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Clinical Trials Billing Toolkit

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October, 2012

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About this Toolkit

This toolkit has been created to provide information and education specific to topics related to Clinical Trial Billing.

Informational sections are designated with the symbol:

Individual tools are designated with the symbol:

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Helpful tools

Tool: Checklist for Corporate Sponsored Clinical Trial Submission to PCRO

Tool: Notification form for Investigational Devices

Tool: Managing / Monitoring Your Study Fund

Tool: End of Trial / Close out Checklist

http://bwhbri.partners.org/research_compliance/documents/billingtools.aspx

What is a clinical trial?

'Although there are many definitions of clinical trials, they are generally considered to be biomedical or health-related research studies in human beings that follow a pre-defined protocol. … Interventional studies are those in which the research subjects are assigned by the investigator to a treatment or other intervention, and their outcomes are measured. Observational studies are those in which individuals are observed and their outcomes are measured by the investigators.'

http://clinicaltrials.gov/ct2/info/understand#types

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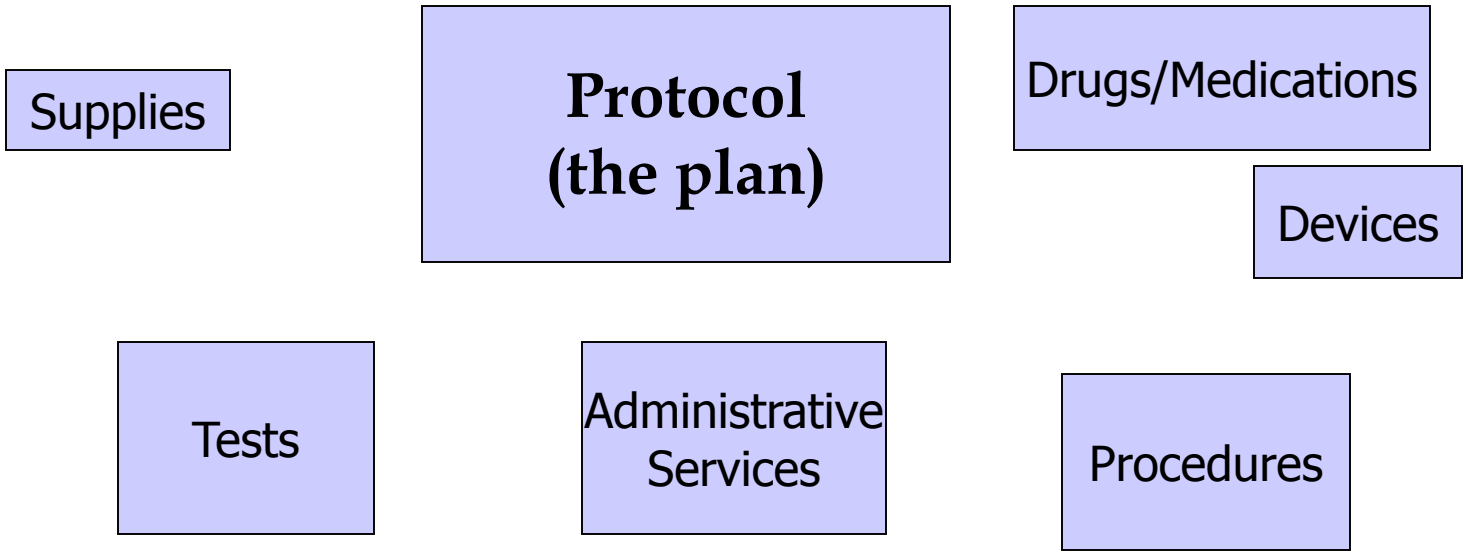
Components of the trial



