

Centers for Medicare/Medicaid (CMS) Clinical Trials Policy (CTP) Training

Contents:

- CMS CTP Background, Definitions and Requirements
- Process Going Forward
- UW Medicine Process Reminders

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Background:

- In 2000, Medicare issued a **National Coverage Decision (NCD)** that offered expanded coverage for “routine costs” of “qualifying” clinical trials (coverage of more than “usual patient care”) and it was voluntary.
 - This expanded coverage required coder application of V70.7 diagnosis code based on medical record documentation.
- In 2007, Medicare significantly updated the NCD to provide clarifications, renamed it the **Clinical Trials Policy (CTP)** and made it a requirement.
 - The Medicare Clinical Trials Policy (CTP) provides coverage beyond “usual” or “conventional” care for studies that qualify.
 - Medicare clarified that for a “deemed-qualified” study, all covered services billed to Medicare (even the “usual care”) must follow the CTP requirements.
 - New modifiers were issued this year which must be used for billing all study services to them (even usual care).

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What is a “Deemed Qualified” Study?

Studies are “Deemed Qualified” when the study meets:

ONE of the following 3 criteria:

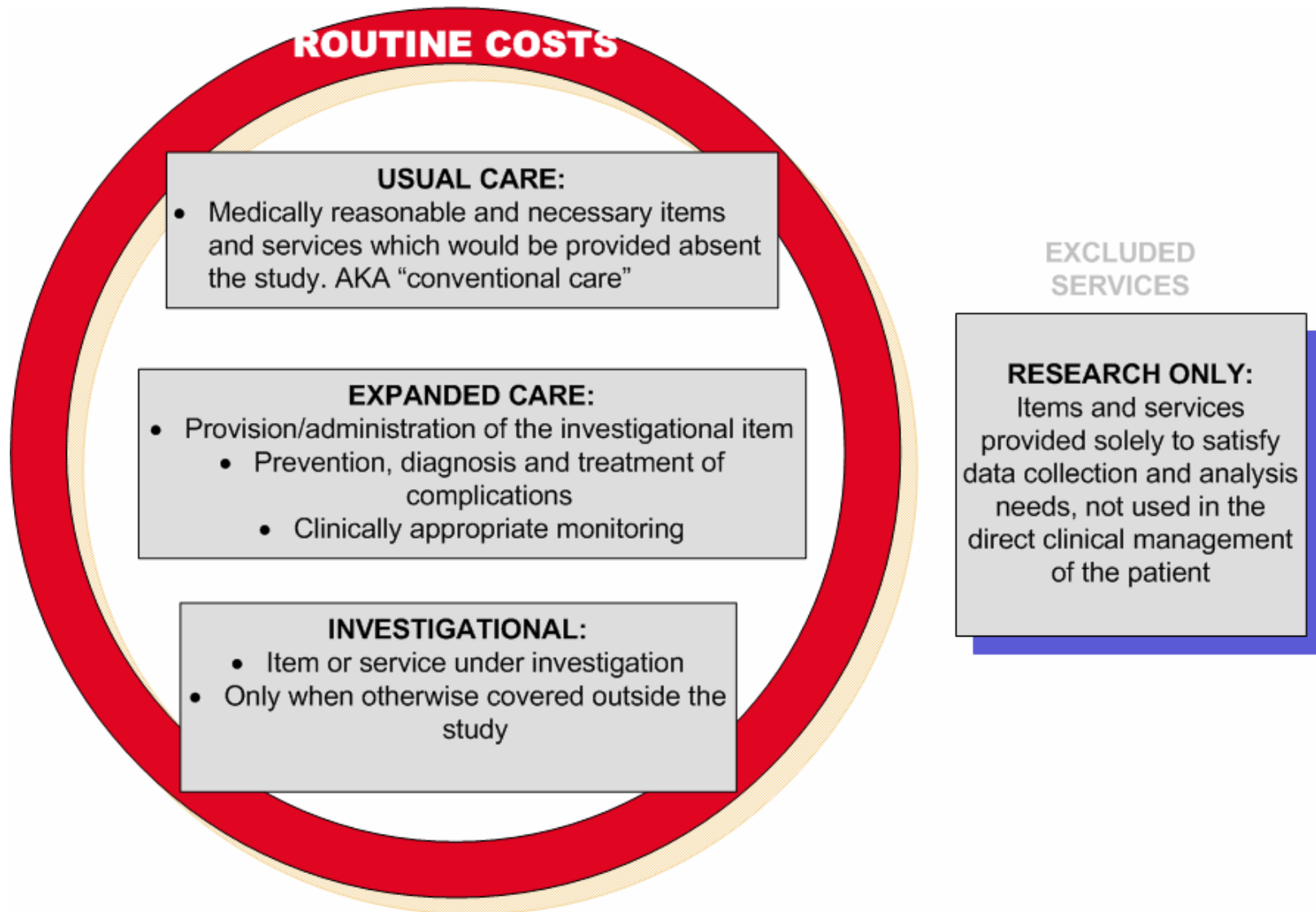
- Funded directly by or conducted at an institution funded by one of six federal agencies
- Under an Investigational New Drug (IND) application
- IND Exempt

AND ALL of the following criteria:

- The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
- Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

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What are “Routine Costs”?



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What are the CTP Requirements?

