Instructions for Completing a Human Research Billing Analysis Form

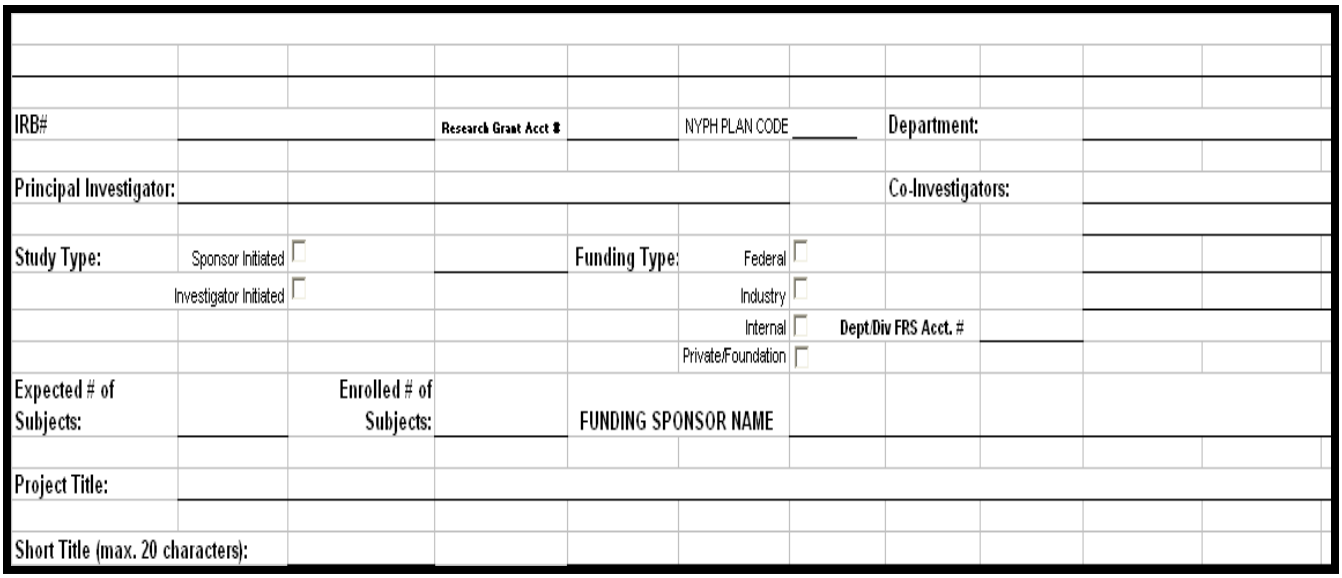
Principal Investigators are required to submit one Human Research Billing Analysis Form per research protocol at the time of the IRB submission application for new protocols and again at the time of continuing review. The purpose of completing and submitting a Human Research Billing Analysis Form is to prospectively identify the list of services required by the study protocol, and indicate when the services will occur, who will provide the service, how the service is to be billed and in general terms, specify payment responsibility.

This document provides step-by-step instructions for completing a Human Research Billing Analysis Form, however, additional assistance can be obtained from your department billing and research compliance personnel, the Office of Billing Compliance, and/or the Office of Clinical Trials.

The Human Research Billing Analysis Form has four main sections that are to be completed by the principal investigator and/or his or her research staff.

Section 1 – Protocol Identifying Information

The first section of the form contains identifying information and is shown here. Each item of information recorded in this section is used to identify and track the study for billing purposes.

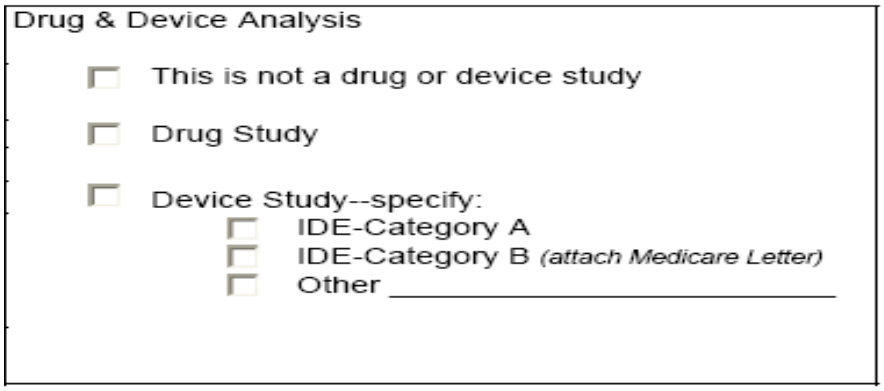


Each information item is described in the following table.