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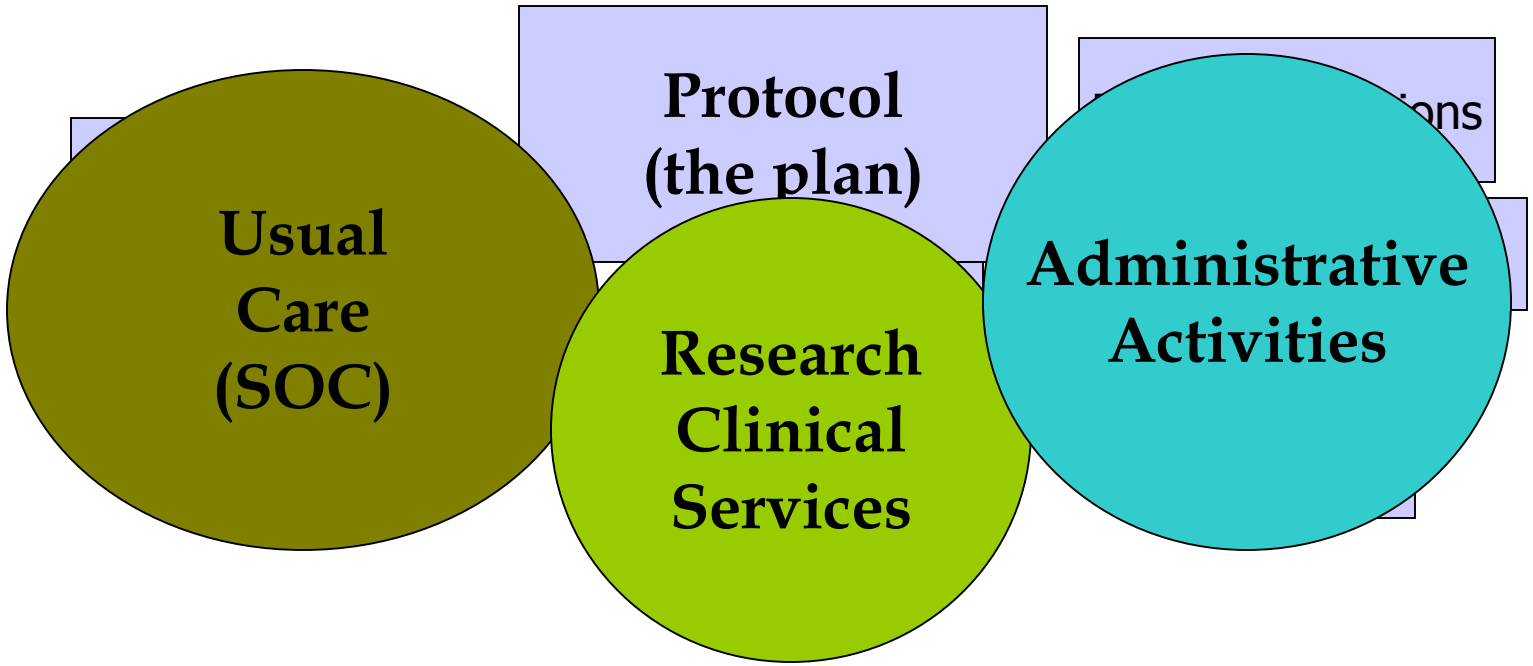
The trial…



Who sponsors clinical trials?

- Corporate sponsors
- Government sponsors
  - National Institutes of Health (NIH)
  - The Department of Defense (DOD)
  - The Department of Veterans Affairs (VA)
- Foundations
- BWH Departmental (Sundry) Funds

http://clinicaltrials.gov/ct2/info/understand#Q14

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Who sponsors clinical trials?

"Clinical trials are sponsored or funded by a variety of organizations or individuals such as physicians, medical institutions, foundations, voluntary groups, and pharmaceutical companies, in addition to federal agencies such as the National Institutes of Health (NIH), the Department of Defense (DOD), and the Department of Veteran's Affairs (VA). Trials can take place in a variety of locations, such as hospitals, universities, doctors' offices, or community clinics."

http://clinicaltrials.gov/ct2/info/understand#Q14

Types of Trials

There are different types of trials including those to test treatments, drugs, or therapies; or to look at approaches to disease prevention.

Getting familiar with the type of trial will assist with defining services and assessing resources required for the trial.

- Treatment trials
- Prevention trials
- Diagnostic trials
- Screening trials
- Quality of life trials

http://clinicaltrials.gov/ct2/info/understand#Q18

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Key Concept:

Every clinical service provided has a patient care 'charge'

- When considering billing in the context of a clinical trial… Every patient care/clinical service provided to a patient/subject has a patient care charge which must be accounted for.