IF study related item/service is:

- A “Routine Cost”, and
- Part of a “Deemed Qualified” clinical research trial, and
- To be billed to Medicare (Note: Other insurance carriers may follow Medicare in the future)

THEN the billing entity must:

- Apply the “Q1” modifier to CPT codes (effective 04/07/08), and
- Apply the “V70.7” as the secondary ICD-9 diagnosis code, and
- Put study information in the participant’s medical record.

Study staff will not be actually doing these items.

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To meet these requirements, we need a process that will:

- Identify “Deemed Qualified” studies.
- Identify when participants enroll on “Deemed Qualified” studies.
- Identify when participants stop receiving billable services (Billing End Date).
- Add Study related information to the medical record.
 - File research consent (SCCA)
 - Create ORCA* Research Care Plan Note (UW Medicine)
- Add the billing modifiers to all services on Medicare claims for patients on “Deemed Qualified” studies.

*ORCA is the “Online Record of Clinical Activity” and serves as the SCCA and UW Medicine’s electronic medical record.

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Before we discuss process, you need to know what these are:

- EPIC Alert
- ORCA Research Care Plan Note

...and WHY they are important to the CTP process

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EPIC Alerts:

- EPIC Alerts are turned on in EPIC to indicate patient is on a “Deemed Qualified” study.
- A participant only needs ONE EPIC Alert turned on to indicate they are on a “Deemed Qualified” study, even if they are on multiple “deemed qualified” studies.
- The SCCA Billing system will use the EPIC Alert to add the appropriate billing modifier to the patient’s SCCA bill.
- SCCA HIM will turn on and turn off SCCA EPIC Alerts based on protocol enrollment reports.
- UW CRBB will turn on and turn off UW Medicine EPIC Alerts based on protocol enrollment reports.

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ORCA Research Care Plan Notes:

- UW Medicine does not file research consents in the participant's Medical Record and needs the ORCA Research Care Plan Note (RCPN) to meet the CTP documentation requirement.
- Also, the RCPN serves a patient safety purpose by notifying clinical staff that the patient is on a research trial.
- For oncology-related studies, SCCA HIM will create the RCPN and amend the RCPN alert based on study enrollment reports.
- A participant will need an ORCA RCPN for EACH study in which they enroll.
- UW Medicine has an ORCA RCPN exemption process if your study contains highly sensitive information that should not be in the medical record and has low clinical and billing risk (see CRBB web site for more information).
 - This only pertains to UW Medicine.
 - Chances are very low that a therapeutic study would receive exemption.
 - SCCA continues to require the signed consent be filed in the participant's Medical Record.


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ORCA Research Care Plan Note Template:

Notice: THIS PATIENT IS INVOLVED IN A CLINICAL RESEARCH STUDY.
Special handling is required when billing for clinical services

Study name: _
Sponsor Name: _
Sponsor-Assigned Protocol Number: _
Investigator(s): _
Study Coordinator: _
Contact number: _
Contact email: _
Emergency number: _
Anticipated dates of participation: Duration of Study = _ Months
Does the study enroll healthy volunteers Y/N?

Study
information
from PIRO



If you are a provider NOT associated with the study, please:

1. Provide care and document as you normally would.
2. If the reason you are seeing the patient is to evaluate or treat a problem which could be a complication of this research study:
 - A. Please indicate this in your documentation
 - B. If you submit a fee sheet, please add "RS" in the modifier column next to the CPT code provided (for services performed at UW Medicine facilities only, with the exception that FHCRC studies on 7NE/8NE DO NOT need to do the "RS" process.)
 - C. Please notify the Study Coordinator about the visit.Also, please notify the study team about any inpatient admission.

If you are a provider seeing patients as part of a study protocol

Clinical services, items and tests that are part of a study protocol are billed either to the study's AAA account, or to the study participant's patient account. The billing grid established for your study is your guide to how each service provided in the study is to be billed.

For services charged to the AAA account

Please indicate "AAA" in your documentation

Use AAA outpatient joint appointment fee sheet or study's AAA essential services requisition forms.

For services charged to the study participant's patient account (for services performed at UW Medicine facilities only, with the exception that FHCRC studies on 7NE/8NE DO NOT need to do the "RS" process.)

Please indicate "RS" in your documentation

If you submit a fee sheet please add "RS" in the modifier column next to the CPT code provided

Use the RS essential services requisition forms

Data should be entered into the appropriate ORCA encounter. Please note that at Harborview Medical Center, separate ORCA encounters are used to document usual care in research billed to patients' accounts versus research care that is billed to the study AAA account. Usual care in research should be documented in the patient's ORCA encounter. Non-covered research care should be documented in the ORCA joint research appointment.

For more information about choosing the correct ORCA encounter check with outpatient clinic front desk staff or visit:

orcaed.washington.edu/print/powerchart/ENC_Select_Correct_Encounter.pdf

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The Challenge:

