CBR SUBMISSION WORKBOOK

Version 11/01/19

The CBR Submission Process consists of completing the appropriate sections of this workbook and attaching specific study documents. Please see below for a list of submission types, required documents for each submission and workbook forms applicable for each submission type. The Bookmark feature to the left will navigate you through the various sections of the Workbook. Blue underline indicates that you will be taken directly to the form or link referenced.

Please note it is required that a CBR Submission Workbook be completed for ALL CBR submissions. The Billing Plan lists all protocol activities: 1) billable services (such as labs and radiology scans that are CPT-coded services billed though the UAB Health System) and 2) non-billable services (such as informed consent and concomitant medications that are study services without CPT codes). Each study activity from the protocol Schedule of Events/ Study Schema is required to be listed under the corresponding header in the Billing Plan. Please use the attached FAQs to assist with completing this Workbook.

CBR SUBMISSION CHECKLIST FOR EACH SUBMISSION TYPE

FEASIBILITY FEE SUBMISSION

Complete the forms specified below and E-mail the CBR Submission Workbook to fap@uab.edu by using the *Submit CBR Workbook to CBR* button on the CTAW Form page.

☐ **CBR Submission Workbook- complete the CBR Submission Form;**

☐ **CTAW Form.**

FULL SUBMISSION

Complete the forms specified below in the CBR Submission Workbook and submit any applicable additional documents via E-mail to fap@uab.edu by using the *Submit CBR Workbook to CBR* button on the Billing Plan page.

☐ **CBR Submission Workbook, at a minimum complete the CBR Submission Form and Billing Plan(s);**

Including additional Billing Plan spreadsheets is done by clicking the "+" button at the bottom of the Excel document, then copy and pasting the Billing Plan template into the new spreadsheets.

☐ **Study Protocol, final version. The UAB IRB Human Subjects Protocol (HSP) can satisfy this requirement if a protocol is not available;**

☐ **Draft Consent(s);**

☐ **Manual of Procedures, if available;**

☐ **Sponsor Draft Clinical Trial Agreement, if available;**

☐ **Draft Sponsor Budget - Industry sponsored trials (required)**

☐ **Sponsor Lab Manual (If UAB Laboratories will be doing any special processing/shipping for the study).**

If applicable, please submit as indicated below:

☐ **UAB Laboratory Use - The Lab Questionnaire in the CBR Submission Workbook must be completed, if the UAB Hospital Laboratories are involved in the study (which includes TKC 2nd Floor Lab, Whitaker Lab, Outreach Lab and CRU/CCTS blood draws sent to UAB Labs for resulting, shipping, or processing);**

☐ **Flow Cytometry Use - The Flow Cytometry Form in the CBR Submission Workbook must be completed if the UAB Flow Cytometry lab will be involved in the study;**

☐ **Clinical Research Unit (CRU) Use - The CRU award letter, when available.**

*****If the study involves Radiology procedures/services, please contact Radiology Research at radresearch@uabmc.edu.***

DEVICE TRIAL SUBMISSION

(Includes all devices including, but not limited to: Cat. A, Cat. B, Post Market, Pre-Market, 510K Summary and Non-Significant Risk Devices)

Complete the forms specified below in the CBR Submission Workbook and submit any applicable documents via E-mail to fap@uab.edu by using the *Submit CBR Workbook to CBR* **button on the Billing Plan page.**

☐ **CBR Submission Workbook, at a minimum complete the CBR Submission Form, Device Form and Billing Plan(s);**

Including additional Billing Plan spreadsheets is done by clicking the "+" button at the bottom of the Excel document, then copy and pasting the Billing Plan template into the new spreadsheets.