- The patient care charge might be billed to insurance or might be charged or 'directed' to the study fund. **All charges must be billed 'somewhere'.**

- It's essential to understand how each patient care charge in your clinical trial will be directed. This will help to ensure proper and accurate billing of clinical services.

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What is a Patient care charge?

- The charge associated with the provision of a clinical service to a patient.
- These services are defined in the institution's rate book.
- Most services have a hospital (technical) component and a physician (professional) component.

Sometimes referred to as 'patient care costs' in regard to research.

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Pre-contract activities for sponsored trials

- Protocol review or development/Planning of services
- Initial discussion with a sponsor
- Communication with PCRO or RM

Protocol review or development/Planning of services

The *protocol* may be prepared by a sponsor or be PI-initiated
It defines the services to be provided:

- Are the clinical services usual care for this patient population, or are they only being provided because of the research protocol?

  Patients may receive care either as part of a clinical trial during their usual care visit, or during a research specific visit/encounter.

- Where will the clinical services be provided, and by whom?

  The research clinical services may be provided in any of the typical locations where usual care is provided – i.e. an inpatient floor, an outpatient clinic, an ambulatory treatment room, or the Emergency Department.

- What are the informed consent issues to be considered?

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Key Concept

Planning of services

It's essential to understand what the research clinical services are in the protocol, as distinct and separate from the usual care clinical services, in order to properly budget and direct the patient care charges appropriately.

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Initial discussion with a sponsor

Your PI may have preliminary discussions with a corporate sponsor, before any of these types of activities have occurred. Although there may appear to be ways to 'shortcut' the process, each component of the process brings value and will help to ensure the proper processing of research related clinical care charges.

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Corporate (industry) sponsored trials - PCRO

The mission of Partners Clinical Research Office (PCRO) is to support research and the translation of Partners HealthCare science to the patient bedside.

- Providing service and support to investigators
- Ensuring compliance with requirements of Partners and sponsors

PCRO:

- Develops, negotiates, and executes agreements and budgets for industry-sponsored clinical research
- Prepares Medicare coverage analyses (MCA) for all clinical trials
- Prepares and submits Category B Investigational Device Exemption (IDE) and PMA carotid stent trial petitions and renewals to Medicare
- Provides contracting services to specialized research service facilities (also known as "recharge centers" or "core facilities")

http://www.partners.org/Medical-Research/Resources/Research-Support/PCRO/About/Mission-and-Goals.aspx

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Helpful tools

Tool: Checklist for Corporate Sponsored Clinical Trial Submission to PCRO

Use this checklist as a step by step guide for working with the Partners Clinical Research Office (PCRO).

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Federal or foundation sponsored trials – RM

The Pre-Award team within Research Management (RM) provides support and assistance to Principal Investigators (PIs) and Department Administrators (DAs) as they prepare proposals for submission to external sponsors. The Pre-Award team works closely with colleagues on RM's Post-Award, Contracts and Research Finance teams to support these research projects throughout various stages in the lifecycle of a grant.

The primary responsibilities of Pre-Award include support to investigators related to budgeting for patient care costs and effort. Click on this link for more details:

http://resadmin.partners.org/RM_Home/Proposals/Proposals.aspx

The contracting process

- CMS Clinical Trial Policy
  - What it is – Why it matters
  - Medicare Coverage Analysis (MCA)

- Budget development and negotiation

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CMS Clinical Trial Policy

What it is – Why it matters…

Since many clinical research services are provided during a patient's outpatient visit or inpatient stay, and the research services become interspersed with the usual care services, it's important to understand the CMS/Medicare guidelines for sorting these out and determining what services are billable to Medicare.

Usual and customary care, appropriately documented for medical necessity, can always be billed to insurance.

Some research (i.e. protocol) specific clinical services may be billable when provided within a qualifying clinical trial and pre-determined to be 'allowed'. We follow the guidance of the CMS Clinical Trial Policy to see if these services may be billed to insurance.

