**Pennsylvania Department of Health**

**Bureau of Medical Marijuana**

**Application for Certification of an**

**Academic Clinical Research Center**

**APPLICATION SUBMISSION DEADLINE**

**May 12, 2024**

**If you have any questions, please contact:**

**The Pennsylvania Department of Health**

**Bureau of Medical Marijuana**

**RA-DHMMRCOMPLIANCE**@pa.gov

**Definitions**

**The following terms have the following meanings, unless the context clearly indicates otherwise:**

*Academic Clinical Research Center (ACRC)*— An accredited medical school within this Commonwealth that operates or partners with an acute care hospital licensed and operating within this Commonwealth that has been approved and certified by the department to enter into a contract with a clinical registrant.

*Accredited medical school*— An institution located within this Commonwealth that is accredited by the Liaison Committee of Medical Education or the Commission on Osteopathic College Accreditation or has gained pre-accreditation or provisional accreditation so that the institution is authorized to enroll students and is affiliated with an accredited institution of higher education located within this Commonwealth.

*Acute care hospital*—A facility having an organized medical staff that provides equipment and services primarily for inpatient medical care and other related services to persons who require definitive diagnosis or treatment, or both, for injury, illness, pregnancy or other disability and is licensed by the Department to operate as a hospital in this Commonwealth under the Health Care Facilities Act (35 P.S. §§ 448.101—448.904b) and the regulations promulgated thereunder.

*Clinical registrant*—an entity that:

1. Holds a permit as both a grower/processor and dispensary;
2. Has a contractual relationship with an ACRC under which the ACRC or its affiliated provides advice to the entity, regarding, among other areas, patient health and sacety, medical appliatoins and dispensing and amanagment of controlled substanctsa; and
3. Is approved by the Department.

*Certified ACRC*—An ACRC that has applied for and has been certified by the Department to enter into a research contract with an approved clinical registrant.

*Research contract*—A written agreement between an approved clinical registrant and a certified ACRC that contains the responsibilities and duties of each party with respect to the research program that the approved clinical registrant and the ACRC intend to conduct under this chapter and under which the ACRC will provide medical advice to the approved clinical registrant regarding, among other areas, patient health and safety, medical applications, and dispensing and management of controlled substances. This term shall include a letter of intent to enter into an agreement for purposes of a clinical registrant application.

*Research program*—Research on the therapeutic or palliative efficacy of medical marijuana limited to the serious medical conditions defined by the act and this part [28 Pa. Code Part IXa].

**Generally**

An ACRC must be approved and certified by the Department of Health (Department) before the ACRC may contract with a clinical registrant. The accredited medical school that is seeking approval from the Department to be certified as an ACRC must provide all demographic information, including information on the individual who will be the primary contact for the ACRC during the Department’s review of the application. The accredited medical school must also provide all information required by the Department for any licensed acute care hospital that it will operate or partner with during the time it may be certified as an ACRC by the Department.

The Department will post a list containing the name and address of each certified ACRC at www.medicalmarijuana.pa.gov and publish the list in the *Pennsylvania Bulletin.*

**Completing the Application**

All sections of the Application for Certification of an Academic Clinical Research Center must be completed. The application and any supporting documentation must be saved as PDF files on a single USB drive in accordance with the following file naming format: medical school name - ACRC*.pdf.*

 Example: ABC Medical School-ACRC.pdf

Please make sure the Application is properly signed and dated. A signature may be scanned and provided electronically in a PDF file. **A hard copy of any affidavit, with original signatures, must be included with the USB drive.**

**Submitting Your Application**

**Applications must be postmarked no later than May 12, 2024 and mailed to the following address:**

Bureau of Medical Marijuana

Attn: PCARD

Department of Health

Room 628, Health and Welfare Building

625 Forster Street

Harrisburg, PA 17120

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| **Accredited Medical School General Information** |
| **Medical School Name:** |
| **Business Address:** |  |
| **City, State and Zip Code:** |  |
| **Telephone Number:** |  |
| **Applicant’s State and Federal Tax ID Numbers:** |  |
| **Business Email Address:** |  |
| **Accrediting Body: (check the appropriate box below)**[ ]  **Liaison Committee of Medical Education**[ ]  **Commission on Osteopathic College Accreditation** |

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| **Primary Contact for the Accredited Medical School** |
| **Name:** |
| **Title:** |
| **Address:** |
| **City, State and Zip Code:** |  |
| **Telephone Number:** |  |
| **Business Email Address:** |

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| **Acute Care Hospital Information** |
| **Hospital Name:** |
| **Health System Name (if applicable):** |
| **Business Address:** |  |
| **City, State and Zip Code:** |  |
| **Telephone Number:** |  |
| **Business Email Address:** |  |
| **DOH Hospital License Number:** |  |

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| **Affidavit of Academic Clinical Research Center** |
| Sign and attach one of the two affidavits provided with the Application for Certification of an Academic Clinical Research Center. **(Check the appropriate box below)**[ ] An affidavit disclosing any payments to the accredited medical school or any of its affiliates made by a person with whom the accredited medical school intends to enter into a research contract for purposes of operating as an approved clinical registrant or by any principal or financial backer of the person, up to and including the date of submission of this Application. The affidavit must include the amount and purpose of each payment made.[ ] An affidavit stating that no payments to the accredited medical school or any of its affiliates have been made by a person with whom the accredited medical school intends to enter into a research contract for purposes of operating as an approved clinical registrant or by any principal or financial backer of the person, up to and including the date of submission of this Application.  |

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| **Signature Section** |
| I hereby certify that I am authorized to sign this Application for Certification of an Academic Clinical Research Center on behalf of the accredited medical school. The information contained herein is true and correct, and there is no misrepresentation, falsification or omissions in this Application.I also certify that the acute care hospital named in this Application has provided information to verify that it holds a valid hospital license with the Department of Health. A false statement made in this Application is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation). |
| Signature: | Date: |
| Printed Name:A photocopy or other electronic version of this document shall be accepted as an original signature.  | Title: |

**Please Note:** Charitable contributions that are part of a history of giving to the applicant established 1 year or more prior to the effective date of the Medical Marijuana Act (35 P.S. §§ 10231.101-10231.2110) are not applicable.

**Affidavit of Academic Clinical Research Center (Payments)**

State of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

County of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The undersigned,\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, hereby certifies the following:

The following payments to the accredited medical school named in the attached Application for Certification of an Academic Clinical Research Center, or any of the accredited medical school’s affiliates, have been made by the following person(s) with whom the accredited medical school intends to enter into a research contract for purposes of operating as an approved clinical registrant or by any principal or financial backer of the person, up to and including the date of submission of this Application.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name of clinical registrant applicant**  | **Role (principal, financial backer, etc.)** | **Business name and address** | **Amount of payment** | **Date of payment**  | **Purpose of Payment** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

I hereby certify that I am authorized to execute this affidavit on behalf of the applicant and that the information contained herein is true and correct and that there is no misrepresentation, falsification or omissions in this affidavit. I acknowledge that any false or misleading statement or omitted information is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

 Signature of Affiant and Title Date

Sworn to and subscribed before me this \_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_, 20\_\_\_\_.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Notary Public

MY COMMISSION EXPIRES:

**Affidavit of Academic Clinical Research Center (No Payments)**

State of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

County of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The undersigned,\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, hereby certifies the following:

No payments to the accredited medical school named in the attached Application for Certification of an Academic Clinical Research Center, or any of the accredited medical school’s affiliates, have been made by any person(s) with whom the accredited medical school intends to enter into a research contract for purposes of operating as an approved clinical registrant or by any principal or financial backer of the person, up to and including the date of submission of this Application.

I hereby certify that I am authorized to execute this affidavit on behalf of the applicant and that the information contained herein is true and correct and that there is no misrepresentation, falsification or omissions in this affidavit. I acknowledge that any false or misleading statement or omitted information is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

 Signature of Affiant and Title Date

Sworn to and subscribed before me this \_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_, 20\_\_\_\_.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Notary Public

MY COMMISSION EXPIRES: