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CLINICAL RESEARCH BILLING 101

HCCA Research Compliance Conference
October 31, 2007

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Objectives

At the end of this session the participants will be knowledgeable about how to:

- Work with researchers to develop a plan for appropriate billing of clinical services provided to research participants during a research study.
- Manage the compliance risks associated with clinical research billing.
- Understand the revenue cycle as it relates to billing for clinical research.
- Protect research participants from unexpected financial responsibility.

Overview of Today's Session

- Background
- High level overview
- Prospective review of studies - "Research Fiscal Review"
- Billing process
- Supporting Elements

Note: Medicare Policy on Clinical Research is not a focus of this presentation

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Background

University of Pittsburgh Medical Center

- University of Pittsburgh Medical Center (UPMC) is separate from University of Pittsburgh (Pitt).
- UPMC includes 19 hospitals, over 2,300 employed physicians and various other health care service providers.
- Cancer services at 43 locations in Western PA
- Research is done primarily at 4 hospitals but is also being done at others.
- Estimate that there are 2,000 active studies.
- Review about 700 new and modified studies per year.

University of Pittsburgh

- Medical School, School of Health Sciences, Graduate School of Public Health, School of Nursing, etc.
- Most researchers are Pitt employees and some are also UPMC clinicians/employees.
- Some of the research support staff is employed by UPMC, some by Pitt.

Division of Activity

- UPMC – clinical side:
  - Provider of clinical services
  - Recipient of Industry sponsored research funds via Clinical Trials Office
  - Responsible for billing compliance
- Pitt – academic side:
  - IRB
  - Recipient of Federally sponsored research funds via Office of Research and academic departments
  - Responsible for human subject compliance

Genesis of our office

- Research Fiscal Review function created at UPMC in 1999.
- Catalyst was a patient complaint about being billed for deductibles associated with routine services provided during a clinical trial.
- Many changes over time.
- Increasingly sophisticated and still learning.

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High Level Overview

Why is Billing an Issue?

- Third party payors usually only pay for services that are well accepted in the medical community. They frequently exclude payment for “experimental or investigational services”.
- Services that are paid for by study sponsors cannot be billed to third party payors.
- Medicare has very specific rules about billing for services related to clinical research.
- Study participants should be aware of any out-of-pocket costs resulting from participation in the study.

Critical Steps

- Study design; Budget; Clinical Research Agreement; Protocol; Schema, Consent, etc.
- Provider risk/compliance review:
  - Legal review, coverage analysis, provider compliance risk, financial analysis, need for Materials Transfer Agreement, etc.==> output is billing plan, sound study documents.
- Enroll subject.
- Identification of study participant in the provider registration process.
- Provide service.
- Accurate charge entry - link services provided to subject to correct payment source – third party payor or study.

Critical Steps, continued

- Process charges through billing systems.
- Documentation of medical necessity if being billed to third party payor.
- Send bill to third party payor and/ or invoice the study.
- Collections
- Audit

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Prospective Review of Clinical Research Studies

“Research Fiscal Review”

Scope of Review

- All studies that involve potentially billable services - hands–on–care.
- Regardless of sponsor or who is paying for clinical services.
- Studies come in to RFR via three avenues: Pitt IRB & Office of Research, UPMC Clinical Trials Office, UPMC Office of Contracts & Grants.
- The only point within UPMC that aggregates all clinical research activity.

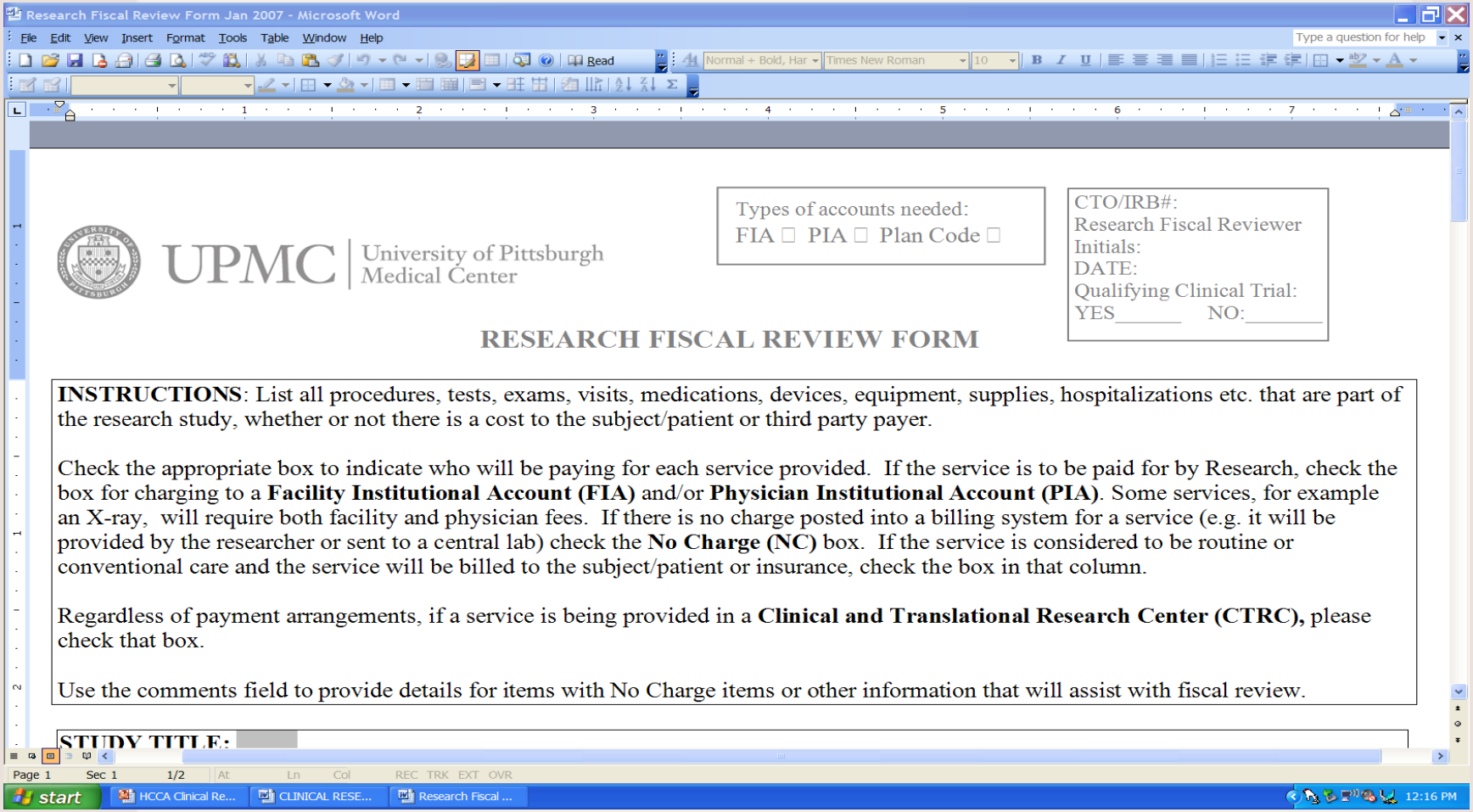
Outcome of Review

- Identify the clinical services to be performed as part of the study, identify how that service is to be paid – by insurance, sponsor, subject, etc. and confirm that documentation is consistent and appropriate.
- Establish a plan, prior to enrollment in a study, for appropriate billing of clinical services provided to research subjects.
- Identify potential financial and compliance risk to the provider.

Research Fiscal Review Form

- Include all potentially billable items, whether being paid for by the study or billed as conventional care.
- If mentioned in study documents, include on RFRF.
- List services, procedures, medications, hospitalization.
- CPT codes if available.
- Visit number.
- Boxes to mark if Research Institutional Account needed for Facility (FIA), Physician (PIA), or No Charge (NC).
- Use comments to explain NC (labs sent to a central lab, or EKG to be read by PI) or if the service is not actually part of the study, such as a hospitalization.
- If Clinical Trials Research Center (CTRC) being used.

