Pursuant to the authority vested in the Cannabis Control Board by sections 13, 38 and 43 of the Cannabis Law, Chapter II of Subtitle B of Title 9 of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended, and a new Part 132 is added, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Part 132

Cannabis Research License

§ 132.1 Definitions.

For purposes of this Part, the following terms shall have the following meanings:

(a) *Adverse event* means any untoward or unfavorable medical occurrence associated with the use of a drug in human subjects, whether or not considered drug related, or damage, or any other serious important medical events.

(b) *Applicant* means an individual applying for a research license issued by the Board pursuant to Article 3 section 38 of the Cannabis Law, who shall also be the principal investigator.

(c) *Board* means the New York State Cannabis Control Board as defined in Article 1 of the Cannabis Law.

(d) *Cannabis-derived product* means concentrated cannabis or cannabis-infused products for use by a cannabis consumer or research participant.

(e) *Cannabis-related product* means a product that may be synthetically produced to mimic or produce similar effects to cannabis.

(f) *Canopy* means an area to be calculated in square feet and measured using clearly identifiable boundaries of all areas that will contain non-immature cannabis, which shall be vegetative or flowering plants, excluding seedlings or small clones, including the space(s) within

the boundaries. Canopy may be noncontiguous, but each unique area included in the total canopy calculations shall be separated by an identifiable boundary including, but not limited to: interior walls, shelves, greenhouse walls, hoop house walls, garden benches, hedge rows, fencing, garden beds, or garden plots.

(g) *Co-principal investigator or Co-PI* means an individual whose role is similar to that of the principal investigator in determining the intellectual content, direction, and conduct of the research project or project activities.

(h) *Curriculum vitae or CV* means a detailed document highlighting academic and professional accomplishments.

(i) *Double-blind trial* means neither the participants of the research project nor the principal investigator and those administering the intervention or treatment know what intervention or treatment the participants are receiving.

(j) *Electronic data capture or EDC* means software used to collect and manage research project data.

(k) *Good clinical practice* means an ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of humans as subjects; assurance that the rights, safety, and well-being of trial subjects are protected.

(l) *Human subject or research participant* means an individual participating in a research project whose data or biospecimens may be collected through intervention or interaction with the individual.

(m) *Informed consent* means the legally effective knowing permission and agreement of an individual or their legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion, to engage in licensed research activities as a human subject.

(n) *Informed consent form or ICF* means a document to explain to the individual giving informed consent of the procedures to be followed, and their purposes, including identification of any procedures which are experimental, a description of any attendant discomforts and risks reasonably to be expected, a description of any benefits reasonably to be expected, a disclosure of any appropriate alternative procedures that might be advantageous for the individual, an offer to answer any inquiries by the individual concerning the procedures, and an instruction that the individual is free to withdraw their consent and to discontinue participation in the research project at any time without prejudice.

(o) *Institutional review board or IRB* means a human research review committee established and approved under the provisions of article twenty-four-A of the public health law, or an institutional review board established and approved under the provisions of Title 45 of the Code of Federal Regulations Part 46 or Title 42 of the US Code section 289(a), for the purpose of reviewing and monitoring research.

(p) *Institutional animal care and use committee or IACUC* means an independent committee established and approved under the provisions of Title 9 of the Code of Federal Regulations Part 2 or Title 7 of the US code section 2143(b) for the purpose of overseeing all research with animals.

(q) *Investigational product* means the cannabis, cannabis-derived product, or cannabis-related product being studied or used in an approved research project.

(r) *Key personnel* means staff, other than the PI, participating in a research project who is delegated to perform research tasks.

(s) *Medical Cannabis Program* means the administration of Article 3 of the Cannabis Law by the Office.

(t) *Office* means the Office of Cannabis Management.

(u) *Principal investigator or PI* means the applicant or research licensee who shall also be the primary individual who leads and oversees a research project and is responsible for all activities conducted under the research license.

(v) *Protected health information or PHI* means information in a medical, or other type of record, related to health care diagnosis or treatment that can be used to identify an individual. It may be transmitted or maintained electronically or in any other form or medium.

(w) *Research* means a systematic investigation, including but not limited to, research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

(x) *Research project or study* means a formulated plan of action to perform research and the execution of such plan.

(y) *Research and development or R&D* means activities that lead to the innovation of new products, processes, or services, or improvements to those that already exist in support of a business.

(z) *Research contract* means a written agreement between an applicant or research licensee and another licensee, permittee or registrant approved by the Board, that contains the responsibilities and duties of each party with respect to the research project or research study that the approved research licensee and the licensee, permittee or registrant intend to conduct under this Part.

(aa) *Research protocol* means a written procedure for conducting a research project or study.

(ab) *Serious adverse event* means an adverse event that results in death, requires hospitalization or prolongation of hospitalization, is life threatening, results in a permanent disability or damage, results in congenital abnormality/birth defect, or requires intervention to prevent permanent impairment.

(ac) *Single-blind trial* means a trial in which participants of a research project do not know what treatment or intervention they are receiving, but key personnel administering the treatment or intervention do.

