clause 25 restricts, prejudices or in any way limits our rights under clause 24.

26. General

26.1 **Publicity:** The Parties will make a joint press release regarding the execution of this Agreement, which will be agreed to by the Parties and issued following the Commencement Date at a time to be agreed by the Parties which time shall be within any regulatory filing deadlines, if any. The Parties recognize that each Party may from time-to-time desire to issue separate press releases and make other public statements or disclosures regarding the terms of this Agreement. Notwithstanding the foregoing, we acknowledge that you are an affiliate of a public reporting company in the United States ("**US**") and that you or your US public affiliate may make any public disclosures with respect to this Agreement that are required or advisable under United States securities laws, rules and regulations or similar laws, rules or regulations of the various states of the US.

In such event, the Party desiring to issue a press release or make a public statement or disclosure will provide the other Party with a copy of the proposed press release, statement, or disclosure for review and approval as soon as practicable prior to publication, which advance approval will not be unreasonably withheld. Notwithstanding the foregoing, if a US public disclosure is required and is subject to time constraints or deadlines and permission has not been received on a timely basis, you may make such disclosure without our permission.

No other public statement or disclosure of, or concerning, the terms of this Agreement will be made, either directly or indirectly, by either Party, without first obtaining the written approval of the other Party.

Once any public statement or disclosure has been approved in accordance with this clause 26.1 (Publicity), then either Party may continue to appropriately communicate information contained in such permitted statement or disclosure, provided that such information remains accurate.

26.2 **Assignment:** Subject to clause 26.3, a Party must not assign, novate or deal with the whole or any part of its rights or obligations under this Agreement without the prior written consent of the other Party (such consent is not to be unreasonably withheld).

26.3 **Assignment of Debt:** You agree that we may assign or transfer any debt owed by you to us, arising under or in connection with this Agreement, to a debt collector, debt collection agency, or other third party.

26.4 **Counterparts:** This Agreement may be executed in any number of counterparts that together will form one instrument.

26.5 **Electronic Execution:** This Agreement may be executed using an Electronic Signature. The Parties acknowledge and agree that if a Party executes this Agreement using an Electronic Signature, then the Party is taken to have entered into this Agreement in electronic form and the Electronic Signature is deemed to be an original execution of the Agreement by the Party. "Electronic Signature" means an electronic method of signing that identifies the person and indicates their intention to sign this Agreement which may include software programs such as Docusign.

26.6 **Disputes:** A Party may not commence court proceedings relating to any dispute, controversy or claim arising from, or in connection with, this Agreement (including any question regarding its existence, validity or termination) (**Dispute**) without first complying with this clause 26.6. A Party claiming that a Dispute has arisen must give written notice to the other Party specifying the nature of the Dispute (**Dispute Notice**). The Parties must meet (whether in person, by telephone or video conference) within 10 Business Days of service of the Dispute Notice to seek (in good faith) to resolve the Dispute. If the Parties do not resolve the Dispute within 20 Business Days of the date the Dispute Notice was served (or such further period as agreed in writing by the Parties), either Party may refer the matter to mediation, administered by the Australian Disputes Centre in accordance with Australian Disputes Centre Guidelines for Commercial Mediation. Nothing in this clause will operate to prevent a Party from seeking urgent injunctive or equitable relief from a court of appropriate jurisdiction.

26.7 **Entire agreement:** This Agreement contains the entire understanding between the Parties and the Parties agree that no representation or statement has been made to, or relied upon by, either of the Parties, except as expressly stipulated in this Agreement, and this Agreement supersedes, all previous discussions, communications, negotiations, understandings, representations, warranties, commitments and agreements, in respect of its subject matter.

26.8 **Further assurance:** Each Party must to promptly do all things and execute all further instruments necessary to give full force and effect to this Agreement and their obligations under it.

26.9 **Force Majeure:** Neither Party will be liable for any delay or failure to perform their respective obligations under this Agreement if such delay or failure is caused or contributed to by a Force Majeure Event, provided that the Party seeking to rely on the benefit of this clause:

(a) as soon as reasonably practical, notifies the other party in writing details of the Force Majeure Event, and the extent to which it is unable to perform its obligations; and

(b) uses reasonable endeavours to minimise the duration and adverse consequences of the Force Majeure Event.

Where the Force Majeure Event prevents a Party from performing a material obligation under this agreement for a period in excess of 60 days, then the other Party may by notice terminate this Agreement, which will be effective immediately, unless otherwise stated in the notice. This clause will not apply to a Party's obligation to pay any amount that is due and payable to the other Party under this Agreement.

26.10 **Governing law:** This Agreement is governed by the laws of Victoria, Australia. Each Party irrevocably and unconditionally submits to the exclusive jurisdiction of the courts operating in Victoria and any courts entitled to hear appeals from those courts and waives any right to object to proceedings being brought in those courts.

26.11 **Notices:** Any notice given under this Agreement must be in writing addressed to the addresses set out in this Agreement, or the relevant address last notified by the recipient to the Parties in accordance with this clause. Any notice may be sent by standard post or email, and will be deemed to have been served on the expiry of 48 hours in the case of post, or at the time of transmission in the case of transmission by email.

26.12 **Waiver:** Any failure or delay by a Party in exercising a power or right (either wholly or partially) in relation to this Agreement does not operate as a waiver or prevent that Party from exercising that power or right or any other power or right. A waiver must be in writing and will be effective only to the extent specifically stated.

26.13 **Severance:** If a provision of this Agreement is held to be void, invalid, illegal or unenforceable, that provision is to be read down as narrowly as necessary to allow it to be valid or enforceable, failing which, that provision (or that part of that provision) will be severed from this Agreement without affecting the validity or enforceability of the remainder of that provision or the other provisions in this Agreement.

26.14 **Survival:** Without limiting the clauses which by their nature survive termination of this agreement, clauses 18 (Commercial Supply Services), clause 20 (Intellectual Property), 21 (Confidential Information), 22 (Privacy), clause 23 (Limitations on liability and Indemnity), and clause 24 (Term and Termination) will survive termination or expiry of this Agreement.

27. Definitions

In this Agreement, unless the context otherwise requires, capitalised terms have the meanings given to them in the Schedule, and:

Affiliate means any company which (directly or indirectly) controls, is controlled by or is under common control with a Party and includes any Group Companies.

Agreement means these terms and conditions, all Appendices and annexures and any Work Order issued under it and any documents attached to, or referred to in, each of them.

ANDA means Abbreviated New Drug Application as defined by the FDA or equivalent non-US major country regulatory authority.

Business Day means a day on which banks are open for general banking business in Victoria, excluding Saturdays, Sundays and public holidays.

Calendar Year means any calendar year beginning on January 1st and ending on December 31st.

Clinical Supply means that Study Product manufactured by us in accordance with GMP practices for use in a Clinical Trial.

Clinical Trial means a human clinical study that is designed to:

(a) establish that a pharmaceutical, biological or diagnostic product is reasonably safe for continued testing,

(b) investigate the safety and efficacy of such product for its intended use, and to define warnings, precautions and adverse reactions that may be associated with such product or

(c) support Regulatory Approval or label expansion of such product, and

includes any human pharmacokinetic study, Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial or any post-approval clinical trial in humans.

Commencement Date means the date this Agreement is signed by the last of the Parties.

Confidential Information means:

(a) any information, whether in visual, documentary, oral or electronic form, that is disclosed directly or indirectly by a Disclosing Party or its Representatives to the Receiving Party which relates to the Disclosing Party's (or its Representatives'), businesses, clients, customers or suppliers, and whether or not such information is marked as "confidential" or is received acquired, overheard, or learnt by the Receiving Party (or any of its Representatives) in any way whatsoever including:

(i) trade secrets, intellectual property, ideas, source code, designs, monetisation plans, concepts, knowledge, know-how, inventions, technology, software;

(ii) financial information, including financial reports, balance sheets, profit and loss statements, sales information and bank accounts, accounting, monetisation, capital raising, marketing and technical plans and information, and information regarding funding arrangements;

(iii) business information, including business plans, strategic plans, budgets, proposals, management reports and marketing and distribution plans, business models, operating procedures, processes, techniques, business methods, customer and supplier lists (including any prospective or proposed customer and supplier lists) and analytical information;

(iv) personal information, including information concerning the Disclosing Party's Representatives, clients, customers or suppliers;

(v) commercially sensitive information or other business intelligence; and

(b) any other information or data that the Receiving Party is told by the Disclosing Party or the Disclosing Party's Representatives is confidential, or that a reasonable person would expect from its nature to be confidential;

(c) all compilations, notes, records, analyses, extracts, summaries or other documents and related information prepared by the Receiving Party or its Representatives which contain or reflect any of the information referred to in (a) or (b), including any copies of the Confidential Information, and copies of the notes, records and related information generated; and

(d) any discussions, presentations, investigations or negotiations between the parties regarding this Agreement and the fact that such discussions presentations, investigations or negotiations are taking place or have occurred.

Consequential Loss means, whether under statute, contract, equity, tort (including negligence), indemnity or otherwise:

(a) any loss or damage that cannot be considered to arise according to the usual course of things from the relevant breach, act or omission, whether or not such loss or damage may reasonably be supposed to have been in the contemplation of the Parties at the time they entered into this Agreement as the probable results of the relevant breach, act or omission; and/or

(b) without limiting subclause (a), any real or anticipated loss of profit, loss of benefit, loss of revenue, loss of business, loss of goodwill, loss of opportunity, loss of savings, loss of reputation, loss of use and/or loss or corruption of data.

However, the Parties agree that your obligation to pay us the Price under this Agreement will not constitute "Consequential Loss".

CRO means contract research organisation.

Defects means any defects, errors, omissions, faults or flaws in the Study Product or where the Study Products are not of merchantable quality, or are non-compliant with any Laws, good industry practice, or any requirement of this Agreement.

Disclosing Party means the Party disclosing Confidential Information to the Receiving Party.

Dispute has the meaning given in clause 26.6.

Drug Master Files or **DMF** is a submission to the FDA or its equivalent in an other major country regulatory authority

that may be used to provide confidential detailed information about facilities and/or human drugs. The information contained in the DMF may be used to support an IND, a NDA, an ANDA, another DMF, an Export Application, or amendments and supplements to any of these.

Event of Default means any event or circumstance described in clause 25.1.

FDA means the Food and Drug Administration of the United States (US) or its equivalent in a major country.

Financial Year means a period of 12 consecutive months ending on 30 June.

Force Majeure Event means any event or circumstance which is beyond a Party's reasonable control including but not limited to, acts of God including fire, hurricane, typhoon, earthquake, landslide, tsunami, mudslide or other catastrophic natural disaster, civil riot, civil rebellion, revolution, terrorism, insurrection, militarily usurped power, act of sabotage, act of a public enemy, war (whether declared or not) or other like hostilities, ionising radiation, contamination by radioactivity, nuclear, chemical or biological contamination, any widespread illness, quarantine or government sanctioned ordinance or shutdown, pandemic (including COVID-19 and any variations or mutations to this disease or illness) or epidemic.

Good Laboratory Practices or **GLP** means the then-current good laboratory practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time.

Good Manufacturing Practices or **GMP** means the then-current good manufacturing practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time.

Government Agency means:

(a) a government or government department or other body;

(b) a governmental, semi-governmental or judicial person including a statutory corporation; or

(c) a person (whether autonomous or not) who is charged with the administration of a law.

Group Company means us and our "related bodies corporate" as that term is defined under the *Corporations Act 2001* (Cth).

IND means Investigational New Drug application required pursuant to US statute 21 C.F.R. Part 312 or its equivalent in another major country.

Insolvency Event means any of the following events or any analogous event:

(a) a Party disposes of the whole or any part of the Party's assets, operations or business other than in the ordinary course of business;

(b) a Party ceases, or threatens to cease, carrying on business;

(c) a Party is unable to pay the Party's debts as the debts fall due;

(d) any step is taken by a mortgagee to take possession or dispose of the whole or any part of the Party's assets, operations or business;

(e) any step is taken for a party to enter into any arrangement or compromise with, or assignment for the benefit of, a Party's creditors or any class of a Party's creditors; or

(f) any step is taken to appoint an administrator, receiver, receiver and manager, trustee, provisional liquidator or liquidator of the whole or any part of a Party's assets, operations or business.

Intellectual Property Rights or **Intellectual Property** means any and all existing and future rights throughout the world conferred by statute, common law, equity or any corresponding law in relation to any copyright, designs, patents or trademarks, domain names, know-how, inventions, processes, trade secrets or confidential information, circuit layouts, software, computer programs, databases or source codes, including any application, or right to apply, for registration of, and any improvements, enhancements or modifications of, the foregoing, whether or not registered or registrable.

Improvements to Your Materials means any development, modification, adaptation or improvement of Your Materials is made by or on behalf of either Party (or any of their respective Personnel), or in respect of which Intellectual Property Rights are acquired by, either Party during the Term.

Improvements to Our Materials means any development, modification, adaptation or improvement of Our Materials is made by or on behalf of either Party (or any of their respective Personnel), or in respect of which Intellectual Property Rights are acquired by, either Party during the Term.

IND means investigational new drug application as defined by the FDA or any similar regulatory authority of a major country.

Laws means all applicable laws, regulations, codes, guidelines, policies, protocols, consents, approvals, permits and licences, and any requirements or directions given by any government or similar authority with the power to bind or impose obligations on the relevant Party in connection with this Agreement or the supply of the Services.

Liability means any expense, cost, liability, loss, damage, claim, notice, entitlement, investigation, demand, proceeding or judgment (whether under statute, contract, equity, tort (including negligence), indemnity or otherwise), howsoever arising, whether direct or indirect and/or whether present, unascertained, future or contingent and whether involving a third party or a Party to this Agreement or otherwise.

Local Sponsor means the acting sponsor of the Study Product for the purposes of the TGA Legislation.

Material Adverse Effect means a material adverse effect upon either the ability of a Party to comply with its

obligations under a Transaction Document or the effectiveness or enforceability of a Transaction Document.

Milestones has the meaning given in the applicable Work Order.

Moral Rights has the meaning given in the *Copyright Act 1968* (Cth) and includes any similar rights in any jurisdiction in the world.

NDA means new drug application as defined by the FDA or any similar regulatory authority of a major country.

New Materials means all Intellectual Property developed, or created by or on behalf of a Party or its respective Personnel in connection with this Agreement or the supply of the Services, whether before or after the date of this Agreement and any improvements, modifications or enhancements of such Intellectual Property, but excludes Our Materials, Your Materials, Improvements to Your Materials and Improvements to Our Materials.

NHMRC means the National Health and Medical Research Council.

NHMRC Statement means the NHMRC National Statement on Ethical Conduct in Human Research (2007) or its replacement.

Order Request has the meaning given in clause 3.4.

Our Materials means all Intellectual Property which is owned by or licensed to us and any improvements, modifications or enhancements of such Intellectual Property.

Personnel means, in respect of a Party, any of its employees, consultants, suppliers, subcontractors or agents, but in respect of you, does not include us.

Phase 1 Clinical Trial means a clinical trial that generally provides for the first introduction into humans of a pharmaceutical or biologic product with the primary purpose of determining safety, metabolism, and pharmacokinetic properties and clinical pharmacology of such product, in a manner that is generally consistent with 21 C.F.R. § 312.21(a), as amended (or its successor regulation), or, with respect to any other country or jurisdiction, the equivalent of such a clinical trial in such other country or jurisdiction.

Phase 2 Clinical Trial means a clinical trial that is intended to explore the feasibility, safety, dose ranging, or efficacy of a pharmaceutical or biologic product, that is prospectively designed to generate sufficient data (if successful) to commence a Phase 3 Clinical Trial of such product, in a manner that is generally consistent with 21 C.F.R. § 312.21(b), as amended (or its successor regulation), or, with respect to any other country or jurisdiction, the equivalent of such a clinical trial in such other country or jurisdiction.

Phase 3 Clinical Trial means, as to a pharmaceutical or biologic product, a Clinical Trial in humans performed to gain evidence with statistical significance of the efficacy of such product in a target population, and to obtain expanded evidence of safety for such product that is needed to evaluate the overall benefit-risk relationship of such product, to form the basis for approval of a NDA or a biological license application (BLA) by a Regulatory Authority, and to provide an adequate basis for physician labelling, in a manner that is generally consistent with 21 C.F.R. § 312.21(c), as amended (or its successor regulation), or, with respect to any other country or jurisdiction, the equivalent of such a Clinical Trial in such other country or jurisdiction.