RFRF


Research Fiscal Review Form Jan 2007 - Microsoft Word
File Edit View Insert Format Tools Table Window Help
Types of accounts needed:
FIA ☐ PIA ☐ Plan Code ☐
CTO/IRB#:
Research Fiscal Reviewer
Initials:
DATE:
Qualifying Clinical Trial:
YES_____ NO:_____
UPMC University of Pittsburgh Medical Center
RESEARCH FISCAL REVIEW FORM
INSTRUCTIONS: List all procedures, tests, exams, visits, medications, devices, equipment, supplies, hospitalizations etc. that are part of the research study, whether or not there is a cost to the subject/patient or third party payer.
Check the appropriate box to indicate who will be paying for each service provided. If the service is to be paid for by Research, check the box for charging to a Facility Institutional Account (FIA) and/or Physician Institutional Account (PIA). Some services, for example an X-ray, will require both facility and physician fees. If there is no charge posted into a billing system for a service (e.g. it will be provided by the researcher or sent to a central lab) check the No Charge (NC) box. If the service is considered to be routine or conventional care and the service will be billed to the subject/patient or insurance, check the box in that column.
Regardless of payment arrangements, if a service is being provided in a Clinical and Translational Research Center (CTRC), please check that box.
Use the comments field to provide details for items with No Charge items or other information that will assist with fiscal review.
STUDY TITLE:
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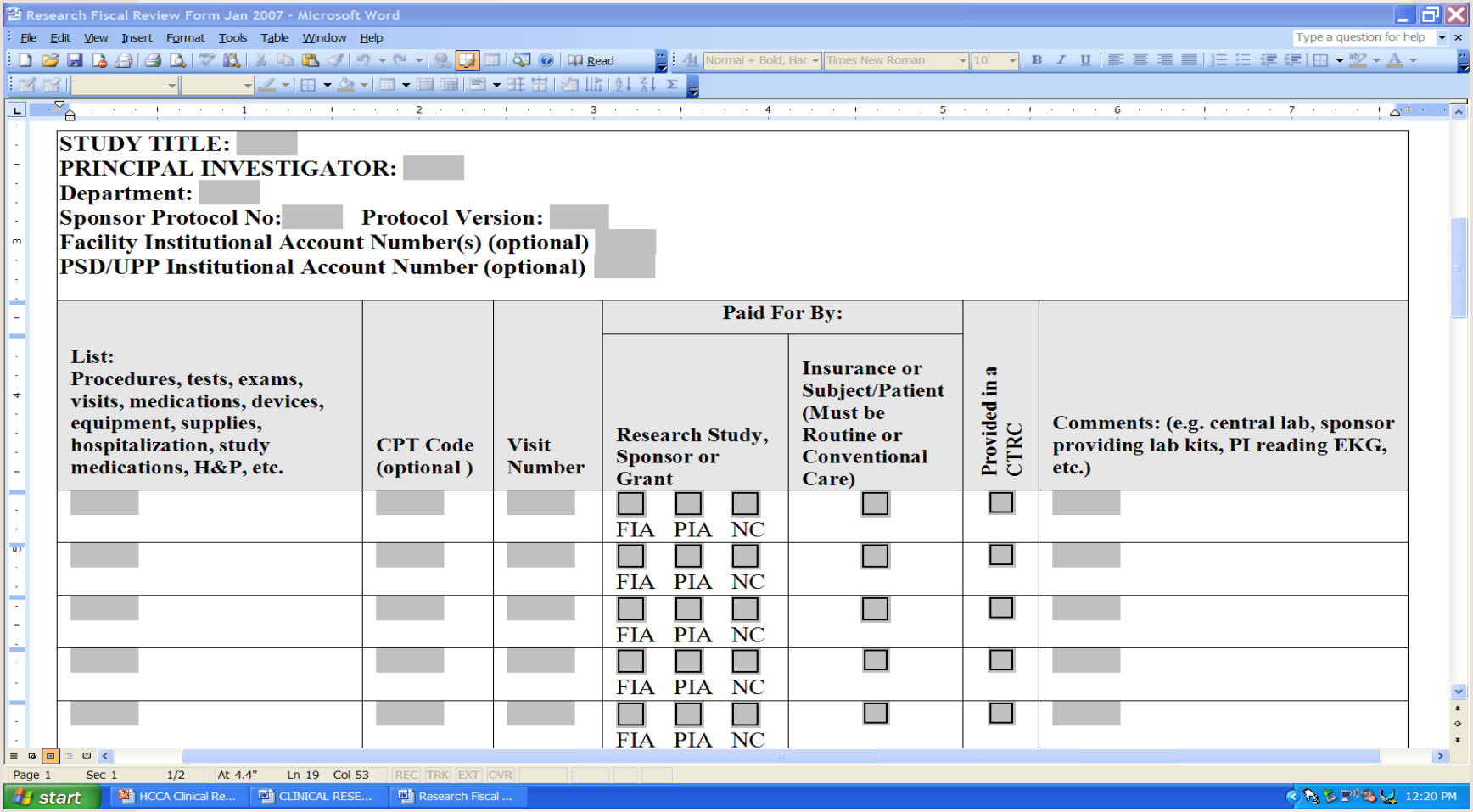
RFRF


Research Fiscal Review Form Jan 2007 - Microsoft Word
File Edit View Insert Format Tools Table Window Help
Type a question for help
Read
Normal + Bold, Har
Times New Roman
10
STUDY TITLE:
PRINCIPAL INVESTIGATOR:
Department:
Sponsor Protocol No:
Protocol Version:
Facility Institutional Account Number(s) (optional)
PSD/UPP Institutional Account Number (optional)
List: Procedures, tests, exams, visits, medications, devices, equipment, supplies, hospitalization, study medications, H&P, etc.
CPT Code (optional)
Visit Number
Paid For By:
Research Study, Sponsor or Grant
Insurance or Subject/Patient (Must be Routine or Conventional Care)
Provided in a CTRC
Comments: (e.g. central lab, sponsor providing lab kits, PI reading EKG, etc.)
FIA PIA NC
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Focus of Research Fiscal Review

- Has legal review been completed?
- Are all potentially billable items identified consistently in the schema, budget, protocol, consent and IRB documents and Research Fiscal Review form?
- Have items that may be related to the listed services been identified such as an x-ray prior to MRI, pregnancy tests, etc.?
- Are the items listed appropriately as routine clinical care vs. research on the RFR form?
  - Talk to PI, check compendiums, payor bulletins, peer reviewed literature as necessary.

Focus, continued

- Is the language in the informed consent cost section consistent with the other study documents (protocol, CRA, budget, schema)? Is it accurate?
- Are all items being paid for the study accounted for in the proposed study budget?
- Are items that are to be billed to third party payors excluded from the proposed study budget?
- Is the language in the CRA consistent with the proposed study budget?

Focus, continued

- Does the research impact service location, e.g. is a procedure that is normally done on an outpatient basis planned to be done on an inpatient basis?
- Does the study include services to be billed to insurance for which reimbursement is unlikely to cover the additional cost?
  - For example, will time in the OR or length of stay (LOS) be impacted by the research procedures? Will items need to be carved out for additional payment by the sponsor?
- Is the study Medicare Qualifying? Follow the CMS Policy on billing for clinical research to make this determination.

Focus, continued

- Does it appear that there will be issues related to the 72 hour rule or other “bundling” logic? Consult with Patient Billing if necessary.
- If the sponsor is requesting billing information does the informed consent include this request? Has the PI/research coordinator been informed about UPMC policy regarding release of billing records and associated costs.
- Does the study involve special equipment? Has this been addressed by legal? Is a Materials Transfer Agreement (MTA) needed? If a potential issue notify the appropriate parties.

Documents Reviewed

- Informed Consent
- Protocol
- Clinical Research Agreement
- Budget
- Schema, Schedule of Events, Timeline
- IRB or CTO Submission
- Research Fiscal Review Form (RFRF)
- Research Fiscal Approval Form (RFAF)

Routine Care?

"Well, yes, it's a routine procedure—if you routinely have someone slice open your body with sharp instruments and then fiddle with your insides."