Information Item	Description/Instructions for Completing
IRB #	For approved studies, use the number indicated in the IRB approval letter and designated as the "Protocol #". (This is sometimes referred to as the Coeus number by members of the research administration staff.) For a brand new study being submitted to the IRB for approval, indicate "pending".

Information Item	Description/Instructions for Completing
Research Grant Account #	Internal Account # issued by WMC Finance for the research study. (Also known as the FRS Account #.) It either begins with a "5" or a "6" and the entire number is six digits long. This is typically issued after contract approval. **Please Note:** The Office of Grants and Contracts will not authorize WMC Finance to issue a Research Grant Account #, unless a completed Human Research Billing Analysis Form is on file.
NYPH Plan Code	The hospital system financial class number associated with a research grant account # and issued by NYPH when it is expected that a protocol will involve hospital services that will be billed directly to the Research Grant Account #. The NYPH Plan Code is requested by the WMC Clinical Trials Office after a review of the submitted Human Research Billing Analysis Form and after the Research Grant Account # has been assigned. A crosswalk of NYPH plan codes to research grant account numbers can be found on the WMC intranet: http://intranet.med.cornell.edu/billingcompliance/pdf/billing_plan_codes.pdf
Department	The name of the WMC department to which the Principal Investigator is assigned. The chairman of this department would have approved and signed off on the protocol submission to the IRB.
Principal Investigator	The name of the physician who is designated as the principal investigator on the IRB application for the protocol.
Co-Investigators	The names of all WMC physicians and non-physician practitioners who are designated as co-investigators on the IRB application for the protocol.
Study Type	Check off the appropriate box, either "Sponsor Initiated" or "Investigator Initiated"
Funding Type	Check off the appropriate box. Select from the choices provided which are "Federal", "Industry", "Internal" or "Private/Foundation". If "Internal" is selected as the funding type, then the department or division FRS account number to which expenses are to be charged must be provided.
Expected # of Subjects	The maximum number of research subjects expected to be enrolled in the protocol.
Enrolled # of Subjects	When the Human Research Billing Analysis Form is being reviewed and updated at the time of the IRB continuing review process, indicate the number of enrolled subjects at that time. For new protocols, this should be zero.
Funding Sponsor Name	The name of the funding source regardless of whether it is industry, federal, or private/foundation.
Project Title Name	Name of the protocol as it appears on the IRB application.
Short Title (max. 20 characters)	The brief name used internally to refer to the protocol such as an acronym, drug name, sponsor name, etc. This will be used to label the study in the IDX case module and other computer systems. For research studies that might be sensitive in nature, it is recommended that the short description be cryptic.

Also at the top of the form and considered "Protocol Identifying Information", is a box labeled "Drug & Device Analysis". There are three main choices (checkboxes) under "Drug & Device Analysis". Indicate whether the research protocol is a drug study, a device study or neither. If the study is a device study, then it is necessary to specify whether the device is approved by the FDA under a Category A or Category B Investigational Device Exemption (IDE) or if it falls into some "Other" classification which requires further explanation on the Human Research Billing Analysis Form



Section 2 – Schedule of Clinical Services/Rendering Providers/Payment Responsibility

The second section of the Human Research Billing Analysis Form is set up as a grid and is intended to replicate the patient services schedule of events as stated in the research protocol and/or informed consent. This section is also used to indicate, in general terms, the service provider and payment responsibility. Completing this grid requires a thorough analysis of the protocol and funding, as well as consideration of whether or not the clinical services are medically necessary standard of care and would have been rendered to the patient regardless of enrollment in the research study. It also requires knowing to what extent the sponsor is paying for clinical services.