☐ **Study Protocol, final version. The UAB IRB Human Subjects Protocol (HSP) can satisfy this requirement if a protocol is not available;**

☐ **Draft Consent(s);**

☐ **Manual of Procedures (If available);**

☐ **The Department of Health and Human Services (FDA) memo indicating device type and device #;**

☐ **Draft Sponsor Clinical Trial Agreement;**

☐ **Draft Sponsor Budget (required);**

☐ **Reimbursement manual/Implant procedure coding from the sponsor (if available);**

☐ **Sponsor Lab Manual (If UAB Laboratories will be doing any special processing/shipping for the study).**

If applicable, please submit as indicated below:

☐ **UAB Laboratory Use - The Lab Questionnaire in the CBR Submission Workbook must be completed, if the UAB Hospital Laboratories are involved in the study (which includes TKC 2nd Floor Lab, Whitaker Lab, Outreach Lab and CRU/CCTS blood draws sent to UAB Labs for resulting, shipping, or processing);**

☐ **Flow Cytometry Use - The Flow Cytometry Form in the CBR Submission Workbook must be completed if the UAB Flow Cytometry lab will be involved in the study;**

☐ **Clinical Research Unit (CRU) Use - The CRU award letter, when available.**

*****If the study involves Radiology procedures/services, please contact Radiology Research at radresearch@uabmc.edu.***

AMENDMENT SUBMISSION

Complete the forms specified below and E-mail with the additional required documents to fap@uab.edu by using the *Submit CBR Workbook to CBR* button on the Billing Plan page. Note that Amendments should be submitted for CBR review *ONLY* if there are certain changes:

1) Additions/deletions made involving clinical billables; 2) Change in clinical billable service location or 3) Change in PI.

☐ **CBR Submission Workbook, at a minimum complete the CBR Submission Form and Billing Plan(s);**

The amended Billing Plan(s) should be the last FAP-Approved Billing Plan(s) with the addition of colored highlight indicating ALL changes being made by this amendment (if changes involve billable activities). Including additional Billing Plan spreadsheets is done by clicking the "+" button at the bottom of the Excel document, then copy and pasting the Billing Plan template into the new spreadsheet.

NOTE: Please create a new Billing Plan spreadsheet for EVERY new amended Billing Plan (each arm/cohort) related to this amendment and any future amendments. All study Billing Plans should be in one Excel document in chronological order from the initial FAP-Approved Billing Plan(s) through to the current amendment in the CBR Submission Workbook.

☐ **Amended study protocol, if study changes are in the protocol document (UNTRACKED VERSION);**

☐ **Summary of Changes (SOC) Document. If amendment changes are not specific protocol changes, then provide a complete listing in your E-mail submission to CBR (i.e. Change in PI or change in billing designation of existing activity at existing visit, etc.).**

If applicable, please submit as indicated below:

☐ **UAB Laboratory Use - The Lab Questionnaire in the CBR Submission Workbook must be completed: 1)If there are NEW UAB Hospital lab services added OR 2) Previous labs occurring at new time points that were not reflected in the last FAP-Approved Billing Plan. The UAB Hospital Laboratories include: TKC 2nd Floor Lab, Whitaker Lab, Outreach Lab and CRU/CCTS blood draws sent to UAB Labs for resulting, shipping, or processing;**

☐ **Flow Cytometry Use - The Flow Cytometry Form in the CBR Submission Workbook must be completed: 1) If there are NEW flow cytometry lab services added OR 2) Previous flow cytometry labs occurring at new time points that were not reflected in the last FAP-Approved Billing Plan;**

☐ **Clinical Research Unit (CRU) Use - If the CRU award letter was amended as a result of this amendment, then CBR needs a copy of this letter as soon as possible.**

*****If the study amendment adds Radiology procedures/services not previously performed in the study, please contact Radiology Research at radresearch@uabmc.edu.***

UAB CLINICAL BILLING REVIEW (CBR) SUBMISSION FORM

Project Title:

Protocol Brief Title/Short Title:

Protocol #:

Sponsor Name (Funding Source):

Sponsor/Funding Type:

- ☐ **Federal**
- ☐ **Industry**
- ☐ **Investigator-Initiated**
- ☐ **Cooperative Group**
- ☐ **Academic Collaboration**
- ☐ **Other:**

Principal Investigator (PI):

PI E-mail: (johndoe@uab.edu)

Assigned Study Coordinator:

Assigned Study Coordinator E-mail: (johndoe@uab.edu)

Department/Division:

Submitter:

Submitter E-mail: (johndoe@uab.edu)

Submitter Phone Number:

Clinical Services will be provided in what setting? Mark all that apply.