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Considerations During Review

- Key Question: Would the subject be having these services if they were not in the study?
- Judge each study on its own merits-read everything, including the footnotes.
- Centralized and standardized process, consistent with every study, similar decisions made by reviewers.
- Documents all consistent and in agreement.
- What is the sponsor paying for-how many, how frequently, and how much for the services.

Considerations, continued

- Three categories of payment:
  - All paid for by research;
  - All billed as conventional care;
  - Mixed costs with both research and conventional care services.
- Informed consent cost language:
  - Review for appropriate category of costs;
  - Appropriate information for subject related to that specific study;
  - Appropriate items are conventional care.

Considerations, continued

- Medicare Coverage Analysis and Clinical Research Policy - may take out the National Coverage Determination (NCD) and read it for that specific study.
- Normal Medicare rules - covered benefits, therapeutic intent.
- Non-Medicare payors- Medicare may pay for certain services with qualifying trials that others will not.
- Medical necessity (and telling Researchers that it needs to be documented).

Considerations, continued

- Routine care - would 80% of the non-study patients have that item/service on their bill.
- Check Compendium or Local Coverage Determination (LCD) for coverage.
- Outpatient versus inpatient.
- Budgets-internal and/or part of CRA, need to see final budget agreed upon by all parties.
- Study objectives, inclusion/exclusion criteria, services being done, versus data collection, risks of study, adverse events; hidden costs of payments.

Considerations, continued

- Medicare Qualifying Trials and billing for Medicare Advantage Plan Enrollees.
- Pre-certification/preauthorization needed?
- Financial Counseling arrangements.
- Inform patient if there is a possibility that they will be responsible for any costs, including co-pays, coinsurances and deductibles – in informed consent or informed consent process.

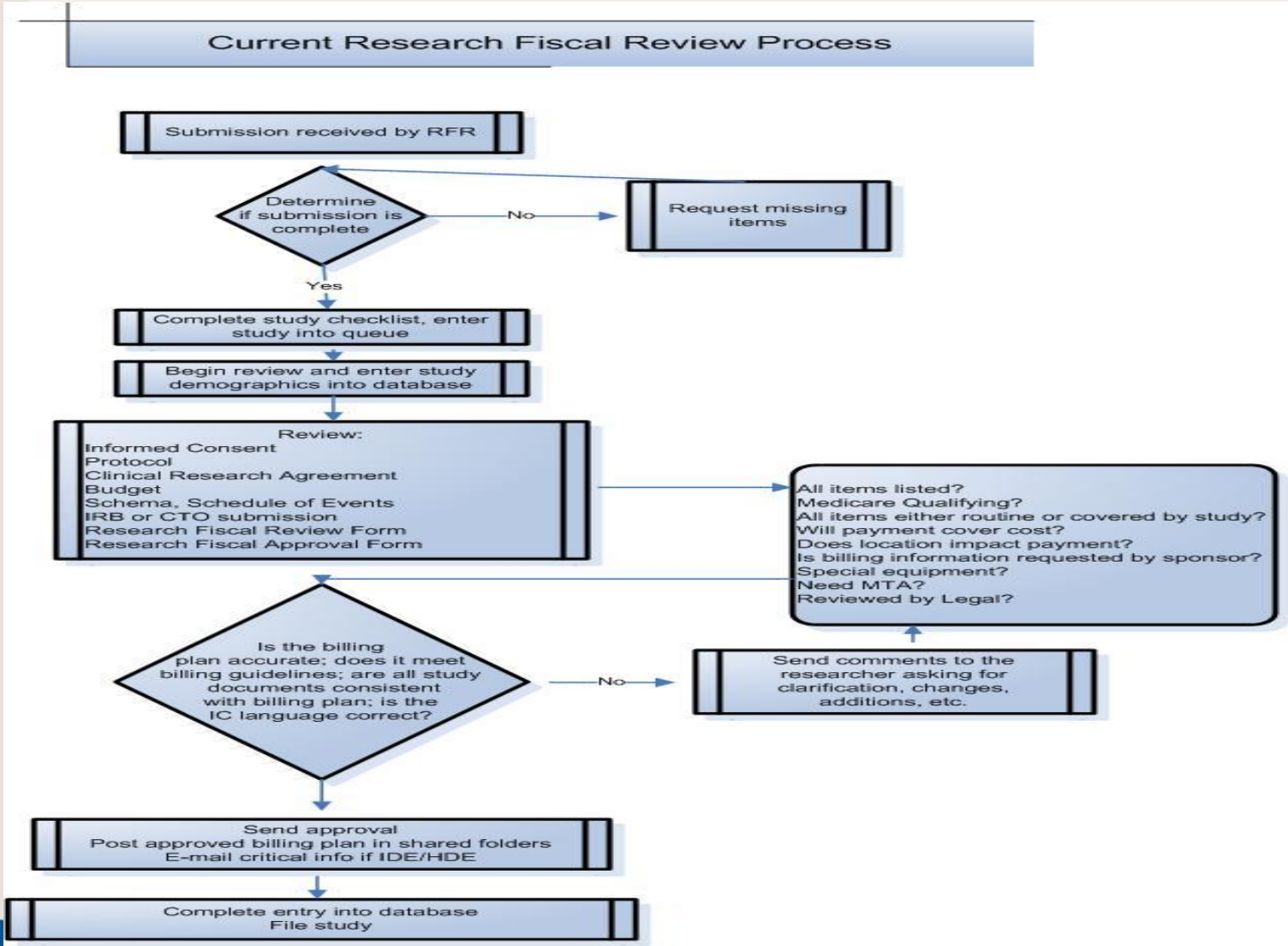
Reimbursement Issues

- Medicare Qualifying
- Local Coverage Decisions
- 72 hour rule, charges rolling together
- Medicare Secondary Payor
- Commercial Payors
- Pennsylvania Medicaid does not cover clinical research.

Additional Tools

- Instructions
- Researcher checklist
- Submission tracking sheet
- Standard informed consent cost language templates

Process Flow



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Billing Process

Process for Billing

- Establish institutional accounts and plan codes for services being paid for by the study.
- Create new Charge Description Master (CDM) code for certain services – IDE/HDE/PMAs.
- Provide participants with a cost estimate if appropriate.
- Obtain pre-certification in some instances.
- Identify study participants at point of registration.
- Use the UPMC Research Requisition to communicate what services should be billed to the institutional accounts and what should be billed to third party payors.

Process for Billing, continued

- Provide and document services for participant.
- Code services as required by Medicare.
- Segregate charges between the bill to third party payor and the bill going to the study.
- Drop the bill.
- Follow-up and audit.