To complete the worksheet grid (shown below), the principal investigator is required to itemize protocol services and indicate the interval at which the service will be rendered.

				INTERVAL: Specify # of Days, Weeks, Months, Cycles,				
	CPT CODE	LOCATION	PRE-ENROLLMENT/ PRE-ACCEPTANCE					
Evaluation & Management:								
Psychiatric Services:								
Diagnostic Tests:								
Treatments:								
Pharmaceuticals/Device:								

Service intervals are indicated as column headings and are defined by the investigator (days, weeks, months, cycles, etc.) to reflect the planned timing of when services will be rendered to enrolled research subjects.

Service descriptions and associated CPT codes are listed in the first two columns. The services should be organized into the broad category headings, which are Evaluation and Management, Psychiatric Services, Diagnostic Tests, Treatments, and Pharmaceuticals/Devices.

A description and examples of each service grouping follows:

Service Grouping	**Description/Instructions for Completing**
Evaluation and Management	Common services in this grouping include Office Visits, Clinic Visits, Consultations, Inpatient Visit**s,** and questionnaires. These are typically the physician services that involve obtaining a patient's history and performing an exam. Generally the CPT code for the specific E&M visit cannot be predetermined and may vary from patient to patient, therefore it is okay to list an appropriate range of CPT codes here. For example, if the service to be rendered will be classified as an office visit, list the entire range of office visits 99201-99215 (new and established). Once enrolled, subsequent office visits might be identified with just the range 99211-99215 for established patients. Refer to the Evaluation and Management section of the CPT manual for more code choices.
Psychiatric Services	Common services in this grouping include Psychiatric diagnostic interview exams, Psychotherapy, and Pharmacologic management. The CPT code range for these services is 90801-90899.
Diagnostic Tests	Common services are laboratory, radiology, and cardiology tests. For many of these services, there is a professional and technical component. When the service is performed in an inpatient or outpatient hospital setting, where the professional component will be billed separately, the service needs to be listed twice--once for the technical component and once for the professional component. Some diagnostic tests are performed in special exam rooms or with the assistance of anesthesia. Make sure all components are itemized for the purposes of planning and budgeting.
Treatments	This is a very broad range category. It might include chemotherapy infusion services, radiation therapy or a surgical procedure. It is important to list all components of the service including hospital room charges and anesthesia, if applicable. Like the diagnostic test category, it is important to differentiate between professional and hospital components.
Pharmaceuticals	List the actual drugs here, including both those that are considered standard of care and billable to the patient and/or their insurance and those that might be the subject of the research. The infusion or injection (other than self-injection), where required, would be listed in the treatment section above.

The column labeled Location is used to indicate specifics about the place of service. This information is important for determining service fees, proper budgeting, and for reconciling billing to the research grant account. Location entries might include inpatient, a specific

outpatient department/division, private office, Cornell Imaging 61st Street, Cornell MRI 55th Street, Cornell Vascular Imaging 55th Street, or Citicorp Biomedical Imaging Center (CBIC), etc.

The remaining columns are used to indicate the timing of the services to be rendered. The column labeled "Pre-enrollment/Pre-Acceptance" is considered to be a time interval and is provided for the purposes of reporting services that are either routinely performed as medically necessary standard of care or are being performed to determine eligibility criteria for the protocol only, and are done prior to the patient's enrollment in a research study. The remaining columns are to be labeled by the principal investigator to indicate the appropriate interval at which the delivery of services are planned, (i.e., days, weeks, months, cycles, years) corresponding to the schedule of events or flowchart in the protocol**.**

The grid formed by the rows of services versus the interval of time, are to be completed using the legend from the bottom of the form (shaded area). The codes listed in the legend near the bottom of the form (and shown below) describe the service provider and how the service will be billed.

