

DCT Reporting – Introduction to OnCore CTMS

November 3, 2025



AGENDA

Speakers:

Jason Malone
Director, UW HSD

Megan Miller
CTMS Training & Support Program
Manager

UW DCT Policy

Introduction to OnCore & Protocol Workflows

Submitting a New Study to OnCore

DCT Minimum Footprint Data Entry Requirements

Access, Training, Resources & Support

Implementation Timeline: When to Take Action

Today's Webinar



Intended Audience: UW study teams that do not currently have access to or manage protocols in OnCore CTMS.



Content: OnCore intro & guidance for protocols in-scope for DCT Reporting, but out of scope for current OnCore Minimum Footprint requirements.

**Current Minimum Footprints cover DCT requirements – no additional data entry, training, access or action needed.*



UW DCT Policy

Jason Malone | Director, Human Subjects Division

Applicability

All new clinical trials (NIH definition) submitted to UW HSD on/after January 1, 2026, where UW employees or agents are responsible for or engaged in recruitment and consent activities.

- Would apply regardless where the interventions occur
- Would apply to UW studies relying on an external IRB
- Would be a condition of the UW serving as sIRB for multicenter studies

Policy Exceptions

- Phase 1 or earlier trials
- Pilot and feasibility studies
- Clinical trials involving ‘small populations’
- Clinical trials reviewed by Seattle Children’s or Fred Hutch IRB

Policy Requirements

- Submit a Diversity Plan to HSD that:
 - Establishes Enrollment Goals - age, race, ethnicity, biologic sex, sexual orientation, geographic location, social economic status
 - Provides rationale for current enrollment goals and any exclusions
 - Includes a strategy for meeting enrollment goals (e.g., study design, recruitment, and retentional plan, reducing barriers to participation)
 - Describes efforts/resources utilized for community engagement that informs recruitment strategy
 - Has a plan for tracking enrollment data

Reporting Requirements

- It is UW policy that all clinical trials that require the submission of a Diversity Plan for Clinical Trials Supplement must provide annual updates on their enrollment targets for underrepresented groups using the [OnCore CTMS](#).
- These studies are required to be registered in OnCore CTMS before study approval or authorization to use an external IRB will be granted.
 - Documentation of registration (i.e., email confirmation from CTMS) must be uploaded to Zipline

Reporting Requirements

- **Clinical trials that already must report into OnCore** (e.g., oncology-related, have UW Medicine billable activities, and/or require Epic activation for orders for subject tracking purposes) **do not need to make any additional reporting nor do study staff need to take any additional training. These studies will continue to follow existing requirements.**
- Beginning January 1, 2026, **NEW** clinical trials that are not already required to report in OnCore AND are subject to the [UW DCT policy](#) will follow the new OnCore reporting requirements outlined in today's training.

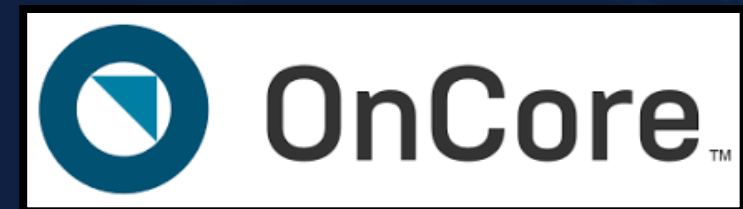


INTRO TO ONCORE & PROTOCOL WORKFLOWS

Megan Miller | CTMS Training & Support Program Manager

WHAT IS CTMS? WHAT IS ONCORE?

- CTMS = Clinical Trials Management System
 - An enterprise software system used to manage clinical trials & human subjects research.
- OnCore is the CTMS used at University of Washington & Fred Hutch Cancer Center (FHCC).
- Managed by cross institutional teams:
 - UW Medicine Research IT
 - CTMS Program Office



! OnCore CTMS, OnCore and CTMS are often used interchangeably.