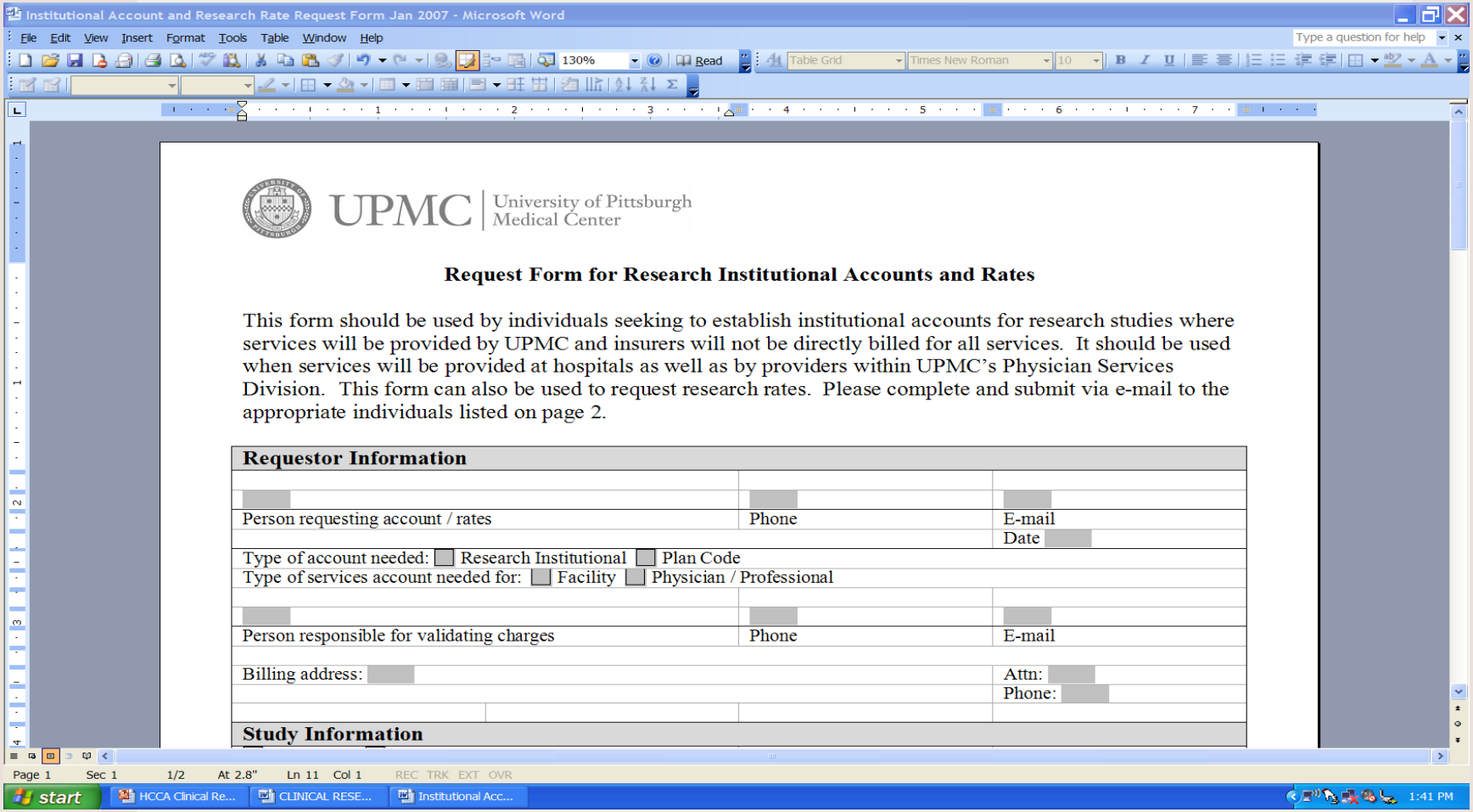
Types of Research Accounts

- Institutional account:
  - Facility (FIA)
  - Professional (PIA)
- Plan code:
  - Facility charges only

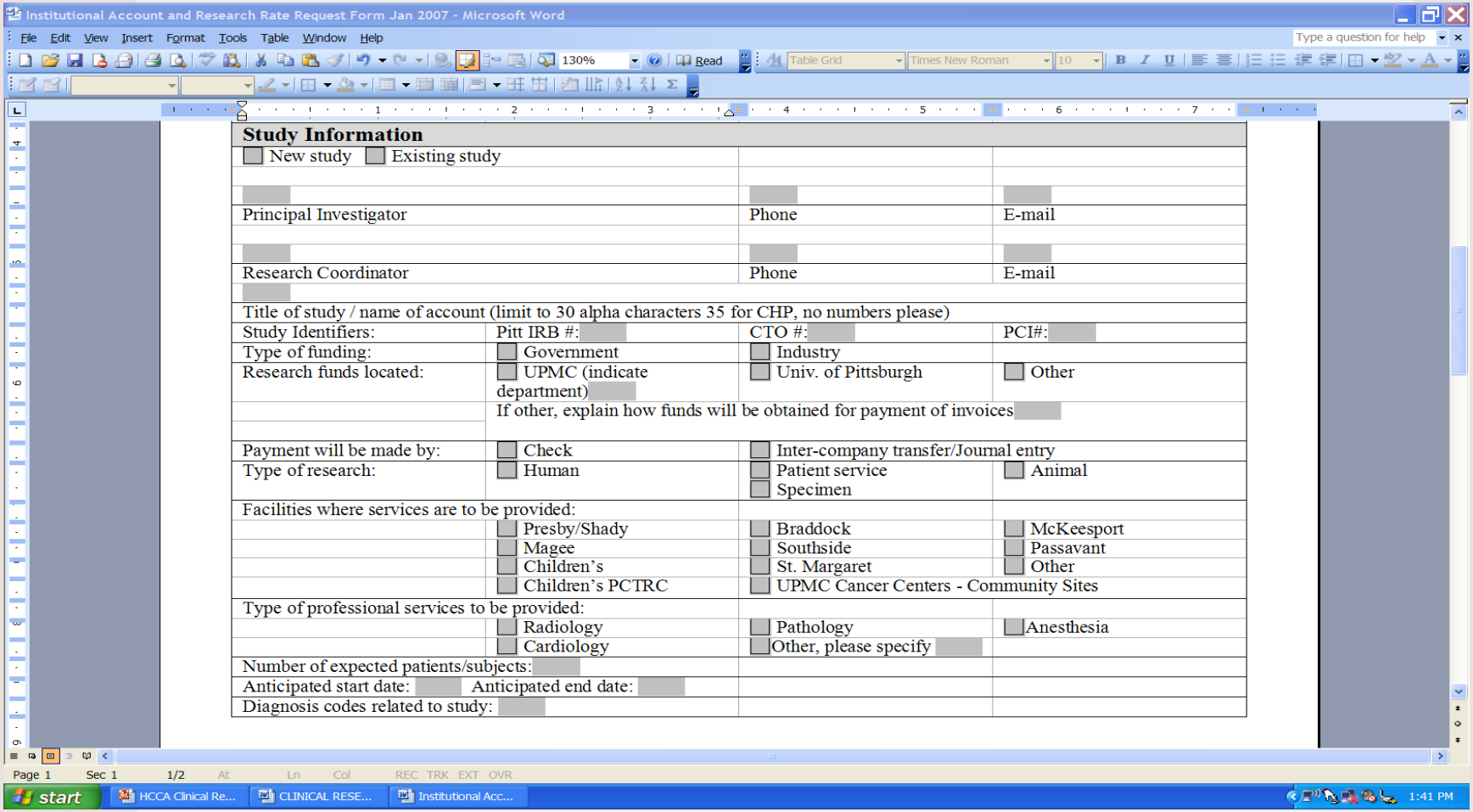
Forms

- Request for Research Rates and Institutional Account
- Research Requisition
- Insurance Verification Form
- Cost Estimate Sheet

Request for Research Institutional Accounts and Rates



Request for Research Institutional Accounts and Rates


Institutional Account and Research Rate Request Form Jan 2007 - Microsoft Word

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Study Information

☐ New study ☐ Existing study			
Principal Investigator		Phone	E-mail
Research Coordinator		Phone	E-mail
Title of study / name of account (limit to 30 alpha characters 35 for CHP, no numbers please)			
Study Identifiers:	Pitt IRB #:	CTO #:	PCI#:
Type of funding:	☐ Government	☐ Industry	
Research funds located:	☐ UPMC (indicate department)	☐ Univ. of Pittsburgh	☐ Other
	If other, explain how funds will be obtained for payment of invoices		
Payment will be made by:	☐ Check	☐ Inter-company transfer/Journal entry	
Type of research:	☐ Human	☐ Patient service ☐ Specimen	☐ Animal
Facilities where services are to be provided:			
	☐ Presby/Shady	☐ Braddock	☐ McKeesport
	☐ Magee	☐ Southside	☐ Passavant
	☐ Children's	☐ St. Margaret	☐ Other
	☐ Children's PCTRC	☐ UPMC Cancer Centers - Community Sites	
Type of professional services to be provided:			
	☐ Radiology	☐ Pathology	☐ Anesthesia
	☐ Cardiology	☐ Other, please specify	
Number of expected patients/subjects:			
Anticipated start date:	Anticipated end date:		
Diagnosis codes related to study:			