Potential Event of Default means an event or circumstance which, with the giving of notice, lapse of time or fulfillment of any condition, would become an Event of Default.

Price means the price set out in the applicable Work Order, adjusted in accordance with this Agreement, and includes the Deposit (if any).

Privacy Laws means the Australian Privacy Principles set out in the *Privacy Act 1988* (Cth) and any other privacy or anti-spam Laws applicable to you

Receiving Party means the Party receiving Confidential Information from or on behalf of the Disclosing Party.

Regulatory Approval means, shall mean any and all approvals (including supplements, amendments, pre- and post-approvals and NDA approvals), licenses, registrations or authorizations (including marketing and Labelling authorizations) of any national, supra-national (e.g., the European Commission or the Council of the European Union), regional, state or local Regulatory Authority, department, bureau, commission, council or other governmental entity, that are necessary for the manufacture, commercialization, use, storage, transport or sale of a product in a given jurisdiction.

Regulatory Authority means any body which has jurisdiction over the conduct of a Study and includes the FDA, TGA, or a equivalent major country regulatory authority, the Reviewing HREC and any overseas regulatory authorities or Government Agency who may audit or require to be audited any part of the Study.

Regulatory Materials means any Regulatory Submission, notification, communication, correspondence (including formal and informal notes), registration, Regulatory Approval, or other filing made to, received from, or otherwise conducted with a Regulatory Authority related to the exploitation of a pharmaceutical, biologic or diagnostic product in a particular country or jurisdiction.

Regulatory Submissions means all applications, filings, dossiers (including a DMF), and other documents submitted to a Regulatory Authority in support of developing, manufacturing, or commercializing a pharmaceutical or biologic product or a diagnostic product (including to obtain, support, or maintain Regulatory Approval from that Regulatory Authority). Regulatory Submissions include all INDs, NDAs, BLAs, IDEs, PMAs, 510(k)s and other applications for Regulatory Approval and their equivalents.

Regulatory Requirements means any requirement by a Regulatory Authority to have the product registered including any requirements for an IND application.

Representatives means a Party's Personnel including Personnel of a Group Company.

Reviewing HREC means the applicable Human Research Ethics Committee reviewing the Study or its equivalent in any jurisdiction other than Australia.

Schedule means a schedule to this Agreement.

Services means the services set out in the Schedule and all applicable Work Orders, as adjusted in accordance with this Agreement.

Sponsor means the person or organisation that is the sponsor of record as provided in 21 C.F.R. §312.50 (and comparable Applicable Law outside of the U.S.) of a Clinical Trial with responsibility, unless otherwise delegated in accordance with 21 C.F.R. §312.52 (and comparable Applicable Law outside of the U.S.), for such Clinical Trial and making all required submissions to Regulatory Authorities related thereto.

Study means a Clinical Trial as set out in the applicable Work Order.

Study Participant means a person recruited to participate in a Study.

Study Product has the meaning given in the applicable Work Order.

Study Site means the sites where a Study will be conducted.

TORO Document means a document setting out the transfer of regulatory obligations as between the Parties as included in the relevant Work Order.

TGA means the Therapeutic Goods Administration of the Commonwealth of Australia or any successor body.

Transaction Documents means:

(a) this Agreement including all Work Orders;

(b) any document which we and you agree is a Transaction Document for the purposes of this Agreement, and any agreement or instrument created under them.

TGA Legislation means the *Therapeutic Goods Act 1989* (Cth) and any applicable regulations, guidelines, standards and policies as updated from time to time.

US means the United States of America.

Variation has the meaning given in clause 4.1.

Variation Request has the meaning given in clause 4.1.

Work Order means an order for the supply of the Services, issued by us in accordance with clause 3.

Your Materials means all Intellectual Property owned or licensed by you or your Personnel before the Commencement Date (which is not connected to this Agreement) and/or developed by or on behalf of you or your Personnel during the course of this Agreement, whether developed independently of this Agreement or not, and any improvements, modifications or enhancements of such Intellectual Property and includes the Product information.

Your Obligations has the meaning given in the applicable Work Order.

2. Interpretation

In this Agreement, unless the context otherwise requires:

(c) a reference to this Agreement or any other document includes the document, all schedules and all annexures as novated, amended, supplemented, varied or replaced from time to time;

(d) a reference to any legislation or law includes subordinate legislation or law and all amendments, consolidations, replacements or re-enactments from time to time;

(e) a reference to a person includes a natural person, body corporate, partnership, joint venture, association, government or statutory body;

(f) a reference to a party (including a Party) to a document includes that party's executors, administrators, successors, permitted assigns;

(g) a reference to a covenant, obligation or agreement of two or more persons binds or benefits them jointly and severally;

(h) a reference to time is to local time in Victoria, Australia; and

(i) a reference to $ or dollars refers to the currency of Australia from time to time.

ANNEXURE 1 – Work Order 1

Study Product Manufacturing Services

The Work Order is issued pursuant to clause 2 of the Services Agreement between **iNGENü CRO Pty Ltd (ACN 656 400 056) (Provider, we, us, our)** and **ResolutionRx Ltd (ACN 664 925 651) (Client, you, your)**, together the Parties and each a Party. Unless otherwise defined in this Work Order, capitalised terms have the meanings given to them in the Agreement.

Date of this Work Order	27/2/2023
Study Product	Proprietary nano-lipid particle formulations of dronabinol for use in the treatment of obstructive sleep apnea (OSA) as described in Attachment 1 - "Project Report - Dronabinol Formulation Screening"
Services	The Services for this Work Order consist of: Study Product Manufacturing Services
Manufacturing Services	In consideration for the Price, we will provide the following Manufacturing Services together with third-party companies with expertise in drug formulation (preferably dronabinol) and packaging expertise. The choice of third-party companies will require Client approval: • Complete Bench Testing and Design Final Dosage Form • Study Product GMP Formulation & Fill (Phase 1) • Study Product GMP Formulation & Fill (Phase 3) • Clinical Supply, Packaging & Distribution (Phase 1) • Clinical Supply, Packaging & Distribution (Phase 3) • CMC Regulatory • Study Product Stability
Your Obligations	Transfer Information on request
Deposit	$50,000 upon execution of this Agreement to be credited against the first invoice(s) until the full $50,000 has been credited.
Price and Timeline	The Prices and Timelines for the Manufacturing Services to be performed during the course of the Clinical Program are described in Attachment 2 - "Dronabinol OSA Budget" in the section entitled "II. Proprietary Dronabinol Formulation Manufacturing". You agree that the Price is based on the assumptions listed in Attachment 2 and subject to modification in accordance with Section 3 below. The Parties agree that the Price may vary if the assumptions change.
Payment Terms	As described in Attachment 2, the Client must pay the Provider the Price as follows: payments are to be made at the beginning of each quarter and 45 days after the rendering of an invoice, net 45 days for that quarter.
End Date	The date this Work Order is terminated according to the Agreement or this Work Order or the date on which we have completed the supply of the Services to you (as reasonably determined by us).

Overview

The Services under this Work Order are further detailed below.

1. Timeline for delivery

We will commence performance of the Services within 30 days after payment of the Deposit.

2. Assumptions

The following assumptions have been made when calculating the resources and Price in this Work Order:

- RespireRx Pharmaceuticals Inc., now an Affiliate of ResolutionRx Ltd (ACN 664 925 651) has completed Phase 2 in human studies with dronabinol

3. Change Process

Changes and alterations to this Work Order will be made in accordance with the Variation provisions set out in clause 4 of the Agreement.

4. Suspension of a Work Order

This Section 4 takes precedence over any clauses in relation to the same subject matter in the Agreement.

a) **Suspending a Work Order:** A Work Order may be suspended, which does not constitute a termination of the Work Order, where you have been unsuccessful in obtaining the funding necessary to continue with the Services provided that:

i. you have given us at least 30 days' prior notice of the suspension in writing (**Notice of Suspension**);

ii. you have provided us with evidence of the lack of funding such as a board resolution, ASX declaration/announcement or letter from the relevant funding body; and

iii. we have agreed in writing to suspend the Study Order.

b) If the Parties cannot reach agreement in relation to the suspension of a Study Order, clause 26.6 (Disputes) of the Agreement shall apply.

c) Once both Parties have agreed that a Study has been suspended:

i. we will cease providing the Services;

ii. you are to pay for all Services provided prior to suspension, including Services which have been provided and have not yet been invoiced to you, and all other amounts due and payable under this Agreement; and

iii. you must pay us any additional costs, reasonably incurred, and which arise directly from such suspension including (i) any and all pass through costs and (ii) any costs that we incur due to the termination or suspension of subcontracts relating to the Services.

d) **Resuming a Study Order:** A Study can only be suspended for a maximum of 90 days (**Suspension Period**). If you have not contacted us to resume the Study before the end of the Suspension Period, the Study will be terminated and Section 5 below shall apply. If you would like to resume a Study Order you agree that:

i. the Price and timelines set out in this Study Order are no longer applicable;

ii. it will constitute a Variation Event and clause 4 (Variation) of the Agreement shall apply.

5. Termination

This Work Order can be terminated as set out in clause 24 of the Agreement.

This Work Order will be subject to, governed by, and will incorporate the terms and conditions contained in the Agreement. To the extent there is any ambiguity, discrepancy or inconsistency in or between the terms of the Agreement and this Work Order, the terms of the Work Order will prevail. Each Party, upon its acceptance of this Work Order, is bound by, and must comply with, its respective obligations under this Work Order and the Agreement.

Executed by **iNGENu CRO Pty Ltd (ACN 656 400 056)** in accordance with section 126 of the *Corporations Act 2001* (Cth), by its duly authorised agent:

DocuSigned by: Dr. Sud Agarwal 00081170F44F495...	Dr. Sud Agarwal
Signature	Name (Print)
CEO	27 February 2023
Position (Print)	Date

Executed by **ResolutionRx Ltd (ACN 664 925 651)** in accordance with section 126 of the *Corporations Act 2001* (Cth), by its duly authorised agent:

DocuSigned by: Mr. Jeff Margolis 7CA04D0508BD4D0...	Mr. Jeff Margolis
Signature	Name (Print)
Senior Financial Officer and Director	27 February 2023
Position (Print)	Date

ANNEXURE 2 – Work Order 2

Regulatory Services

The Work Order is issued pursuant to clause 2 of the Services Agreement between **iNGENü CRO Pty Ltd (ACN 656 400 056) (Provider, we, us, our)** and **ResolutionRx Ltd (ACN 664 925 651) (Client, you, your)**, together the Parties and each a Party. Unless otherwise defined in this Work Order, capitalised terms have the meanings given to them in the Agreement.

Date of this Work Order	27/2/2023
Study Product	Proprietary nano-lipid particle formulations of dronabinol for use in the treatment of obstructive sleep apnea (OSA) as described in Attachment 1 - "Project Report - Dronabinol Formulation Screening"
Services	The Services for this Work Order consist of: • Regulatory Services
Regulatory Services	**In consideration for the Price, we will provide the following Regulatory Services:** • Act as your regulatory interface and conduct all necessary work in support of the of the Clinical Trial Program consisting of a pharmacokinetic clinical trial and required pivotal Phase 3 or other pivotal clinical trial(s) of your Study Product, • Meetings with FDA, TGA or other appropriate regulatory authority(ies) and key experts to discuss the Pre-IND meeting strategy to support the rationale for and design of a Clinical Trial Program; • Manage, prepare, validate and submit a Pre-IND meeting request (including a Full Dossier preparation and all expert reports required) on behalf of ResolutionRx Ltd (ACN 664 925 651) to the appropriate regulatory bodies as well as preparing any needed responses to any comments from the appropriate regulatory bodies; • Prepare and manage required INDs during the course of the Clinical Trial Program on behalf of ResolutionRx Ltd (ACN 664 925 651) to be filed with the appropriate regulatory bodies;
Your Obligations	Transfer Information on request
Expenses	The Expenses are: • FDA and Statutory application fees related to this project • any disbursements, reasonably and directly incurred by the us and approved in advance by you for the purpose of the supply of the Services.

Price and Timeline	The Prices and Timelines for the Regulatory Services to be provided during the course of the Clinical Program are described in Attachment 2 – "Dronabinol OSA Budget" in the section entitled Regulatory with line items describing Pre-IND and IND costs You agree that the Price is based on the assumptions listed in Attachment 2 and subject to modification in accordance with Section 4 below. The Parties agree that the Price may vary if the assumptions change. Subject to clause 4.3 of the Agreement, if a Milestone is not achieved within one quarter of its original estimated completion date, you will be entitled to a 20% reduction with respect to the costs attributable to that Milestone, each quarter until the Milestone is achieved but only where the delay in that milestone is due to circumstances set out in clause 4.3(c) of the Agreement.
Payment Terms	As described in Attachment 2, you must pay us the Price as follows: For the line items describing Pre-IND and IND costs, payments are to be made at the beginning of each quarter and 45 days after the rendering of an invoice, net 45 days for that quarter.
End Date	The date this Work Order is terminated according to the Agreement or this Work Order or the date on which we have completed the supply of the Services to you (as reasonably determined by us).

Overview

The Services under this Work Order are further detailed below.

1. Timeline for delivery

We will commence performance of the Services within 30 days after payment of the Deposit described in Annexure 1 - Work Order 1.

2. Assumptions

The following assumptions have been made when calculating the resources and Price in this Work Order:

- RespireRx Pharmaceuticals Inc., now an Affiliate of ResolutionRx Ltd (ACN 664 925 651) has completed Phase 2 human studies of dronabinol

3. Change Process

Changes and alterations to this Work Order will be made in accordance with the Variation provisions set out in clause 4 of the Agreement.

4. Suspension

This section 5 takes precedence over any clauses in relation to the same subject matter in the Agreement.

a) **Suspending a Work Order:** A Work Order may be suspended, which does not constitute a termination of the Work Order, where you have been unsuccessful in obtaining the funding necessary to continue with the Services provided that:

   i. you have given us at least 30 days' prior notice of the suspension in writing (**Notice of Suspension**);

   ii. you have provided us with evidence of the lack of funding such as a board resolution, ASX declaration/announcement or letter from the relevant funding body; and

   iii. we have agreed in writing to suspend the Study Order.

b) If the Parties cannot reach agreement in relation to the suspension of a Study Order, clause 26.6 (Disputes) of the Agreement shall apply.

c) Once both Parties have agreed that a Study has been suspended:

   i. we will cease providing the Services;

   ii. you are to pay for all Services arising directly from such suspension, including Services which have been provided and have not yet been invoiced to you, and all other amounts due and payable under this Agreement; and

   iii. you must pay us any additional costs, reasonably incurred, and which arise directly from such termination including (i) any and all pass through Costs and (ii) any costs that we incur due to the termination or suspension of subcontracts relating to the Services.

d) **Resuming a Study Order:** A Study can only be suspended for a maximum of 90 days (**Suspension Period**). If you have not contacted us to resume the Study before the end of the Suspension Period, the Study will be terminated under Section 6 below. If you would like to resume a Study Order you agree that:

   i. the Price and time lines set out in this Study Order are no longer applicable;

   ii. it will constitute a Variation Event and clause 4 (Variation) of the Agreement shall apply.

5. Termination

This Work Oder can be terminated as set out in clause 24 of the Agreement.

This Work Order will be subject to, governed by, and will incorporate the terms and conditions contained in the Agreement. To the extent there is any ambiguity, discrepancy or inconsistency in or between the terms of the Agreement and this Work Order, the terms of this Work Order will prevail. Each Party, upon its acceptance of this Work Order, is bound by, and must comply with, its respective obligations under this Work Order and the Agreement.

Executed by **iNGENu CRO Pty Ltd (ACN 656 400 056)** in accordance with section 126 of the *Corporations Act 2001* (Cth), by its duly authorised agent:

DocuSigned by: Dr. Sud Agarwal 00981179F44F495...	Dr. Sud Agarwal
Signature	Name (Print)
CEO	27 February 2023
Position (Print)	Date

Executed by **ResolutionRx Ltd (ACN 664 925 651)** in accordance with section 126 of the *Corporations Act 2001* (Cth), by its duly authorised agent:

DocuSigned by: Mr. Jeff Margolis 7CA04D06056D4C0...	Mr. Jeff Margolis

Signature	Name (Print)
Senior Financial Officer and Director	27 February 2023
Position (Print)	Date

ANNEXURE 3 – Work Order 3

Clinical Services

The Work Order is issued pursuant to clause 2 of the Services Agreement between **iNGENū CRO Pty Ltd (ACN 656 400 056) (Provider, we, us, our)** and **ResolutionRx Ltd (ACN 664 925 651) (Client, you, your)**, together the Parties and each a Party. Unless otherwise defined in this Work Order, capitalised terms have the meanings given to them in the Agreement.