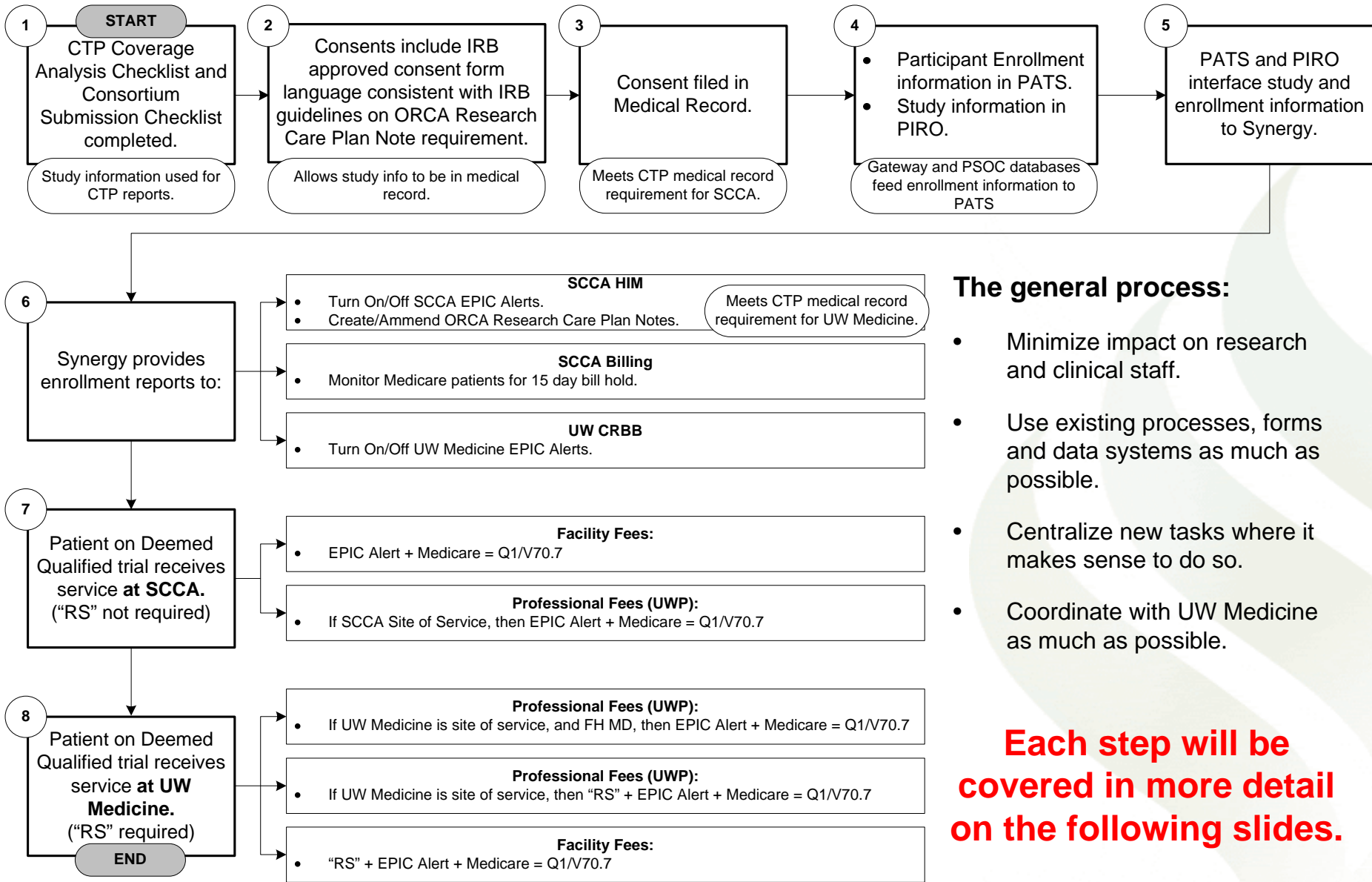
- HOW will SCCA know WHEN to turn on the EPIC Alerts and ORCA RCPN and WHO to turn them on for?
- HOW will SCCA know WHEN to turn off the EPIC Alerts and (ammend) the ORCA RCPN and WHO to turn them off/amend for?

What's the Process?

Please Note:

- The following process will work for you if:
 - You complete the Consortium Submission Checklist (f.k.a Protocol Office Submission Checklist), and
 - Protocol participant enrollment information for your study is in PATS, Gateway and/or PSOC databases.
- If you do not do these, please contact Steve Johnson, SCCA Research Integration Manager, 288-1287.

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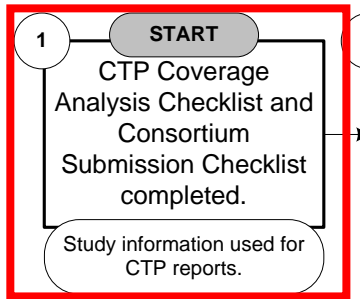


The general process:

- Minimize impact on research and clinical staff.
- Use existing processes, forms and data systems as much as possible.
- Centralize new tasks where it makes sense to do so.
- Coordinate with UW Medicine as much as possible.

Each step will be covered in more detail on the following slides.

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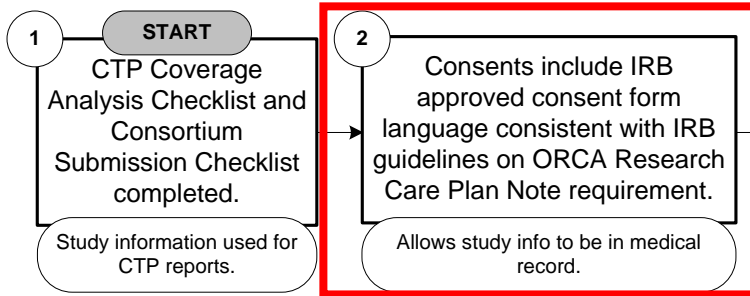
CTP Coverage Analysis Checklist:

- Required for all studies that include services at the SCCA or UW Medicine, except for Category 4/Minimal Risk studies.
- Copy of completed CTP Coverage Analysis Checklist needs to be sent (scan/email) to SCCA Research Implementation Office (RIO) – rio@seattlecca.org with Protocol Number in the Subject Line.
- This includes oncology studies that plan to include services at UW Medicine only.