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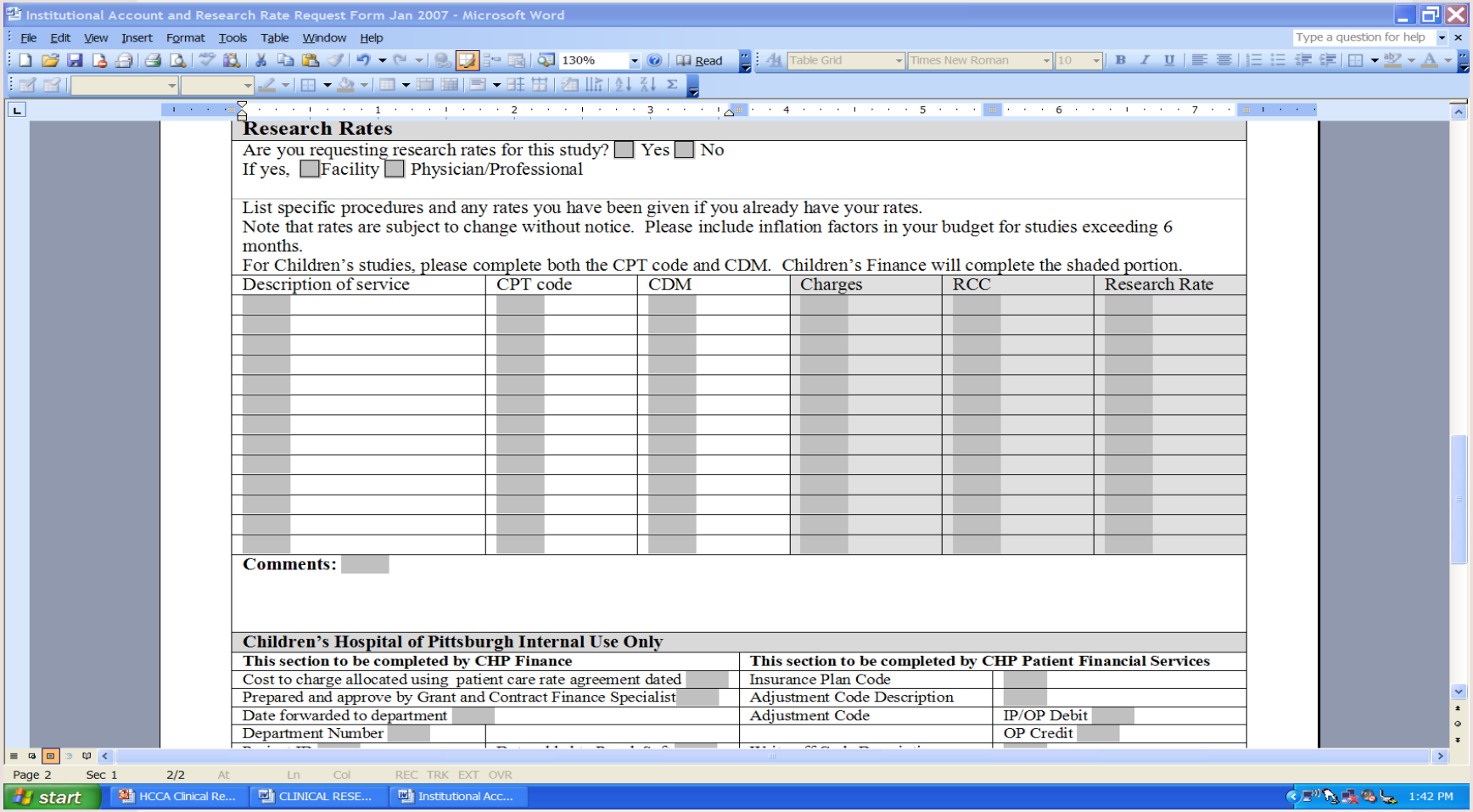
Request for Research Institutional Accounts and Rates



Institutional Account and Research Rate Request Form Jan 2007 - Microsoft Word

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Research Rates

Are you requesting research rates for this study? ☐ Yes ☐ No
If yes, ☐ Facility ☐ Physician/Professional

List specific procedures and any rates you have been given if you already have your rates.
Note that rates are subject to change without notice. Please include inflation factors in your budget for studies exceeding 6 months.
For Children's studies, please complete both the CPT code and CDM. Children's Finance will complete the shaded portion.

Description of service	CPT code	CDM	Charges	RCC	Research Rate

Comments:

Children's Hospital of Pittsburgh Internal Use Only

This section to be completed by CHP Finance		This section to be completed by CHP Patient Financial Services	
Cost to charge allocated using patient care rate agreement dated		Insurance Plan Code	
Prepared and approve by Grant and Contract Finance Specialist		Adjustment Code Description	
Date forwarded to department		Adjustment Code	IP/OP Debit
Department Number			OP Credit

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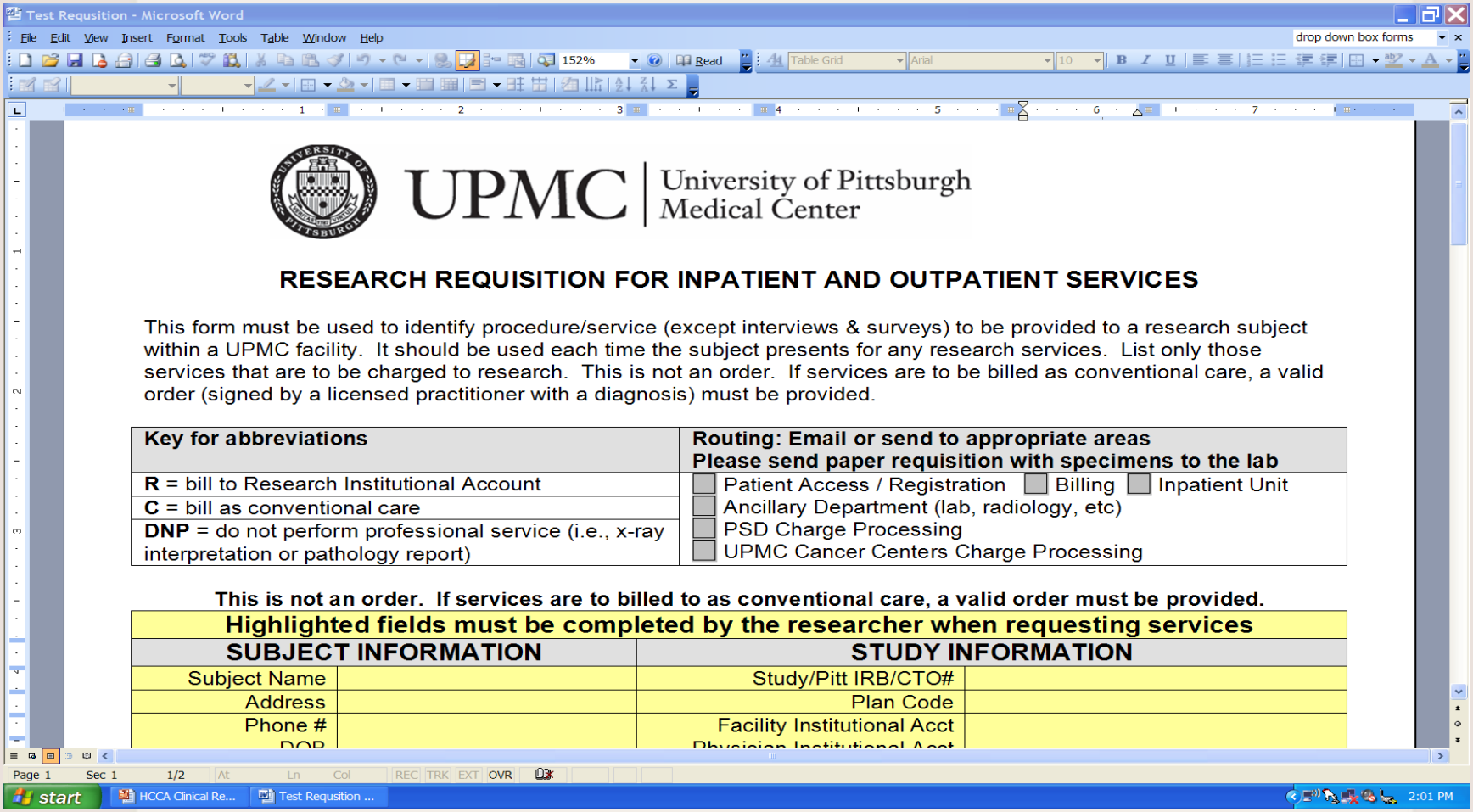
Research Requisition