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CMS Clinical Trial Policy

The Centers for Medicare and Medicaid Services (CMS) Clinical Trial Policy (CTP) says that the study must meet these criteria in order to bill Medicare for patient care services related to a clinical trial:

1. The study must meet the 'qualifying' requirement
2. The services must meet the definition of 'routine cost'
3. Medicare must typically pay for those services when provided outside of the context of the clinical trial

More details are available:

http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&bc=BAABAAAAAAAA&

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PCRO and the Medicare Coverage Analysis (MCA)

Partners Clinical Research Office (PCRO) conducts a Medicare coverage analysis for all non-oncology clinical research protocols at Brigham and Women's Hospital/Faulkner Hospital, Massachusetts General Hospital, and Spaulding Rehabilitation Hospital.

'A Medicare coverage analysis (MCA) is required for all clinical trials in which tests, procedures, and interventions associated with a clinical trial are invoiced to third party payers.'

This will determine whether the trial is qualifying, and therefore if some research clinical services may be billed to Medicare/insurance.

If qualifying, the PCRO will create a billing summary/grid (i.e. MCA), which will document the source of funding for each clinical service.

http://www.partners.org/Medical-Research/Resources/Research-Support/PCRO/For-Investigators/Medicare-Coverage-Analysis.aspx

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The MCA

- ✓ IS a study-specific billing summary that lists all items and services to be provided as part of a qualifying clinical trial with notations of what should be billed to the research sponsor and what can be billed to Medicare.
- ✓ IS a Partners requirement since January, 2008 (BWH, Faulkner, Spaulding, and MGH).
- ✓ IS required by the IRB before protocol activation will be completed.
- ✓ IS required for both industry sponsored and federal/foundation sponsored qualifying clinical trials.

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Why an MCA is important…

- Informs the PI / study staff of how to direct the patient care charges.
- Becomes a tool for research billing compliance.
- Helps to avoid the risks of non-compliance.
  - Billing for services paid for by the sponsor >> ***fraud***
  - Billing for services promised free in the informed consent >> ***fraud***
  - Billing for services that are specific to the research protocol, but not medically necessary >> ***fraud***

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What an MCA is not…

- Not a reimbursement analysis
- Not quantitative (does not detail actual billing codes)
- Not a definition of coverage by private payers

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Sample Final MCA – with PI input

Procedure	Screening	2 wks	3 mo	6 mo	9 mo	12 mo	15 mo	Comments
Informed consent	NB							This service is research only and not billable to Medicare.
Inclusion / Exclusion	NB							This service is research only and not billable to Medicare.
Vitals	n/a							This service is bundled with the physical exam and not separately billable.
Randomization		NB						This service is research only and not billable to Medicare.
Physical exam	M	M	M	M	M	M	M	Given the patient's condition, a physical examination appears reasonable and necessary at work-up to address signs and symptoms. A physical examination in follow-up and during unscheduled visits appears appropriate to monitor and detect for complications
Pregnancy test	NB							This is not a covered service.
TTE	M		NB			M	NB	We assume that given the patient's presenting symptoms and procedure performed that a transthoracic echocardiogram is reasonable and necessary at this frequency to initially diagnose and then monitor patient's condition. Coverage supported by Massachuset PI has indicated 3 and 15 mo are not usual and customary care at BWH.
Study drug		ICF	ICF	ICF	ICF	ICF	ICF	Study drug promised free of charge in informed consent..
Study drug administration		M	M	M	M	M	M	IV administration of the investigational drug is a covered service under NCD 310.1.
Adverse events		F	F	F	F	F	F	This involves filling out a form and this activity is not separately billable to Medicare.
Concomitant meds	F	F	F	F	F	F	F	This involves filling out a form and this activity is not separately billable to Medicare.
SF 36	NB	NB	NB	NB	NB	NB	NB	This service is research only and not billable to Medicare.

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What if my clinical trial is not 'qualifying'?

Most clinical trials are ***not qualifying*** under Medicare's CTP. This typically means that the investigational (research) services in the study do not meet the requirement for therapeutic intent - and the trial is likely considered primarily observational in nature.

- PCRO will not create a billing grid – **You should create a grid, based on the services defined in the protocol.**
- The IRB will be informed by PCRO that the MCA requirement for this study has been completed.
- All of the research only procedures associated with the study on your grid must be charged to your study fund.

If the subject is receiving usual and customary care services on the same day as investigational (research) clinical services, the usual and customary care may be billed to Medicare or insurance in the usual manner.