Consortium Submission Checklist (f.k.a. Protocol Office Submission Checklist):

- No changes in process or content as a result of the CTP.
- Study information collected from this checklist is important to the CTP process.

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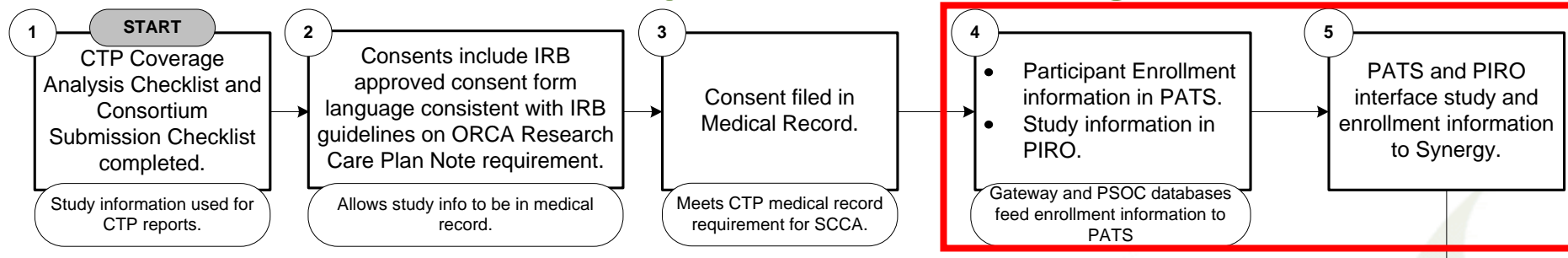


For studies approved by FH IRB on or after 1/1/09:

- Consents should include IRB approved consent form language consistent with new IRB guidelines on ORCA Research Care Plan Note requirement.
- The IRB Model Consent has been updated with this language.
- See FH IRB Web Site for more information

Note: UW HSD working with WIRB to accept the FH IRB template language and recommendations for oncology-related studies approved by WIRB.

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Study and participant information needed for CTP process:

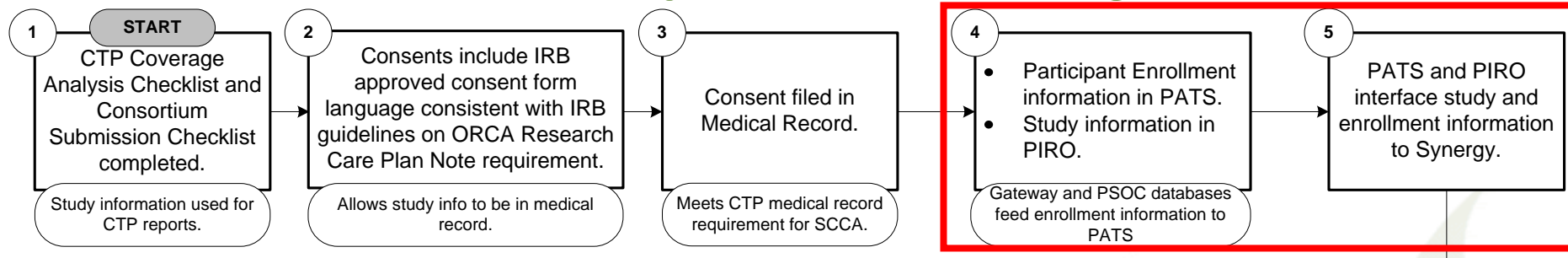
Study Level:

- Study Name
- Sponsor Name
- Protocol Number
- Investigator
- Anticipated Duration of Study
- Institution receiving grant/award/contract
- IRB Number
- Initial IRB Approval Date
- Study AAA Name
- Study AAA Number
- Deemed Qualified? **NEW**
- Healthy Volunteers? **NEW**
- Oncology Study? **NEW**
- RCPN Study Contact **NEW**
- RCPN Study Contact Phone Number **NEW**
- RCPN Study Contact E-mail Address **NEW**
- RCPN Study Emergency Number **NEW**

Participant Level:

- Last Name
- First Name
- MRN (U#)
- DOB
- Healthy Volunteers **NEW**
- Insurance Carrier
- Date Subject Enrolled
- Billing End Date **NEW 8/1/08**
- Protocol Number

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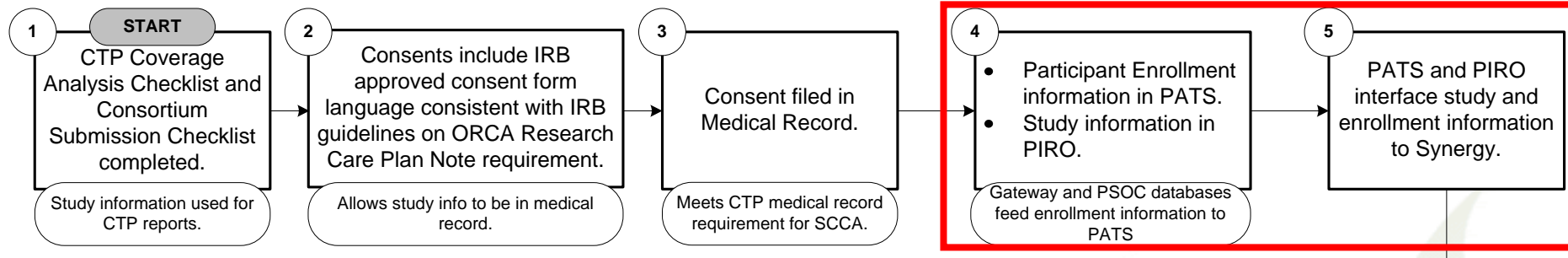