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RESEARCH REQUISITION FOR INPATIENT AND OUTPATIENT SERVICES

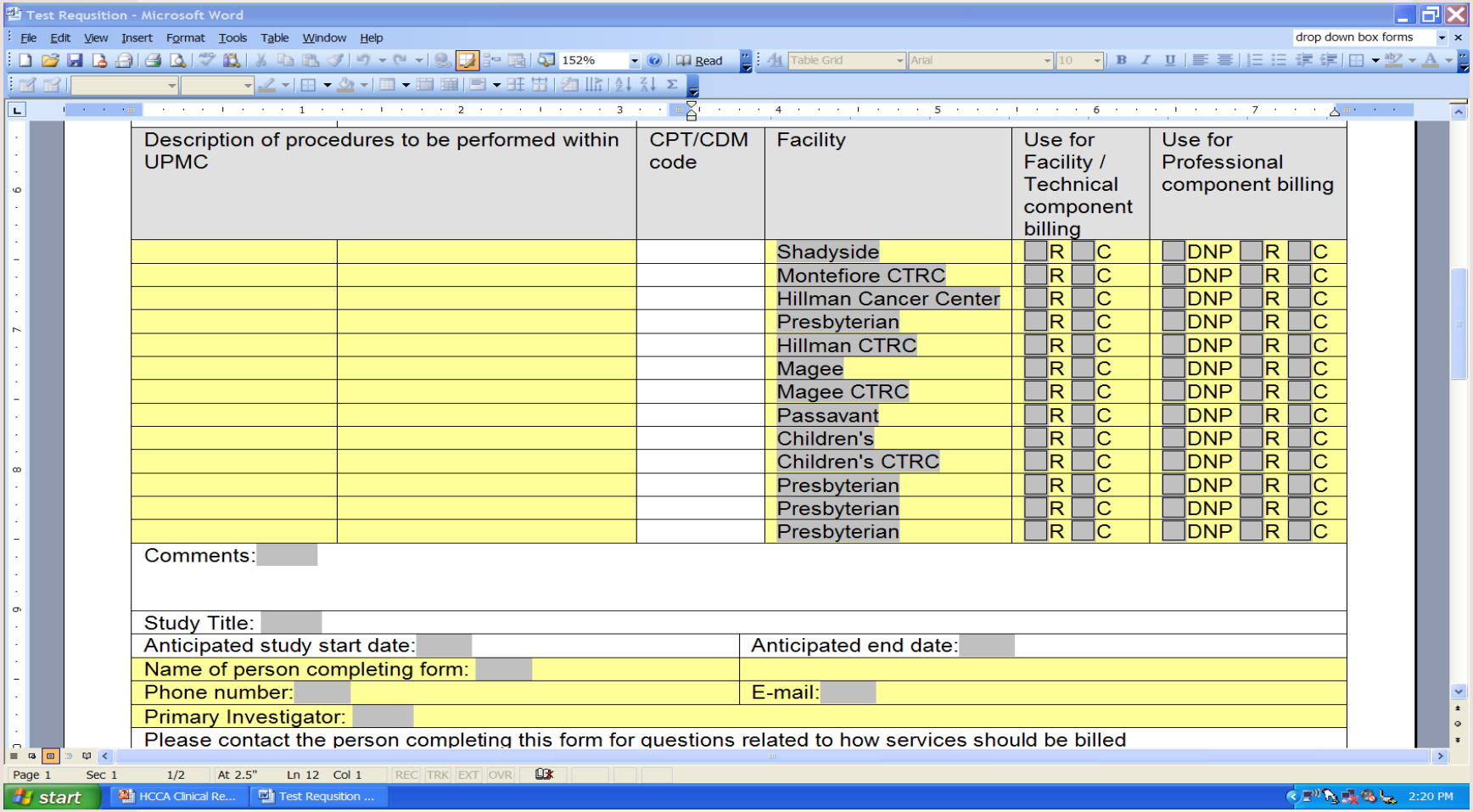
This form must be used to identify procedure/service (except interviews & surveys) to be provided to a research subject within a UPMC facility. It should be used each time the subject presents for any research services. List only those services that are to be charged to research. This is not an order. If services are to be billed as conventional care, a valid order (signed by a licensed practitioner with a diagnosis) must be provided.

Key for abbreviations	Routing: Email or send to appropriate areas Please send paper requisition with specimens to the lab
R = bill to Research Institutional Account	☐ Patient Access / Registration ☐ Billing ☐ Inpatient Unit
C = bill as conventional care	☐ Ancillary Department (lab, radiology, etc)
DNP = do not perform professional service (i.e., x-ray interpretation or pathology report)	☐ PSD Charge Processing ☐ UPMC Cancer Centers Charge Processing

This is not an order. If services are to billed to as conventional care, a valid order must be provided.

Highlighted fields must be completed by the researcher when requesting services			
SUBJECT INFORMATION		**STUDY INFORMATION**	
Subject Name		Study/Pitt IRB/CTO#	
Address		Plan Code	
Phone #		Facility Institutional Acct	
DOB		Physician Institutional Acct	

Research Requisition



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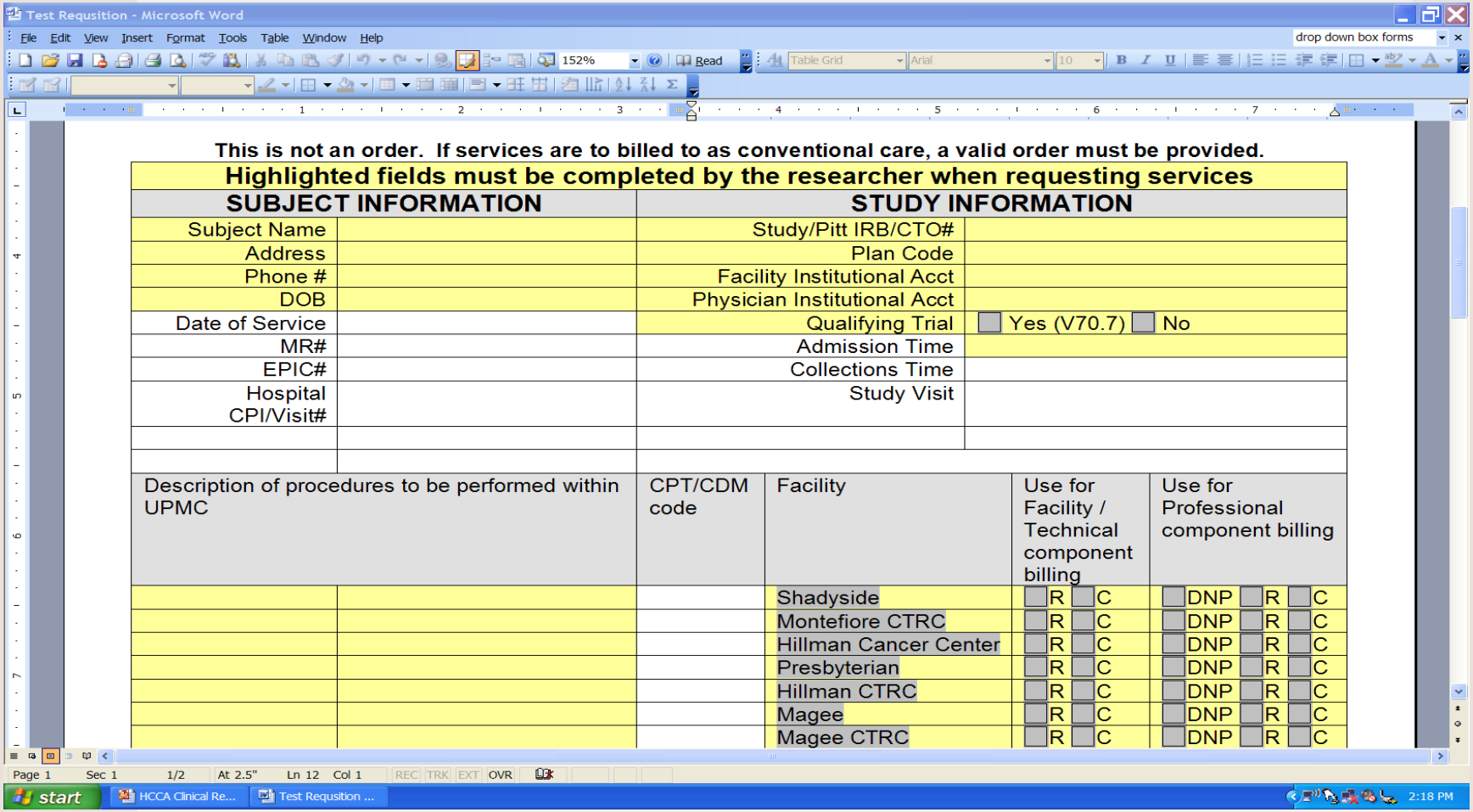
Research Requisition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drop down box forms

This is not an order. If services are to billed to as conventional care, a valid order must be provided.

