**Title:** Clinical Site Certification Approval Email Template

**General Description & Purpose:** This is the template for the Clinical Site Certification Approval Email which is sent by the MCC Study team to a METRC clinical site upon Certification Approval.

**Instructions:** When appropriate, a member of the MCC Study Team sends the approval notice below via email to the clinical site receiving Certification Approval. The sections of the template noted in red should be updated to reflect the name of the institution, individual, or study, as necessary.

**Distribution List:**

- To → PI of the site receiving Clinical Site Certification Approval
- CC → All other clinical site study team members who are being certified, the Overall PI of the study, all members of the MCC Study Team including the MCC PI, the MCC REDCap User Administrator

**Subject Line**: METRC Clinical Site Certification Approval

**Email Body:**

Dear <<PI Name>>,

Congratulations! Your site has successfully demonstrated readiness to implement the <<Study Acronym/Short Name>> Study.  This message serves as your official Clinical Site Certification Approval from the METRC Coordinating Center. Effective immediately, your site is permitted to initiate screening and enrollment activities per the study protocol.

The following members of your study team are certified, as of today, to conduct the study activities specified based on their study role and on the documentation submitted in support of Certification:

| Name | Email | Study Role | Study Activities | REDCap Access (Y/N) |
|---|---|---|---|---|
| *Example:* John Doe | John.Doe@email.org | PI | 1,2,3,5,6 | Y |
| *Example*: Jane Doe | Jane.Doe@email.org | PT | 5, 8 | N |
|  |  |  |  |  |

Study Roles:
- Principal Investigator (PI)
- Associate Investigator (AI)
- Research Coordinator (RC)
- Research Assistant (RA)
- Physical Therapist (PT)
- Other: <<Specify>>

Study Activities Key:
1. Screening
2. Consent & Enrollment
3. Data Collection
4. Data Entry
5. Administration of the Study Intervention
6. Participation in Follow-up Visits

7. Study Surgeries
8. Physical Therapy
9. Study Sample Processing
10. Study Sample Shipping

The MCC User Administrator for REDCap, <<REDCap User Admin Name>> (cc'ed here), will provide <<Study Acronym/Short Name>> REDCap access to the individuals specified in the above table.  These individuals will then receive a separate email, automatically generated by REDCap, within a few days; that email will contain instructions for activating REDCap user privileges.

Please file a copy of this email approval notice in your <<Study Acronym/Short Name>> Regulatory Binder. Should your site choose to use it as such, the above table may also serve as your Delegation of Authority Log; your site should use a log which is compliant with your institutional IRB's policy regarding Delegation of Authority Logs.

Please Note: If new individuals join your study team, they must be certified by the MCC prior to initiating study activities.
- You should notify the MCC of any new study team members ASAP. Make sure to submit the required certification materials for those individuals along with your notice.
- After verifying all required documentation, the MCC will then *Reply All* to this initial approval message and will include a new table (like the one above), this time listing the newly certified individuals. The certification approval date for those new study team members will be the date that the *Reply All* message is sent.
- This process will be repeated any time there are new study team members to certify; each time the most recently sent certification-approval-related message will be the starting point. This will allow for a complete history of all certification approval activity (initial approval and new study team member approvals) to be maintained in one email chain.

Please let us know if you have any questions as you initiate study implementation- we are here for you! As a reminder, all <<Study Acronym/Short Name>> Study Materials are posted to the Study Materials section of the METRC website.

We thank you in advance for your contributions to this important study!

<<MCC Study Team Member Name>>

<< MCC Study Team Member Standard Signature Block>>