☐ Hospital Inpatient ☐ Outpatient ☐ CRU Inpatient
☐ CRU Outpatient ☐ Child Health Research Unit (CHRU)

Anticipated Study Start Date: (MM/DD/YYYY)

Estimated number of participants to be enrolled at UAB: (numeric response)

IRB # assigned to this study (Required):

Is this study registered on ClinicalTrials.gov currently or will it be in the future?

◯ Yes ◯ No If Yes, please provide the NCT number assigned to this study or indicate "PENDING" if not yet received:

Is this study conducted under an IND or Device application reviewed by the FDA?

◯ Yes ◯ No If Yes, please provide the FDA# (IND#, IDE#, K#, P#, etc.) assigned to this study or indicate "PENDING" if not yet received (***NOTE:*** *Study will be put On Hold until # received*)

Has this study been granted an exemption from being required to have an FDA IND?
◯ Yes ◯ No
*If Yes, please provide documentation to CBR confirming this exemption (Required)

If the Physical Exam is in a billable location (TKC, Hospital, etc), is physician receiving effort for the exam? ◯ Yes ◯ No

Please select the correct submission type below, include all required documents, and submit to fap@uab.edu via the buttons on one of the last two pages of this Workbook. CBR review will begin once ALL required documents are received.

SUBMISSION TYPE: Use drop-down box

Previous FAP# assigned for a Feasibility Fee Submission and/or Full Submission associated with this study:

LAB QUESTIONNAIRE

Use this form if you have lab work performed by CRU, CCTS, UAB Outreach/Hospital Laboratories

******NOTE:* *Please ensure set up and feasibility assessment have been performed by the lab(s) before the study has begun*

1. **How many participants do you plan to enroll in this study?**

2. **What is the planned study start date and study close date?**

VENIPUNCTURE

Below please check all that apply

- ☐ **Study staff will perform blood draw**
- ☐ **CRU will perform blood draw (*NOTE*: blood drawn by CRU staff is sent to Hospital Lab for results)**
- ☐ **Hospital Lab/Outreach Lab phlebotomist will perform blood draw**

RESULTS

Below please check all that apply

- ☐ **Specimens will be sent to a central or off-site laboratory for results (Please see PROCESSING section below)**
- ☐ **Hospital Lab/Outreach Lab will provide results for local labs (ex. will perform "chemistries", serum pregnancy test, urinalysis, etc and provide results). *If this box is checked, please answer questions below.***

1. **Location? TKC ☐ UAB Hospital ☐**
2. **The labs performed at the TKC/UAB Hospital Lab will be?**
   - ☐ **Standard of Care (billed to insurance)**
   - ☐ **Research (billed to study)**
   - ☐ **Both standard of care and research**
3. **Will the study require auto fax to receive reports? If so, please provide the contact information below**
   Name, campus address, phone, email of person receiving fax:
   Fax number to send reports:
4. **Will local labs require specific instructions beyond hospital lab normal process for reporting (i.e. cell count reported in triplicates, reporting not available the same day)? Refer to LabSource at www.labsource.hs.uab.edu for turnaround times. If yes, provide brief description below.**

PROCESSING *(centrifuge, specimen storage, preparation for shipping, and shipping)*

Below please check all that apply

- ☐ **Study staff will perform processing and shipping**

If PROCESSING assistance is required, please check all that apply:

	CCTS (SPAN)	UAB Hospital/Outreach Lab
Processing	☐	☐
Storage	☐	☐
Shipping to an off-site or central lab	☐	☐
After hours, weekends, holiday processing	☐	☐
Stool specimens	N/A	☐
Complexity processing such as buffy coat	☐	☐

Please give a brief description:

For more information on CRU or CCTS lab, please visit their website at www.uab.edu/ccts/clinical-translation/clinical-services

[Note - CRU and CCTS lab are separate requests]

. Or contact by email, cctsclinical@uab.edu. For more information about Hospital Labs, please visit their website at www.labsource.hs.uab.edu. Or contact by email at kacklin@uabmc.edu.