Highlighted fields must be completed by the researcher when requesting services			
SUBJECT INFORMATION		**STUDY INFORMATION**	
Subject Name		Study/Pitt IRB/CTO#	
Address		Plan Code	
Phone #		Facility Institutional Acct	
DOB		Physician Institutional Acct	
Date of Service		Qualifying Trial	☐ Yes (V70.7) ☐ No
MR#		Admission Time	
EPIC#		Collections Time	
Hospital CPI/Visit#		Study Visit	

Description of procedures to be performed within UPMC		CPT/CDM code	Facility	Use for Facility / Technical component billing	Use for Professional component billing
			Shadyside	☐R ☐C	☐DNP ☐R ☐C
			Montefiore CTRC	☐R ☐C	☐DNP ☐R ☐C
			Hillman Cancer Center	☐R ☐C	☐DNP ☐R ☐C
			Presbyterian	☐R ☐C	☐DNP ☐R ☐C
			Hillman CTRC	☐R ☐C	☐DNP ☐R ☐C
			Magee	☐R ☐C	☐DNP ☐R ☐C
			Magee CTRC	☐R ☐C	☐DNP ☐R ☐C

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Billing Specifics

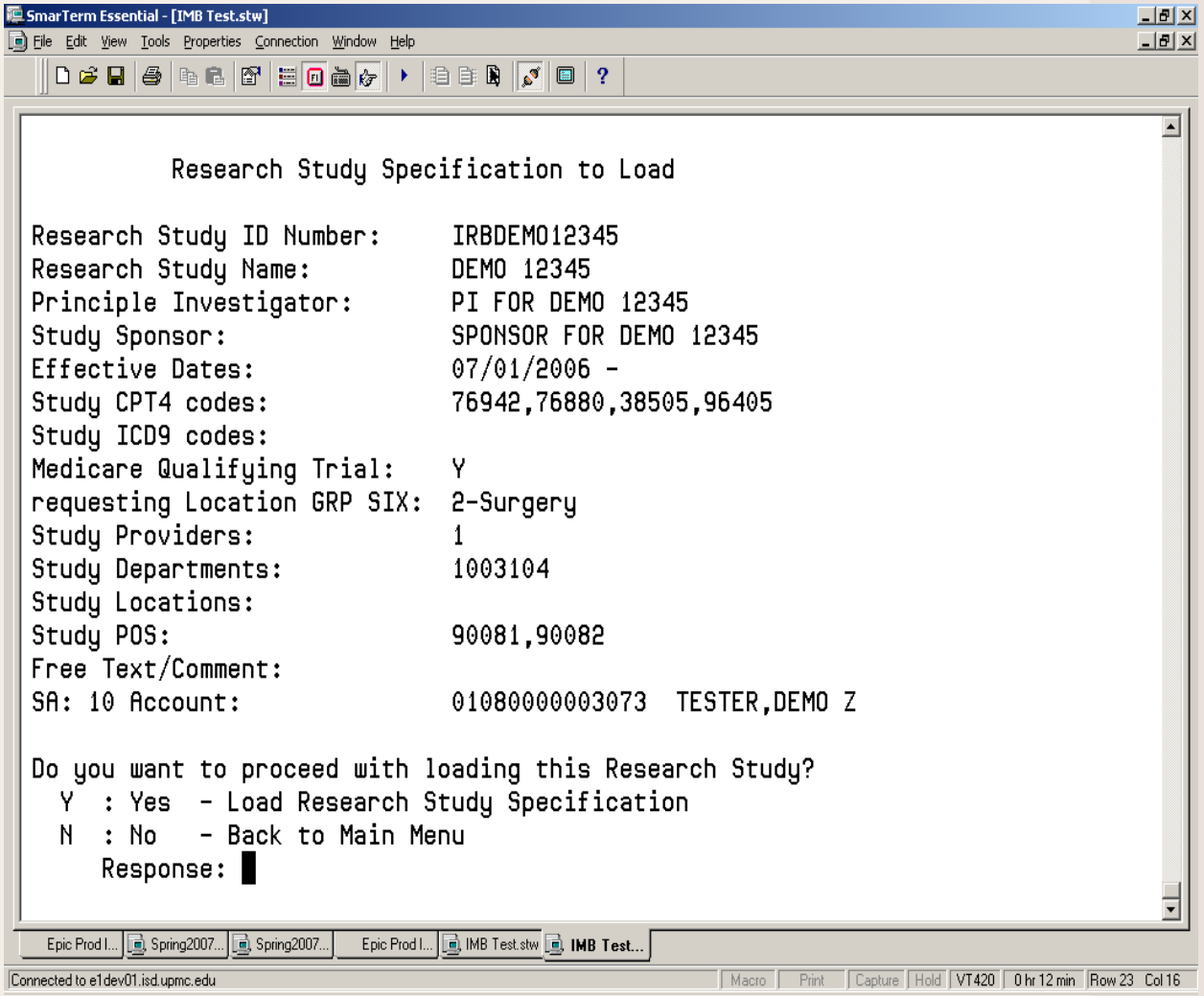
- Interfaces between IT systems to identify study participants, flag patient accounts, process charges, create review queues.
  - CTMA (clinical trials management application)
  - EPIC (professional billing system)
  - Medipac (facility billing system)

EPIC – Professional Billing

Research Study Parameter Definition

Research Study Protocol Elements

- ❖Research Study ID No#:
- ❖Research Study Name:
- ❖Principle Investigator:
- ❖Study Sponsor:
- ❖Effective Dates:
- ❖Medicare Qualifying
- ❖Requesting Location GRP
- ❖Study Providers:
- ❖Study Departments:
- ❖Study POS:
- ❖Study CTP4 Codes:
- ❖Study ICD9 Codes:
- ❖Diagnosis:
- ❖Free Text/Comment:
- ❖Service Area Account