A (Not So) Brief History of OnCore

• OnCore Implementation Timeline

2018

- WHO: **Oncology-related & FH Non-oncology Human Subjects Research**
- WHAT: Protocol & Subject Management, SRC Review Process
- WHY: Data collection for National Cancer Institute Reporting (NCI), institutional admin tracking, monitoring, centralized system for study document access

2021

- WHO: New protocols with clinical research billing (**Oncology, FH non-oncology, UW non-oncology**)
- WHAT: Subject Calendars, Coverage Analysis, Study Financials, integration with Epic EHR
- WHY: Centralize cross-institutional research workflows, streamline clinical research billing, standardizes sponsor invoicing activities

2023

- WHO: Backload of protocols w/ clinical research billing that started prior to 2021
- WHAT: Subject Calendars, Coverage Analysis, Study Financials, integration with Epic EHR
- WHY: Centralize cross-institutional research workflows, streamline clinical research billing, standardizes sponsor invoicing activities

OnCore Today

Teams Working in OnCore

- UW & FH Study Teams
- UW Clinical Trials Office (CTO)
- CTMS Program Office
- UW & FH Investigational Drug Service (IDS)
- UW & FH Clinic teams (*Drs, APPs, nurses, assistants, etc.*)
- Other Research Admin, Regulatory, Compliance Offices
- FH Clinical Research Support (CRS)
- FH Scientific Review Committee (SRC)
- FH Clinical Research Business Office (CRBO)
- FH Clinical Readiness Team (CRT)



System Integrations

- UW Workday
- UW/FH Epic Electronic Health Record (EHR)
- UW & FH Vestigo (IDS system)
- UW Florence
- Trial Finder App (Oncology only)

Cross-Institutional Research Workflows

- Scientific Review Committee Approval (Oncology only)
- Coverage Analysis, Coding & Pricing
- Billing Grid production & approval
- Centralized Protocol Document repository
- Sponsor invoicing & payment reconciliation
- Research Billing Compliance
- NCI Reporting

Why Use OnCore for DCT Reporting?

1. Centralized, web-based single sign-on (SSO) system w/ the ability to:
 - ✓ Provision access by research areas, departments, groups & teams that meets IT security requirements.
 - ✓ Support data entry requirements for DCT Reporting.
 - ✓ Export data into customized reports.
2. There will be a subset of protocols in-scope DCT Reporting AND meet other requirements of OnCore usage (*e.g., clinical research billing*).
 - ✓ By using OnCore for DCT data collection, these teams would not need to manage data entry in two separate systems.

Why Use OnCore for DCT Reporting?

3. CTMS Program Office has the staff, resources & systems needed to support DCT data collection and reporting.

QC & Reporting

Perform routine data reviews and study team outreach to ensure accurate data extraction.

- Generate an average of 980 study team outreach tickets per month
- 214 active reports in OnCore
- Respond to an average of 120 data extraction inquiries per month
 - Questions or needs for data/metrics?
Email ctms@fredhutch.org!

Intake Team

Process new studies submitted to REDCap Study Intake Form:

- Weekly average: 15
- Monthly average: 60
- Yearly average: 550
- Average turnaround time: ~2 hours!

Training & Support

In 2025, Training & Support has:

- Solved/resolved 4,790 inquiries
- Helped >300 staff members in Office Hours
- Held 13 Webinars w/ >1,500 attendees
- Published 20 Tips & Tricks newsletters
- Maintained 50 Reference Documents & 8 eLearning Modules
- Trained 190 users for new edit permissions

OnCore Protocol Workflows

Aka: Pre-Open to Accrual (OTA), activation, startup, pre-award



Study Team submits new study to **REDCap Study Intake Form** (~at time of Initial IRB Review)



CTMS Intake Team builds OnCore Protocol Record; notifies study team via email



Recommended: **Study Team** reviews protocol record for accuracy; completes data entry of protocol information

Aka: Post-OTA, post-award, active study



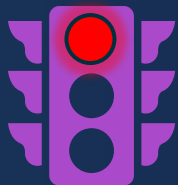
CTMS Intake Team opens the protocol to accrual → Subjects can now enroll



Study Team performs data entry including entering subjects; updating protocol statuses, staff & information; responding to queries



CTMS QC & Reporting will be performing data quality checks and exporting data for policy reporting



When IRB file is closed, **Study Team** performs outstanding subject data entry (all subjects have Off Study statuses) & updates Protocol Status to IRB Study Closure*