Date of this Work Order	27/1/2023
Study Product	Proprietary nano-lipid particle formulations of dronabinol for use in the treatment of obstructive sleep apnea (OSA) as described in Attachment 1 - "Project Report - Dronabinol Formulation Screening"
Services	The Services for this Work Order consist of: Clinical Services
Clinical Services	In consideration for the Price, we will provide the following Clinical Services, together with third-party companies with expertise in clinical trial expertise. The choice of third-party companies will require Client approval: • Phase 1/2 Clinical Trials • Phase 3 Clinical Trial - 240 patients More detailed description of services may be found in Attachment 2 - "Dronabinol OSA Budget" in the section entitled "III. Clinical".
Your Obligations	Transfer Information on request
Price and Timeline	The Prices and Timelines for the Clinical Services to be performed during the course of the Clinical Program are described in Attachment 2 - "Dronabinol OSA Budget" in the section entitled "[need to insert the correct reference]. You agree that the Price is based on the assumptions listed in Attachment 2 and subject to modification in accordance with Section 3 below. The Parties agree that the Price may vary if the assumptions change.
Payment Terms	As described in Attachment 2, the Client must pay the Provider the Price as follows: payments are to be made at the beginning of each quarter and 45 days after the rendering of an invoice, net 45 days for that quarter.
End Date	The date this Work Order is terminated according to the Agreement or this Work Order or the date on which we have completed the supply of the Services to you (as reasonably determined by us).

Overview

The Services under this Work Order are further detailed below.

1. Timeline for delivery

We will commence performance of the Services within 30 days after payment of the Deposit.

2. Assumptions

The following assumptions have been made when calculating the resources and Price in this Work Order:

- RespireRx Pharmaceuticals Inc., now an Affiliate of ResolutionRx Ltd (ACN 664 925 651) has completed Phase 2 human studies with dronabinol

3. Change Process

Changes and alterations to this Work Order will be made in accordance with the Variation provisions set out in clause 4 of the Agreement.

4. Suspension

This Section 4 takes precedence over any clauses in relation to the same subject matter in the Agreement.

a) **Suspending a Work Order:** A Work Order may be suspended, which does not constitute a termination of the Work Order, where you have been unsuccessful in obtaining the funding necessary to continue with the Services provided that:

   i. you have given us at least 30 days' prior notice of the suspension in writing (**Notice of Suspension**);

   ii. the Study can be safely suspended without putting the Study Participants at any risk;

   iii. the Study Sites have agreed to suspend the Study;

   iv. you have provided us with evidence of the lack of funding such as a board resolution, ASX declaration/announcement or letter from the relevant funding body; and

   v. we have agreed in writing to suspend the Study Order.

b) If the Parties cannot reach agreement in relation to the suspension of a Study Order, clause 26.6 (Disputes) of the Agreement shall apply.

c) Once both Parties have agreed that a Study has been suspended:

   i. we will cease providing the Services;

   ii. the Parties will discuss and coordinate the termination of the Study to ensure compliance with Law, Study Participant safety and where required or necessary provide continuity of treatment in a safe and efficient manner;

   iii. you are to pay for all Services arising directly from such suspension, including Services which have been provided and have not yet been invoiced to you, and all other amounts due and payable under this Agreement; and

   iv. you must pay us any additional costs, reasonably incurred, and which arise directly from such suspension including (i) any and all pass through costs and (ii) any costs that we incur due to the termination or suspension of subcontracts relating to the Services.

d) **Resuming a Study Order:** A Study can only be suspended for a maximum of 90 days (**Suspension Period**). If you have not contacted us to resume the Study before the end of the Suspension Period, the Study will be terminated and Section 6(b) below shall apply. If you would like to resume a Study Order you agree that:

i. the Price and time lines set out in this Study Order are no longer applicable;

ii. it will constitute a Variation Event and clause 4 (Variation) of the Agreement shall apply.

6. Termination

In addition to the termination provisions set out in clause 20 **(??)**of the Agreement, the following shall apply:

a) Either Party may terminate this Work Order by giving the other Party 90 days' written notice, provided that:

i. the Study can be safely terminated without putting the Study Participants at any risk; or

ii. you have another contract research organisation (**Incoming CRO**) which will take over the Services; and

iii. the Study Sites have agreed to terminate the Study.

b) Upon termination of the Work Order:

i. we will cease providing the Services provided this will not impact on the safety of Study Participants. Where the Study will not be terminated, and you have organised for an **Incoming CRO** to take over the provision of the Services, we will continue providing the Services until such time as we have completed a hand over to the Incoming CRO as reasonably determined by us;

ii. the Parties will discuss and coordinate the termination of the Study to ensure compliance with Law, Study Participant safety and, where required or necessary provide continuity of treatment in a safe and efficient manner;

iii. you are to pay for all Services provided prior to termination, including Services which have been provided and have not yet been invoiced to you, and all other amounts due and payable under this Agreement and, where applicable, any Services that we provide (as reasonably determined by us) until the handover to the Incoming CRO is complete;

iv. you must pay us any additional costs, reasonably incurred, and which arise directly from such termination including any and all pass through costs, and where you have terminated the Study Order you also agree to pay any costs that we incur due to the termination or suspension of subcontracts relating to the Services; and

a. we will retain your documents (including copies) as required by law or regulatory requirements. Your express or implied agreement to this Study Order constitutes your authority for us to retain or destroy documents in accordance with the statutory periods, or on expiry or termination of this Study Order.

This Work Order will be subject to, governed by, and will incorporate the terms and conditions contained in the Agreement. To the extent there is any ambiguity, discrepancy or inconsistency in or between the terms of the Agreement and this Work Order, the terms of this Work Order will prevail. Each Party, upon its acceptance of this Work Order, is bound by, and must comply with, its respective obligations under this Work Order and the Agreement.

Executed by **iNGENu CRO Pty Ltd (ACN 656 400 056)** in accordance with section 126 of the *Corporations Act 2001* (Cth), by its duly authorised agent:

DocuSigned by:
Dr. Sud Agarwal
00851178F44F495...

Signature

Dr. Sud Agarwal

Name (Print)

CEO

Position (Print)

27 February 2023

Date

Executed by **ResolutionRx Ltd (ACN 664 925 651)** in accordance with section 126 of the *Corporations Act 2001* (Cth), by its duly authorised agent:

DocuSigned by:
Mr. Jeff Margolis
7CA04D05080D4D0...

Signature

Mr. Jeff Margolis

Name (Print)

Senior Financial Officer and Director

27 February 2023

Position (Print) Date

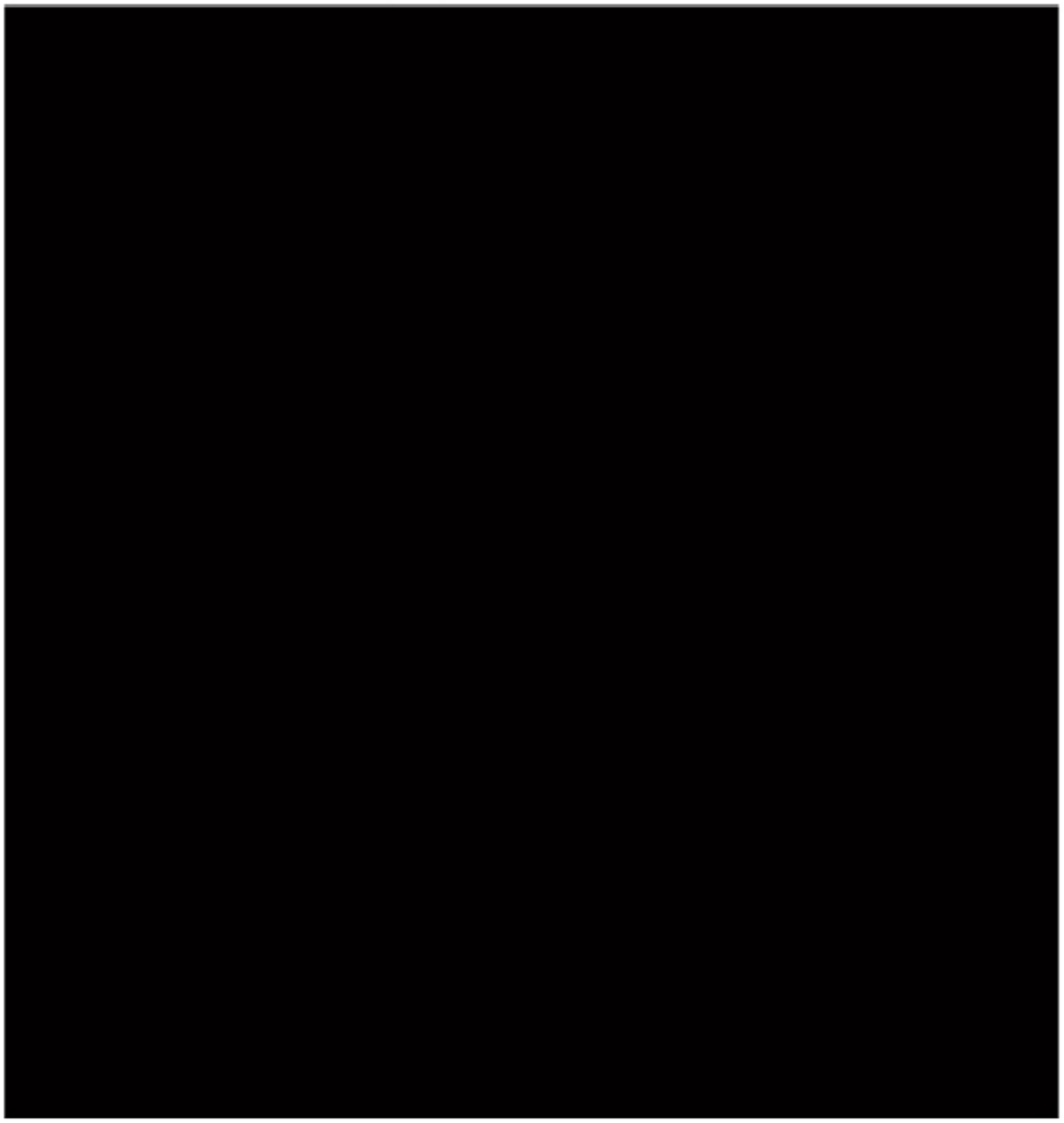
Attachment 1 – Formulation Report

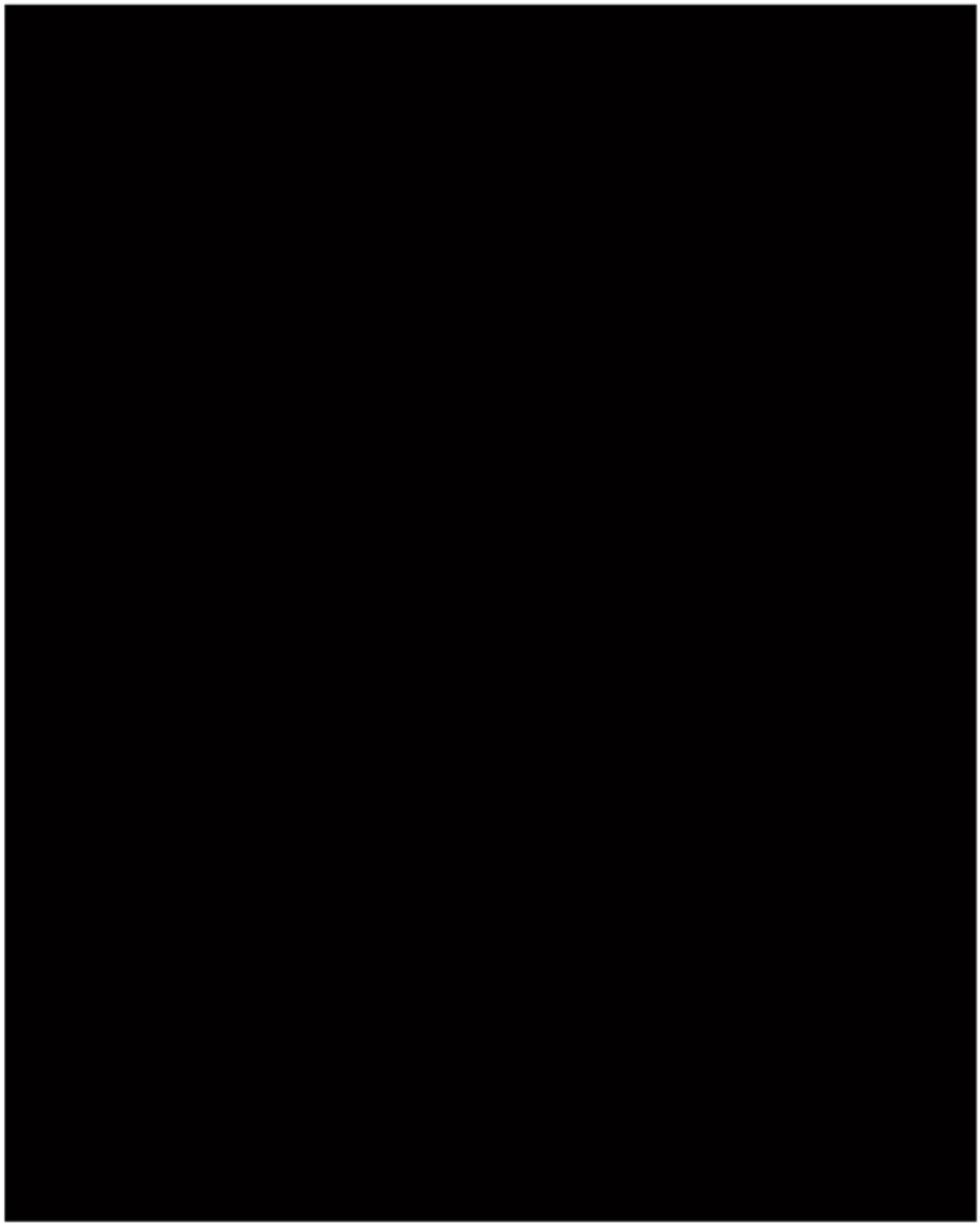
Project Report - Dronabinol Formulation Screening