New study information (CTP Coverage Analysis Checklist):

- **Deemed Qualified?** - This was defined earlier. This data Will be entered into PIRO. We will be able to run reports to make sure participants of these studies are identified so the appropriate billing modifiers can be applied.
- **Healthy Volunteers?** - This means your study enrolls healthy volunteers to a control group. This data will be entered in PIRO.
- **Oncology Study?** - This means the objective of this study is to treat cancer or its complications.

- **RCPN Study Contact** ➤ This data will appear on the ORCA Research Care Plan Note for your study.
- **RCPN Study Contact Phone Number** ➤ Study staff will need to determine the most appropriate contact information for their study in that context.
- **RCPN Study Contact E-mail Address** ➤ This information might be different than the contact information currently recorded in PIRO.
- **RCPN Study Emergency Number**

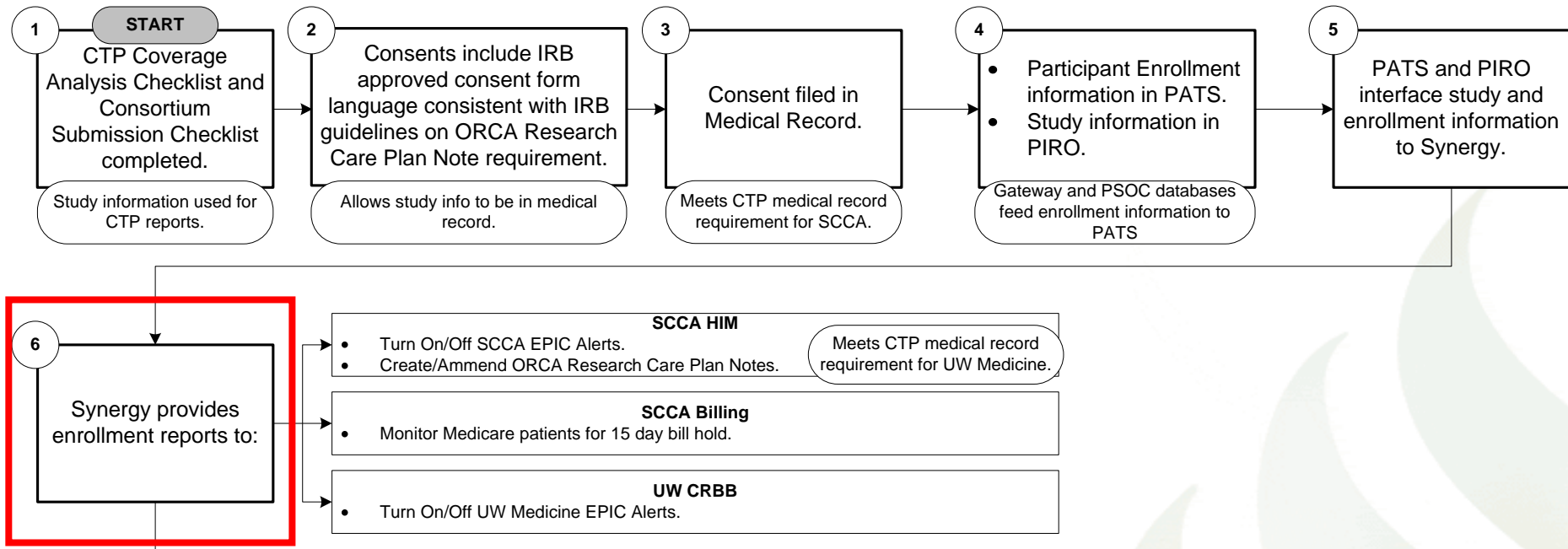
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New participant information:

- **Healthy Volunteers** - If your study enrolls Healthy Volunteers, those volunteers need to be identified at enrollment.
- **Billing End Date** - Date when the participant stops receiving *research protocol required clinical services at the partner institutions (SCCA/UW Medicine)*.
 - For FHCRC transplant, the Discharge date will be used as the Billing End Date.
 - For FHCRC CRD non-transplant studies, a solution is still being developed.