Again – the investigational (research) specific clinical services are billed to/charged to the study fund.

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Create your own 'services' grid

Study Assessment	Day of Procedure	6 Month Contact	1 Year Contact	2 Year Contact	3 Year Contact
inclusion/exclusion criteria	NB				
Informed consent (pre procedure)	NB				
Verification of consent (post procedure)	NB				
Blood draw for blood analysis (using catheter in place, but in addition to usual care)	NB				
Additional biopsy 'single' sample (post routine biopsy)	NB				
Survey - Medicare death index for patient survival		NB	NB	NB	NB
Administer Standardized Health Survey		NB	NB	NB	NB
Adverse Events		NB	NB	NB	NB

This grid becomes the guide for properly directing research clinical services charges to the study fund.

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Budget development and negotiation

Know the protocol

- what is 'usual and customary care'
- what are 'research specific' services

Know the billing rules

Cannot bill for any services that are:

- paid for by the research sponsor
- promised free in the informed consent
- not ordinarily covered by Medicare
- provided solely to determine eligibility or for data collection/analysis

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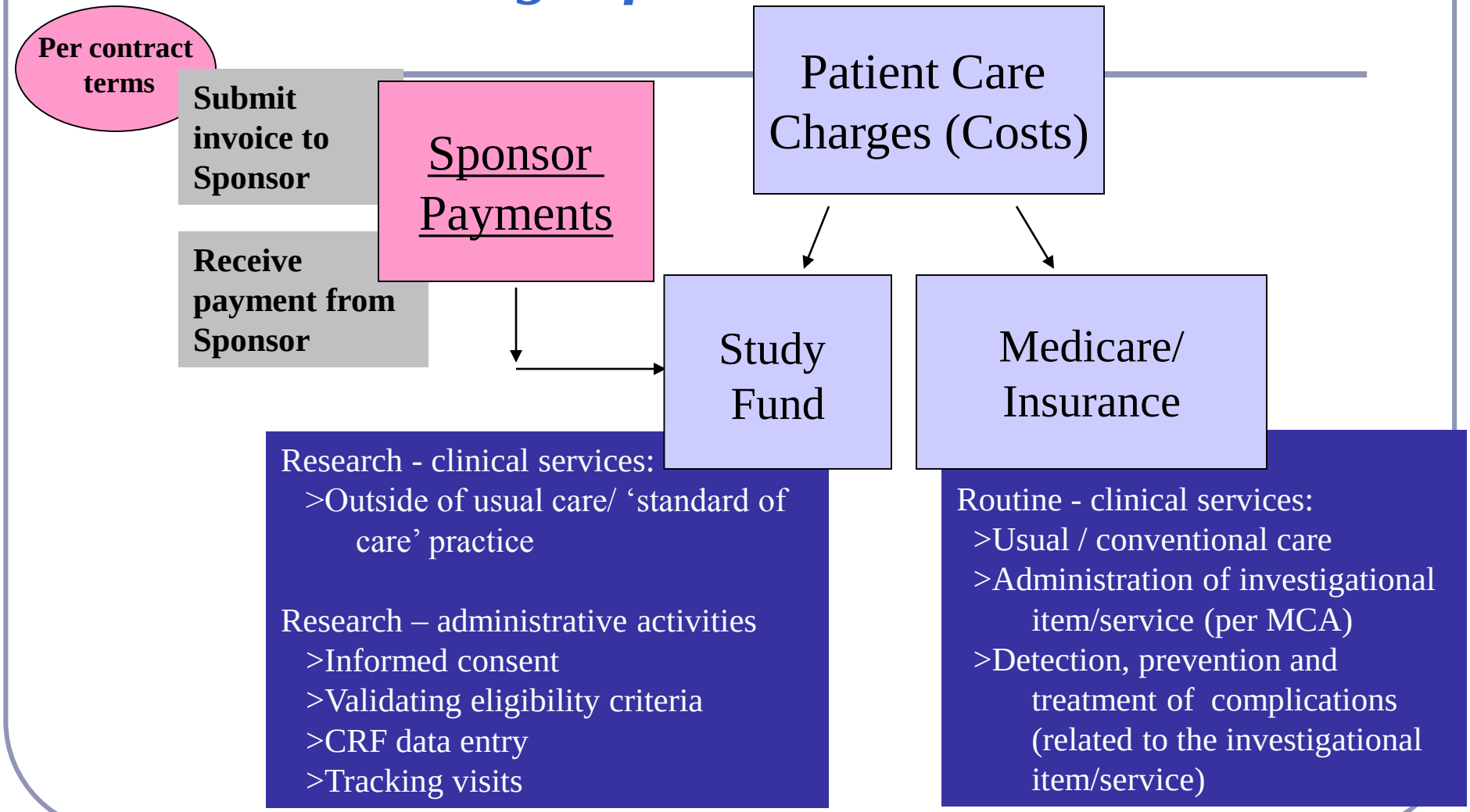
Patient care charges flow in a clinical trial