(ad) *Sub-investigator or Sub-I* means an individual delegated by the principal investigator to perform critical study procedures and assist with making key decisions.

(ae) *Vulnerable participant* means an individual whose willingness to volunteer in a research project may be unduly influenced by the expectation, whether justified or not, of the benefits associated with participation, or of a retaliatory response from research staff if they refuse to participate. A vulnerable participant may include, but not be limited to, prisoners, minors, and those incapable of giving consent.

§ 132.2 General Provisions.

(a) A research license shall:

(1) be required in order to conduct research studies with investigational product, or on populations that use investigational product.

(2) be issued in the name of the applicant who will serve as the PI of the research project. The applicant shall register all research projects they lead, as PI, under the same research license. A PI may serve as a co-principal investigator or sub-investigator on other research projects under a different research license.

(b) A research license shall not be required for:

(1) research and development activities conducted by licensees, permittees, or registrants approved by the Board, provided that the research activities are within the scope of their existing license type;

(2) data only studies that do not directly involve human subjects or use of investigational product directly or in any whole or processed form; or

(3) studies conducted using federally sourced cannabis supplied by the National Institute on Drug Abuse Drug Supply Program, provided that the researcher supplies the Office with documentation of such federal approvals once received.

(c) Investigational products provided for research purposes shall not enter the medical or adult-use supply chain for use by a cannabis consumer for adult-use purposes or a medically certified patient for medical purposes, unless it is being provided to human subjects or key personnel in accordance with an approved research project.

(d) A research licensee may:

(1) deliver, transport, or provide investigational products to:

(i) a licensee or permittee approved by the Board under Article 4 and 6 of the Cannabis Law;

(ii) a cannabis testing laboratory permitted by the Board;

(iii) a registered organization;

(iv) another research licensee;

(v) key personnel or a human subject, as part of, and in compliance with, the conditions of an approved research project; or

(vi) individuals or entities as approved by the Board.

(2) in accordance with the authorizations of their research project(s), produce, process, purchase, and/or possess investigational products for the purpose of conducting cannabis research.

(3) conduct research involving investigational products for the following limited research purposes:

(i) to conduct agricultural research;

(ii) to conduct genomic research;

(iii) to test chemical potency and composition levels;

(iv) to conduct clinical investigations with investigational products, including human observational studies;

(v) to conduct research on the efficacy and safety of administering investigational products as a component of medical treatment; or

(vi) other research topics approved by the Board that comply with Cannabis Law section 38.

(4) contract with a licensee, permittee or registrant approved by the Board to assist with the testing, cultivating, processing, or the dispensing of investigational products for research purposes.

(5) share premises with another licensee, permittee or registrant approved by the Board provided that:

(i) the research licensee receives prior written approval from the Board;

(ii) all investigational products used for research purposes are physically segregated and designated as such; and

(iii) inventory records pertaining to research can be distinguished from other records.

(6) contract with an institution of higher education, including but not limited to, a hospital within the State University of New York, to perform research in conjunction with such institution. An institution of higher education may also apply for a research license.

(e) A research licensee shall not, for the purposes of fulfilling the authorizations under this license:

(1) obtain or transport investigational products outside of New York State;

(2) acquire investigational products from a person other than a licensee, permittee or registrant approved by the Board, unless approved by the Board; or

(3) employ, or permit to be employed, or allow to work, any persons under 18 years of age, on any research project.

(f) An applicant shall demonstrate to the Board that there are effective procedures to safeguard against diversion, theft or loss of investigational products, including proving that the security measures are adequate for storing the quantity of investigational products the research licensee may have in possession.

(g) All human subjects shall be 21 years of age or older unless they are certified patients in the Medical Cannabis Program.

(h) Access to stored investigational products, whether ambient or refrigerated, must be restricted to the principal investigator and key personnel.

(i) A research licensee shall:

(1) maintain a record of all key personnel involved with the research project.

(2) abide by the worker health and safety standards as set forth in any applicable law, or regulation.

(j) The issuance of a research license to a research licensee shall not convey upon the research licensee, or any of the research studies authorized to be conducted by the research licensee, that the:

(1) opinions, points of view, research methods, or conclusions expressed in such research studies represent the Office;

(2) investigational products discussed in such research studies constitutes product approval or endorsement by the Office; and

(3) Office:

(i) controls or guarantees the accuracy, legality, relevance, timeliness or completeness of the information contained in the research study;

(ii) endorses such research licensee's:

(a) expressed views or opinions,

(b) research studies;

(c) methods of research;

(d) conclusions in such research studies; or

(e) the investigational products or cannabis plants in such research studies; and

(iii) authorizes the use of copyrighted materials, if any, used in such research study.

(k) Publication. All publications that result from research studies associated with research licenses issued by the Board shall include the following statement: "The content herein is solely the responsibility of the authors and does not necessarily represent the official views of the Office of Cannabis Management."

§ 132.3 Applying for a License.