FLOW CYTOMETRY FORM
UAB HOSPITAL LABS - FLOW CYTOMETRY LAB
PRELIMINARY RESEARCH LAB TESTING QUESTIONNAIRE

*** This form must be completed and submitted no later than 2 weeks before research protocol testing begins.**

1, Cluster Designations (CD) to be reported (Please specify particular subsets. CD3+CD4 + % of lymphocytes and CD3+CD8+ % of lymphocytes, not just CD3, CD4, CD8)

NOTE: In order to perform Flow Cytometry, results from CBC/Diff are required.

2. Estimated patient volume:

Number of Subjects:

Number of Specimens Per Subject:

Duration of Study (Months specimens will be received):

3. Attach protocol and reference the protocol page(s) specific to Flow Cytometry:

DEVICE FORM
Submission Form for Hospital Review of Device Trials

Purpose: UAB Hospital, The Kirklin Clinic, and other UAB Medicine clinical facilities support the conduct of Device trials in their facilities. To ensure UAB Medicine facilities appropriately submit claims for these services, please furnish the following information to the UAB Clinical Billing Review Office (FAP).

1. Type of device (attach FDA letter):

- ☐ Category A
- ☐ Category B
- ☐ 510K Summary
- ☐ Non-Significant Risk
- ☐ FDA-Approved
- ☐ Wearable Device
- ☐ Post-Market Appr. - Carotid Stenting
- ☐ Pre-Market Approval
- ☐ Other _____

2. Name of Device:

_____

3. Specify the venue/location where the procedure to implant the device will be performed:

- ☐ TKC
- ☐ UAB Hospital
- ☐ UAB Highlands
- ☐ Children's Hospital
- ☐ Other _____

4. Provide the specific procedure area for your response in Question # 3 (i.e. OR, HVC, etc.):

_____

5. Financial arrangements for the device and related procedure (5a-f):

a. Is the sponsor furnishing/providing the device at no charge?

- ☐ Yes ☐ No
- ☐ If No, what is the amount being charged? _____
- ☐ If Yes, will device be sent directly to study team or will it go through Central Supply? _____

b. Provide the name, number and E-mail for the sponsor contact responsible for negotiation of the device purchase agreement and/or the price for the device.

_____

c. Who is paying for the procedure to implant the device?

- ◯ Sponsor
- ◯ Insurance (SOC)
- ◯ Other _____

d. What is the volume of patients expected to participate in the trial at UAB?

e. Specify the name of the procedure(s) related to the device implant:

f. Provide a list of patients who have had this procedure performed in the last 6-9 months. This includes names, MRNs and dates of service when the procedure was performed.

CLINICAL TRIALS ACTIVITY WORKSHEET (CTAW) FORM

The CTAW Form Template is attached to this document. Once you have completed the CTAW Form for this study submission, please save the new document and use the buttons below to:

1) Upload CTAW Form and any additional documents. Upload CTAW Form & Addl Docs

2) Submit this study submission for CBR review. Submit CBR Workbook to CBR

BILLING PLAN

The Billing Plan Template is attached to this document. Including additional Billing Plan spreadsheets is done by clicking the "+" button at the bottom of the Excel document, then copy and pasting the Billing Plan template into the new spreadsheet. Once you have completed the Billing Plan(s) for this study submission, please save the new document and use the buttons below to:

1) **Upload Billing Plan(s) and any required documents.** Upload Billing Plan(s) & Required Docs

2) **Submit this study submission for CBR review.** Submit CBR Workbook to CBR