B-PI	Rendered by PI (or co-investigator) and billable to the patient or insurer
B-WMD	Rendered by WMC MD and billable to the patient or insurer
B-HOSP	Rendered by NYPH and billable to the patient or insurer
B-OF	Rendered by outside facility and billable to the patient or insurer
Done	Data Obtained From Prior Evaluation
Free	Provided Free of Charge by Sponsor (i.e. drug, device, outside lab)
S-PI	Rendered by PI (or co-investigator) and billable to the study
S-WMD	Rendered by WMC MD and billable to the study
S-HOSP	Rendered by NYPH and billable to the study
S-OF	Rendered by outside facility and billable to the study
GCRC	Service rendered in GCRC -- NO BILLING ALLOWED

The codes that begin with the letter "B" indicate that the service is a medically necessary standard of care service and may be billed to the patient or their insurance.

The codes that begin with the letter "B" would also be used if the service being rendered is being done solely for research purposes and is not medically necessary, standard of care AND the patient has agreed to pay for the service out-of-pocket. It is important to make sure the patient is aware of their personal responsibility to pay, even though this is specified in the informed consent. For Medicare patients, an Advanced Beneficiary Notice (ABN) might be required. For other patients, a Notification of Non-Covered Services might be needed.

The codes that begin with the letter "S" would be used for services designated in the protocol or contract as paid for by the research sponsor, private/foundation or internal funds. Services already paid for by another source **may not** be listed as billable to the patient or their insurance.

"Free" would be listed for services or products provided directly by the study sponsor. For example, a laboratory service would be designated as "Free", if the protocol requires that labs are sent to a central lab facility and will be paid for by the sponsor (and no direct billing to the research account at WMC or the patient/insurance will take place). Another example is when the sponsor provides the study drug "free of charge".

When protocol services will be rendered in the GCRC, the GCRC handles the billing for the technical component of the services and therefore the PI should list "GCRC" as the provider and to indicate billing/payment responsibility. However, the GCRC is not responsible for any professional components and the PI must incorporate these expenses into the budget for services that have two-part billing such as X-rays and other imaging services. This code should only be used when an application to use the GCRC has been submitted and discussions with the GCRC staff are underway. For more information on the GCRC see **http://gcrc.med.cornell.edu**.

A basic example of a completed Human Research Billing Analysis Form's service grid is included with this document (page 7).

What if the research protocol does not require any patient services?

A Human Research Billing Analysis Form is required for all research protocols, however, there are some instances where it is not necessary or possible to complete the "Schedule of Services" portion of the Human Research Billing Analysis Form.

If no patient services are rendered as part of a research study and therefore there is no potential for patient service billing, complete the box to the right of the schedule of services grid by checking off the circumstance that best describes why no billing is required.

Use this Section If No Billing Is Required

- ☐ Retrospective Chart Review Only
- ☐ Retrospective Data Analysis Only
- ☐ Retrospective Image Review
- ☐ Tissue Sample/Specimen Waste Analysis
- ☐ Patient Involvement Limited to Interview
- ☐ Patient Involvement Limited to Questionnaire
- ☐ Closed to Patient Accrual; No Active Treatment, Procedures or Diagnostic Tests Remaining
- ☐ Other _____

Section 3 – Diagnosis Codes and Descriptions

The third important section of the Human Research Billing Analysis Form asks for diagnosis information. The diagnosis code(s) and description for the condition(s) that qualified the patient to be eligible to enroll in the study should be listed first. The diagnosis codes and descriptions for the most common complications and or side effects should also be listed. These are needed to help identify potential research related services that are not defined in the protocol, but occur as medically necessary services when there is monitoring for a side effect or complication or when a side effect or complication occur. Simply list the ICD9 codes in the first column and the description of the diagnosis in the second column.