(a) All research license applications shall be approved by the Board and meet the requirements of this Part. To apply for a license, the applicant shall have at least one proposed research project to register under the license. Applicants shall submit the following information in a form and manner as determined by the Board:

(1) full name of the applicant;

(2) applicant contact information;

(3) street address of the intended research site, including the floor location or room number, if applicable;

(4) the mailing address of the applicant, if different from the research site;

(5) the name, address and telephone number of the attorney or representative of the applicant, if any;

(6) the following information regarding all cannabis research project(s) that the applicant wishes to engage in:

(i) projected goals and outcomes of the research project(s) covered by the license that the applicant intends to conduct within the next year following submission of the application, including project quality, study design, value, and impact;

(ii) information demonstrating the applicant has the appropriate key personnel, expertise, facilities and infrastructure, funding, and appropriate approvals, such as IRB or IACUC, to successfully conduct the project(s);

(iii) the name and curriculum vitae (CV) of key personnel participating in the research project(s);

(iv) the name and address of the licensee, permittee or registrant, including any cultivator, processor, manufacturer, dispensary facility, or laboratory associated with the research project(s), if applicable;

(v) disclosures of any contracts and agreements between the applicant and any licensee, permittee, or registrant approved by the Board involved in any aspect of the project(s);

(vi) disclosures of contracts and agreements, if any, between the applicant and an institution of higher education;

(vii) the IRB that will be utilized for ethics review of research involving human subjects including the status of approval, if applicable, and the contact information for the IRB;

(viii) the IACUC that will be utilized for ethics review of research involving animals, the current status of approval, if applicable, and the name of each licensed veterinary doctor in good standing, that will lead the research project(s) as principal investigator, co-principal investigator, sub-investigator, or monitor the participation of animals, if any, in the research project(s);

(ix) a description of the project(s) funding or resources that includes an attestation that the project(s) is/are adequately funded or resourced, the sources of the funding, and disclosure of any known conflicts of interest, if applicable;

(x) a description of the proposed human subjects, which includes, but is not limited to, demographic information, and details on those deemed vulnerable participants and any applicable safety precautions for those participants;

(xi) a description of proposed animals to be used in the research, if any;

(xii) attestation and/or certification of good clinical practice training, if applicable; and

(xiii) the quantity of investigational products anticipated to be needed over the duration of the research project(s) and information regarding:

(a) the proposed canopy size of the cultivation space, if applicable;

(b) justification for the amount of investigational products to be cultivated or purchased by the applicant and information detailing how the proposed canopy or purchased investigational products are consistent with the project's scope and goals;

(c) the laboratory where the investigational products will be tested, if applicable;

(d) the source of the investigational products, including the following for the source: licensee name, address and date of sale or donation to the research licensee; and

(e) a plan for the disposal or donation of investigational products at the conclusion of the research project.

(7) if working within an organization, the following information of such affiliated organization shall be submitted unless waived by prior written approval by the Board:

(i) the organization's name and address;

(ii) applicant's role in the organization;

(iii) documentation attesting to the following:

(a) the organization is aware that the applicant is applying for a research license;

(b) the organization has no objections to the research project(s) being proposed;

(c) the applicant is qualified to serve as the PI and has the organizational authority to oversee and make decisions regarding the research activities being performed;

(d) the researcher may use the organization's staff as key personnel in the research study, if applicable;

(e) the researcher may utilize the organization's facilities to perform the research; and

(f) the organization may be held responsible if:

(1) there is any undue harm to a human subject as a result of the research being performed;

(2) there is any adverse event that the research licensee is unable to contain or provide sufficient restitution; and

(3) there are any violations of the Cannabis Law or the regulations that the research licensee is unable to adequately compensate or that the organization should have reasonably known would have caused damages.

(b) The application fee for a research license shall be $250. The licensing fee shall be $500. The application and licensing fees may be waived by the Office:

(1) based on the size, scope, or duration of the proposed research project; or

(2) if the applicant can demonstrate financial hardship.

(c) The Board shall approve or deny a research application after an application review period as determined by the Board; all applications in review will be assessed for completion and accuracy.

(d) An application shall be denied for the following reasons:

(1) description of the project does not meet the requirements of Cannabis Law;

(2) proposed research poses a danger to public health or safety;

(3) proposed research poses a health or safety risk to the human subjects;

(4) applicant has not received approval or conditional approval from an IRB or IACUC, if applicable;

(5) applicant failed to be registered with the U.S. Department of Agriculture for a research project involving animals, if applicable;

(6) applicant has not provided sufficient justification for the scientific value or validity of the proposed research project;

(7) applicant is not qualified to conduct the proposed research project;

(8) applicant's research protocol, funding, or other resources are insufficient to perform the proposed research project;

(9) the application is incomplete;

(10) the information provided within the application is false or misleading;

(11) the applicant failed to supply information and/or documents requested by the Office within the deadline imposed by the Office;

(12) the application does not meet the requirements set forth by this Part; or

(13) any other reason as determined by the Board.

(e) The Board shall provide notice of denial in writing to the applicant and include the reason for the denial.

(f) The applicant may submit a new completed application for consideration if the reason for previous denial has been addressed.