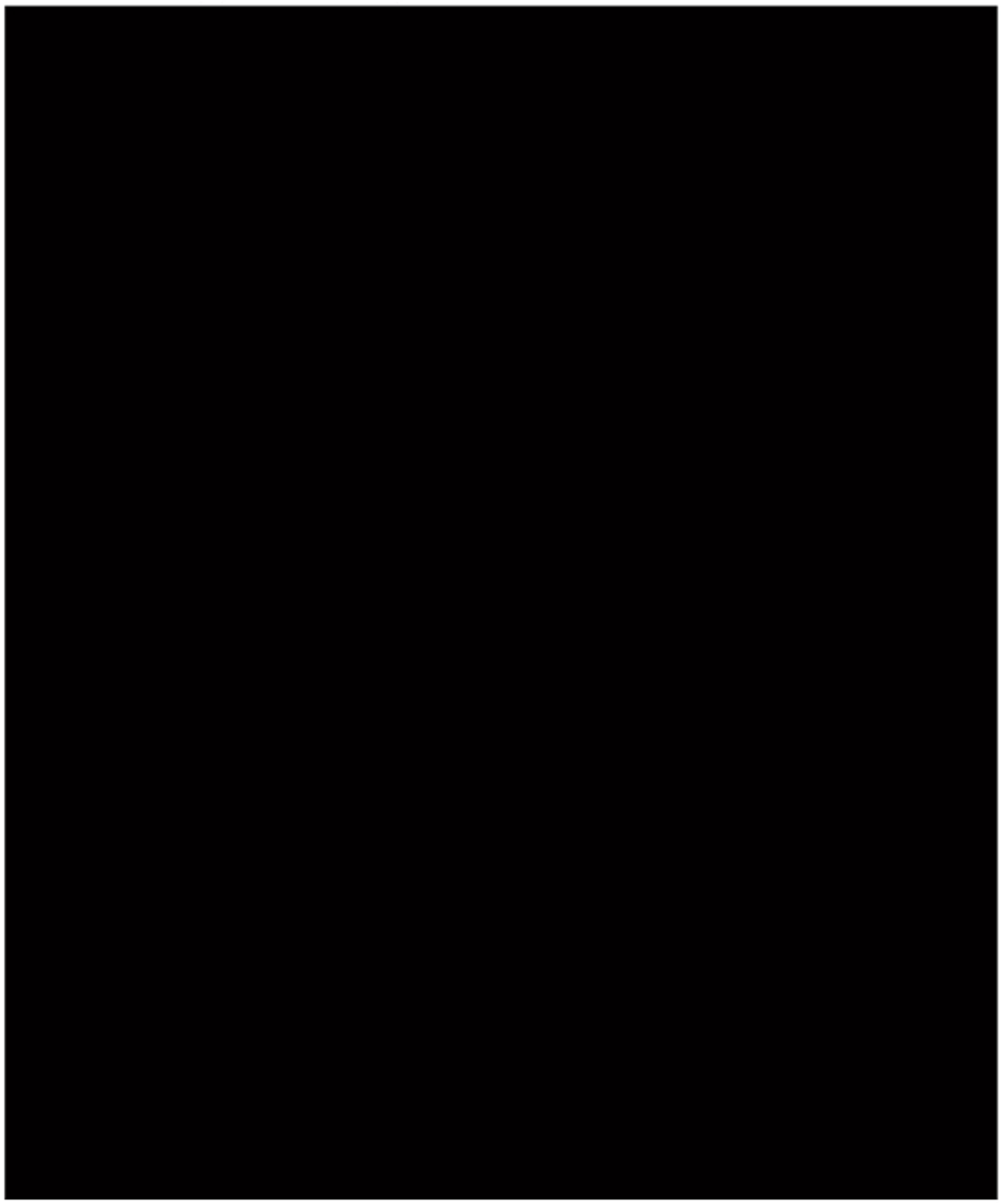
December 2020

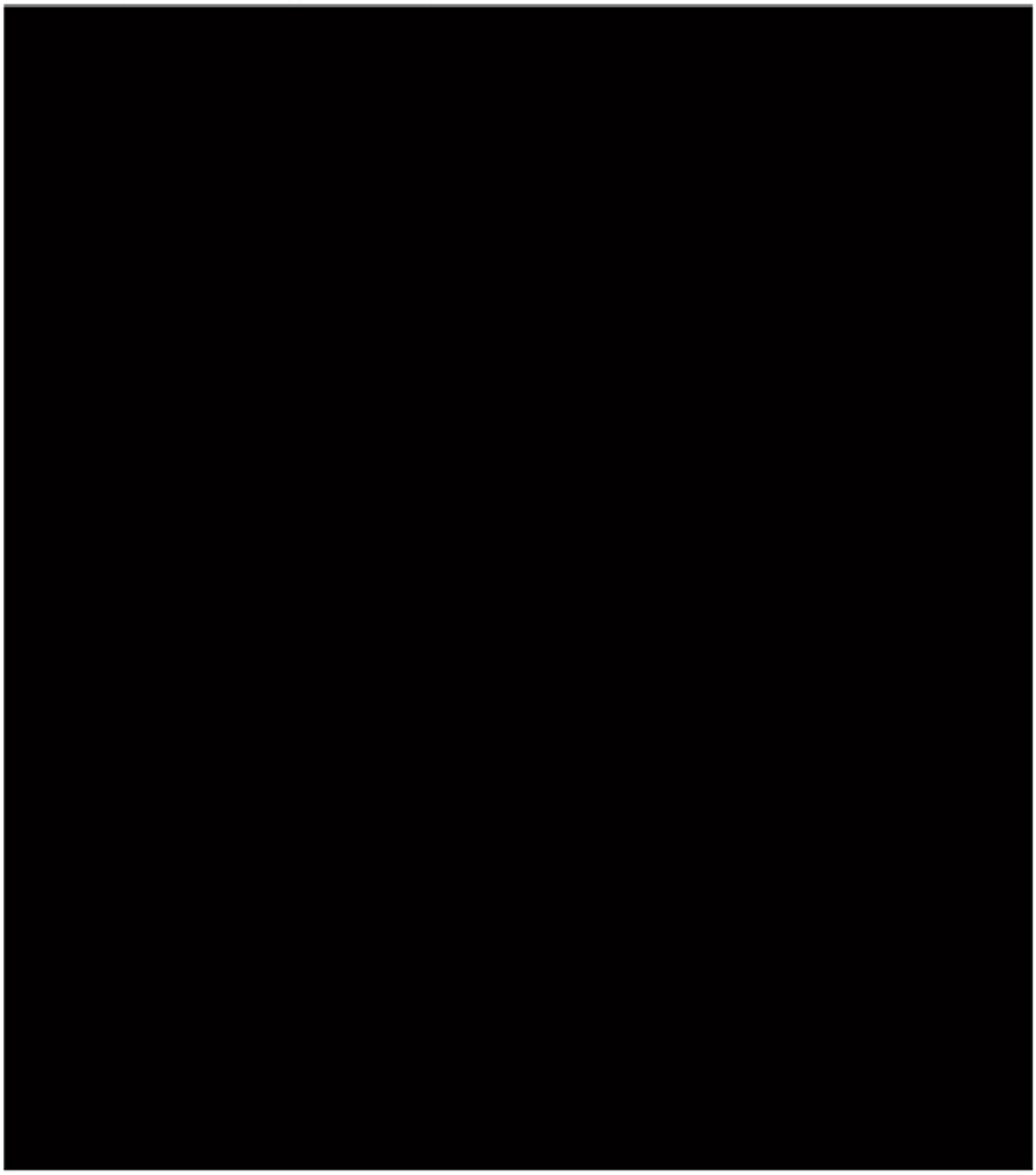
Ascension Sciences

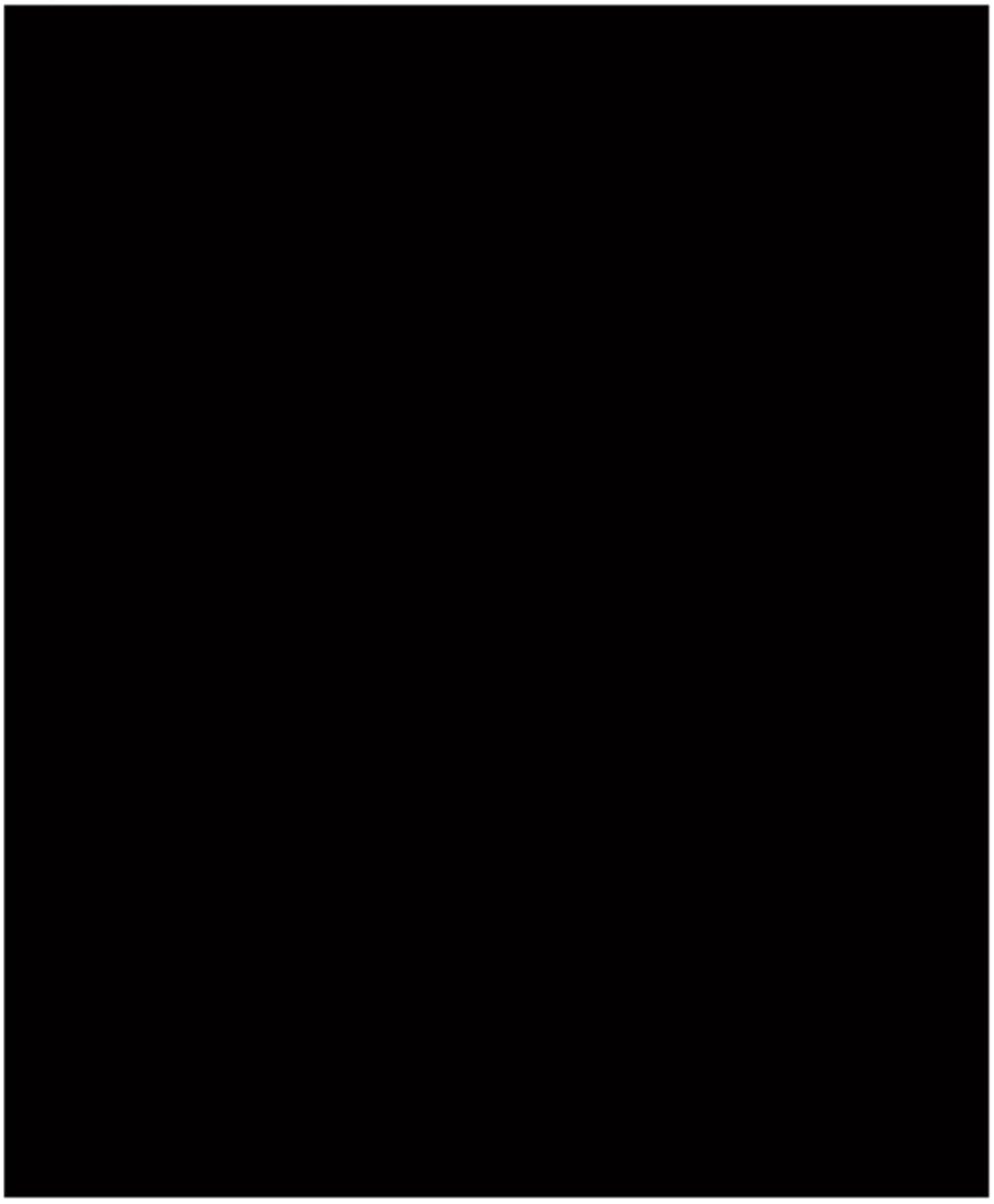
Inc.