**Final QC checks sent out*



Submitting a New Study to OnCore

Megan Miller | CTMS Training & Support Program Manager

Submitting New Studies – Jan. 1 2026

- Starting Jan. 1st a **REDCap New Study Intake Form** will need to be submitted for studies meeting the following criteria:
 1. New study submitted for UW HSD review **on or after January 1, 2026**, *AND*
 2. Research that meets the definition of a [clinical trial](#), *AND*
 3. UW employees or agents are responsible for or engaged in recruitment or consent activities.
- Link to REDCap Intake Form is available on the [CTMS Program Office Website](#)
- Reach out to CTMS@fredhutch.org for questions
 - NOTE: If you have access to OnCore, a link to the REDCap Intake Form is available on the landing page when you first login.



DCT Minimum Footprint Data Entry Requirements

Megan Miller | CTMS Training & Support Program Manager

What is the Minimum Footprint?

- Guidance document on minimum required protocol & subject data that must be entered into OnCore.
- Established in coordination with policy requirements, administrative needs & system functionality.
- Two established Minimum Footprints for current OnCore protocols:
 - Full Minimum Footprint
 - Short Minimum Footprint
- DCT Minimum Footprint being developed for studies out of scope for Full or Short Minimum Footprint protocols.
 - E.g., UW non-oncology clinical research protocols w/ no Epic billing or other activities

DCT Minimum Footprint – Data that Study Teams Enter/Maintain in OnCore

Protocol Information

Management Tab

- IRB number

- ✓ Entered by study team prior to or at Open to Accrual (OTA) status

Protocol Staff Roles

- Primary Clinical Research Coordinator
- Principal Investigator
- Research Manager
- Study Submission Contact

- ✓ Initially entered by CTMS prior to OTA
- ✓ Updates maintained by study team, as needed (pre & post-OTA)

Protocol Status

- Status Date
- Initiator
- Reason

- ✓ Required pre-OTA (& OTA) statuses updated by CTMS
- ✓ As needed pre-OTA updates entered by study team
- ✓ Two required post-OTA updates entered by study team:
 - Closed to Accrual
 - IRB Study Closure

Subject Information

Register Subject

- Study Site
- Primary subject ID

Demographics

- Last Name
- First Name
- Birth date
- Expired date*
- Expired date approx.*
- Biological sex
- Ethnicity
- Race
- Address
- Country

Consent

- Signed date
- Accepted consent

On Study

- Zip at registration

Follow Up

- Off study date

- ✓ Study team enters all subject data (post OTA only)
- ✓ Subject data entered (*at a minimum*) once per year prior to IRB Renewal
 - For high-accruing studies it's recommended to complete subject data entry as study activities occur or on a more frequent basis.

OnCore is a Resource for Study Teams!

Study teams may utilize other available fields in OnCore for their own data collection or protocol/subject tracking needs. Data can be exported from OnCore via:

1. OnCore Reports

- E.g., Subject status updates, subject demographics data (Annual IRB Report Format)

2. Protocol & Subject Searches

- Customizable “reports” study teams can configure and run ad hoc data exports
- Configured reports can be saved and shared with other team members