(g) An application to renew a research license that was issued under this Part shall be filed with the Board not more than six months nor less than four months prior to the date of expiration. The license will be considered expired if a renewal application is not submitted to the Board within such time limits.

(1) The research license shall be renewed every two (2) years.

(2) The renewal fee for a research license shall be $200. The renewal fee may be waived based on financial hardship or the size, scope, or duration of the ongoing research project.

(3) The renewal application shall be in a form prescribed by the Board and include the following:

(i) a list of the research projects approved by the Board that are continuing or, if any of them are concluded, the dates they were concluded;

(ii) a report of the current status of active registered research projects being conducted by the research licensee, including preliminary findings, if applicable, and any anticipated future research projects over the course of the two years following the date of submission of the report;

(iii) a description of any new proposed research projects that the research licensee intends to register with the Office and conduct within the next licensing period following submission of the renewal application, including evidence of IRB approval or conditional approval for each research project, if applicable;

(iv) any updated contracts between the research licensee and other licensees, permittees, or registrants of the Board involved in the research project; and

(v) any other information deemed necessary by the Board.

(4) Additional research projects may be added or considered at the time of renewal. The Board shall evaluate the proposed research project activities to ensure that they meet the requirements of section 38(2) of Article 3 of the Cannabis Law as well as the requirements under this Part.

(5) The Board will not approve a renewal of a research license under this Part if the Board determines that the research licensee does not intend to begin any additional approved research projects within the first 6 months following the approval of its application for renewal.

(h) Any false statement made by the research licensee is punishable under section 210.45 of the Penal Law.

(i) Materials supplied to the Office in support of an application for a research license may be subject to release pursuant to the law or regulation, other compulsory legal process, or at the discretion of the Board, where legally permissible.

§ 132.4 Acquisition of Investigational Products.

(a) Research licensees may acquire investigational products, by sale or donation, from licensees, permittees, or registrants approved by the Board provided that:

(1) the transaction amount is below the individual possession limits established in Penal Law; or

(2) if the transaction amount exceeds the possession limits, research licensees shall enter into a formal contractual agreement with the adult-use licensees, permittees, or registrants.

(b) Research licensees may cultivate their own cannabis for research projects provided they are conducted in accordance with the activities approved by the Board as set forth in their research protocol and the requirements of this Part.

(c) All investigational products used in research and consumed by human subjects or animals shall be tested in accordance with Part 130 of this Title prior to consumption by human subjects or animals.

(d) For the purposes of the research project, a research licensee shall only possess the amount of investigational product that was approved in their application or otherwise approved by the Board.

(e) Investigational products that are used by participants of a research project may be purchased at a registered organization's dispensing site or an adult-use dispensary. If however, a research project involves individuals under 21 years of age, designated caregivers, or designated caregiver facilities, then the investigational products may only be purchased at a registered organization's dispensing site.

(f) A research licensee shall not sell or donate investigational products to any other person or entity, except to another research licensee. Such sale or donation shall be documented by the research licensee in a form and manner determined by the Office.

(g) Any investigational products cultivated, produced, acquired, or received by donation for use in a research project shall be documented by the research licensee in a form and manner determined by the Office.

(h) Any investigational products sold or donated for use in a research project shall be documented by the research licensee in their inventory tracking system. The record in the inventory tracking system shall include the following data fields:

(1) transaction date and time;

(2) transaction type;

(3) product description;

(4) product quantity; and

(5) any other fields required by the Office.

§ 132.5 Labeling Requirements.

(a) Investigational products stored for research purposes that do not involve human subjects must have, at a minimum, affixed to the immediate container:

(1) the description of the product and potency, if applicable;

(2) the date of production;

(3) the date of storage;

(4) name of principal investigator;

(5) research protocol number;

(6) the following messages:

(i) “NOT FOR HUMAN CONSUMPTION”;

(ii) “For research purposes only”; and

(iii) “Not for sale or distribution”.

(b) Cannabis plants stored for research purposes that do not involve human subjects must have, at a minimum, affixed to the immediate plant tag:

(1) cultivator name;

(2) lot name;

(3) lot number;

(4) principal investigator name; and

(5) research protocol number.

(c) Any research licensee conducting research approved by the Board involving human subjects shall comply with all packaging and labeling requirements, as set forth in Part 113 of this Title, unless the research licensee receives prior written approval by the Office. The approval may extend to a licensee providing investigational products for an approved research study. Products shall also be labeled with:

(1) research protocol number;

(2) principal investigator name and contact information;

(3) the name of the research licensee's affiliated organization, if applicable;

(4) the following statement "For research or investigational purposes only"; and

(5) any other information as required by the Office.

(d) Investigational products that are dispensed as treatment in a single-blind or double-blind project shall be labelled so as to not hinder the integrity of the research project and shall disclose on the label:

(1) all potential investigational products; and

(2) that the investigational product may be a placebo, if applicable.

§ 132.6 Research Involving Human Subjects.