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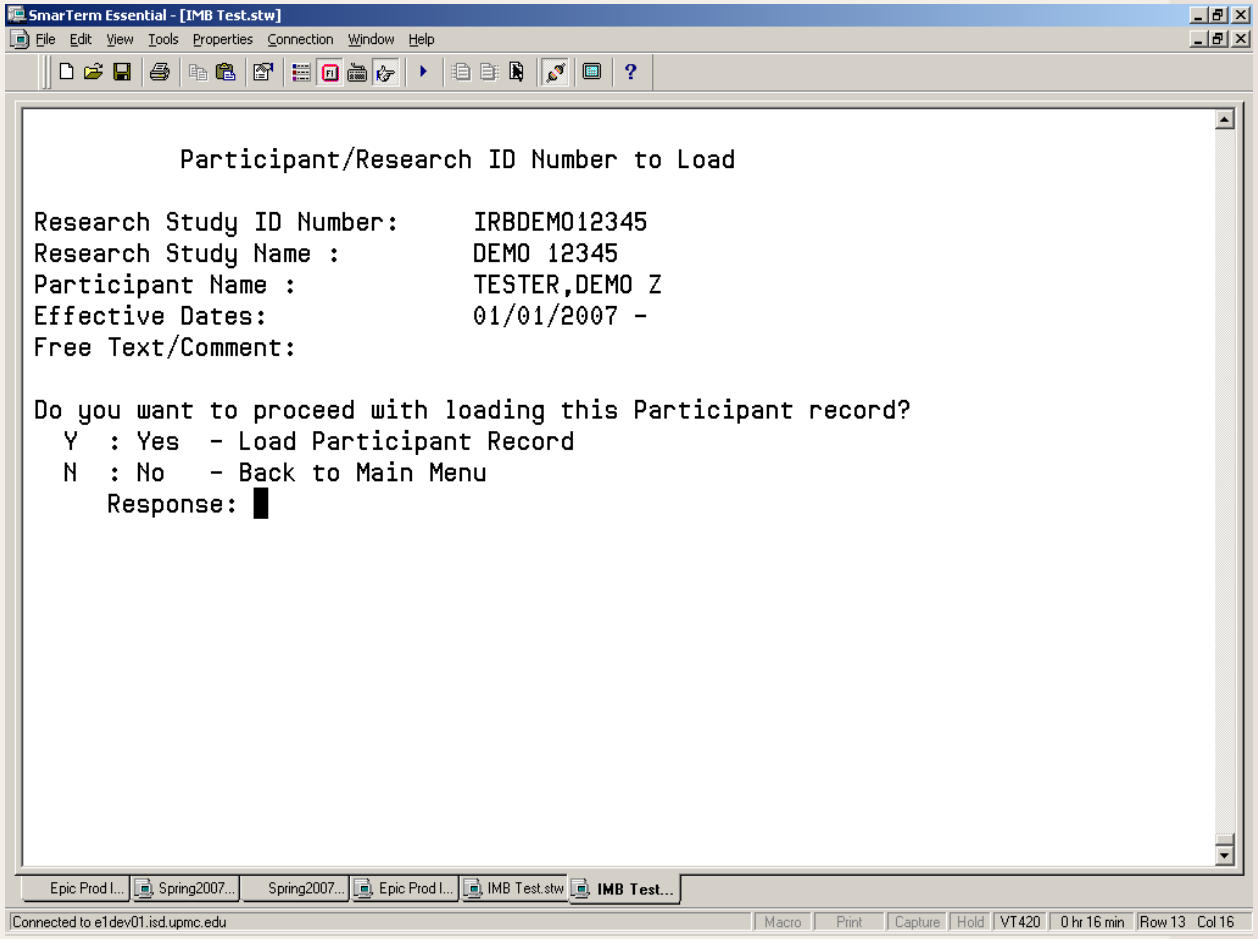
EPIC – Professional Billing, continued

Research Patient Participation Definition

Research Study Protocol Elements

- Participant Name :
- Research Study ID No#
- Effective Dates:
- Free Text/Comment:



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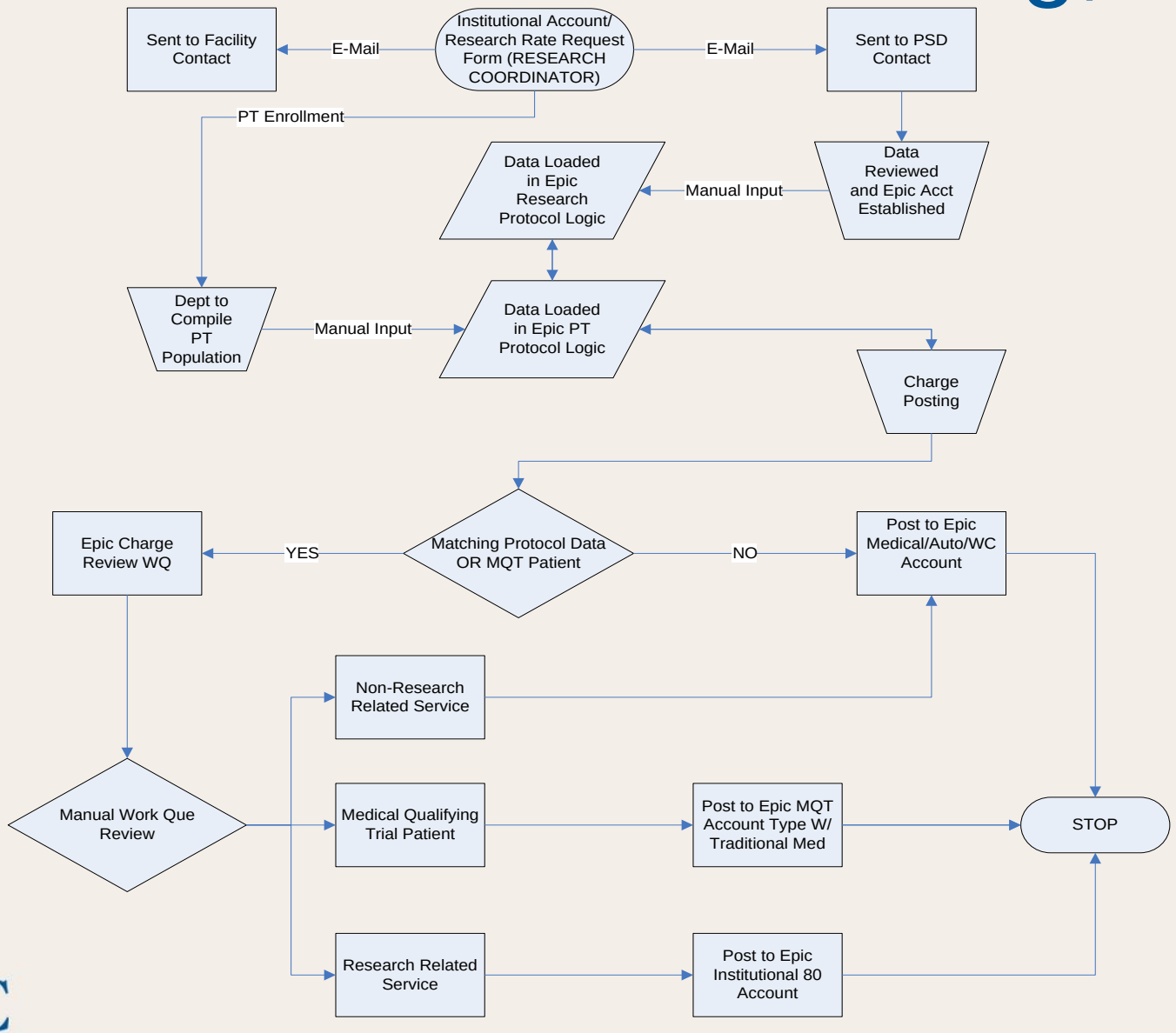
EPIC – Professional Billing, continued



Medipac – Facility Billing

- Research requisition goes to many areas including the area of patient billing responsible for research accounts.
- The staff reviews the requisition to ensure charges have been posted appropriately.
- Currently involved in a trial of a work review queue for oncology studies.

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Supporting Elements

Supporting Elements

- Policies and Procedures
- Education
- Database

Policies

- IRB Approval of Studies Conducted at UPMC
- Research Fiscal Review
- Medicare Qualifying Trials
- Investigational and Humanitarian Use Devices
- Sponsor Requests for Billing Records

Education

- Regular meetings for updates, general education, Q&A
- E-mail updates
- Website
- IDE Training
- Meetings with clinical departments
- UPMC revenue cycle staff

Database

- Track studies reviewed.
- Includes many data elements:
  - Basics – title, PI, date received, sponsor
  - Study detail – location, Medicare qualifying, institutional account, IND #, IDE#, comments

Challenges

- Bringing together all of the individuals that are part of the process
- Organization of documents (electronic & paper)
- Increasing number of studies to review
- Increasing complexity of studies
- Education & communication – changes in environment and research staff

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Questions?

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Resources

- Medicare Policy on Clinical Trials
  http://www.cms.hhs.gov/clinicaltrialpolicies/
- Medicare Advantage Information
  http://www.medicare.gov/Choices/Advantage.asp