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Sponsor	Nora Olsen: CR Reg Affairs&Compliance Dir.
Area	Cancer Consortium - Institutional
Applicability	FHCC Institutional Policies
References	Org Wide/ Institutional

Collection and Maintenance of Credentialing Documentation for Clinical Research Use

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SCOPE:

This policy applies to all Fred Hutchinson Cancer Center (Fred Hutch), University of Washington (UW), and Seattle Children's (SC) workforce members supporting Cancer Consortium clinical research activities.

PURPOSE:

The purpose of this policy is to describe the collection and maintenance of credentialing documentation in the Cancer Consortium for clinical research use.

DEFINITIONS:

- **Clinical Research Staff:** Individuals involved in the design, conduct, and/or reporting of a clinical trial and to whom an investigator delegates study-related duties. Meaning and interpretation of terms used in the policy. Use bullet points. If no definitions are required, enter N/A.
- **Clinical Research Support (CRS):** The Consortium central office that provides central

management and oversight functions for coordinating, facilitating, and reporting on the Consortium's clinical research.

- **Credentialing Documentation:** Curricula vitae and medical licenses.
- **Curriculum Vitae (plural: Curricula vitae):** A summary of a person's career, qualifications, education, and publications. Also known as a résumé.
- **Florence eBinder:** An electronic web and cloud-based clinical trial system utilized by the Consortium for electronic regulatory (eReg) study binders, or investigator site files (ISF). Florence eBinders is compliant with U.S. regulations pertaining to clinical research records.
- **Food and Drug Administration (FDA):** the United States federal agency that regulates food, drugs, medical devices, and other products in the U.S.
- **Good Clinical Practice (GCP):** An international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.
- **Investigator:** A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

POLICY:

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Curricula Vitae (CVs)

Investigators and clinical research staff supporting clinical research trials conducted at Cancer Consortium institutions and community sites will provide a CV to demonstrate their qualifications by education, training, and experience.

- Research Managers are responsible for providing current CVs for investigators and clinical research staff to CRS (CSCTraining@fredhutch.org). CRS will maintain current and archived CVs in the central credentials folder in Florence.
- CVs will not be collected from Cancer Consortium clinic staff who are not acting outside their normal scope of duties, are not conducting study-specific activities, and do not make a direct or significant contribution to the clinical study data.
- CVs will not be collected from individuals providing or overseeing services within their normal scope of duties at internal or external facilities, when credentials have been demonstrated through existing certification or licensure (e.g., directors of CLIA-certified laboratories; licensed clinical specialists).

Consistent with Food and Drug Administration (FDA) regulations and Good Clinical Practice (GCP) guidelines, Consortium investigator and staff CVs do not expire.

CVs will be signed and dated using one of the methods described below. Compliance with FDA regulations under 21 CFR Part 11 will not be required.

- Wet ink signature with date handwritten by signer.
- Certificate-based electronic signature with digital ID issued by an institutional or commercial

vendor (e.g., Florence, DocuSign, Adobe Sign).

- Electronic signature with self-signed certificate/self-signed digital ID (such as Adobe Acrobat).
- Other electronic signature methods may be permissible when the signer's identity and date of signature are verifiable, and the signature is permanently affixed to the electronic document such that it cannot be altered or applied elsewhere.

CVs will not be modified, abbreviated, or redacted at sponsor request. Should a study sponsor require redactions, the sponsor may redact information on the CV per their internal requirements. Redacted CVs will not be retained in study files nor maintained by Cancer Consortium staff.

CVs must be updated when the following events occur:

- Name change
- Institution change
- Significant role/title change or faculty promotion
- New academic degree
- Change in board certification status

A CV should include the following information at a minimum:

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- Full name, matching clinical license
- Professional licensure
- Name of employer/institution (include all institutional affiliations)
- Job title (include for each institutional affiliation)
- Work address, including mail stop
- Email address
- Education and training
- Professional experience
- Date updated
    - This should be separate from the signature date.

Medical Licenses

All Washington State medical licenses are posted to a public-facing website:

- https://fortress.wa.gov/doh/providercredentialsearch/default.aspx

Clinical Research Support (CRS) will collect medical licenses and post them to the central credentials folder in Florence.

REFERENCES:

- *FDA Guidance for Industry – Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects. Oct 2009.*
- *FDA Guidance for Industry – Part 11, Electronic Records; Electronic Signatures — Scope and Application. Aug 2003.*
- *ICH E6(R2): Guideline for Good Clinical Practice*

Approval Signatures

Step Description	Approver	Date
	Natalie Simpson: Policy & Practices Mgr	02/2025
	Mari Schwab: AVP & Deputy General Counsel, Labor & Employment	02/2025
	Kristi Stiffler: Vice President, Clinical Research	02/2025
	Nora Olsen: CR Reg Affairs&Compliance Dir.	02/2025

Applicability

FHCC Institutional Policies