(a) Prior to receiving a research license for a research project that includes human subjects, the following shall be required:

(1) one or more licensed practitioners in good standing to monitor participants shall be included, if required by the IRB of record;

(2) for any research project involving the consumption of investigational products by human subjects:

(i) all products shall be tested in accordance with Part 130 of this Title;

(ii) research participants shall be subject to all applicable laws and regulations; and

(3) for any multi-site research projects involving the consumption of investigational products by human subjects, all research sites shall be located in New York State.

(b) Prior to receiving a research license for a research project that includes human subjects, the applicant shall submit evidence of approval or exemption of the project by the identified IRB. Evidence of IRB approval or exemption may be submitted separately from the information required in this part but shall be submitted to receive a final research license.

(c) Advertisements used to recruit human subjects must be reviewed and approved by the IRB of record.

(d) An applicant or research licensee shall be prohibited from conducting any research involving human subjects unless:

(1) all aspects of its proposed research project have been reviewed and approved by an IRB that is registered and in good standing with the Office for Human Research and Protections, U.S. Department of Health and Human Services;

(2) the applicant provides copies to the Office of the IRB's determination that:

(i) the research project has been conditionally approved and is pending final approval;

(ii) the research project has been approved; or

(iii) the research project has been exempted from IRB review.

(e) A research licensee shall at all times comply with requirements for protection of human subjects, including additional safeguards necessary for vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, Title 45 of the Code of Federal Regulations Part 46, and all other relevant federal and/or state laws and regulations regarding research on human subjects, as well as all prevailing ethical standards and requirements for research involving human subjects.

(f) A research licensee shall abide by the following conditions when utilizing an informed consent form in research involving human subjects:

(1) A research licensee shall ensure informed consent from any individual participating in such research is obtained prior to the individual's participation in the research project. For studies involving minors, the research licensee shall also ensure assent from minors is obtained, as determined by the IRB of record.

(2) A research licensee shall comply with requirements for informed consent, specifically the safeguards for children in clinical investigations, under Title 21 of the Code of Federal Regulations Part 50, as part of approval and ongoing oversight and review by an IRB, including, but not limited to:

(i) sufficient opportunity to consider whether or not to participate;

(ii) information given to the participant is in a language and reading level understandable to the participant or their representative; and

(iii) the ICF shall not include any language that waives or appears to waive the participant's legal rights, nor appears to release the PI or the research licensee from liability for negligence.

(3) A copy of the signed ICF and documentation showing that the process of obtaining informed consent complied with the research licensee's IRB standards shall be available to the Office upon request.

(g) A research licensee may serve as a designated caregiver, or a designated caregiver facility, provided that:

(i) the research licensee registers as a designated caregiver or designated caregiver facility, as applicable, in accordance with Part 113 of this Title; and

(ii) the investigational products are purchased exclusively from a registered organization.

(h) PHI may be used or reported in an aggregated, nonidentifiable form.

(i) A research licensee shall not disclose the PHI of human subjects participating in the research project. Participant records shall be confidential and shall not be subject to disclosure

under the Freedom of Information Law. If necessary, and upon written request to the Office, reasonable access to participant records obtained under this part may be provided to:

(1) the Office and local law enforcement agencies for purposes of investigating and enforcing what is set forth in any applicable regulation;

(2) licensed practitioners, advanced practice registered nurses, pharmacists or other dispensaries for the purpose of providing patient care and drug therapy management;

(3) the human subject participating in the research project, but only with respect to information related to the human subject, themselves;

(4) third party payors who pay claims for a qualifying patient's medical cannabis or who have a formal agreement or contract to audit any records or information in connection with such claims;

(5) any person, the state or federal government, or any agency thereof pursuant to an order of a court of competent jurisdiction or pursuant to a search warrant; and

(6) any person upon the express written consent of the human subject and only with respect to information related to such human subject. Such written consent shall clearly identify the specific human subject and purpose for which consent is being granted, but in no event shall such information be disclosed for data capture into an EDC system.

(j) No electronic equipment utilized by a dispensary shall collect a research participant's PHI for use outside of the research project unless:

(1) the patient has consented to the release of PHI by informed consent; or

(2) the Office has requested PHI be disclosed for purposes of an inspection or investigation.

(k) No electronic equipment utilized by an approved research project shall collect PHI specific to human subjects for use outside of the research project, except that such data shall be disclosed to the Office or law enforcement for purposes of an inspection or investigation.

(l) A research licensee, key personnel, or research participant who is acting within the scope of his or her involvement in an approved research project shall not be subject to arrest or prosecution, penalized in any manner, including, but not limited to, being subject to any civil penalty or denied any right or privilege, including, but not limited to, being subject to any disciplinary action by a professional licensing board, for the use of investigational products.

(m) The provisions of subdivision (l) of this section shall not apply to:

(1) any use of investigational products that endangers the health or well-being of a person other than the research subject or a research project employee; or

(2) the use or consumption of investigational products:

(i) in a motor bus or a school bus or in any other moving vehicle;

(ii) on any school grounds unless it is the site of a research project and such use is pursuant to the terms of the approved research project; or

(iii) in any public place, unless required by an approved research project.

§ 132.7 Research Involving Animals.

