METRC Policy & Procedure Manual

Title: Clinical Site Certification Documentation Checklist Template

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General Description & Purpose: This checklist is intended to serve as a resource for both the Clinical Site and the MCC Study Team, ensuring that all required documentation has been submitted in support of the site's certification for the given METRC Study.

Clinical Site Certification Documentation Checklist Template

Instructions: This checklist is intended to serve as a resource for both the Clinical Site and the MCC Study Team, ensuring that all required documentation has been submitted in support of the site's certification for the given METRC Study. The first table lists all minimally required documentation. The MCC will add study-specific documentation requirements to the second table. The study-specific requirements will also be specified during study kick-off trainings and the checklist will be posted to the relevant Study Materials section of the METRC website.

Minimally Required Certification Documentation:

	Document/ Documentation	**Description**	**When Documentation is Usually Submitted**
☐	IRB Application Materials	IRB Application materials include the local or single IRB application, the study protocol submitted to the local or single IRB, consent Form(s), HIPAA Authorization, study advertisements such as brochure inserts, etc.	For DoD sponsored studies, the IRB Application Materials are submitted at the time of DoD HRPO Submission. For non-DoD sponsored studies, materials are submitted to the MCC upon approval. For studies using the JHM SIRB, the MCC will retrieve the materials directly form the eIRB application.
☐	IRB Approval Letter(s)	Official approval letter from the local or Single IRB	For DoD sponsored studies, the IRB Approval Letter is submitted at the time of DoD HRPO Submission. For non-DoD sponsored studies, the letter is submitted to the MCC upon approval. For studies using the JHM SIRB, the MCC will retrieve the letter directly form the eIRB application.

☐	*For DoD Sponsored Studies only:* DoD Human Research Protections Office (DoD HRPO) Approval Letter	Official approval memo from the DoD HRPO. This memo is sent via email by the DoD HRPO reviewer to the Site PI and other study team members at the site and the MCC.	The MCC study team is typically carbon copied on the DoD HRPO approval memo. The site does not need to forward or submit the approval memo to the MCC unless the site notices that the appropriate contacts at the MCC were not cc'ed on the memo; in this case the site should also request that the reviewer updates his or her distribution list. Likewise, the MCC will verify that the appropriate contacts at the clinical site were cc'ed on the memo and will rectify the distribution list with the HRPO reviewer as necessary.
☐	Clinical Site Certification Form	This is a study specific form on which the study team must document certification-specific information, e.g., basic descriptions of study implementation plans, dates of submission of other documentation, which individuals will conduct which study activities, etc. Please note: If certification approval is being requested for study team members who have never before been certified for a METRC study, it is important to include their complete contact information on the Clinical Site Certification Form.	The Clinical Site Certification Form may be submitted to the MCC once IRB approval (by local IRB or single IRB) is obtained. For DoD sponsored studies, this form may be completed and submitted even if the HRPO approval is pending.
☐	Medical Licenses (clinicians only)	Each study surgeon/clinician must submit a current medical license, if not previously submitted to the MCC as part of certification for another METRC study.	The MCC maintains a "Certification Document Repository" in which it files non-study-specific documents submitted in support of certification. If the MCC already has copies of the clinicians' current medical licenses, they do not need to be re-submitted at the time of certification for the given study. Otherwise, the licenses may be submitted at any time during the regulatory review and approval process, prior to certification.
☐	Curriculum Vitae or Resume	Each member of the study team seeking certification approval must submit a CV or resume, if not previously submitted to the MCC as part of certification for another METRC study.	CVs and Resumes are filed in the MCC's "Certification Document Repository" (described in the row above). If the MCC already has copies of the study team members CVs or resumes, they do not need to be re-submitted at the time of certification for the given study. Otherwise, the CVs or

			resumes may be submitted at any time during the regulatory review and approval process, prior to certification.
☐	Basic Human Subjects Research Training Completion Certificate	Each member of the study team seeking certification approval must submit a Basic Human Subjects Research Training Completion Certificate. This may be a CITI-training certificate (Collaborative IRB Training Initiative), or a certificate from an institutional training equivalent to CITI. Certificates must be current within 3 years; individuals must take a Refresher course upon expiration of their previous certificate.	Human Subjects training certificates are filed in the MCC's "Certification Document Repository" (described in the rows above). If the MCC already has copies of the certificates, and if those previously-submitted certificates are not expired, they do not need to be re-submitted at the time of certification for the given study. Otherwise, the certificates may be submitted at any time during the regulatory review and approval process, prior to certification.
☐	Good Clinical Practice (GCP) Training Completion Certificate	The Site PI and all Research Coordinators and Research Assistants seeking certification approval must submit a Good Clinical Practice Training Completion Certificate. This may be a CITI-training certificate, or a certificate from an institutional training equivalent to CITI. There are multiple options for GCP trainings, e.g., GCP for social and behavioral research, GCP for drug and device trials, etc. Any of these trainings meet the MCC requirement; it does not matter which GCP training was taken. Certificates must be current within 3 years; individuals must take a Refresher course upon expiration of their previous certificate. **Research Coordinators or Research Assistants who are <u>only</u> involved in regulatory work, e.g., submitting continuing reviews, etc., do not need to submit GCP certificates.*	GCP training certificates are filed in the MCC's "Certification Document Repository" (described in the rows above). If the MCC already has copies of the certificates, and if those previously-submitted certificates are not expired, they do not need to be re-submitted at the time of certification for the given study. Otherwise, the certificates may be submitted at any time during the regulatory review and approval process, prior to certification.
☐	Conflict of Interest (COI) Disclosures	Each member of the study team seeking certification approval must have COI disclosure current within the year. For investigators on the study team who are members of the American Academy of Orthopaedic Surgeons (AAOS), the annual required disclosure to AAOS will suffice; this disclosure is publicly	Conflict of Interest reporting occurs on an ongoing basis. Study team members may confirm that their COI disclosures are complete and up-to-date at any time prior to certification. If an individual has not submitted a COI disclosure, s/he must do so prior to certification using the AAOS-

		searchable, includes the date of disclosure, and is renewed every year. For non-AAOS members, disclosure may happen via the AAOS mechanism (it is available to the public, regardless of AAOS membership) or via a METRC-specific REDCap COI disclosure report form. Conflict of Interest reporting is described in further detail in other METRC PPM documents.	mechanism or the METRC-specific REDCap COI disclosure report form.

Required Study-Specific Certification Documentation:

	Document/ Documentation	**Description**	**When Documentation is Usually Submitted**
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