METRC Policy & Procedure Manual

Title: Clinical Site Certification Form Template

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General Description & Purpose: This is a template which is intended to be used a starting point for developing the Clinical Site Certification Form for a given METRC Study. The MCC Study team updates this form prior to initial study trainings and posts the form to the relevant Study Materials section of the METRC website. The Clinical Site Certification Form, once made study-specific and completed by a site seeking certification approval, is intended to serve as the official record of critical information regarding the participating site including: expectations for screening and enrollment, plans for implementing for critical or logistically complex components of the study protocol, it's listing of study team members, etc.

<<Study Acronym/Short-Name>> Clinical Site Certification Form

METRC Site Instructions: Your site must receive Clinical Site Certification Approval prior to initiating any study activities. This form is an important component of the documentation you will submit to the MCC, demonstrating your site and study team's preparedness to conduct the <<Study Acronym/Short-Name>> study. Please do not hesitate to contact the MCC Study Team should you have any questions or concerns as you work to complete this form. By the time this form is submitted to the MCC, your team should have solid plans for implementing all critical or logistically complex components of the study protocol.

The completed form should be submitted by email to: <<Study Manager Name and Email Address>>. Please also consult the Clinical Site Certification Documentation Checklist to ensure that all other required documentation has been submitted.

I. Clinical Center Information

Clinical Site Name:

Name of Study Principal Investigator:

II. Administrative and Approval Information

Approval Dates

Date of local or single IRB approval:

Date of local IRB or single IRB expiration:

Study Documents

Version/Date of the most recently approved protocol:

Version/Date of the most recently approved consent form(s):

Version/Date of the most recently approved CRFs (if applicable):

Expected Screening & Enrollment

Expected number of patients screened per month:

Expected number of patients enrolled per month:

III. Study-Specific Training or Documentation Requirements

MCC Study Teams: In this section, you should ask sites to provide information or verification that they have completed all required study-specific trainings and provided all study specific documentation. Please also be sure to add any required documentation to the Clinical Site Certification Documentation Checklist.

Examples of trainings or certifications you may ask about:

- *Completion Date for Training on Outcome Measures*
- *Completion Date for Training provided to RC by PT on how to deliver intervention instructions*
- *Verification that study team members who will be responsible for handling, processing, or shipping study samples, have received the necessary training certificates (add certificates to certification documentation checklist)*

IV. Study Implementation Plans

MCC Study Teams: In this section, you should ask sites to provide descriptions of their implementation plans pertaining to critical or logistically complex components of the study protocol. Depending on the study, you may wish to ask for summary statements in this section and separately ask for the site to submit complete local SOPs which more thoroughly describe their plans (in which case, be sure to add the SOPs to the Clinical Site Certification Documentation Checklist).

Examples of questions you might ask in this section:

- *In this study, participants should not be charged for Physical Therapy visits because the PT time will be paid for by the study. Describe how your study team will ensure that participants are not charged for these visits:*

- *This study requires that an initial blood sample be drawn within 3 hours of admission to the ER or Trauma Center. Briefly describe how you will ensure that potential participants are identified and how and by whom the blood samples will be drawn within the specified time window. Please*

note that we have also requested a more thorough local SOP document which should describe your site's plans for managing this critical component of the study protocol (see the Clinical Site Certification Documentation Checklist).

- *This study will require data sourced from EMS providers. Please describe how and when this information will be obtained. Please also indicate the names of the EMS providers and the contact information your study team will use to reach out to those providers.*

- *For this study, it will be important to review participants outpatient medical records to determine how many orthopaedic encounters the participant had between study visits. Please verify that all members on your study team who will be involved in follow-up data collection have access to the necessary medical record systems.*

V. Plans for Enrollment of Non-English Speakers

*MCC Study Teams: For studies in which non-English speakers have not been *deliberately* excluded (e.g., studies where primary outcome is a standardized PRO for which there is no certified translation; studies for which there are complex intervention materials such that participants would be put at risk if not provided with translated instructions or materials), you should include this section of the Clinical Site Certification Form.*

Non-English-speaking participants are not automatically excluded from this METRC study, i.e., there is no specific exclusion criterion which states that non-English speakers will be excluded. If your institution has the resources to enroll non-English-speaking participants, without incurring additional costs that would be charged back to the study, and if your study team plans to access these resources, please respond to the items below.

If your institution does not have access to the necessary resources to enroll non-English-speaking participants, or if your study team does not plan to pursue enrollment of these participants regardless of the institutional resources available, please make note of that here and skip the remaining items in this section:

Please describe your institutions interpreter services available to your study team. Please include information about how these interpreters are accessed, how and by whom the services are paid, and what languages the interpreters speak.

Given the above description of the interpreter resources available to your study team, please describe whether you plan to enroll non-English-speaking participants. If so, what language(s) will you seek to enroll, should those otherwise-eligible participants present to your trauma center?

VI. Study Team Information

Please complete the table below including all members of your study team for whom you are seeking certification approval. Please specify in the appropriate columns the role of each study team member and the study activities that each study team member will be responsible for. There is a list of Study

Roles and a Study Activities Key below the table for your reference. Please indicate in the last column whether the study team member will require access to the REDCap database for this study.

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

Please note below the complete contact information for any study team member who has not been previously certified for another METRC study, i.e., for whom the MCC would not already have his or her complete contact information.

Does the IRB of record (your local IRB or the single IRB) require that all study team members are listed on the IRB application? (Yes or No):

If you answered “yes” to the above question, have all of the study team members for whom you are seeking certification approval been included in your IRB application, per the IRB’s requirement? (Yes or No):