(a) Prior to receiving a research license for a research project that includes animals as participants, the applicant shall submit evidence of approval of the project by the identified Institutional Animal Care and Use Committee (IACUC). Evidence of IACUC approval or exemption may be submitted separately from the information required in this Part but shall be submitted to receive a final research license.

(b) A research licensee conducting research involving animals as defined in the Animal Welfare Act, Title 7 of the US Code, section 2132(g) shall:

(1) be registered and provide proof of registration with the U.S. Department of Agricultural pursuant to the Animal Welfare Act, Title 7 of the US Code sections 2131 et seq.

(2) treat animals involved in research, humanely and consistent with all relevant federal and/or state laws and regulations, as well as all ethical standards and requirements for research on such animals.

(c) Investigational products not adequately tested pursuant to Part 130 of this Title, shall not be used in animal studies.

(d) A research licensee shall not distribute or administer investigational products to an animal unless such animal is a participant in a research project.

§ 132.8 Agricultural Research.

(a) Research licensees performing agricultural research shall:

(1) keep all areas used for the cultivation of cannabis for research purposes, including any growing, harvesting, drying, or storage areas, separate and distinct from any area designated for hemp cultivation authorized under the Department of Agriculture and Markets, if applicable;

(2) keep all areas used for the cultivation of cannabis for research purposes, including any growing, harvesting, drying, or storage areas, separate and distinct from any area designated for cannabis cultivation authorized by the Board pursuant to Article 3, 4 or 6 of the Cannabis Law, if applicable;

(3) comply with all rules, regulations, and policies applicable to a cultivator related to pesticide use and other agriculture inputs, security requirements, sanitary conditions, record keeping and tracking, and disposal of cannabis as set forth in any applicable regulation.

(b) If the research licensee intends to cultivate cannabis, the research licensee shall propose on its application to the Office a square foot canopy to accomplish the goals of the research project(s). The canopy shall only be approved if the canopy size is consistent with the scope and goals of the research project(s) being performed.

§ 132.9 Reporting Requirements.

(a) A research licensee shall maintain and shall make available all documentation related to:

(1) the proper disposal of investigational products as required by this Part; and

(2) an occurrence that is reportable, including:

(i) any investigational products cultivated, produced, or acquired for use in an approved research project;

(ii) an annual report to the Board. The Board shall review such report and determine whether the research project continues to meet the research qualifications under this Part; and

(iii) any adverse events that occur during trial participation which shall be documented by the research licensee and reported to the Office, in a manner determined by the Office, if the event becomes serious. Serious adverse events shall be reported to the Office within 24 hours from the time of awareness.

(b) A research licensee shall immediately (within 24 hours) notify appropriate law enforcement authorities and the Office upon becoming aware of any:

(1) unresolved discrepancies identified in the inventory;

(2) diversion, theft, loss, or unauthorized destruction of any investigational products; or

(3) loss or unauthorized alteration of records related to investigational products, qualifying patients, or human subjects.

(c) A research licensee reporting an incident to duly authorized law enforcement shall notify the Office by way of a signed statement, which shall be made no later than 24 hours after discovery of the event, which details:

(1) the circumstances of the event;

(2) an accurate inventory of the quantity and brand names of investigational products diverted, stolen, lost, destroyed or damaged; and

(3) confirmation that local law enforcement authorities were notified.

(d) A research licensee shall notify the Office no later than the next business day upon discovery, followed by written notification, in a manner determined by the Office, no later than ten business days, of any of the following:

(1) an alarm activation or other event that requires response by public safety personnel;

(2) a breach of security; and

(3) the failure of any required security alarm system that may be required due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours.

(e) Once the research project concludes, the research licensee shall provide a final synopsis or publication of the research project specific to the Office and the work undertaken as it aligns with the research license.

(1) Peer reviewed publications: If the research licensee intends to submit any part of their work to a peer review journal, it is acceptable to submit all papers, findings, and documentation to the Office after it is accepted for publication.

(2) No peer reviewed publications: If the research licensee does not intend to publish their work in a peer review journal, all copies of all final reports, findings, or documentation regarding the outcomes of approved research projects receiving a research license shall be submitted to the Office prior to being shared publicly.

(f) Research licensees shall submit to the Office all IRB determinations made related to a research project, including but not limited to, amendments and continuing reviews, within 10 business days of when the determination was received by the PI.

(g) Research licensees shall submit an application for an amendment to the Board prior to making a substantial change to the research project. Such application shall provide the following information, where applicable, in a manner and form as determined by the Board:

(1) updated research project information, including but not limited to:

(i) change in scope;

(ii) relocation of study site;

(iii) change in key personnel;

(iv) amount of investigational products required; and

(v) any other conditions determined by the Board;

(2) justification for why the change is necessary; and

(3) copies of updated IRB or IACUC approvals, documenting acknowledgement of the amendment, if applicable.

(h) Research licensees proposing to conduct any additional research projects under their research license shall have their research projects approved and registered by submitting the information listed in section 132.3 of this Part. The fee to add additional research projects shall be $150.

§ 132.10 Inspections and Audits.

