How do I fill out the Billing Plan?

Gather necessary documents:

1. Protocol
2. CTA
3. Informed Consent Form
4. Billing Plan Template
5. Standard of care practice guidelines for anything you plan to bill as routine care

Protocol:
You will need the schedule of events and specific tests/procedures that will occur at each time point.

CTA:
Note if there is any specific billing information listed. The study sponsor may be paying for specific items/tests. These items should not be listed as routine care in the Billing Plan. They are "pure research."

Informed Consent:
Note if there is any specific billing information. If the consent says an item is provided for free it should not be listed in the Billing Plan as routine care. They are "pure research."

Create a list of all the billable services and procedures necessary throughout the protocol.

<u>This will come directly from the protocol's schedule of events</u>.

Divide that list into 4 categories:

1. UH resources:
   - Items or tests where a University Hospital facility is providing the service
2. Non-UH Resources:
   - Items or procedures that do not use UH resources
   - For example: if the service would be done by an NJMS Core lab or by the investigator or UPA (i.e. physical exams, etc)
3. Additional Invoiceable Items
   -Any procedures or items that will use UH resources but do not have a CPT code
   -For example Investigational Pharmacy fees
4. Items/tests done at a Central Laboratory that are paid for by the sponsor.

Open the excel Billing Plan Template to begin filling it out.
Separate Billing Plans may be completed if study procedures vary by arm.

Fill in the basic information at the top of the template

NJMS-OCRA BILLING PLAN TEMPLATE

ALL APPLICABLE YELLOW AREAS MUST BE COMPLETED. Contact Nancy Reilly at 973-972-1268 or reillyna@njms.rutgers.edu for assi

PI Name & Degree:		Projected Start Date:		Type of Submission:	New (check here) ☐	Date:
PI Signature & Date:		Projected End Date:			Modification (check here) ☐	Date:
Protocol Title						
Total # of subjects for goal enrollment:		Clinicaltrials.gov #		NCT		
Department/Division:		FOR OFFICE USE ONLY	Index Number:			

Once approved by OCRA and University Hospital (if applicable), the PI must sign this form to attest to the accuracy of the information provided and to accept financial resp

Using the list you've already created, fill in column A and column B, rows 13 and below.
If you know the CPT code, you can also fill in Column C.
List the procedures in terms of how they would be ordered clinically ("CMP" or "BMP" not "chemistries")

	List Services & Items	Facility providing service (central lab, UH Pathology, UH radiology, etc.)	CPT Code	Research Rate*	Number per patient for entire study	Total cost (column D x E)		
12	UH Services (i.e. laboratory tests, Radiology, etc.)							
13								
14								
15								
16								
17								
18								
19								
20	Billable Clinical Services from sources other than UH, i.e. UPA (if applicable)							
21								
22								
23								
24								
25	Additional Invoiceables - Use this space for other UH services such as Investigational Pharmacy Fees, etc.							
26								

Category 1 UH Resources items should be listed here

Category 2 Non-UH Resources items should be listed here

Category 3 Additional Invoiceables items should be listed here.

Category 4 Central Laboratory
DO NOT LIST THESE ITEMS IN THE BILLING PLAN.
Scroll to the bottom right of the billing plan and check off the box that denotes a Central Lab will be used.

24																				
25	H services such as Investigational Pharmacy Fees, etc.																			
26																				
27																				
28																				
29																				
30																				
31																				
32	or UPA					COMMENTS:	☐ Check here to denote that a Central Laboratory will be used for the remainder of laboratory tests listed in the protocol schedule of events but not itemized above, and that the cost of these tests will be paid for by the sponsor.													

Fill in the schedule of visits (directly from protocol) in row 11, columns G and beyond.
Add more columns if necessary.

For Example:

For each item listed in column A, code as “RC” (routine care) or “PR” (pure research) at each time point when they occur in the study.

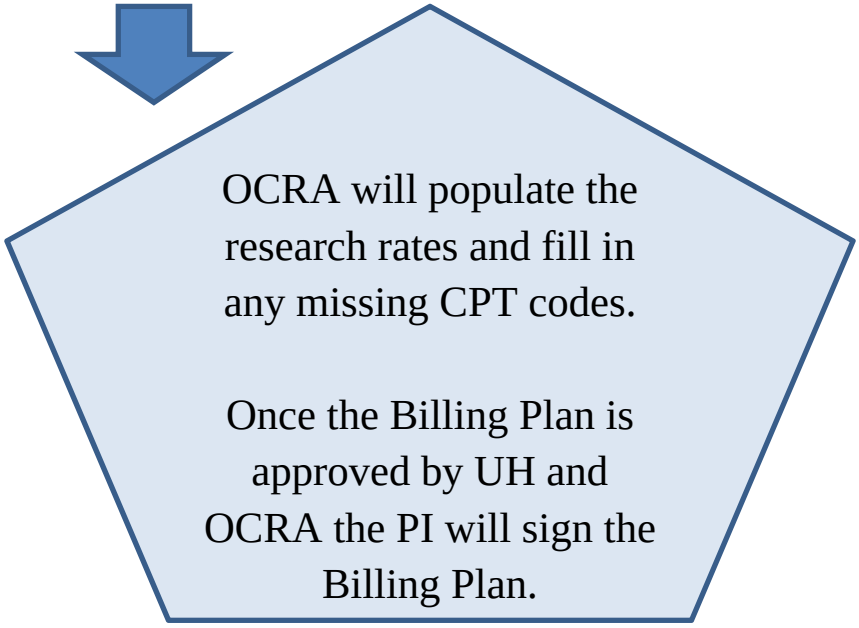
<u>You will need to check the CTA and Informed Consent to be sure you coding properly. If the sponsor is paying for something or the consent says it is free, it must be coded as PR.</u>

See below for an example.

	List Services & Items	Facility providing service (central lab, UH Pathology, UH radiology, etc.)	CPT Code	UH Research Rate*	Number per patient for entire study	Total cost (column D x E)	Screening	Day 1	Day 14	Month 1	Month 3	Month 6	Month 9	Month 12
Codes: PR = Pure Research, RC = Routine Care														
UH Services (i.e. laboratory tests, Radiology, etc.)														
	Chest x-ray (technical)	UH radiology	71020				PR							
	Ultrasound guided liver biopsy	UH	47000				RC[1]					RC[1]		PR
	Liver and abdominal Ultrasound -technical	UH radiology					RC[2]					RC		RC
Billable Clinical Services from sources other than UH, i.e. UPA (if applicable)														
	Physical Exam	UPA					PR							PR
	Chest x-ray (professional)	UPA	71020				PR							
	Liver and abdominal Ultrasound -	UPA	76700				RC[2]					RC		RC

Submit to OCRA:

1. the Billing Plan
2. standard of care practice guidelines for anything you plan to bill as routine care
3. all other documents required for OCRA review (See Main Page for details)



NOTE: If you amend the protocol and it affects the UH Scope of Services agreement you will also need to amend this document.

Send OCRAreview@njms.rutgers.edu a copy of the amended protocol as well as the revised UH Scope of Services form with an explanation of the changes made. NJMS-OCRA will assist in executing the amended documents.