Title: Provisional Certification Approval Email Template

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

Instructions: When appropriate, a member of the MCC Study Team sends the provisional approval notice below via email to the clinical site receiving Provisional 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: Provisional 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 Provisional Site Certification Approval from the METRC Coordinating Center. Effective immediately, your site is permitted to initiate screening and enrollment activities per the study protocol.

You are provisionally approved to enroll n participants; once you enroll this number of participants, you must temporarily suspend screening and enrollment. The MCC Study Team will conduct a thorough, prospective review of your initial cases and will provide you with detailed feedback.

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