(a) Approved research study sites, regardless of the type of premises, and all records related to a research project, including but not limited to financial statements and corporate documents, shall be subject to inspection by the Office, by the duly authorized representatives of the Office, by any peace officer acting pursuant to his or her special duties, or by any police officer.

(b) All research projects that report serious adverse events shall be subject to inspection by the Office if the events are thought to jeopardize the immediate health, safety, or well-being of the research participants.

(c) A research licensee shall make themselves, or an agent thereof, available and present for any inspection required by the Office. Such inspection may include, but is not limited to, ensuring compliance by the research licensee with all requirements of the regulations pursuant thereto, and other applicable state and local building codes, fire, health, safety, and other applicable regulations.

(d) Any inspection finding, which the Office determines jeopardizes the immediate health, safety, or well-being of the public shall be deemed a critical deficiency and shall require a corrective action to remove the immediate risk and may result in the immediate suspension of the research license. The research licensee shall submit a corrective action plan to the Office within 24 hours of notification by the Office of the critical deficiency.

(e) If the Office determines that the corrective action plan needs modification, the research licensee shall modify the plan until it is in its final form, as accepted by the Office.

(f) Upon written approval of the Office, the research licensee shall implement the corrective action plan.

(g) Nothing herein shall limit the application of any other remedies or sanctions that are available through local, state, and federal laws, and these rules.

§ 132.11 Record Retention.

(a) A research licensee shall keep and maintain records required by this Part, or any other applicable federal or state rule or regulation, including all books and electronic records located on the premises, in a readily retrievable manner for at least seven years from the date of creation, unless a shorter time is specified by the Office.

(b) Records shall account for all activities of the research licensee. Records of all investigational products received, stored, delivered, distributed, dispensed, lost, or destroyed shall be readily retrievable and made available to the Office upon request. The research licensee shall provide accountability of all investigational products to help reduce the potential for theft or diversion. Records shall be legible and accurate.

(c) Records shall be stored in a secure area and in a manner in which they are protected from debris, moisture, contamination, hazardous waste, and theft.

(d) The failure of the research licensee to comply with the requirements set forth in this section may result in fines and possible suspension or revocation of licensure.

§ 132.12 Conditions for License Suspension or Revocation.

(a) Each of the following, in and of itself, may be used to suspend or revoke a research license:

(1) The research project is:

(i) not operational within the time projected in the application or the time otherwise approved by the Board;

(ii) denied pursuant to any of the provisions in section 132.3(d) of this Part; or

(iii) not registered with the Office in association with the research license.

(2) Information provided by the research licensee was deceptive, misleading, inconsistent with the facts, false or fraudulent, or deceives or creates a misleading impression, whether directly, or by omission or ambiguity, including lack of disclosure or insufficient disclosure.

(3) The research licensee has failed to comply with any requirement of this Part or any applicable law or regulation.

(4) There has been a lack of responsible operation of the research licensee, as shown by, but not limited to, a failure to maintain research project:

(i) quality;

(ii) study design;

(iii) value and impact;

(iv) appropriate personnel;

(v) expertise;

(vi) facilities and infrastructure;

(vii) funding;

(viii) human, animal, or appropriate approvals, such as IRB or IACUC, in place to successfully conduct the research project;

(ix) inconsistency with the amount of investigational products approved to be grown or purchased for the research project's scope and goals; or

(x) other incompetent or negligent operation as determined by the Board.

(5) The financial management of the research licensee has resulted in the filing of a petition for a Court Appointee related to the financial solvency of the research site or affiliated organization.

(6) A research licensee fails to satisfy the security requirements of this Part, as applicable.

(7) The principal investigator or key personnel on the research project has a history of criminal conduct as evidenced by any criminal proceedings that resulted in conviction, guilty plea, plea of *nolo contendere*, or admission to sufficient facts in New York State.

(8) The principal investigator or key personnel on the research project has committed, permitted, aided or abetted, or conspired to commit any illegal practice(s) in the operation of any research site including, but not limited to, engaging in the diversion investigational products.

(9) The research licensee has failed to cooperate or give information to a law enforcement official acting within his or her lawful jurisdiction related to any matter arising out of conduct at any research site.

(10) The conduct or practices of the research licensee have materially diverged from the research, and the research licensee's approved research project violates what is set forth in any applicable regulation, or the rules promulgated thereto, or presents a risk to public health and safety.

(11) The research licensee approved to cultivate cannabis grew over a canopy size as approved in their research project(s).

(b) Each of the following, in and of itself, may be used to deny, suspend or revoke the registration of a research project:

(1) the research project does not meet the requirements of Cannabis Law;

(2) the proposed research is or may become a danger to public health or safety;

(3) the proposed research poses a health or safety risk to the human subjects;

(4) the research licensee has received a denial from an IRB or IACUC, if applicable;

(5) the research licensee failed to be registered with the U.S. Department of Agriculture for a research project involving animals, if applicable;

(6) the research licensee has not provided:

(i) sufficient justification for the scientific value or validity of the proposed research project;

(ii) justification for the canopy sizes for the research study;

(iii) valid justification for the use or disposal of the research licensee's excess cultivated cannabis plant(s) for the research study;

(7) the research licensee becomes unqualified to conduct the proposed research project;

(8) the research protocol, funding, or other resources become insufficient to perform the proposed research project;

(9) any information provided is false, misleading, or inconsistent with the facts presented;

(10) the research licensee failed to supply information and/or documents requested by the Office within the deadline imposed by the Office;

(11) research licensee does not meet the requirements for the research project as set forth by this Part; or

(12) any other reason as determined by the Board.