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The budget

The budget is typically comprised of:

Administrative activities

- Informed consent
- Assessing eligibility criteria
- Capturing data required for the protocol
- Performing Partners IRB requirements

Clinical services/procedures

- Tests/procedures that are usual care and research clinical services
  - (Use Insight/Budget Builder to identify specific charge codes)

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Summary – Steps for budgeting for a clinical trial

- Understand the protocol
- Identify all the services in the protocol
  - Know what's billable to either insurance or the study fund
  - Determine if you are going to use Research Core services in the trial
- Know 'where' (physical location) services are being provided
- Price all research clinical services using the CPT codes (Insight/Budget Builder)
- Apply the institutional research discounts

➢ Reminder - Some services are combinations of CPT codes ('bundled').

➢ We want to ensure that the sponsor's support will cover the charges.

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Research Cores

Research Core Services have been created to provide research clinical services to subjects in clinical trials.

- Review your protocol services requirements, then evaluate if a core service may be a more efficient delivery manner.
- Services have associated 'user' fees.
- Fees are invoiced to investigators monthly, then cross-charged to study funds directly.

http://www.partners.org/researchcores/home.asp

www.bwhbri.partners.org
Quick Links: How do I…
Find a Core Facility?

Budgeting Checklist

A 'per patient budget' covers items / services directly related to patient enrollment:

- Ancillary clinical services charges
- Professional fees
- Inflation
- Payment for services performed by staff, based on time estimate (cost based on hourly rate)
- Fringe rates – anticipate fiscal year (beginning each Oct 1st) increases in fringe rates

Total budget will also include one-time fees: IRB fee, MCA fee (if applicable), start up fees, storage fees, FDA audit fees

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Draft Per Patient Budget (typical industry)

Procedure	Screening	2 weeks	3 mo	6 mo	9 mo	12 mo	15 mo	Total
Informed consent	100							100
Inclusion / Exclusion	50							50
Vitals	included in phys exam							0
Randomization		50						50
Physical exam	Usual and customary care	Usual and customary care	Usual and customary care	Usual and customary care	Usual and customary care	Usual and customary care	Usual and customary care	0
Pregnancy test	65							65
TTE	Usual and customary care		750			Usual and customary care	780	1,530
Study drug		sponsor	sponsor	sponsor	sponsor	sponsor	sponsor	0
Study drug administration		M	M	M	M	M	M	0
Adverse events		50	50	50	50	50	50	300
Concomitant meds	50	50	50	50	50	50	50	350
SF 36	40	40	40	40	40	40	40	280
Patient parking	25	25	25	25	25	25	25	175
Coordinator - crf completion, scheduling, administrative mgmt	150	125	125	125	125	125	150	925
PI - crf signoff, study oversight, clinical mgmt of patients study related	175	150	150	150	150	150	175	1,100
Subtotal	655	490	1,190	440	440	440	1,270	4,925
Overhead @ 25%	164	123	298	110	110	110	318	1,231
Total	819	613	1,488	550	550	550	1,588	6,156

Nuance on charges …

For industry sponsored clinical trials:

The budget incorporates both technical and professional charges.

For federal sponsored clinical trials:

Professional charges for services provided by the principal investigator cannot be charged to a study fund where the principal investigator has effort assigned. But the professional fees for other investigators involved in the trial, and the hospital technical charges (patient care costs) should be directed to study funds appropriately.