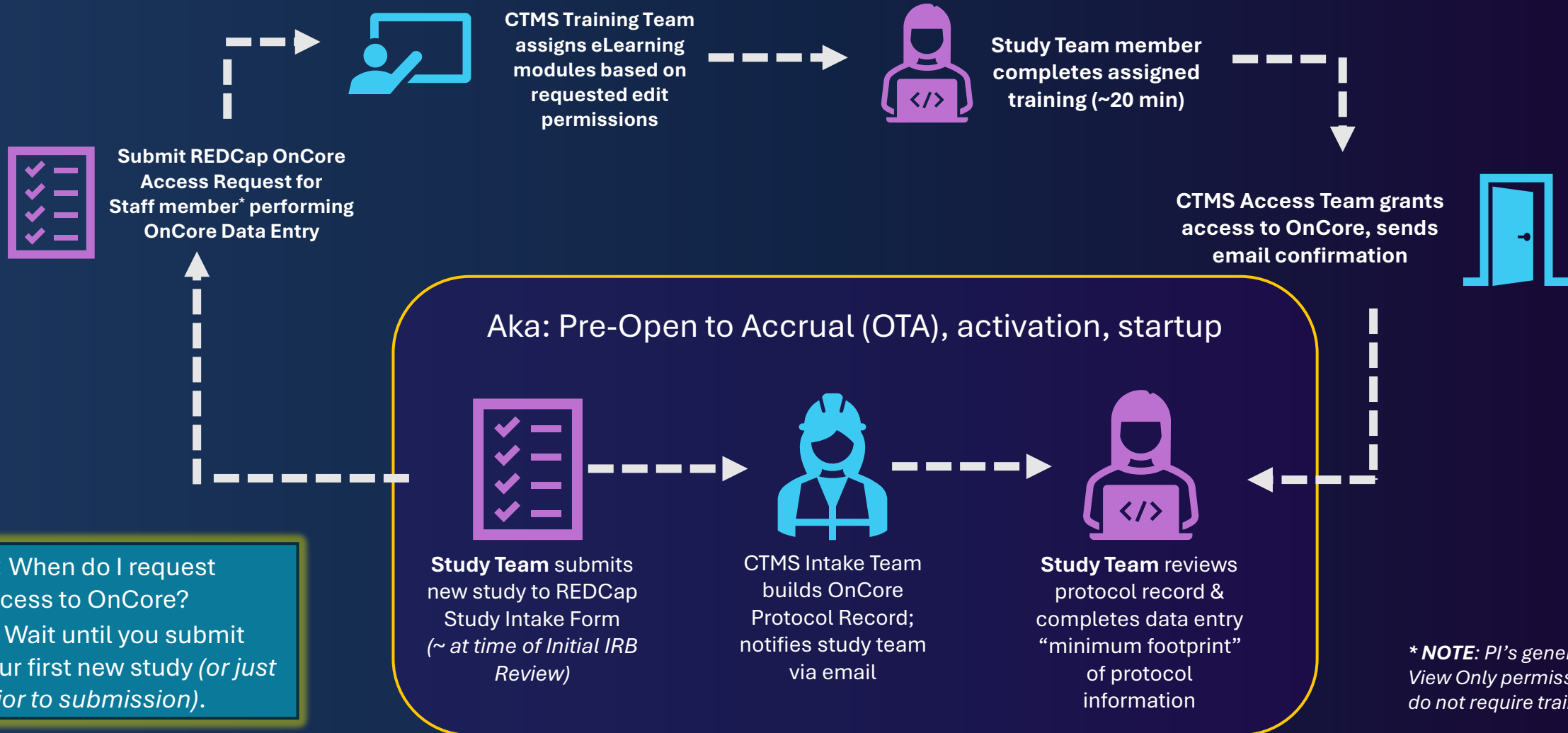




Access, Training, Resources & Support

Megan Miller | CTMS Training & Support Program Manager

When do I need access to OnCore?



Q: When do I request access to OnCore?
A: Wait until you submit your first new study (or just prior to submission).

*** NOTE:** PI's generally request View Only permissions, which do not require training.

Training for DCT Edit Permissions

General OnCore Training Info:

- Training is required for Edit permissions only.
- OnCore training is in a self-paced, eLearning format completed via the [ITHS TREE](#) Learning Management System (LMS).
- Training for requested permissions is assigned “Just in Time” upon submission of OnCore Access Request.
- A passing score of 80% must be obtained before OnCore access is granted
 - Training may be re-taken if passing score is not reached.

For DCT Edit Permissions:

- A single DCT Data Entry eLearning module will be assigned to staff members ONLY managing DCT Minimum Footprint protocols.
- DCT Data Entry training will take approximately 20-30 min long.
- OnCore users will retain access to the eLearning module – may review at any time.