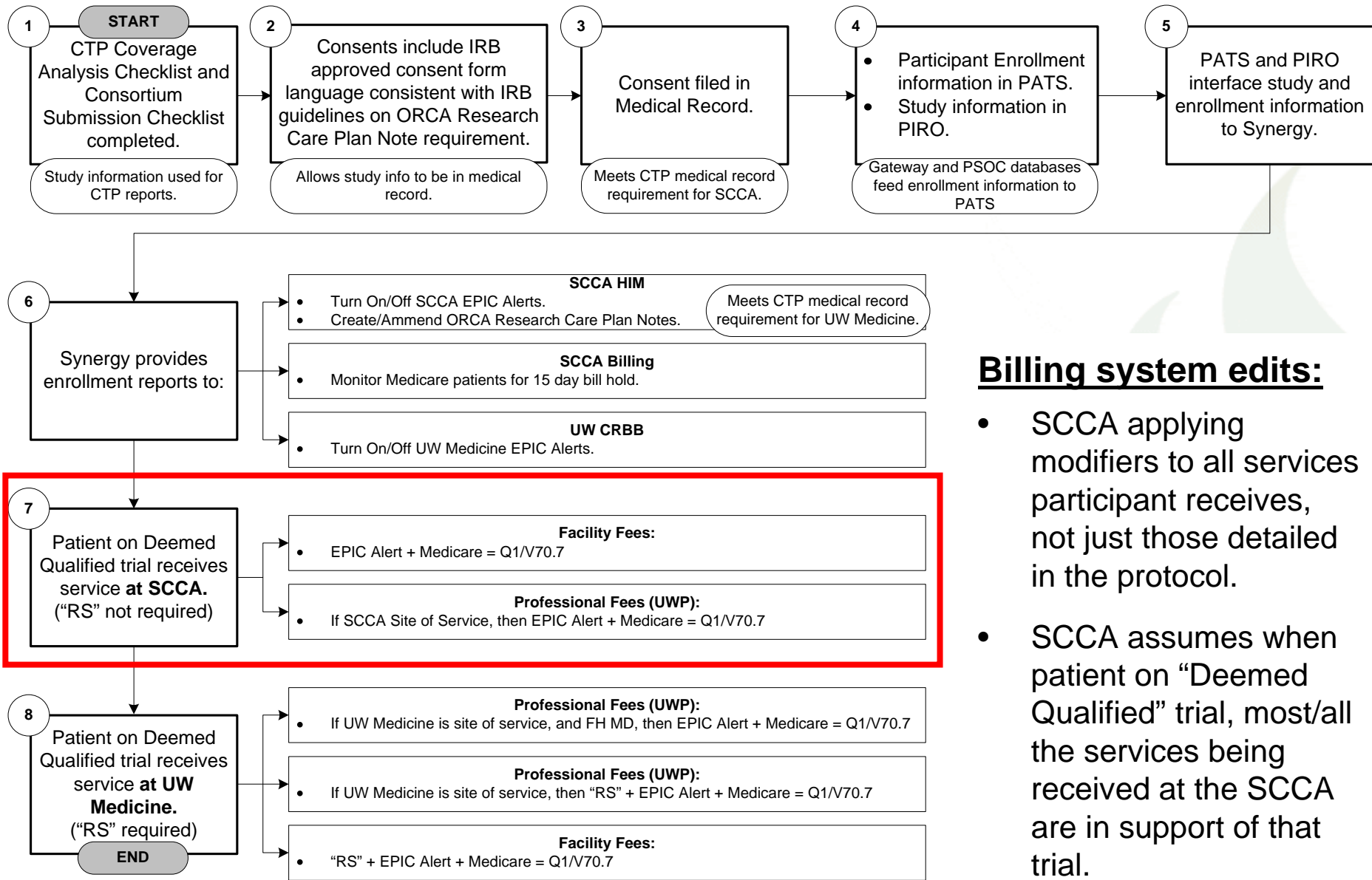
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Synergy Reports:

- Synergy is a data system used by SCCA Decision Support.
- PATS, PIRO and EPIC feed data into Synergy.
- Enrollment reports will facilitate EPIC Alert and ORCA RCPN processing.
- For Oncology studies, enrollment information entered in PATS will also be shared with UW CRBB. Research staff do not need to enter enrollment information in BOTH PATS and UW CRBB.

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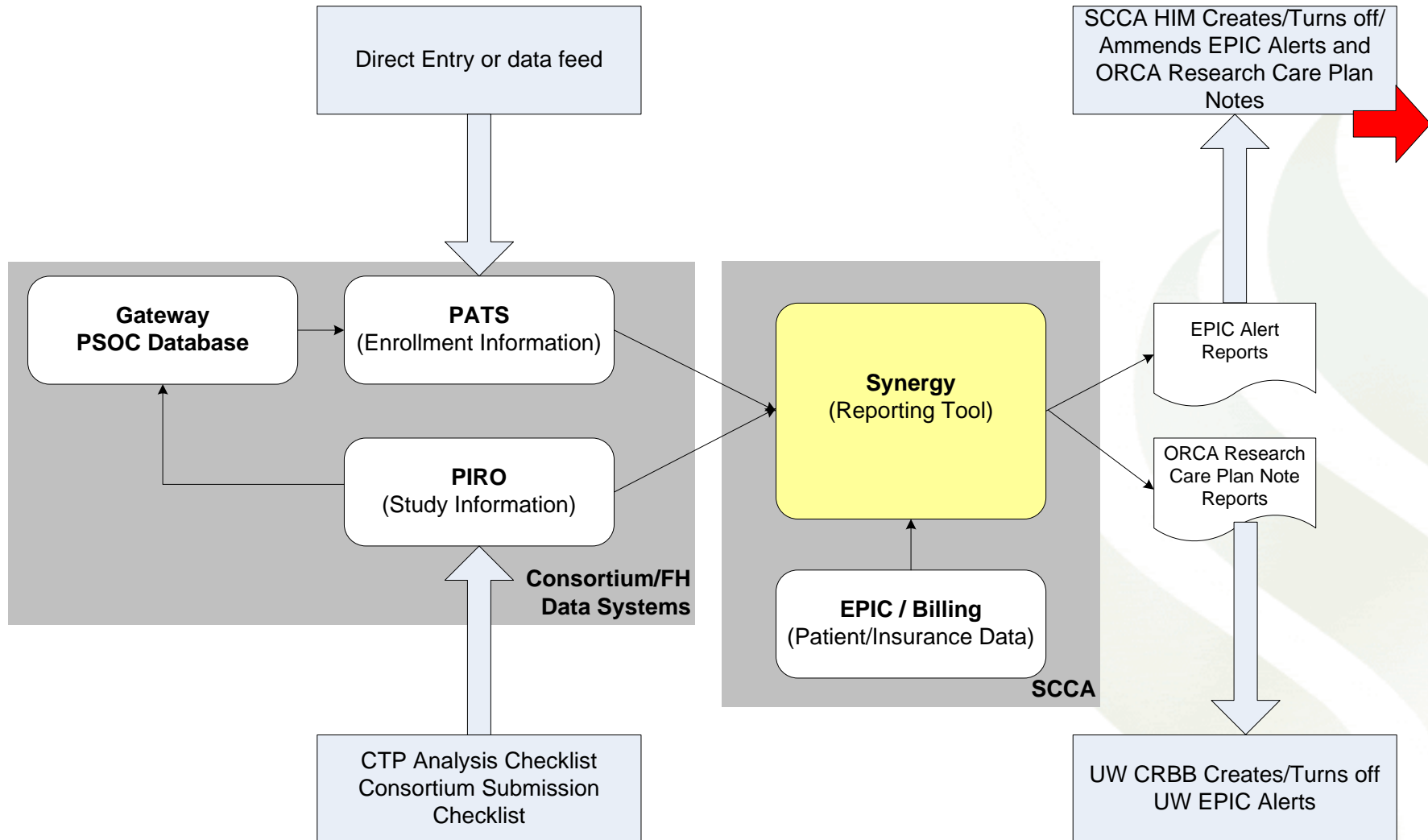