Dx Code(s)	Dx Description

Section 4 – Authorizations/Approvals

To finalize the form at the time of **INITIAL SUBMISSION**, the person completing it should sign and date it. This person will serve as a key contact for the additional information that might be required. The form must be reviewed and signed off on by the Principal Investigator and, also by the Department Chairperson, Division Chief, or Department Administrator**.**

When the Human Research Billing Analysis Form is being submitted for an I**RB Continuing Review**, the previously submitted form for that protocol may be copied or reprinted and updated. Updates at the time of continuing review might include changes in the service delivery schedule, changes in the protocol required services, changes to the applicable diagnosis codes, or possibly an indication that billing review is no longer required because the study is now closed to patient accrual and no active treatments, procedures, or diagnostic tests are remaining. The continuing review preparation date and the name of the reviewer should be indicated in the box labeled "Renewal Submission Date/Reviewed and or Updated By". It is recommended that the department compliance liaison be involved in this process, as CPT and ICD codes may change from year-to-year.

Finally, the department Compliance Liaison and/or Compliance Leader must also approve the form and verify its accuracy by indicating their review in the box labeled "Compliance Department Review". The compliance reviewer's signature is required. The Department Compliance Review will consist of the following key steps:

1. Verify the validity of CPT codes,
2. Verify the validity of ICD9 codes
3. Confirm that appropriate discussions took place with Radiology, Pathology, and other departments to verify the services required by protocol and associated costs, if necessary. Written confirmations in the form of a letter, memo, email, form should be attached to the Human Research Billing Analysis Form.
4. Determine if any services to be rendered will require an Advanced Beneficiary Notice or Notice of Non-Covered Service to be signed by the patient.

The Human Research Billing Analysis Form is to be submitted to the IRB with the application and other paperwork for new or continuing review protocols.

ADDITIONAL ASSISTANCE can be obtained from:

- Your department billing and research compliance personnel,
- The Office of Billing Compliance (212-746-0145),
- The Office of Clinical Trials (646-253-2833)

. Additional information is also available on the following intranet websites:

http://intranet.med.cornell.edu/billingcompliance/

Example of a Completed Human Research Billing Analysis Form

Sample Protocol Summary:

Determine the response of using antithrombin Drug XYZ, for patients with atrial fibrillation.

The principal investigator is a cardiologist. The informed consent indicates that patients enrolled in the study will receive an evaluation and ECG from a cardiologist at Day 1, Day 8, and Day 16.

See Rows 1, 2 & 8. With the appropriate referral for the cardiologist to evaluate the patient for atrial fibrillation and recommend treatment, the initial consultation and follow-up visits would be considered medically necessary, standard of care. Since the sponsor did not provide payment for the consultation, office visits, or ECGs, and the services are considered medically necessary standard of care, they are listed as being "Done" prior to enrollment in the study or as billable to the patient/insurance for those rendered after the patient is enrolled in the study.

In order to verify that the patient is eligible for the trial, the study protocol calls for a full coagulation evaluation (CBC, PT/PTT/INR) and a transesophageal echo which will be paid for by the sponsor.

See Rows 3-6. These services were required specifically for research, to verify eligibility. Furthermore, the study documents show that the sponsor has indicated that they will pay for these services.

The study drug provided by the sponsor and is to be taken by the patient orally on Days 1-16.

See Row 9. The sponsor provided the study drug. There is no billing involved. The drug is "Free".

The patient is tested at Day #8 and day #16 for drug toxicity by performing a LFT, which is not paid for by the sponsor.

See Row 7. According to the Medicare National Coverage Decision, it is okay to bill for medically necessary, standard of care services required to monitor for or treat possible side effects associated with the study. The LFT is to monitor for such a side effect and is therefore billable.

Interval:	CPT Code	Pre-Enrollment/ Pre-Acceptance	Day 1	Day 8	Day 16
Evaluation & Management:					
1. Consultation	99243	Done			
2. Office Visit	99212			B-PI	B-PI
Psychiatric Services:					
Diagnostic Tests:					
3. CBC	85027		S-HOSP		
4. PT/PTT/INR	85610 & 85730		S-HOSP		
5. TEE Technical	93312		S-HOSP		
6. TEE Professional	93313		S-WMD		
7. Liver Function (LFT)	84450 & 84460			B-HOSP	B-HOSP
8. ECG	93000	Done		B-PI	B-PI
Treatments:					
Pharmaceuticals:					
9. Drug XYZ			Free	Free	Free