SECTION 1 - Orientation

Clinical Research Orientation Sheet Job Description Clinical Research Orientation Timeline

SECTION 2 - CITI Training/SOCRA/Licensing

Training Requirements for Individuals Involved in Human Subjects Research Policy Training Overview from EIRH CITI Training FAQs from EIRH SOCRA CCRP Certification Program Essentia Health East Region Dress Code Policy Nursing License Verification (Nursys) Nurse State Licensing

SECTION 3 - EHCCRP Overview and Contact Information

EHCCRP Study Umbrella
Essentia Health NCORP Site Codes
Research Personnel CTEP and SWOG IDs
Resource Contact List
Investigational Drug Room Contact Information
Welcome to EIRH

SECTION 4 – Resources / Tips and Tricks

Training and Resources
Research Guidelines with NPs and Pas
Where to Find Study Documents
How to Send Secure Emails
How to Page a Provider (Spok)
Telephone Instructions

SECTION 5 – Standard Operating Procedures

Data Submission

East Region Dress Code Policy Generation, Use, and Revision of SOPs **Informed Consent Process** Providing Clinical Trial Information to Patients - Oncology Requesting Time Off and Holidays CRA and RN Coverage Unanticipated Problems/Deviations/Violations/Noncompliance Review **Submitting Expedited Reports to CTEP-AERS CREDIT Checkoffs** Long Term Follow Up PHI Disclosure Human Subject Research - Access, Use, and Disclosure of PHI Investigational Drug Recall Notices **Eligibility Checklist Process Just in Time Study Determination** External Research Lab Kits - Billing Oral Study Drug Management at Outreach Sites Patient Phone Messages

SECTION 6 - Oncology Clinical Trials 101

Oncology Clinical Trials slides
Thriving as a Clinical Research Professional
Navigating Alliance Protocols
Abbreviations

SECTION 7 - Roles and Responsibilities

CRA Roles and Responsibilities
RN Roles and Responsibilities
Specialist Team and Manager Responsibilities
Responsibilities with Mailings
Responsibilities for Reporting Deviations UPIRTSO & Slides

SECTION 8 - Study Start Up

Study Feasibility Worksheet (Duluth)
IRB's (Who, What, Where, When, Why, and How)
Required Elements of Informed Consent
HIPAA Rules
Protocol Binder Layout
CTSU Regulatory Submission Portal
Study Briefing Template (Duluth)
General Opening a Study Workflow
Opening a COG Study Workflow

SECTION 9 - Components / Outreach

Workflow for Opening Studies at Component Sites
Communication for New Patients at Component Sites
Brainerd and Fargo Process/Responsibilities
Brainerd Process for IDR Supplied Study Drug
Riverwood Process/Responsibilities
Riverwood New Patient Checklist
Availability of Common Lab Tests at Essentia Regional Sites
Study Feasibility Worksheet (Affiliate)
Study Briefing Template (Affiliate)
Study Briefing Template (Fargo)
Ashland Radiation Patient Workflow

Duluth Radiation patient Workflow

SECTION 10 - Checklists / Charts

Layout of Charts

Patient Chart Labels

EHCCRP Treatment Chart "GUTS"

Prior Authorization Labels

RN Pre-Study Checklist

Prepping Chart Before Appointments Checklist

On Study Checklist (Treatment)

On Study Checklist (CCDR/Registry)

Oral Treatment Checklist

Processing Chart Checklist

Off Study Checklist

Internal Transfer of Patient Worksheets (CRA and RN)

Nurse to Nurse Coverage Worksheet

Workflow for Patients that No Longer Need Follow Up/Deceased

Request for Additional Information - Demographic Form

SECTION 11 - EPIC

Prior Authorization Process

Prior Auth Process & Responsibilities

Patient Insurance Verification Form

Imaging Prior Authorization

Problem List in EPIC (Z00.6)

Research Study Record (RSH Record)

Linking to RSH Record in EPIC

How to Create a New Episode in EPIC

Treatment Note Encounter Smartphrase

Level of Service (LOS) Process in EPIC

Lab Profiles/Panels at Essentia Health

EPIC Lab Order Preference List

Out of Office InBasket

Point of Care Scanning

Beacon Guide for Research Nurses

Non-Beacon Order Guide for Nurses

Creatinine Clearance Calculation Guidelines

Source Documentation

Standardized Nurse Dictations

MyHealth Recruitment Process

MyHealth Recruitment Patient Notification

Remind Me Button in EPIC

Interpreter Scheduling

Patient Recruitment Contact Preferences

SECTION 12 - CREDIT

CREDIT Definitions
CREDIT Training 101
Where to Find Approved Protocols and Consents in CREDIT
How to Enter Events in the OCT Calendar
How to Determine What Studies are Open at Certain Sites
Patient Checkoffs Manual and Examples
Archiving Patients and Protocols
How to find general study documents in CREDIT

SECTION 13 - Clinical Trials Billing

Clinical Trials Billing Slides
OPEN Funding User Guide
Study Funding Sheet example
Study Highlighted Test Schedule example
Study MCA example
CTSU NCI Protocols Accrual Tracking
NCTN Funding Slides 2021

SECTION 14 - Pathology / Biospecimens

SECTION 15 - Adverse Events

Adverse Event Reporting Slides
Recording Adverse Event Start and Stop Dates
How to Complete the AE Assessment Form
CTEP-AERs Training Presentation
CTEP-AERs FAQs

SECTION 16 - RECIST / RANO

RECIST Training Slides
RECIST, iRECIST, irRC Slides Alliance
RECIST Journal Article,
irRECIST Article
Baseline Modified RECIST Form
Modified RECIST Form
RECIST Worksheet
Example RANO form