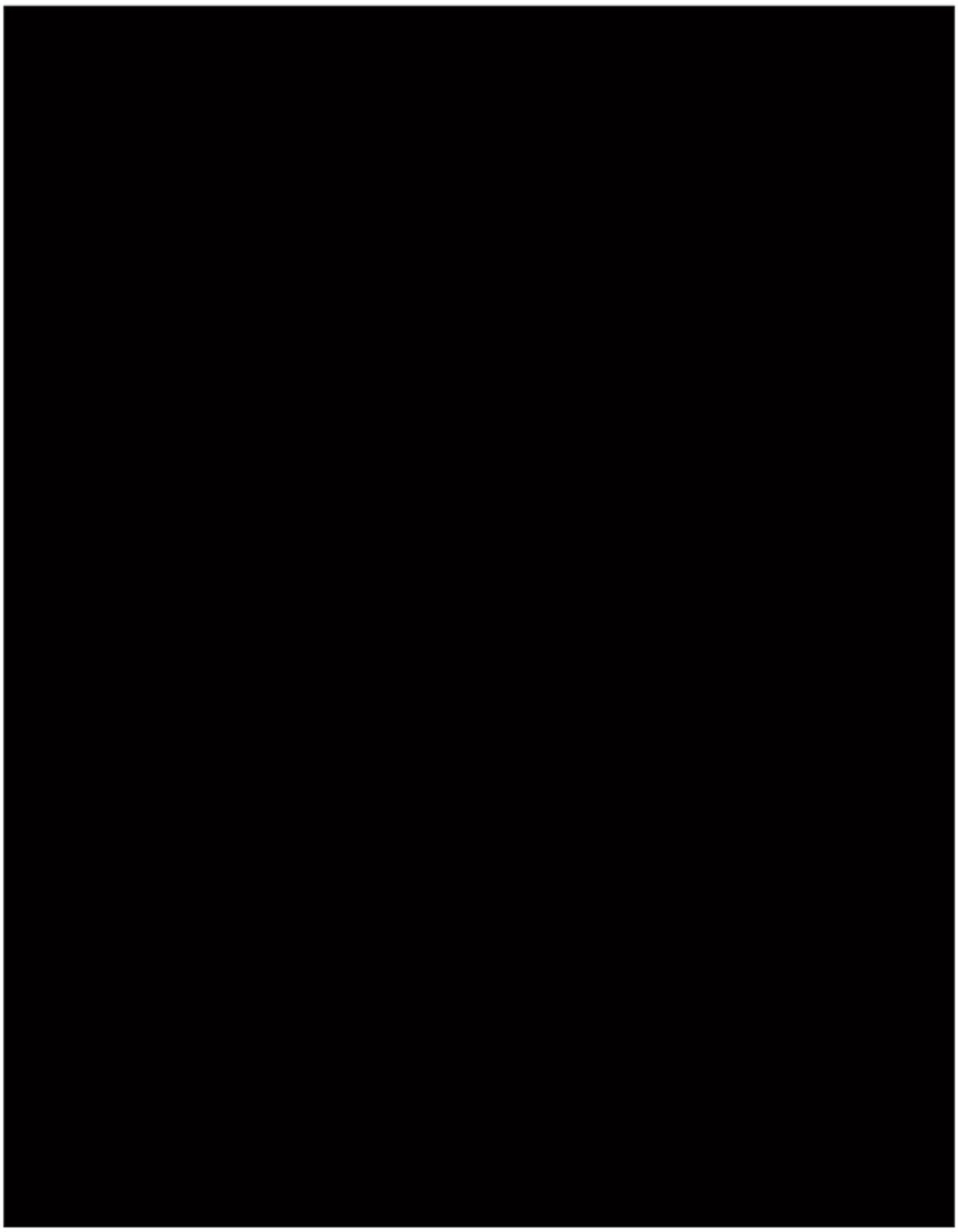


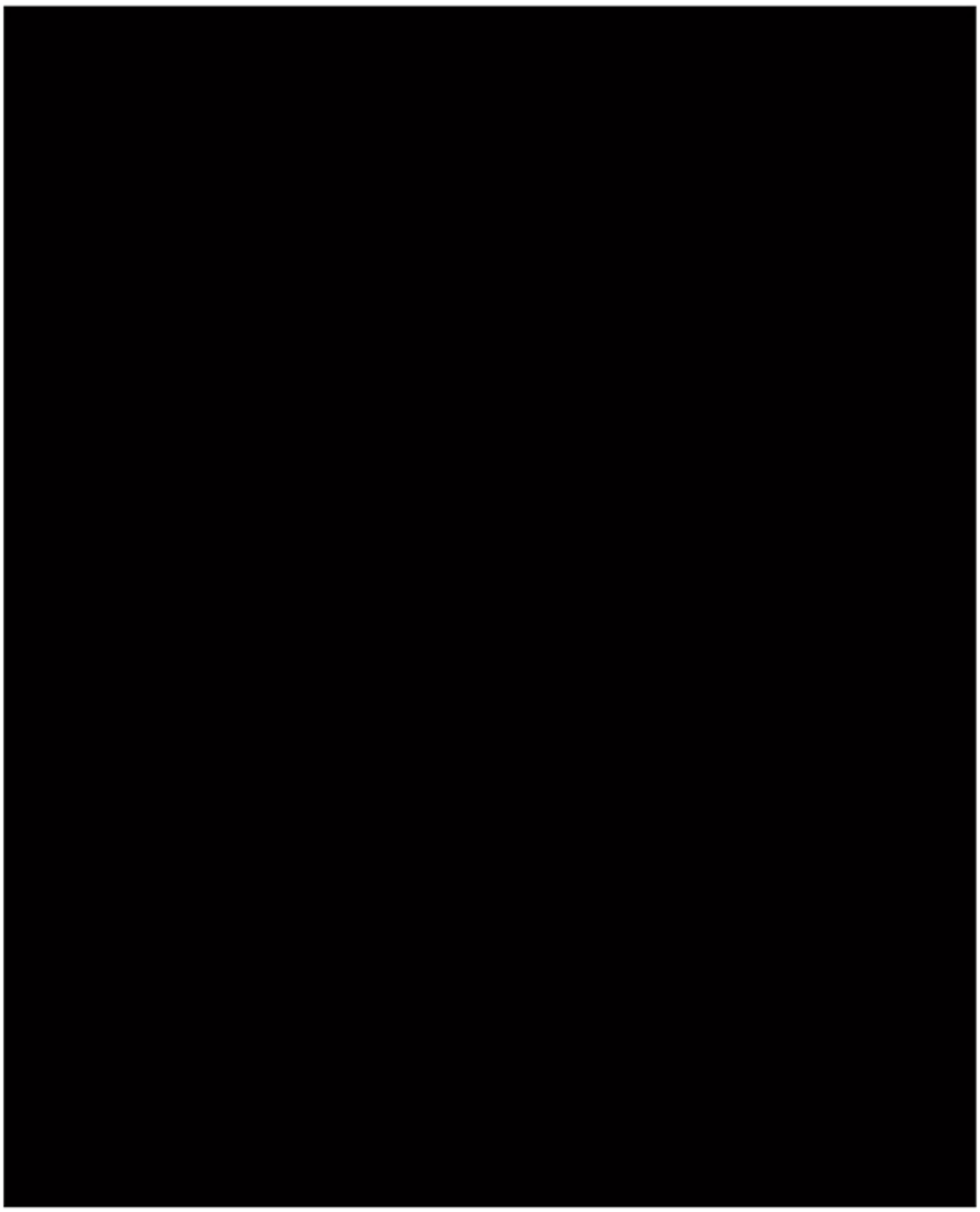


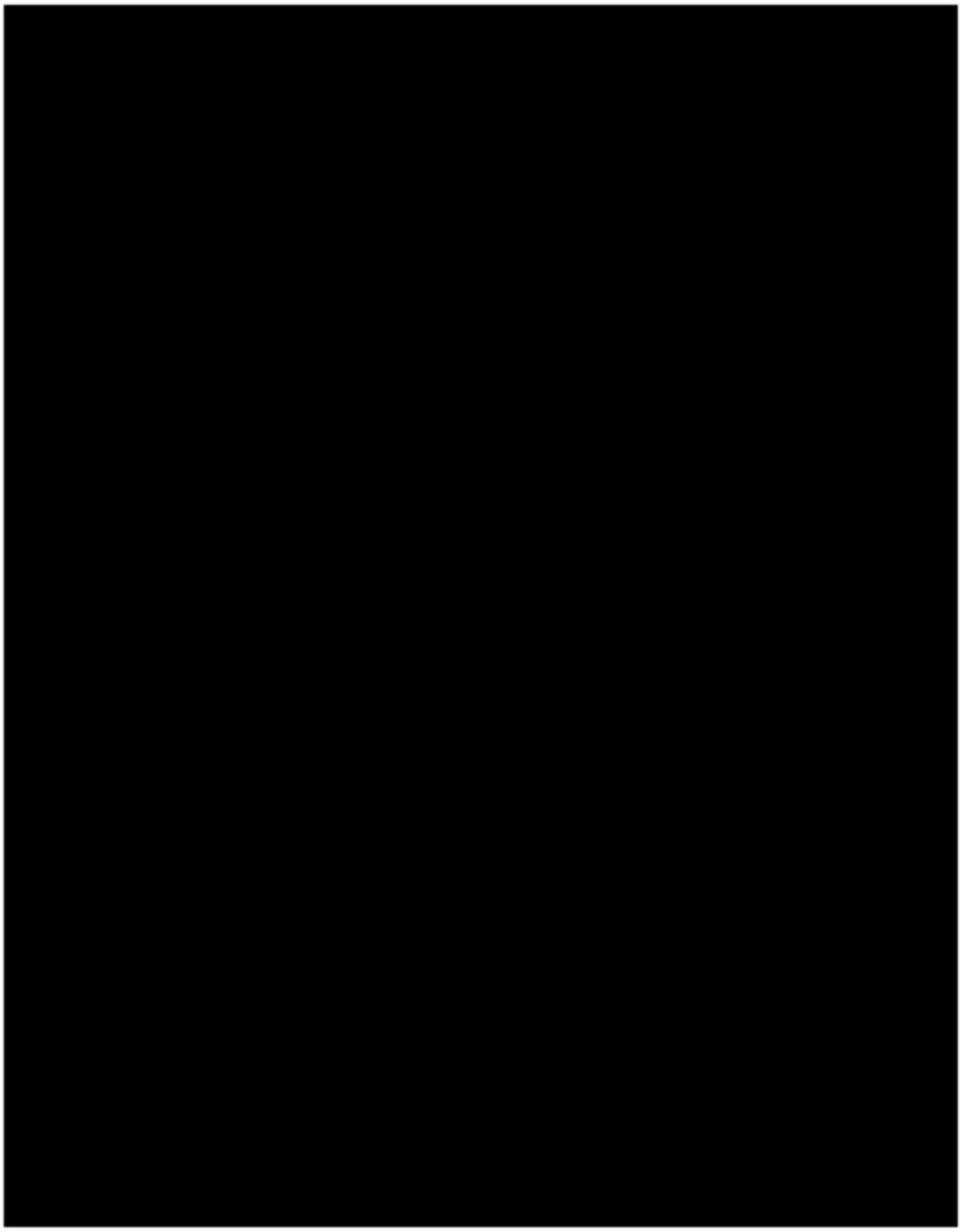




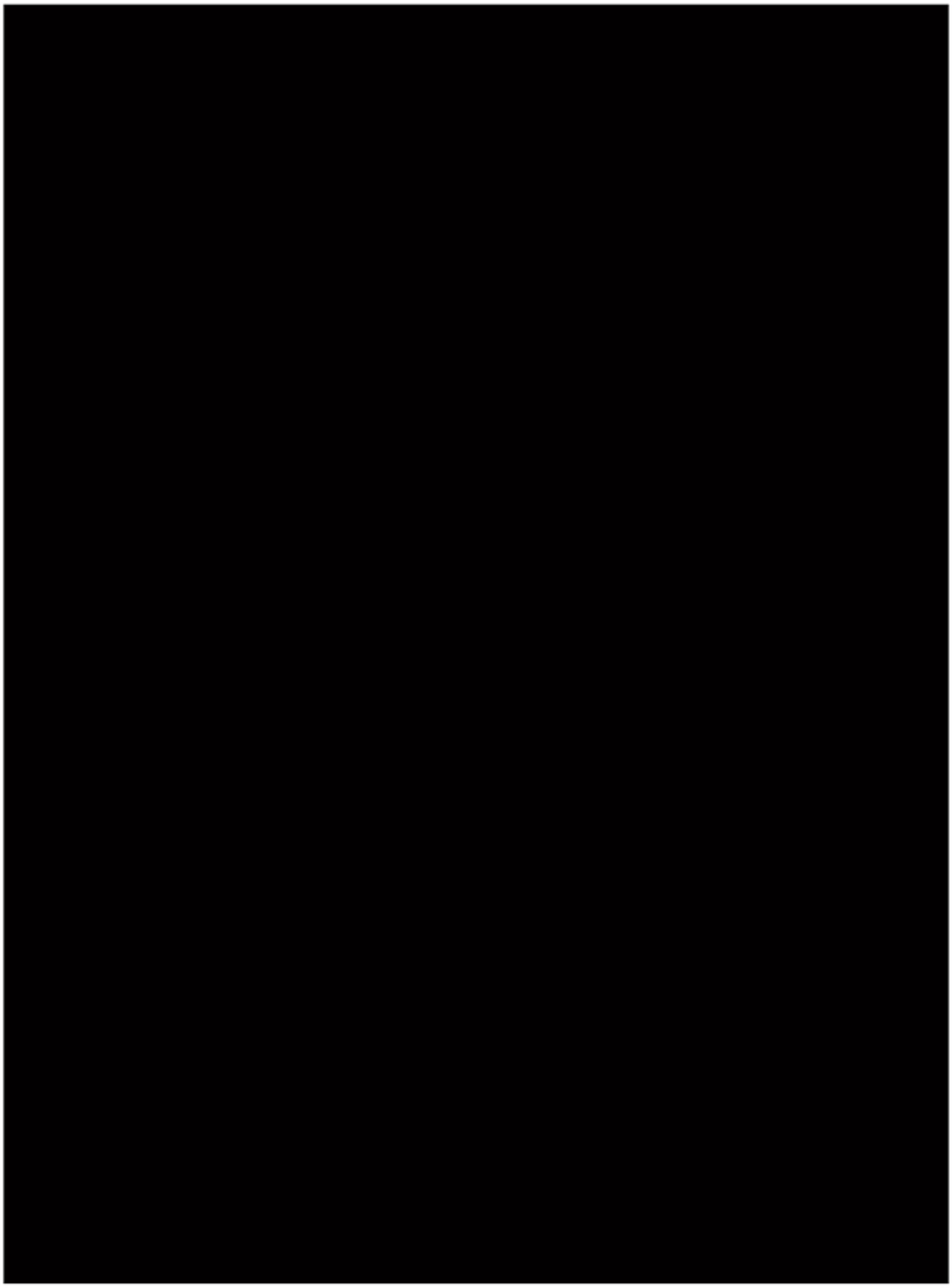


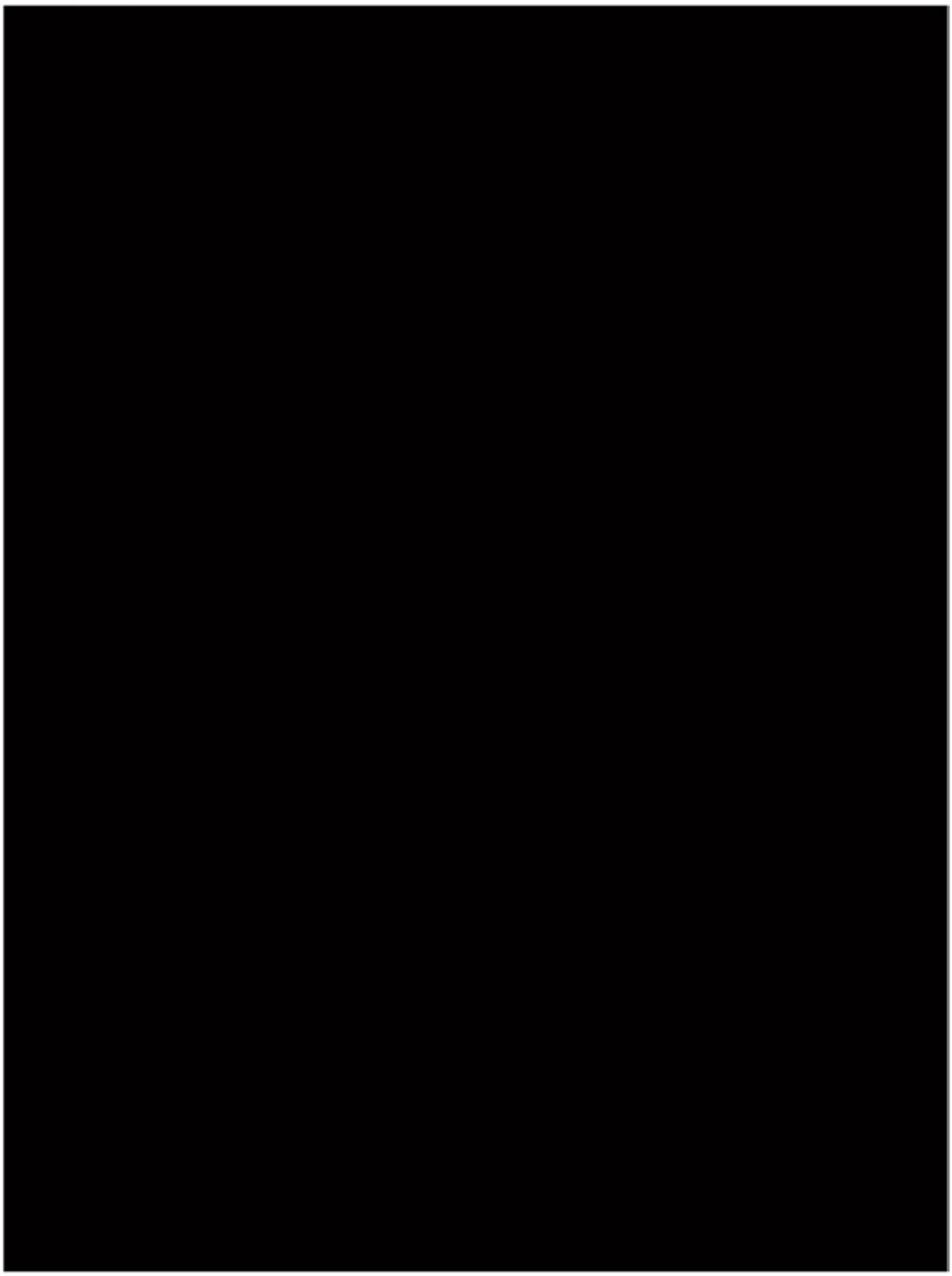


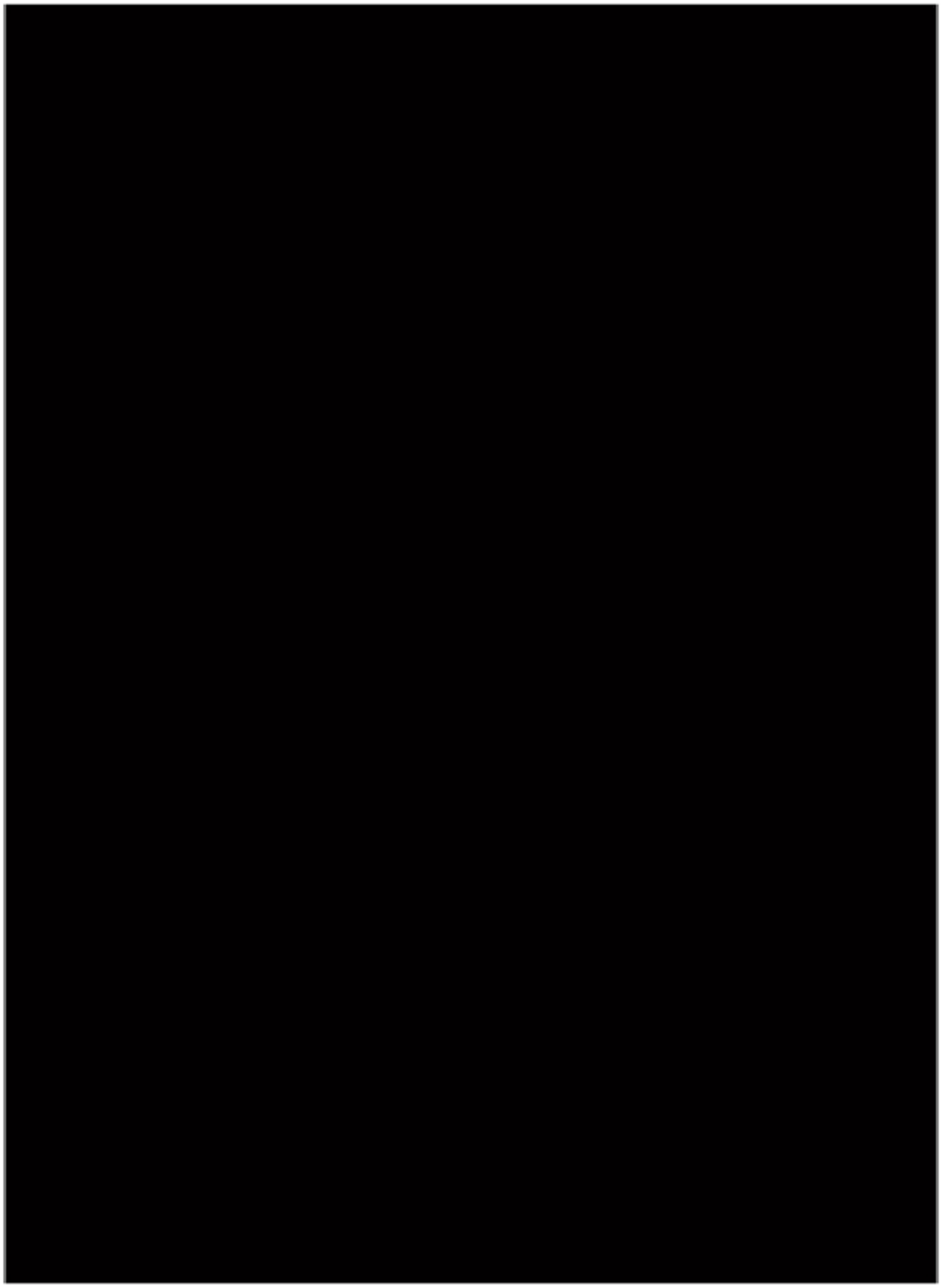


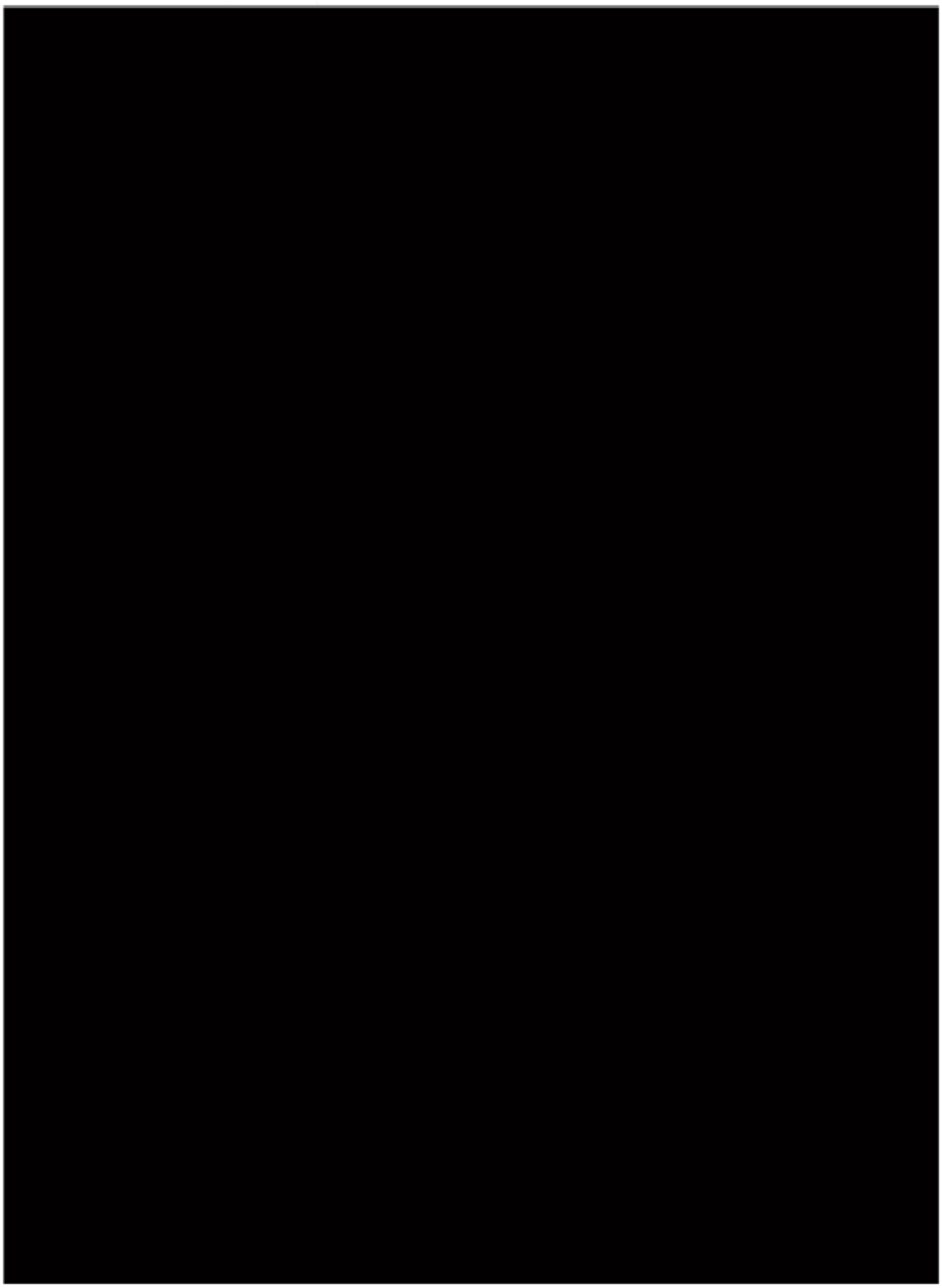


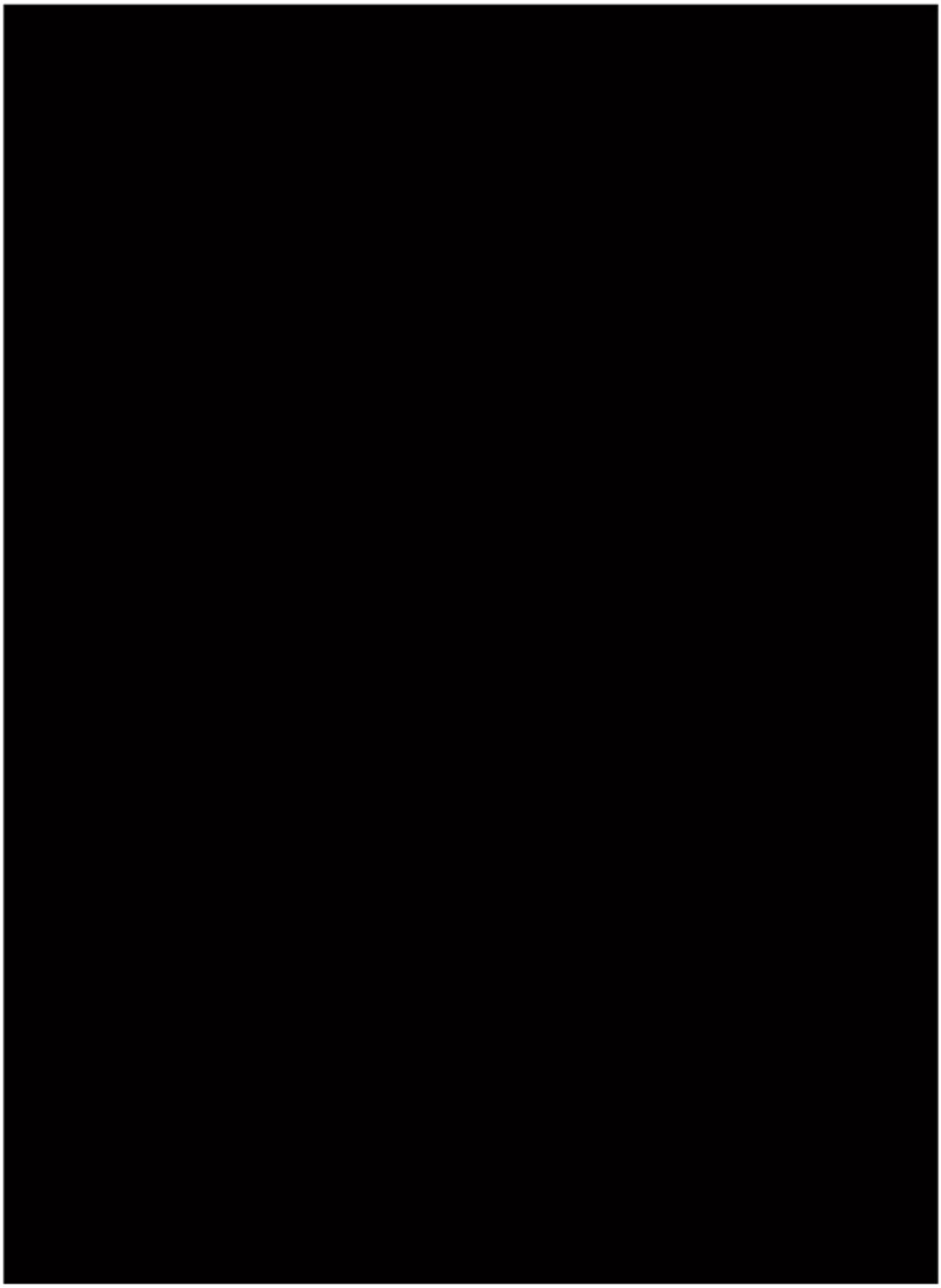
Attachment 2 – Dronabinol Budget

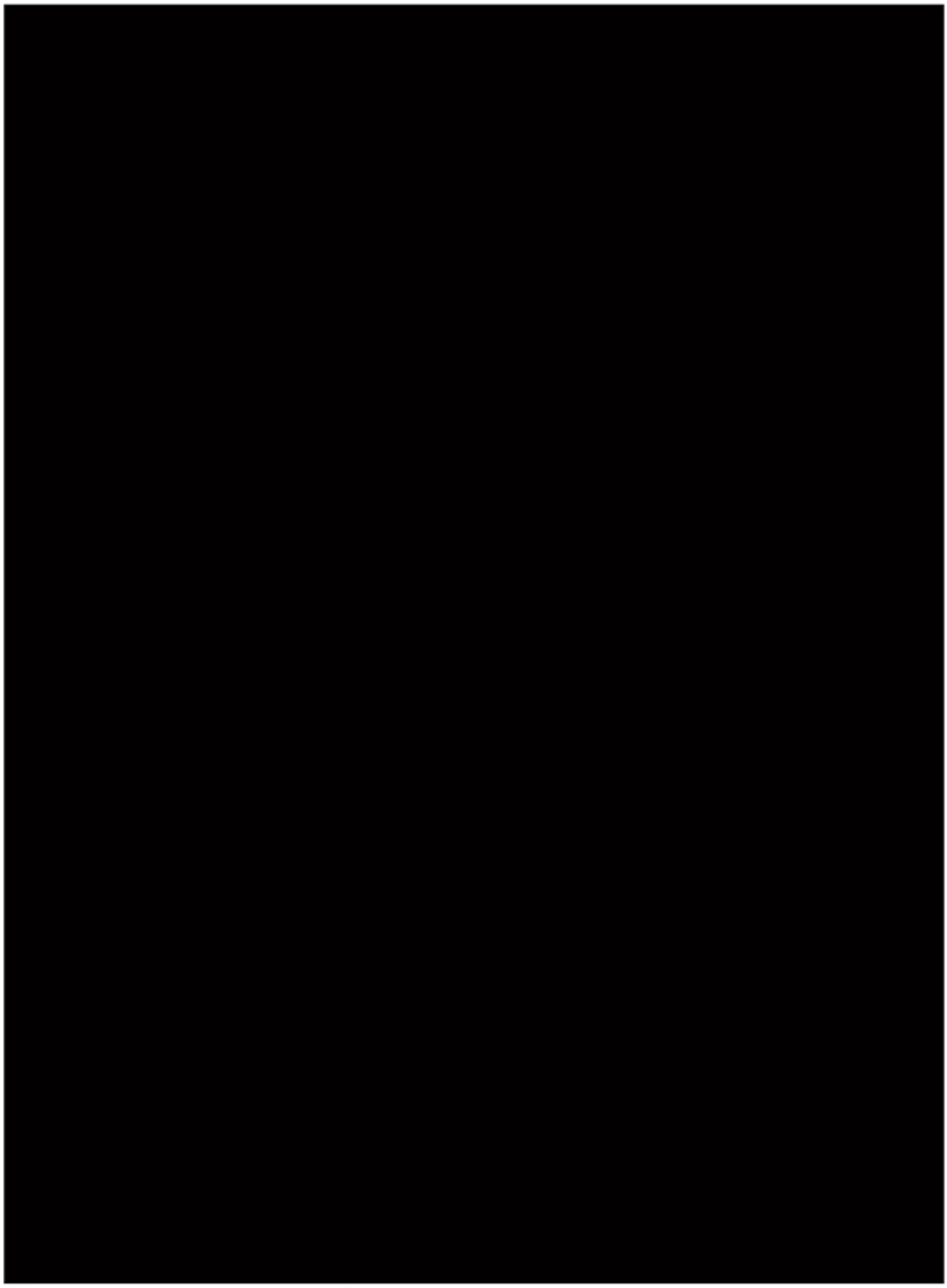


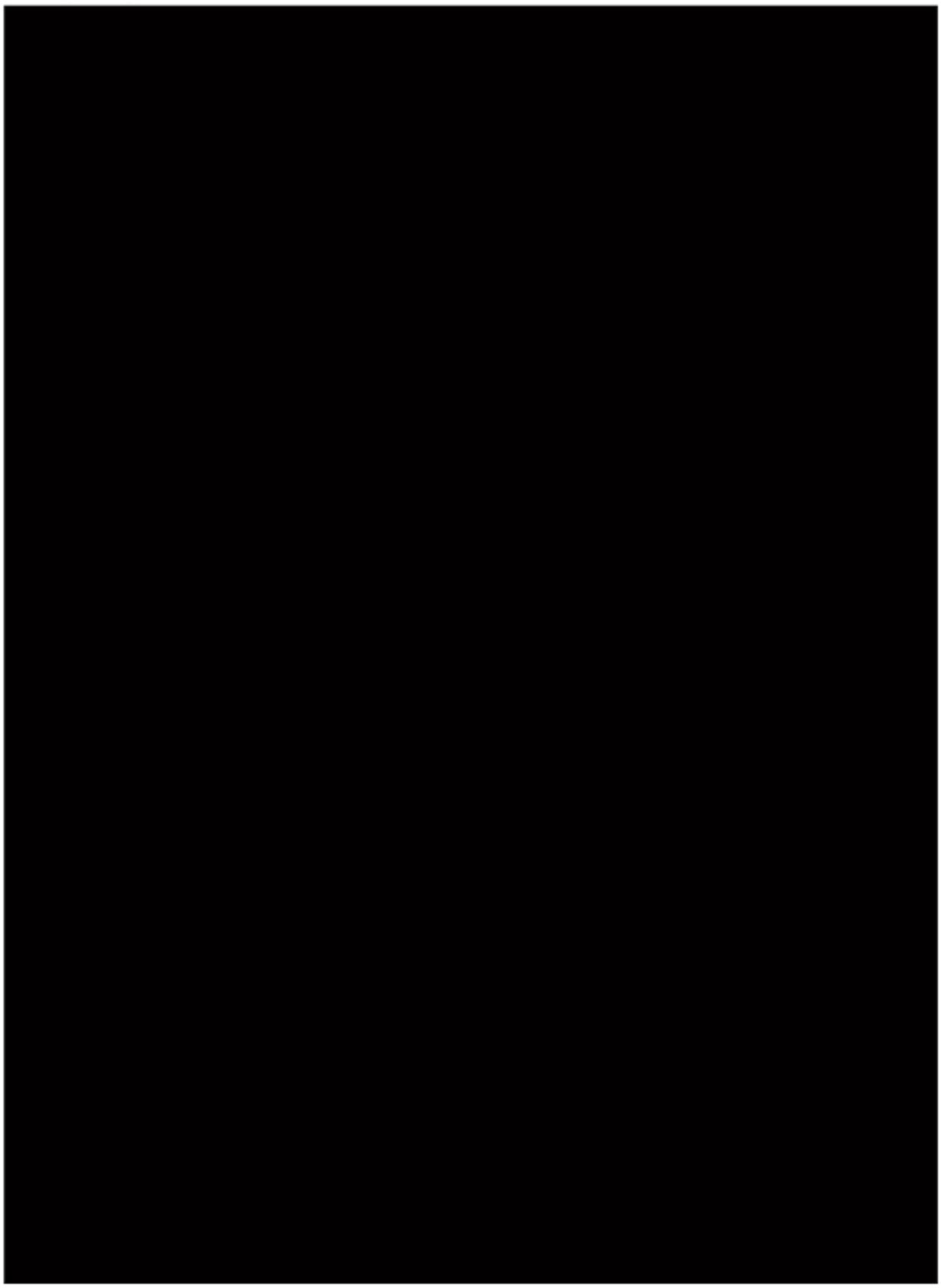


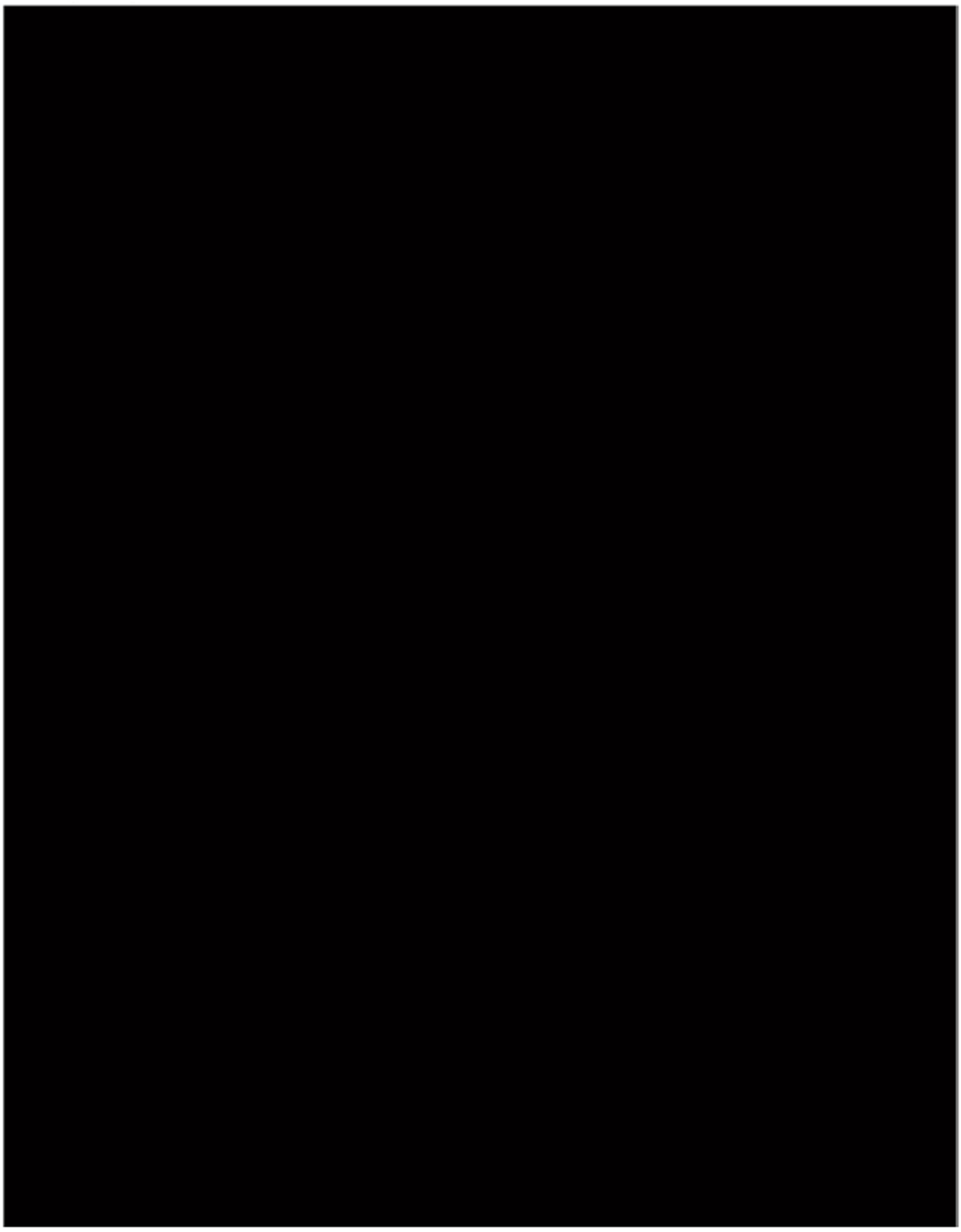


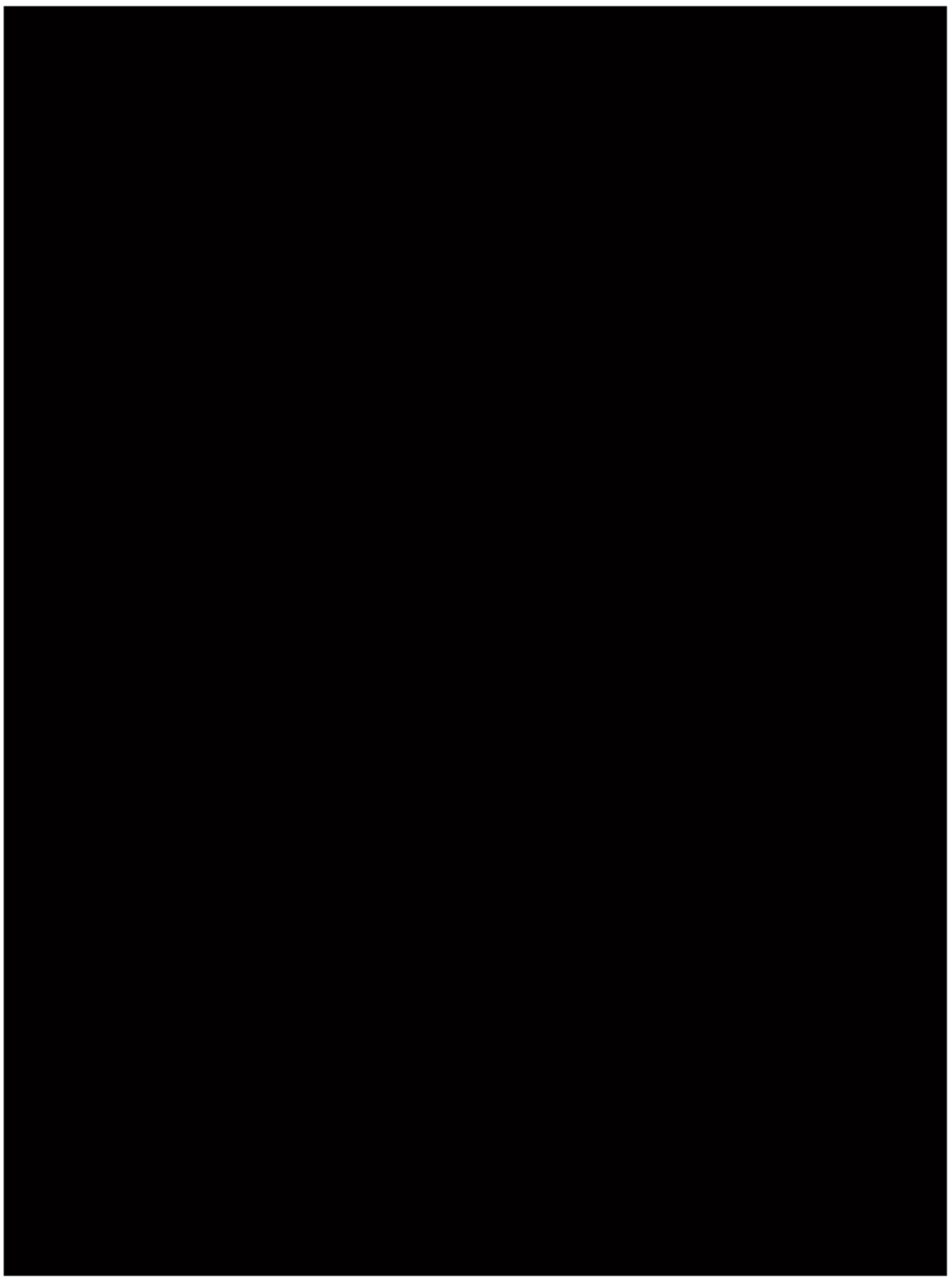


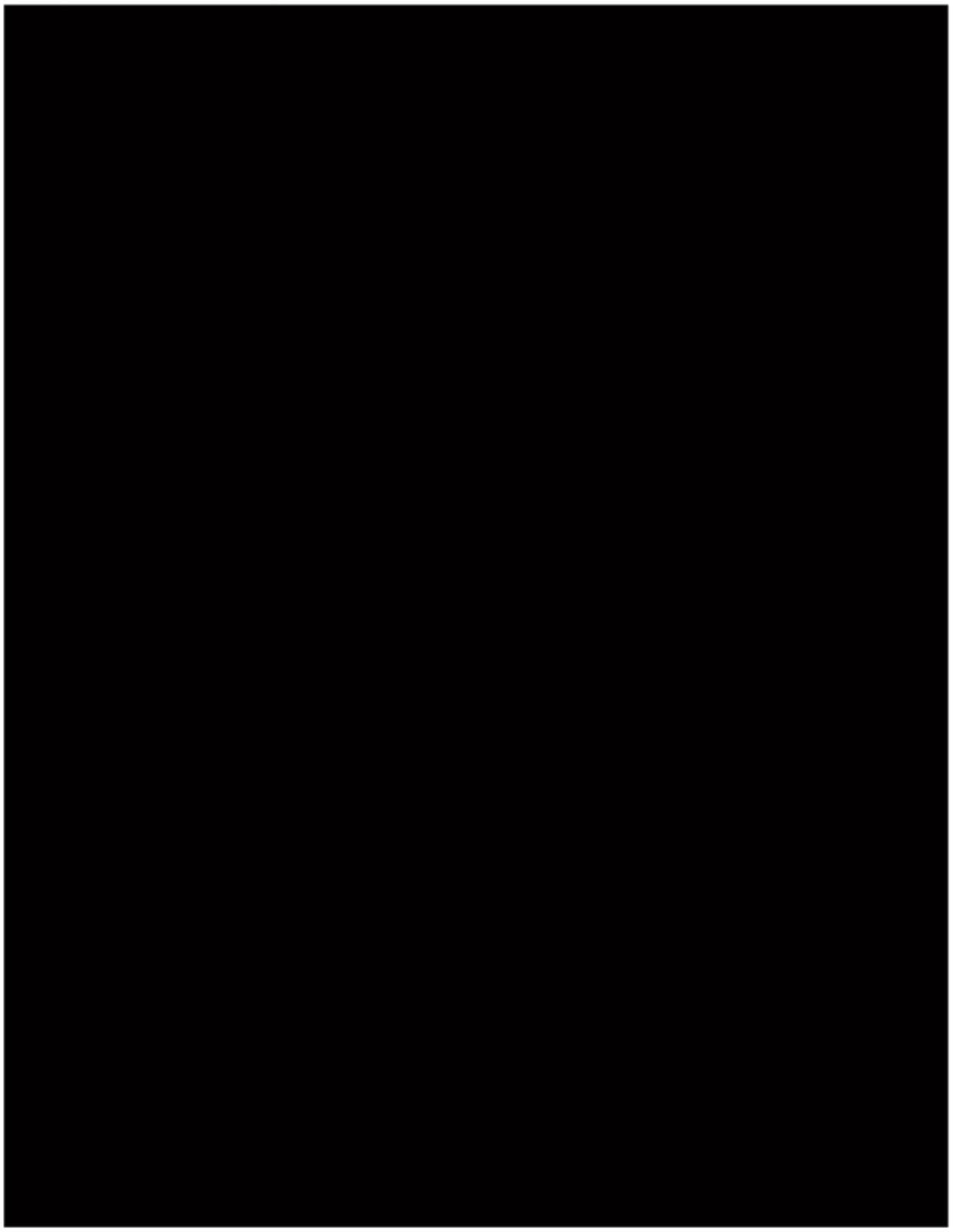


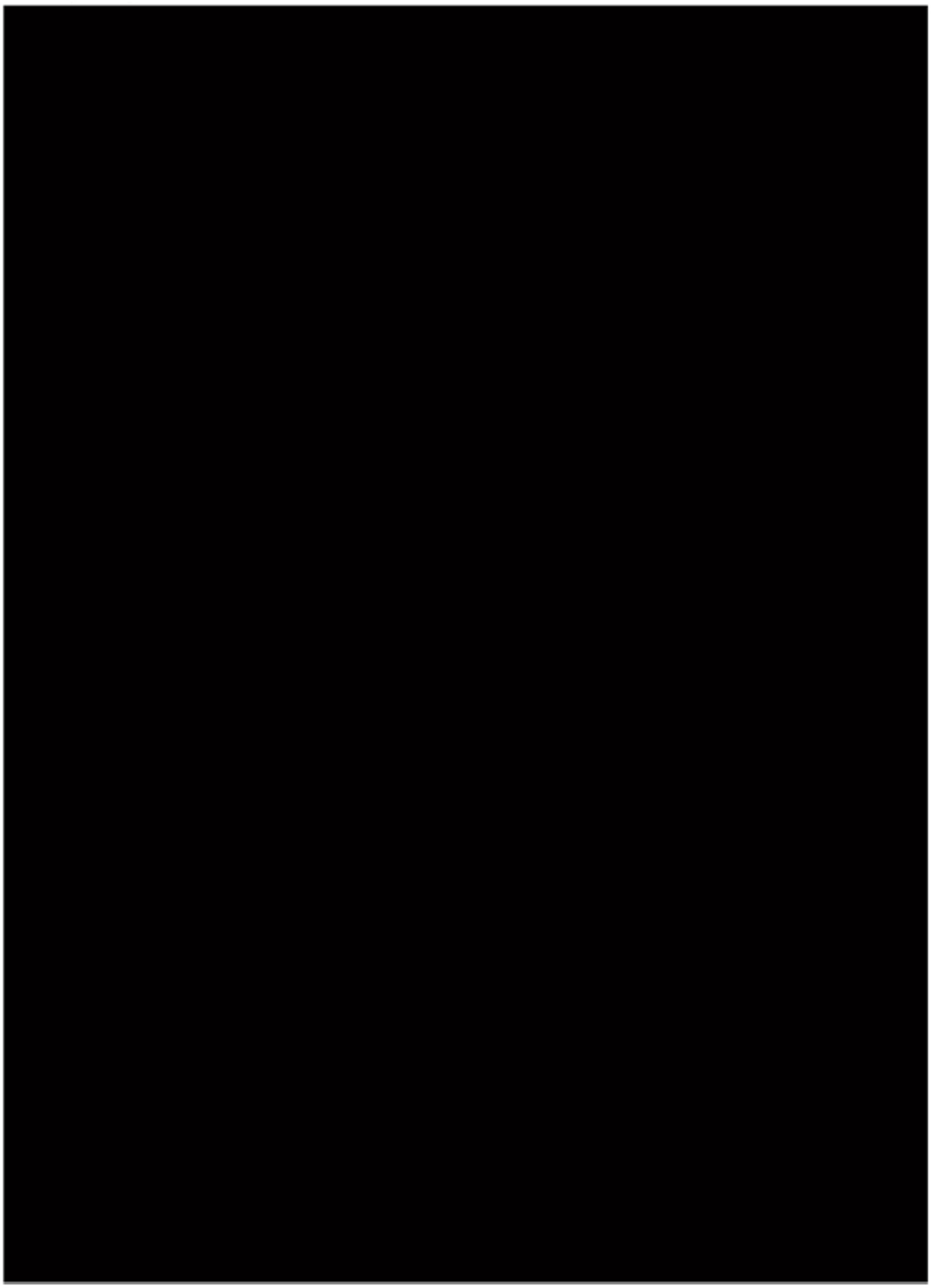


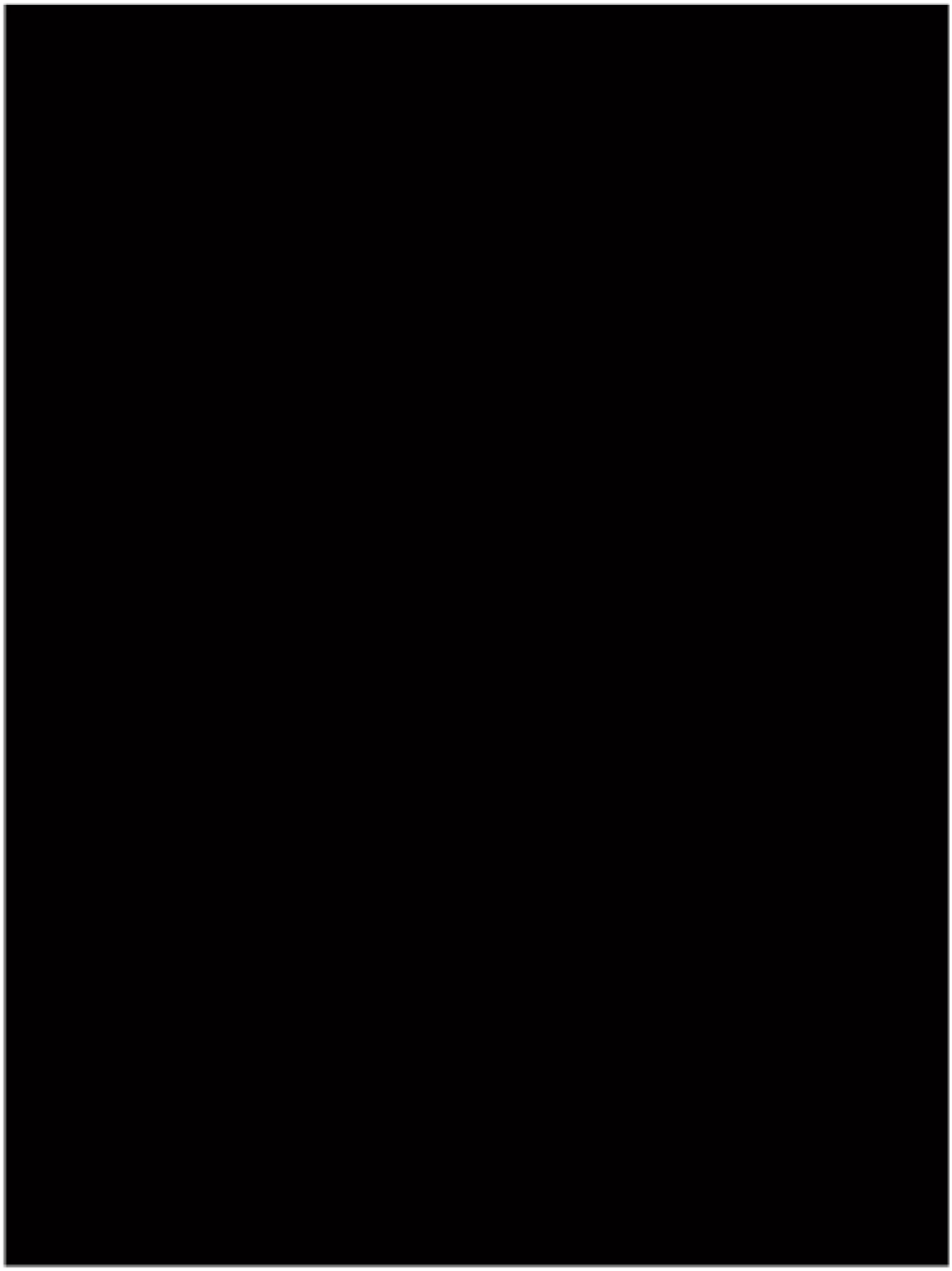


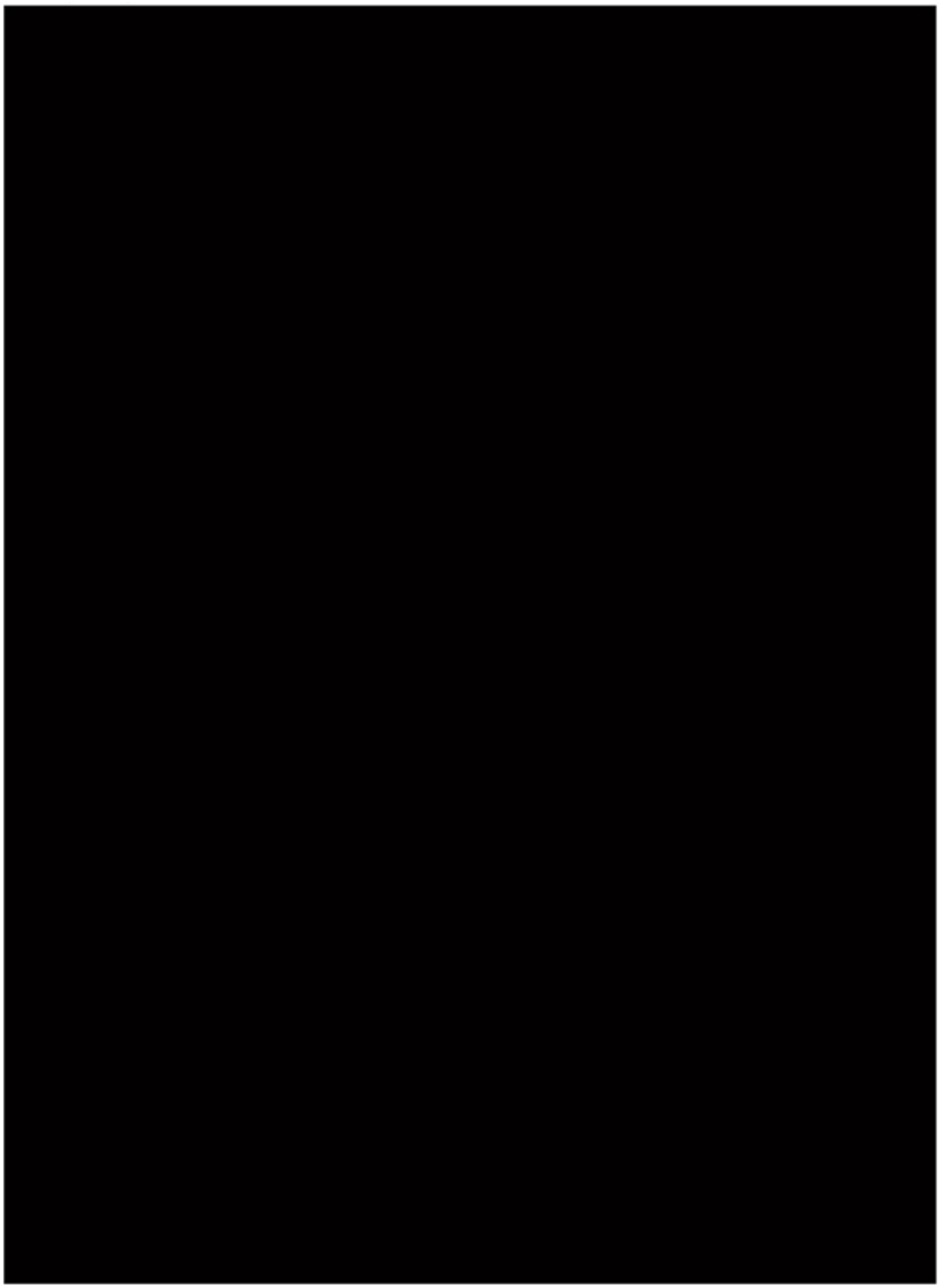


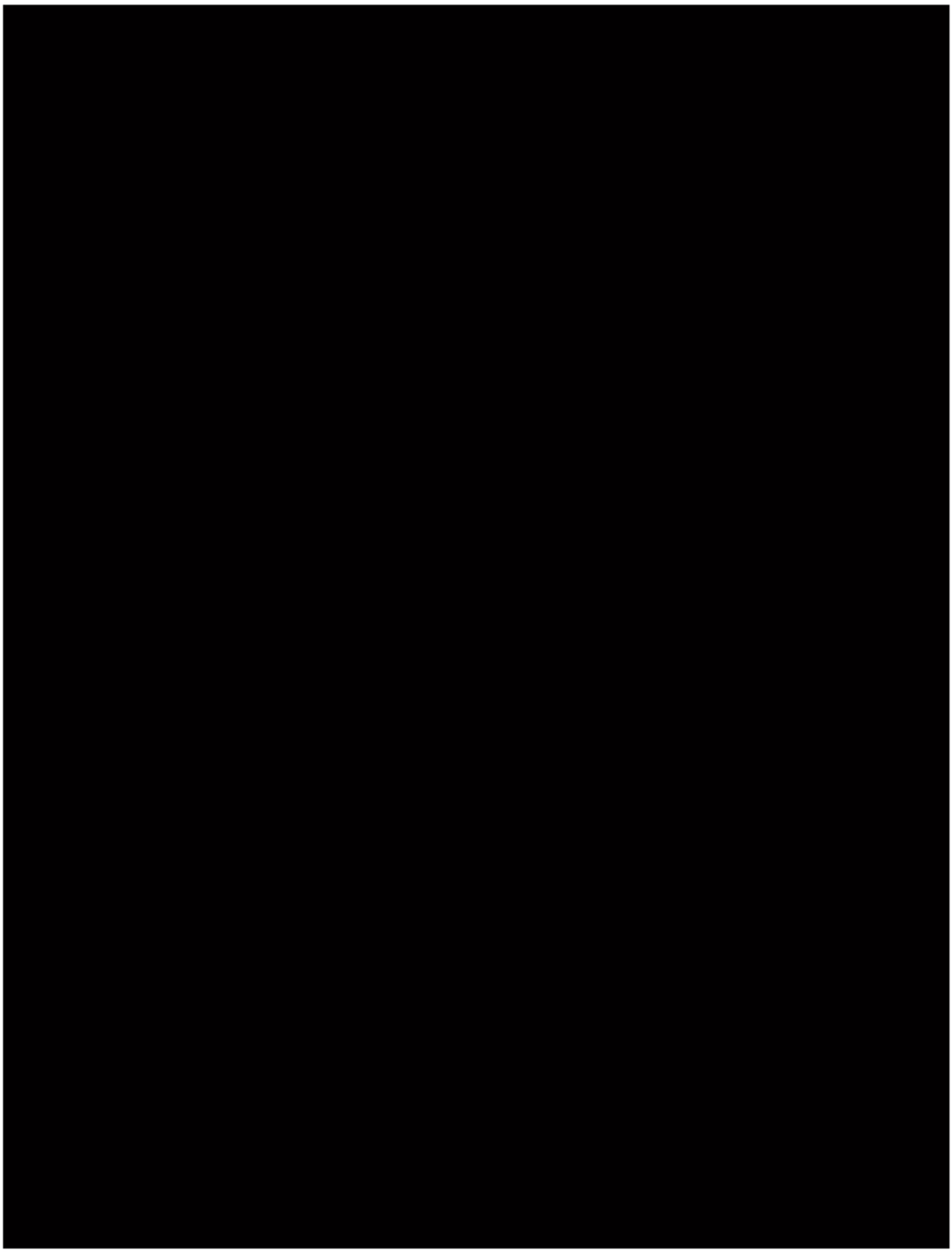












Attachment 3 – Transfer of Regulatory Obligations (TORO) Document

Description of Responsibility	Responsibility		Shared Responsibility Comment
	(Yes) Assigned to iNGENū	Retained by Sponsor	
A. Preparing and submitting a Clinical Trial Application	**If responsibility for any item in this section is shared by iNGENū and Sponsor, check both boxes and clarify the division of responsibilities in the Shared Responsibility Comment column.**		
1. Act as Agent for Sponsor; submit and receive all applicable Regulatory Authority correspondence	☑	☐	
2. Prepare Clinical Trial Notification	☑	☐	
3. Submit Clinical Trial Notification to Regulatory Authority	☑	☐	
4. Prepare and submit all required documentation to HREC	☑	☐	
B. Maintaining an effective Clinical Trial Application with respect to the investigations by preparing and submitting the following amendments, as necessary:	**If responsibility for any item in this section is shared by iNGENū and Sponsor, check both boxes and clarify the division of responsibilities in the Shared Responsibility Comment column.**		
1. Protocol amendments	☑	☐	

2. Information amendments: • API Chemistry, manufacturing and controls • Pharmacology / Toxicology • Clinical	☐ ☐ ☑	☑ ☑	
3. Safety Reports • Preparation of initial written report • Follow-up reports • Notification of Regulatory Authority	☑ ☑ ☑	☐ ☐ ☐	
4. Annual Reports to the TGA, HREC and Trial registry.	☑	☐	