Post-contract – preparing to enroll subjects

- IRB approval
- Subject enrollment documentation
- Device trials
- Directing patient care charges

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What is the IRB?

'The Partners Human Research Committee (PHRC) is the Institutional Review Board (IRB) of Partners Research Management. The PHRC must approve all human-subject research conducted by a Partners-affiliated investigator. Human-subject research is a systematic investigation designed to develop or contribute to generalizable knowledge where an investigator obtains data on individuals either through direct intervention/interaction or through the use of identifiable private information (medical records) or specimens. Research limited to the use of non-identifiable patient information may qualify for exemption from full IRB review, however all exemptions must be determined or granted by the Human Research Office.'

You must have IRB approval before proceeding with the trial.

http://healthcare.partners.org/phsirb/abouthrc.htm

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Subject recruitment/enrollment and identifying research specific services

Once the contract has been executed and IRB approval has been received, activities specific to recruitment and enrollment can begin.

Reminders about the Informed Consent:

- You cannot bill insurance for or receive payment from a sponsor for anything offered as 'free' in the consent
- The contract and the consent should be 'in sync' regarding who is paying for what clinical services

http://healthcare.partners.org/phsirb/consfrm.htm

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Subject recruitment/enrollment and identifying research specific services

Once the contract has been executed and IRB approval has been received, activities specific to recruitment and enrollment can begin.

Before you begin ordering clinical services for subjects you will need a way to identify the services as 'related' to the trial, for proper charge direction.

When ordering or scheduling services it must be clear which services will be billed to insurance and which services will be charged to the study fund.

You should use your services grid or the MCA to guide this.

Remember, if there is no MCA, all investigational (research) services must be directed to the study fund.

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Proper charge direction

If research patient care charges are to be directed to the study fund, they must be identified in all BWH clinical and administrative systems with an F number…

What's an F number ??

An F number is a 'Financial Medical Record Number'

This number defines the charge as research, and provided a means to direct the charge to the Special Accounting Department, where the research fund is expensed.

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F number setup process

Who does this?

Industry sponsored clinical trial agreement – PCRO

Federal/foundation sponsored clinical trial agreement – RM

- The ***Post Award*** Grant Administrator within the Grants & Contracts Department in Research Management will initiate the F number setup process through Special Accounts. This will only occur if the IRB approval for the protocol is in place.

- Once the F number has been assigned, Special Accounts will notify you and the Principal Investigator via email.

- After the account is set-up you will receive an embossed orange F number card.

- This card should be in the possession of the Study Coordinator or Principal Investigator only, and never given to the research subject.

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Documentation – Qualifying Clinical Trials

CMS requires for billing to Medicare ...

For patients enrolled in a qualifying trial, as per the MCA, any charges billed to Medicare:

- Must have a secondary diagnosis of V70.7 on the claim
- Must be document that the patient is enrolled in a qualifying clinical trial, with the sponsor and trial name included in the patient/subject record.

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Documentation – Qualifying Clinical Trials

CMS requires modifiers on outpatient claims for qualifying clinical trials. Outpatient encounters should have the V70.7 documented by the Provider. Finance will edit all, and will assign the appropriate modifiers.

Q0 Modifier – A CMS outpatient modifier created to identify trial related investigational items (devices and drugs) and their administration in a qualifying trial.

Q1 Modifier – A CMS outpatient modifier created to identify routine trial related services in a qualifying trial.

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Ordering research services to charge to the study fund:

- Paper requisitions should include the F number for the services to be directed to the study fund

- Service Order Systems (i.e. Percipio) must include PI/Protocol/MRN/F number in the 'note' field

For other systems, or questions around ordering research services contact Terry Stone, Research Billing Compliance.

Subject Enrollment Log
Enhanced for Visit Tracking

Use the required IRB subject enrollment log, to document and track all subject visits/services.