Billing system edits:

- SCCA applying modifiers to all services participant receives, not just those detailed in the protocol.
- SCCA assumes when patient on "Deemed Qualified" trial, most/all the services being received at the SCCA are in support of that trial.

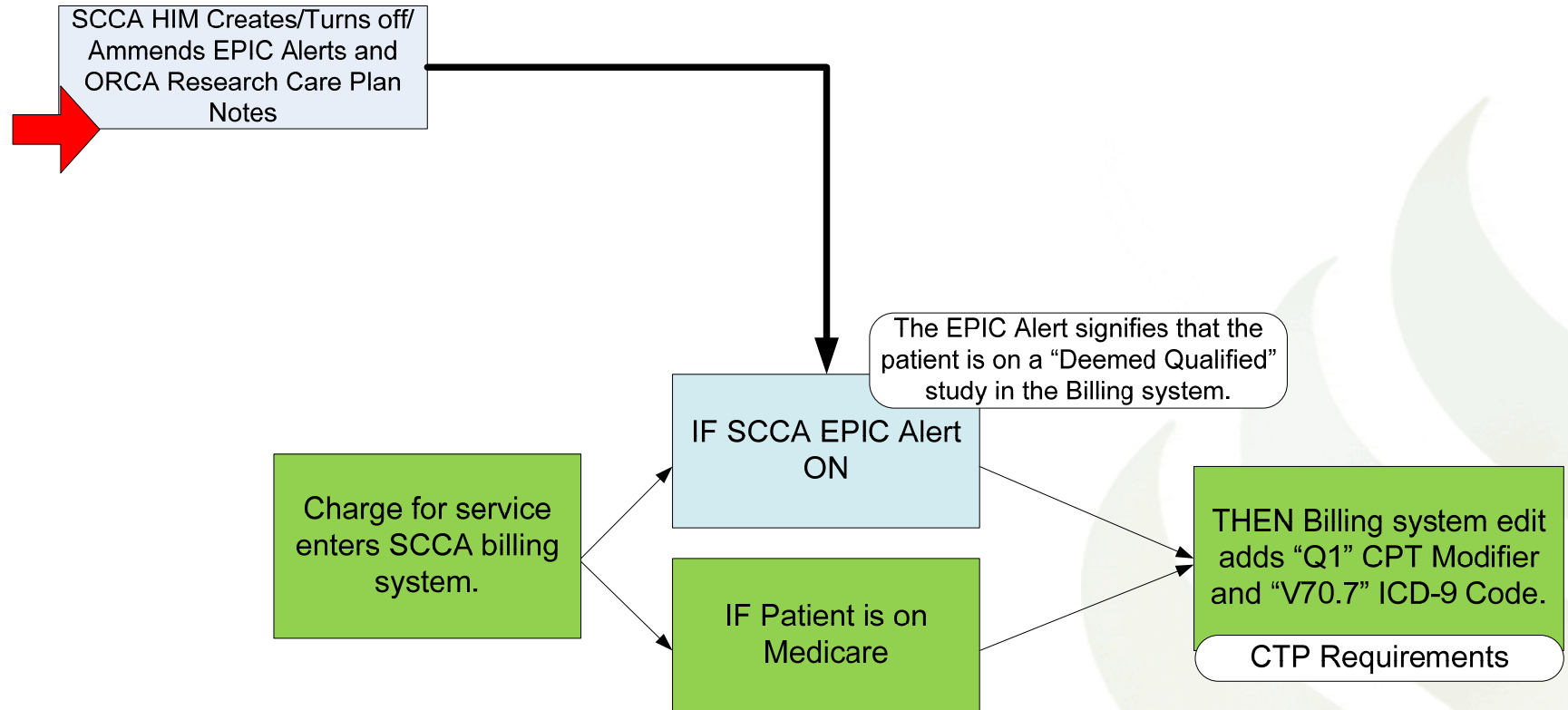
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Another View:

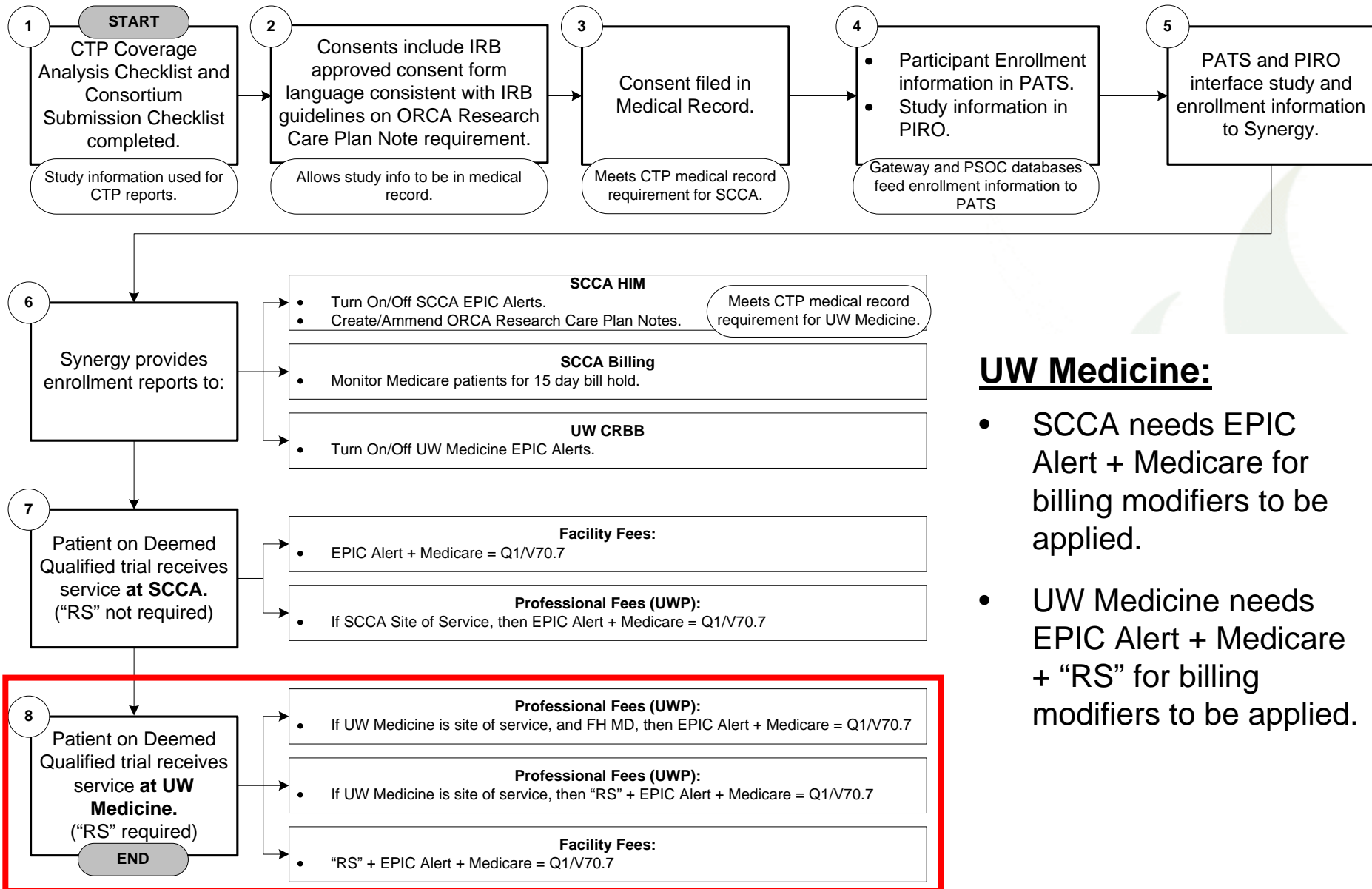


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Another View (continued):



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UW Medicine:

- SCCA needs EPIC Alert + Medicare for billing modifiers to be applied.
- UW Medicine needs EPIC Alert + Medicare + "RS" for billing modifiers to be applied.

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UW Medicine Process Reminders:

Main Area of difference - “RS” Process:

- UW applying billing modifiers to services detailed in the protocol only.
- When providing research services at UW Medicine facilities (except for FH studies on 7NE/8NE), providers must follow UW Medicine policy for “RS” documentation.
- When ordering research services at UW Medicine facilities, research staff must identify research services by writing “RS” next to each research service on the order and/or using the appropriate research services form (goldenrod). Research Service forms exist for:
 - o UW Radiology
 - o UW Labs
 - o UW Pathology

See CRBB Web Site for more information

FH Transplant Inpatient Service Process still being evaluated. Do not change current process until new solution identified.

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In Summary:

Research staff role:

- Complete CTP Coverage Analysis Checklist (if appropriate).
- Complete the Consortium Submission Checklist (no change).
- Ensure Informed Consent document has the FH/CC IRB approved consent form language.
- Enter enrollment data in a timely manner, Billing End Date in particular if you enter data into PATS.
- Follow “RS” process if ordering services at UW Medicine.