5. Letter to Withdraw a Clinical Trial Application	☑	☑	
6. Responses to Regulatory Authority Information Requests	☑	☐	
7. Responses to Regulatory Authority Clinical Hold	☑	☐	
C. Selecting investigators and monitors	**If responsibility for any item in this section is shared by iNGENū and Sponsor, check both boxes. iNGENū accepts regulatory responsibility (ies) only for those sites or monitors selected by iNGENū or assigned to iNGENū as specified in the study agreement.**		
1. Select qualified investigators and obtain evidence of the qualifications	☑	☐	
2. Inform investigators • Provide Investigator's Brochure • Provide the Protocol	☑ ☑ ☑	☐ ☑ ☑	IB and Protocol to be drafted by the Sponsor, however shared with the site by the CRO.
3. Control the shipping of the investigational product • Approve the investigational product shipment to investigators after review of site regulatory documents • Ship the investigational product to investigators	☑ ☑ ☑	☐ ☐ ☐	
4. Select qualified monitors	☑	☐	
D. Review of ongoing investigation	**If responsibility for any item in this section is shared by iNGENū and Sponsor, check both boxes. iNGENū accepts the regulatory responsibility (ies) only for**		

	those sites assigned to iNGENû as specified in the study agreement.		
1. Monitor the progress of the clinical investigation (including investigator compliance applicable Regulatory Authority mandates)	☑	☐	
2. Submit protocol amendments	☑	☐	
3. Review and evaluate evidence relating to safety and effectiveness as it becomes available	☑	☐	
4. Provide new safety information as it becomes available	☑	☐	
5. Secure compliance or discontinue investigator participation	☑	☐	
6. If investigator participation is discontinued: • Ensure return and disposition of investigational product per applicable Regulatory Authority mandates • Notify Regulatory Authority of discontinuation of investigator participation	☑ ☑	☐ ☐	
7. Indicate which Party is responsible for Serious Breach reporting responsibilities	☑	☐	