CTMS Support Resources



Documents*:

- DCT Minimum Footprint
- DCT Data Entry Work Instructions

**Available Jan. 1*



Online Office Hours:

- Drop-in assistance via Zoom
- Breakout rooms for personalized assistance
- Tue. 10am -12pm \ Fri. 12 – 2pm



CTMS Support Desk:

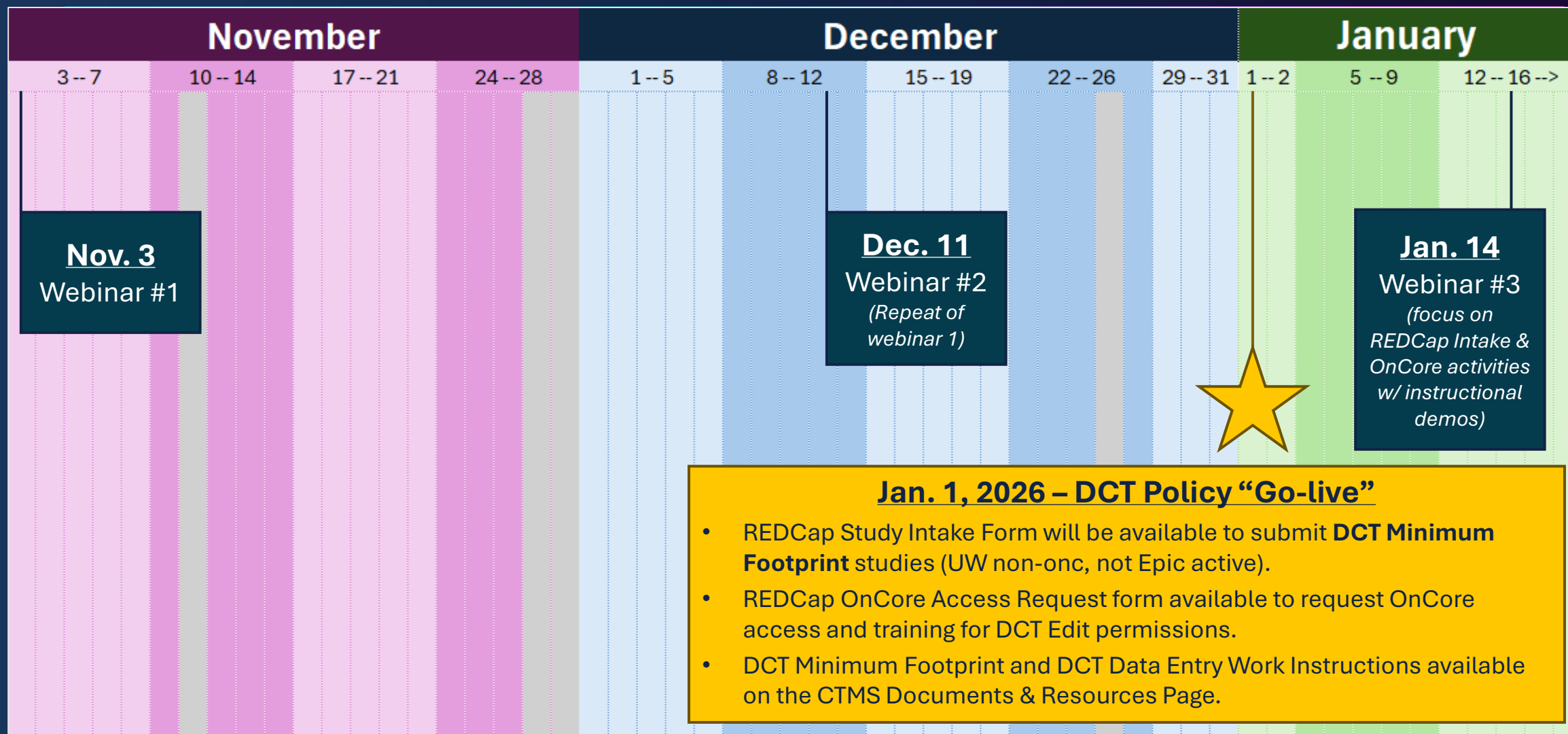
- Mon - Fri 8am – 4:30pm PT
- Email: CTMS@fredhutch.org
- Phone: 206-667-2868



