**Pennsylvania Department of Health**

**Office of Medical Marijuana**

**Application for Approval of a**

**Clinical Registrant**

**APPLICATION DUE DATE: NOVEMBER 8, 2018**

**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.

*Applicant*—A person who submits an application to the Department to become an approved clinical registrant.

*Approved clinical registrant*—an entity that applied for and received the approval of the Department to do all of the following:

1. Hold a permit as both a grower/processor and dispensary.
2. 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.

*Institution of higher education*—A community college, State-owned institution, State-related institution, or private college or university approved by the Department of Education.

*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 certified ACRC intend to conduct under this chapter and under which the certified 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.

*Research program*—Research on the therapeutic or palliative efficacy of medical marijuana limited to the serious medical conditions defined by the act and the temporary regulations.

**Generally**

An applicant must be approved by the Department of Health (Department) before the clinical registrant can hold a grower/processor and dispensary permit and execute a research contract to implement a research program. An applicant must also provide all information required by the Department for the certified ACRC that will contract with the applicant during the time it may be approved as a clinical registrant by the Department. A list containing the name and address of each certified ACRC by the Department can be found at www.medicalmarijuana.pa.gov and in the *Pennsylvania Bulletin.* The applicant may only choose one certified ACRC for the applicant’s Application for Approval of a Clinical Registrant.

An applicant must indicate in the application whether it currently holds a valid grower/processor and/or dispensary permit under sections 601—616 of the act (35 P.S. §§ 10231.601—10231.616). An applicant that currently holds one, or both, of these permits must file with its Application for Approval of a Clinical Registrant a request for conversion of the existing permit(s). If an applicant does not hold one, or both, of these permits, it must complete and include with the Application for Approval of a Clinical Registrant an initial permit application for either a grower/processor permit, a dispensary permit, or both. Failure to file the initial permit application, or both initial permit applications where necessary, will result in the Department rejecting the applicant’s Application for Approval of a Clinical Registrant.

**Completing the Application**

An applicant seeking approval from the Department must complete all sections of the Application for Approval of a Clinical Registrant, including information on the individual who will be the primary contact for the applicant during the Department’s review of the clinical registrant application.The application and any required supporting documentation must be saved as PDF files on a single USB drive in accordance with the following file naming format: medical school name - CR*.pdf.*

 Example: ABC Clinical Registrant-CR.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 NOVEMBER 8, 2018, and mailed to the following address:**

Office of Medical Marijuana

Attn: Field Operations – Clinical Registrant

Department of Health

Room 628, Health and Welfare Building

625 Forster Street

Harrisburg, PA 17120

**Application for Approval of a Clinical Registrant**

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| **Section 1. Clinical Registrant General Information** |
| **Applicant’s Name:** |  |
| **Business Address:** |  |
| **City, State and Zip Code:** |  |
| **Telephone Number:** |  |
| **Name of Primary Contact:** |  |
| **Primary Contact Telephone Number:** |  |
| **Primary Contact Business Email Address:** |  |
| **Applicant’s State and Federal Tax ID Numbers:** |  |
| **Does the applicant currently hold either of the following permits issued by the Office of Medical Marijuana? (Check the appropriate box or boxes below)**[ ]  **A Grower/processor permit**[ ]  **A Dispensary permit**[ ]  **The applicant does not hold a grower/processor permit or a dispensary permit** |

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| **Section 2. Certified ACRC Information** |
| **Name of Certified ACRC:** |  |
| **Address:** |  |
| **City, State and Zip Code:** |  |
| **Telephone Number:** |  |
| **Name of ACRC Primary Contact:** |  |
| **Primary Contact Telephone Number:** |  |
| **Primary Contact Business Email Address:** |  |

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| **Section 3. Institution of Higher Education Information** |
| Does the applicant intend to partner with an institution of higher education to participate in any research project? [ ]  **Yes**  [ ]  **No. (If yes, please complete the following information.)**   |
| **Institution’s Name:** |  |
| **Business Address:** |  |
| **City, State and Zip Code:** |  |
| **Telephone Number:** |  |
| **Name of Primary Contact:** |  |
| **Primary Contact Telephone Number:** |  |
| **Primary Contact Business Email Address:** |  |