8. Determine whether the investigational product presents an unreasonable and significant risk to the subjects and if so, discontinue the investigation and: • Notify Regulatory Authority • Notify all IRBs/IECs • Notify all Investigators • Assure the disposition of all stocks of the investigational product • Furnish Regulatory Authority with a full report of the Sponsor's actions	☐ ☑ ☑ ☑ ☑ ☑	☑ ☐ ☐ ☐ ☐	

E. Recordkeeping and record retention	**Unless otherwise specified herein, iNGENû will return all study documents (including the TMF) to the Sponsor upon completion of the project as specified in the study agreement.**		
1. Maintain records required under applicable regulations during the conduct of the study including but not limited to: • Records of shipment, receipt and disposition of study drug • Records relating to financial interests of investigators subject to applicable Regulatory Authority mandates. • Reserve samples of any investigational product and reference standard identified in, and used in any of the bioequivalence or bioavailability studies	☑ ☑ ☑ ☑	☐ ☐ ☐ ☐	
F. Inspection of Sponsor Records	**If responsibility for any item in this section is shared by iNGENû and Sponsor, check both boxes and clarify the division of responsibilities in the Shared Responsibility Comment column.**		
1. Permit access to, copying and verification of records or reports relating to the clinical investigation to Regulatory Authority upon request from Regulatory Authority	☑	☐	
2. Submit the records or reports relating to the clinical investigation (or copies of them) to Regulatory Authority upon written request from Regulatory Authority	☑	☐	
3. Discontinue shipment of investigational product to any investigator who has failed to maintain or make available to a Regulatory Authority records and reports of the clinical investigation	☑	☐	
4. Provide records or reports concerning shipment, delivery, receipt, and disposition of "controlled substances" upon request from the relevant Regulatory Authority.	☑	☐	

G. Disposition of unused investigational product	**If responsibility for either item in this section is shared by iNGENū and Sponsor, check both boxes. iNGENū accepts the regulatory responsibility (ies) only for those sites assigned to iNGENū as specified in the study agreement.**		