Visit Tracking	**Principal Investigator** **PHRC Protocol #:** **Study Title:** **IRB-Approved Enrollment Target:** **Per PHRC policy, a subject is considered enrolled once s/he signs the written informed consent form, OR (with IRB approval) provides verbal or implied consent by completing a questionnaire or participating in a focus group.**

N	Subject ID	MRN	Enrollment			Treatment		Follow up						
			Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12
1														
2														
3														
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Device trials

'Medicare will pay for care provided to subjects enrolled in device studies that are carried out under a Category B Investigational Device Exemption (IDE) or carotid stent device trials with Premarket Approval (PMA) or510k Approval. The Centers for Medicare & Medicaid Services (CMS) requires an approved petition prior to any Medicare billing associated with the trial.'

http://www.partners.org/Medical-Research/Resources/Research-Support/PCRO/For-Investigators/Medicare-Petitions-for-Device-Studies.aspx

Device trials require additional language in the contract negotiated with the sponsor, to properly manage the financial risk of non-payment by insurance.

Device Petitions

- CMS petition approval is required in order to bill Medicare for routine costs associated with an IDE or PMA/510k carotid stent trial

  IDEs

  - Category A – usually not covered, at discretion of FI if covered
  - Category B – usually covered

- Category designation for IDEs can be found on FDA letter denoting IDE # assignment

Helpful tools

Tool: Notification form for Investigational Devices

If you are enrolling a subject in a clinical trial involving an investigational device, a notification to PHS Finance for tracking and managing payments is required.

Device Notification Form rev 12-15-11.doc

Study financial 'operations'

- Monitoring and Fund reconciliation
- Patient Care Corrections
- Residual Balance Transfers

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Monitoring and Review and Reconciliation of the Study Fund

Although current systems impose challenges, it is essential to monitor and reconcile the study fund on a regular basis.

- Track services ordered specific to research
- Review statements from Finance and Insight fund statements

The fiscal 'health' of the study fund is the PI's responsibility.

Helpful tools

Tool: Managing / Monitoring Your Study Fund

Note: Use your enrollment log and billing grid to assist with reconciling patient care charges posted to your study fund.

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Patient Care Corrections

Sometimes, when reviewing a fund, patient care charges are there, but do not belong. Other times, your subject's charges are missing. When you have a correction to process, complete the Patient Care Correction Form and email to Terry Stone. (tstone@partners.org)

Typical errors:

1) fund to fund correction - assumes right patient right chg, on wrong fund
2) insurance/self pay to fund – assumes right patient, billed to insurance in error
3) fund to insurance/ self pay – assumes the fund should have been charged
4) wrong patient on fund
5) wrong charge on fund
6) rate correction - tech, pro, discount or room and board

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Residual Balance Transfers

- At the completion of a project under a fixed price award, such as an industry-sponsored clinical trial, a residual balance may remain. Principal Investigators (PIs) are usually permitted to keep this surplus, but they must transfer the remaining funds to an unrestricted account, such as a new or existing sundry fund. **PIs and Department Administrators (DAs) can initiate this transaction by completing the Residual Balance Transfer form** (see link below). **The form must be signed by the PI and the Department Chief.**
- Please Note: If the residual balance is greater than 20% of the total amount provided by the sponsor or $100,000, whichever is less, then it is considered to be a "significant balance" and additional documentation will be required before the transfer can be considered. That additional documentation must be provided in writing and must include:
  - A detailed explanation of how the work and deliverables were completed without expenditure of the revenue received
  - Confirmation of approval by the PIs' Department Chief or his/her designee

http://resadmin.partners.org/RM_Home/documents/new%20RF/ResidualBalanceTransfer.pdf

Helpful tools

Tool: End of Trial / Close out Checklist

http://resadmin.partners.org/RM_Home/Research_Finance/Closeout/CloseFund.aspx

IRB/QI Tools

Responsibility Log

- Include tasks specific to management/oversight of research billing

Subject Enrollment Log

- Include details of subject visits/services

http://www.partners.org/phsqi/ToolsPage.htm

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Charge Questions/Discrepancies

If you experience any discrepancies in your research fund due to improper assignment of patient care charges, or if your research subject's insurance carrier has been charged for services covered under the study protocol, please contact us and we will provide instruction and/or assistance in how you should request the correction:

Deborah A. Goodman, BWH Revenue Operations/Patient Business Systems, 617-732-5360

dagoodman@partners.org

Terry Stone, BWPO/BWH Billing Compliance, 617-582-0091

tstone@partners.org

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To contact me with questions, issues or request for assistance:

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Ph: 617-582-0091 / Fax: 617-582-0095