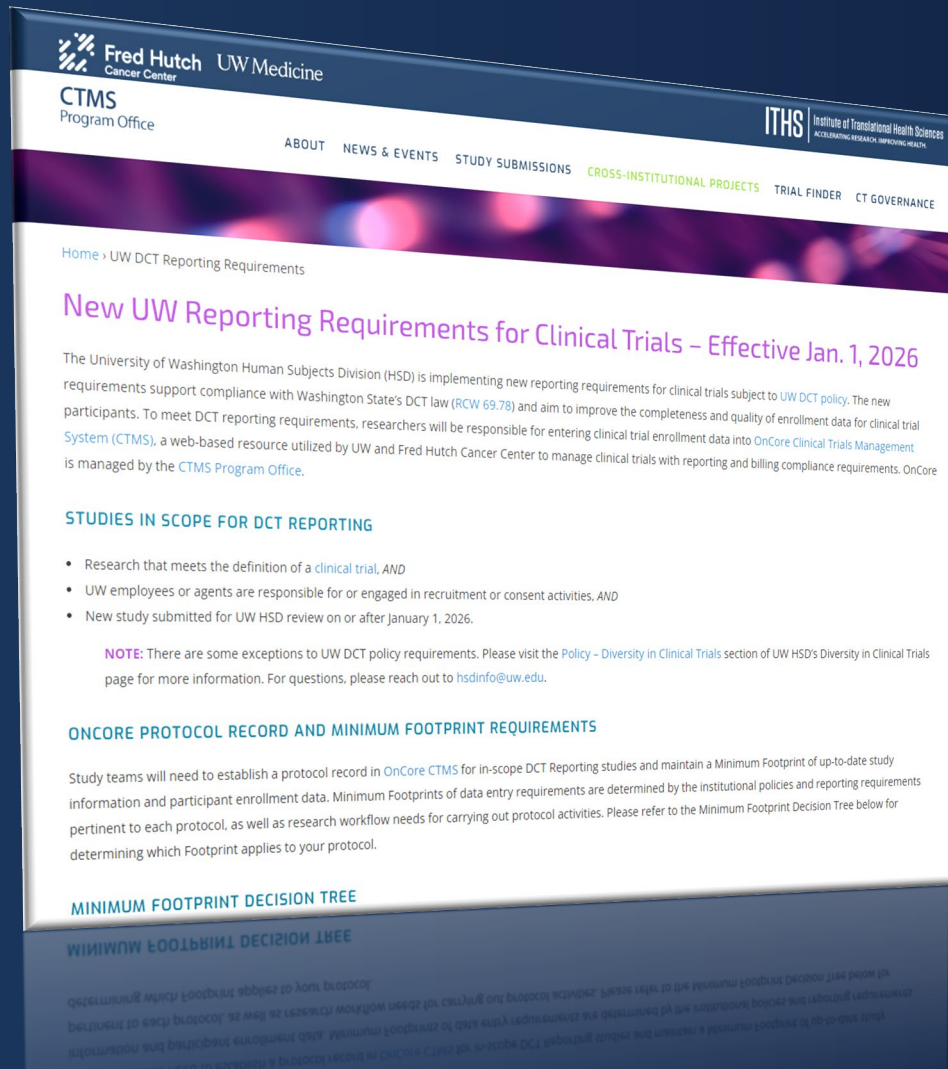
Other Resources:

- Individual Team Training on Request
- Monthly Webinars & bimonthly newsletters sent to OnCore users
- CTMS Website

DCT Implementation – When to Take Action



Where to Go for Updates & Info



- CTMS Program Office Website
 - Webpage dedicated for DCT Reporting; general info on OnCore
 - <https://www.iths.org/ctms/uw-dct-reporting-requirements/>
- Communications via UW HSD Newsletters
- [UW HSD Diversity in Clinical Trials](#)
- [UW Medicine Office of Healthcare Equity](#)

OnCore CTMS Webinars



Upcoming DCT Reporting – Intro to OnCore CTMS Webinars:

- ❖ Thurs, December 11th
 - 12:00 - 1:00 PM PT
 - Repeat of this webinar
- ❖ Weds, January 14th
 - 9:00 - 10:00 AM PT
 - Training focused

Links to register for the webinars is available on the [CMTS Website DCT Reporting Page](#)



Thank you
for attending.