1. Assure the return of all unused supplies of the investigational product	☑	☐	
2. Dispose of or destroy all unused supplies of the investigational product	☑	☐	
H. Apply for Regulatory Authority approval to export the investigational product.	☑	☐	
I. Administration & Setup	**If responsibility for either item in this section is shared by iNGENū and Sponsor, check both boxes. iNGENū accepts the regulatory responsibility (ies) only for those sites assigned to iNGENū as specified in the study agreement.**		
1. Database selection	☑	☐	
2. Database build	☑	☐	
3. Data Management	☑	☐	
4. Electronic Data Capture	☑	☐	
5. Clinical Quality Assurance (CQA) Auditing (vendor selection)	☑	☑	
6. Statistical Analysis (Biostatistics)	☑	☐	
7. Medical Writing	☑	☐	
8. Medical Monitoring	☑	☐	
9. Independent Data Monitoring Committee (IDMC)	☑	☐	
10. Project Management	☑	☐	

Attachment 4 – FORM OF AUTHORITY TO WORK WITH STUDY SITES ON YOUR BEHALF

iNGENu Pty Ltd
Office C2, level 1, 459 Toorak Road, Toorak VICTORIA By email
sud.agarwal@ingenucro.com

Dear Dr Sud,

LETTER OF AUTHORISATION

27/2/2023

ResolutionRx Ltd (ACN 664 925 651) of C/- Bentleys (SA) Pty Ltd, Level 5, 63 Pirie Street, Adelaide SA 5000 [(Sponsor)] is the sponsor of the clinical trial known as the RESPIRE-XXXX-2023

On or around 27/2/2023, the Sponsor entered into a clinical trial agreement with Vitalis Clinical Research Pty Ltd (ABN 43 659 694 863) of unit 15 456 St Kilda Rd, Melbourne 3000, VIC (Site). On or around 27/2/2023, the Sponsor entered into an agreement with a clinical research organisation, iNGENu Pty Ltd (ACN 656 400 056) of Office C2, level 1, 459 Toorak Road, Toorak VICTORIA (iNGENu). The Sponsor has transferred some of its obligations as Sponsor to iNGENu under the attached Study Work order and Transfer of Regulatory Obligations (TORO) document.

This letter is to authorise iNGENu to communicate with the Site and to represent Sponsor and perform its obligations to the Site as set out in the TORO document.

Signed. . . . . DocuSigned by: Mr. Jeff Margolis 7CA04D6B86D4D0... . . . . .

Jeff Margolis

Title Senior Financial Officer and Director

27 February 2023