(c) The following shall authorize the Office to enforce and impose fees and fines for violations pursuant to Part 133 of this Title against the affiliated organization as described in section 132.3(a)(7) of this Part if it is discovered that the affiliated organization behaved in the following manner regarding a cannabis research license's registered research project:

(1) the proposed research is or may become a danger to public health or safety as a direct result of the affiliated organization's behavior;

(2) the proposed research became a health or safety risk to the human subjects as a direct result of the affiliated organization's behavior;

(3) information provided by the affiliated organization was deceptive, misleading, inconsistent with the facts, false or fraudulent, or deceives or creates a misleading impression, whether directly, or by omission or ambiguity, including lack of disclosure or insufficient disclosure; or

(4) the affiliated organization's actions have directly caused the research licensee to violate any requirement of this Part or any applicable law or regulation.

(d) Failure by the research licensee to comply with any requirements in this Part may result in suspension, revocation, and or a civil penalty in accordance with all applicable rules and regulations of the Office and pursuant to section 133 of the Cannabis Law.

§ 132.13 Disposal

(a) The disposal of cannabis shall mean that the cannabis has been rendered unusable, except for stalks, stems, fan leaves, root balls, and soil media which do not have to be rendered unusable prior to disposal.

(b) Research licensees shall dispose of any investigational products that are outdated, damaged, deteriorated, contaminated, or otherwise deemed not appropriate for usage or any plant-based waste produced.

(c) Research licensees shall dispose of liquid and chemical waste in accordance with applicable federal, state, and local laws and regulations.

(d) Research licensees shall, at the conclusion of the research, dispose of all remaining investigational products subject to the research licensees approved research project. Unless otherwise approved by the Office, a research project will be deemed concluded on its estimated end date, as provided in the approved research licensee's application, or the license expiration date, whichever occurs first. The research licensee shall ensure remaining investigational products are disposed of in conformance with this Part.

(e) Research licensees shall ensure the return of all investigational products by research participants by the conclusion of the research project for disposal.

(f) Research licensees shall maintain records of disposal, which shall include:

(1) the type of plant material being disposed, if the material is a by-product of the processing or manufacturing process;

(2) investigational products being disposed, if a finished product;

(3) the weight of the disposed material, the number of plants, or in the case of a finished product, the quantity of the disposed product for each research project and in total as of the date of the reporting of the materials in this section; and

(4) the signatures of at least two (2) research licensee staff members who witnessed the disposal.

(g) All unused investigational products shall be recorded as waste in the research licensee's inventory tracking system.

§ 132.14 Referenced Materials

(a) Regulations included in Part 132 of this Title contain references to documents for information as to the standards to be met or guidelines and methodologies to be used in meeting the requirements of specific regulations. In addition, copies of referenced materials are available for public inspection and copying at the Albany office of the New York State Department of State.

Table 1

Regulation	**Referenced Material**	**Availability**
9 NYCRR **Part/sec./etc.**	**CFR (Code of Federal Regulations) or other**	
§ 132.1(o)	Public Health Law Article twenty-four-A	****
§ 132.1(o)	42 USC § 289(a)	**

§ 132.1(o); § 132.6(e)	45 CFR Part 46	*
§ 132.1(p)	7 USC §2143(b)	*
§ 132.1(p)	9 CFR Part 2	*
§ 132.3(h)	Penal Law §210.45	***
§ 132.6(f)(2)	21 CFR Part 50	*
§ 132.7(b)	7 USC § 2132(g)	**
§ 132.7(b)(1)	7 USC §§ 2131 et seq	**

* Any printed editions of the *Code of Federal Regulations* (CFR) can be obtained by calling the Superintendent of Documents, U.S. Government Printing Office, at (202) 512-1800. Electronic copies of CFR sections may also be obtained at Government Printing Office (GPO) which contains the most recent revisions, can be searched directly at: https://www.ecfr.gov/

** Any printed editions of the *United States Code* (USC) can be obtained by calling the Superintendent of Documents, U.S. Government Printing Office, at (202) 512-1800. Electronic copies of CFR sections may also be obtained at Government Printing Office (GPO) which contains the most recent revisions, can be searched directly at: https://uscode.house.gov/

*** Electronic copies of New York State Law, including but not limited to, Public Health Law, Vehicle and Traffic Law, Education Law, Mental Hygiene Law, Social Services Law and Penal Law may be searched directly under the Laws tab (which drops down to "Laws of New York") at: http://public.leginfo.state.ny.us/lawssrch.cgi?NVLWO: