Pennsylvania Department of Health
Office of Medical Marijuana

Application for Certification of an Academic Clinical Research Center

APPLICATION DUE DATE: MAY 3, 2018

If you have any questions, please contact:
The Pennsylvania Department of Health
Office of Medical Marijuana
RA-DHMEDMARIJUANA@pa.gov

OFFICE OF MEDICAL MARIJUANA
APPLICATION FOR CERTIFICATION OF
AN ACADEMIC CLINICAL RESEARCH CENTER
(28 Pa. Code § 1210.25)

Definitions

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

ACRC—An accredited medical school in this Commonwealth that operates or partners with an acute care hospital licensed and operating in this Commonwealth.

Accredited medical school—An institution that is:
- (i) Located in this Commonwealth.
- (ii) Accredited by the Liaison Committee of Medical Education or the Commission on Osteopathic College Accreditation.

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.

Approved clinical registrant—an entity that applied for and received the approval of the Department to do all of the following:
- (i) Hold a permit as both a grower/processor and dispensary.
- (ii) Enter into a research contract with a certified ACRC.

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.

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 for 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.*

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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.

Submitting Your Application

Applications must be postmarked no later than MAY 3, 2018 and mailed to the following address:

Office of Medical Marijuana
Attn: Field Operations - ACRC
Department of Health
Room 628, Health and Welfare Building
625 Forster Street
Harrisburg, PA 17120

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Application for Certification of an Academic Clinical Research Center

Accredited Medical School General Information	
Medical School Name:	
Business Address:	
City, State and Zip Code:	
Telephone Number:	
Business Email Address:	
Accrediting Body: ☐ **Liaison Committee of Medical Education** ☐ **Commission on Osteopathic College Accreditation**	

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

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. (See the **notation** below and check the appropriate box.)

☐ 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.

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.

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APPLICATION FOR CERTIFICATION OF
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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:

A photocopy, facsimile or other electronic version of this document shall be accepted as an original signature.

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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:

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