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| **Section 4. Affidavit of Capital Sufficiency for a Clinical Registrant** |
| Sign and attach the affidavit stating that the applicant meets the capital requirements set forth in §1211.24 (relating to capital requirements). Execute the affidavit and save as a PDF file. **Also include a hard copy of the affidavit, with the original signature, with the USB drive.**  |

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| **Section 5. Release Authorization** |
| Sign and attach the Release Authorization as set forth in §1211.24 (relating to capital requirements). Execute the affidavit and save as a PDF file. **Failure to provide a release will result in the rejection of the application for approval of a clinical registrant.** |

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| **Section 6. Payment to a Certified ACRC** |
| Sign and attach one of the two affidavits provided with the Application for Approval of a Clinical Registrant. **(Check the appropriate box below.)** Execute the affidavit and save as a PDF file. Also include a hard copy of the affidavit, with the original signature, with the USB drive. **☐**  An affidavit disclosing any payments made by the applicant, or by a principal or financial backer of the applicant, to a certified ACRC or to any affiliates of a certified ACRC, up to and including the date of the submission of the application. The affidavit must include the amount and purpose of each payment made.[ ] An affidavit stating that no payments have been made by the applicant, or by a principal or financial backer of the applicant, to a certified ACRC or any affiliates of a certified ACRC, up to and including the date of the submission of the application.  |

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| **Section 7. Research Contract with a Certified ACRC** |
| Attach a signed copy of the research contract between the applicant and the certified ACRC. If the applicant does not have a signed research contract with a certified ACRC at the time of filing the Application for Approval of a Clinical Registrant, the applicant may include a Letter of Intent signed by both the applicant and the primary contact for the certified ACRC. **The Letter of Intent must state that a research contract will be executed between the applicant and the certified ACRC and will be provided to the Department before the Department will approve the Application for Approval of a Clinical Registrant.**  |

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| **Section 8. Research Projects**  |
| Attach a description of each research program the applicant and the certified ACRC intend to conduct. Include the name and location of each dispensary that will be participating in the research program and dispensing medical marijuana for the research program.  |

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| **Section 9. Request for Conversion of an Existing Permit** |
| **Please affirm one of the following statements by checking the appropriate box.** [ ]  **The applicant currently holds** a grower/processor permit or a dispensary permit, or both, under sections 601—616 of the act (35 P.S. §§ 10231.601—10231.616) and has completed and attacheda Request for Conversion of an Existing Permit for any permit it holds sections 601—616 of the act. [ ]  **The applicant does not currently hold** a grower/processor permit or a dispensary permit, or both, under sections 601—616 of the act (35 P.S. §§ 10231.601—10231.616). |

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| **Section 10. Application for a Grower/processor and Dispensary Permits** |
| An applicant that does not hold a grower/processor permit or a dispensary permit, or both, under sections 601—616 of the act (35 P.S. §§ 10231.601—10231.616), shall include in its Application for Approval of a Clinical Registrant one or both of the following permit applications. **(Please check the appropriate box or boxes pertaining to the initial permit application that is being filed with the Application for Approval of a Clinical Registrant.)** [ ] An initial permit application for a grower/processor permit under Chapters 1141 and 1151 (relating to general provisions; and growers/processors).[ ] An initial permit application for a dispensary permit under Chapter 1141 and Chapter 1161 (relating to dispensaries).[ ] The applicant is not required to file an initial application for grower/processor or dispensary permit. |

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| **Section 11. Signature Section** |
| I hereby certify that I am authorized to sign this Application for Approval of a Clinical Registrant. The information contained herein is true and correct, and there are no misrepresentations, falsifications or omissions in this Application.I acknowledge that 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: |

**Section 4:** Affidavit of Capital Sufficiency for a Clinical Registrant

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

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

The undersigned,\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, hereby certifies that the Applicant named in this Application for Approval of a Clinical Registrant has at least $15,000,000 in capital on deposit with one or more financial institutions, as follows (capital may include cash or securities, real estate, or other assets):

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of Capital** | **Source of Capital** | **Total Value of Capital** | **Value not encumbered by debt or other obligations** | **If on deposit, name and address of financial institution** | **If on deposit, account number** |
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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 are no misrepresentations, falsifications or omissions in this affidavit. I acknowledge that any false or misleading statement or intentionally 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\_\_\_\_.

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Notary Public

**Section 5: RELEASE AUTHORIZATION**

TO: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (Do not write above this line – For Department of Health Only)

FROM: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Applicant’s Name

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, by and on behalf of the undersigned applicant, have filed a permit application with the Pennsylvania Department of Health (“Department”). I certify that I am authorized by the applicant to submit this Release Authorization on its behalf and to bind the applicant to all provisions within this Release Authorization. I understand that the applicant is seeking the granting of a privilege and acknowledge that the burden of proving the applicant’s qualifications and suitability for a favorable determination is at all times the burden of the applicant.

I understand that a background investigation may be conducted by the Department pursuant to its statutory duty to investigate the character, honesty, integrity and suitability of myself and any entity with which I am associated. I further understand and agree that I am voluntarily executing this Release Authorization to expressly authorize and permit the Department to obtain any and all information it deems necessary, and accept any risk of adverse public notice, embarrassment, criticism, or other action or financial loss which may result from action with respect to this permit application.

The rights and powers herein are granted to facilitate the background investigation being conducted by the Department at my request and on behalf of the applicant and is not otherwise intended to create or establish a legal or fiduciary relationship between the Department, its agents and employees, and me. I hereby acknowledge that no such relationship exists.

1. I hereby authorize and request every person, firm, company, corporation, board, association or institution of any kind, and every Federal, state or local government entity, including but not limited to every court, law enforcement agency, criminal justice agency or probation department, without exception, both foreign and domestic, to whom this Release Authorization is presented having any knowledge, information, documents, forms, photographs, computer files, accounts, ledgers or other items about, relating to or concerning the applicant and to fully discuss with and answer any inquiry made by any duly authorized investigator of the Pennsylvania Department of Health.
2. If this Release Authorization is presented to any brokerage firm, bank, savings and loan, or other financial institution or officer of same, I hereby authorize and request any and all documents, records or correspondence pertaining to the applicant, including but not limited to past loan information, notes, checking account records, savings deposit records, safe deposit box records, passbook records and general ledger folio sheets.
3. I hereby authorize an agent of the Department to obtain and review copies of any and all documents, records or correspondence pertaining to myself and the applicant, and I hereby authorize any Federal, state or municipal agency or body, law enforcement agency or criminal justice agency or department, tax agency or authority, regulatory agency, authority or body, to make full and complete disclosure of any and all information and documents including, but not limited to, documents and information otherwise privileged or not subject to public disclosure, as well as other information on file or available concerning the applicant.
4. This Release Authorization extends to the review and copy of any information protected by law or contact from disclosure, privilege or obligation.
5. I do for the applicant, as well as for myself, my heirs, executors, administrators, successors and assigns, hereby release, remise, exonerate and forever discharge the Department, its members, agents and employees, the Commonwealth of Pennsylvania and its instrumentalities, and any agents and employees thereof, from any and all liabilities including but not limited to all manner of actions, causes of action, suits, debts, judgments, executions, claims, and demands whatsoever, known and unknown, in law or equity, which exist now or in the future against those entities and persons other than relating to a willfully unlawful disclosure or publication of material or information acquired during my investigation.
6. I do for the applicant, as well as for myself, my heirs, administrators, successors and assigns, hereby release, remise, exonerate and forever discharge every person, firm, company, corporation, board, association or institution of any kind, and every Federal, state or local government entity, including but not limited to every court, law enforcement agency, criminal justice agency or probation department, without exception, both foreign and domestic, to whom this request is presented, and any agents or employees thereof, from any and all liabilities, including but not limited to all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known or unknown, in law or equity, which exist now or in the future against those entities and persons to whom this request is presented, and any agents or employees thereof, arising out of or by reason of the furnishing or inspection of documents, records or other information released in compliance with a request made pursuant to, or as a result of, having been presented with, this Release Authorization.
7. The applicant agrees to indemnify and hold harmless the Department, its officials and employees and every person, firm, company, corporation, board, association or institution of any kind, and every Federal, state or local government agency, to whom this request is presented and form and against all claims, damages, losses, and expenses including reasonable attorneys’ fees arising out of or by reason of, the acts permitted and provided for in the Release Authorization.
8. I agree that a reproduction of this request by photocopy, facsimile or other similar process shall be for all intents and purposes as valid as the original.

IN WITNESS WHEREOF, I have executed this Release on this \_\_\_\_\_ day of \_\_\_\_\_\_\_\_, 2018.

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

 Authorized Signatory

STATE OF \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ )

 )

COUNTY OF )

On this \_\_\_\_\_ day of \_\_\_\_\_\_\_\_, 2018, before me, a Notary Public, personally appeared \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (known to me or satisfactorily proven) to be the person whose name is subscribed in this Release, and acknowledged that he/she executed the same for the purposes herein contained.

IN WITNESS THEREOF, I hereunto set my hand and official seal.

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

 Notary Public

MY COMMISSION EXPIRES:

**Section 6: Affidavit of Clinical Registrant (Payments)**

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

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

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

The following payments have been made by the Applicant, or by a principal or financial backer of the Applicant, to a certified ACRC or to any affiliates of a certified ACRC, 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 of ACRC** | **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:

**Section 6: Affidavit of Academic Clinical Research Center (No Payments)**

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

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

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

No payments to certified ACRC, or to any affiliates of a certified ACRC, 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 are no misrepresentations, falsifications or omissions in this affidavit. I acknowledge that any false or misleading statement or intentionally 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:

**Section 9: REQUEST FOR CONVERSION OF AN EXISTING PERMIT**

**(28 Pa. Code § 1211.28)**

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| **Medical Marijuana Organization (MMO)** |
| Name of MMO: | Permit Number: |
| Primary Contact: | Email Address: |
| Phone Number: | Operational Date: |
| **Facility Information** |
| Check the type of facility.  |
| Grower/processor  Dispensary  |
| Provide the facility’s name, address and municipality/county information.  |
| Name of Facility: |
| Street Address: |
| City, Zip Code: |
| Municipality and County: |
| Check the type of facility. |
| Grower/processor  Dispensary |
| Provide the facility’s name, address and municipality/county information.  |
| Name of Facility: |
| Street Address: |
| City, Zip Code: |
| Municipality and County: |
| **Conversion Information****The medical marijuana organization shall check off each of the statements below and attach any applicable documentation as required.**  |
|  [ ]  The medical marijuana organization is requesting to convert an existing grower/processor permit, dispensary permit, or both, issued for the above facility under sections 601—616 of the act.  [ ]  The medical marijuana organization has attached a written plan for converting an existing grower/processor, an existing dispensary permit, or both, issued under sections 601—616 of the act that includes the following information:* The process the medical marijuana organization will use to notify, prior to the conversion, any recipient of medical marijuana products or services from the permittee at its current location.
* The process the medical marijuana organization will use to notify, prior to the conversion, any entity holding contracts with the permittee, to purchase seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products or medical marijuana services from the permittee at its current location. The process must include how the applicant plans to terminate these contracts.
* A statement that the medical marijuana organization, as an approved clinical registrant will work with the Department to use the electronic tracking system under § 1211.33 (relating to dispensing and tracking medical marijuana products) to track any seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products or medical marijuana services under the control of the approved clinical registrant.
 |
| **Conversion Information (cont’d)****The medical marijuana organization shall check off each of the statements below.**  |
| [ ]  The medical marijuana organization agrees that until the Request for Conversion of an Existing Permit is approved by the Department, the medical marijuana organization shall not dispense or offer to dispense, as a clinical registrant, any medical marijuana, medical marijuana products or medical marijuana services at any dispensary location until: (1) The Department has determined that the medical marijuana organization, as an approved clinical registrant, is ready, willing and able to operate as a grower/processor and a dispensary. (2) The medical marijuana organization, as an approved clinical registrant, demonstrates to the satisfaction of the Department that it will be able to begin an approved research program within 6 months following the date the Department determines the approved clinical registrant's grower/processor and dispensary to be operational. |
| [ ]  The medical marijuana organization agrees that the Department may enter and inspect the site and facility listed above at any time before approving the medical marijuana organization’s conversion plan. |
| [ ]  Upon the Department’s approval of the medical marijuana organization's plan to convert the existing permit, the medical marijuana organization shall surrender to the Department the grower/processor permit or dispensary permit, or both, previously issued for the above site under sections 601—616 of the act. |
| **Attestation** |
| I acknowledge that a false statement made by me in this document is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Printed Name Title in MMO |