# <u>IRB Financial Services Form & Participant List Summary</u>

- Based on previous discussions, the following guidelines have been developed:
  - If the patient encounter is **not** registered in the Electronic Medical Record (EMR) at ECU or any Vidant facility, the Financial Services Review Form or the Participant List will **not** need to be completed.
  - When the active phase of a trial is completed and the patient is no longer receiving study-related procedures, labs, radiology, pharmacy, interventions, etc, the Participant List will no longer need to be submitted to us.
    - For those patients enrolled in Oncology studies in which the patient is followed until death, we will work with the Study Coordinator to establish the completion of the active phase on a study by study basis.
  - When the active phase of a trial is completed and the patient is considered in the follow up phase and only data collection is being done, the Participant List will no longer need to be submitted to us.
    - For those patients enrolled in Oncology studies in which the patient is followed until death, we will work with the Study Coordinator to establish the completion of the active phase on a study by study basis.
  - The Financial Services Form will need to be filled out if any procedures, labs, radiology, pharmacy, etc are being performed at ECU or a Vidant facility **<u>AND</u>** the encounter is registered in the Electronic Medical Record (EMR) at ECU or any Vidant facility, even if everything is routine.
  - All Financial Services Forms must have a **<u>handwritten signature and date</u>**.
  - The Participant List can be populated once as a template, and then a copy can be created for each patient filling in only the top section and the dates of service for their encounters.

- The Participant List will need to be created for each patient enrolled in the study and emailed to the designated individuals after each encounter via secure email. We are required to report the NCT number on the claim for billing purposes, even if all services provided during the encounter are considered routine or paid for by the sponsor. ***NOTE:** Once the patient has completed the study, or completed the active phase of the study, the Completed Study Date field should be populated on the Participant List and forwarded to the same designated individuals.

    - The Participant List will need to be emailed either prior to the encounter or on the day of the encounter for Outpatients and at discharge for Inpatients via secure email.

    - There is no automatic order/charge/flag, etc to notify Vidant Health Finance that a patient is enrolled in a research study. You **must** notify Finance via secure email of these patients.

- If a patient is seen in an outpatient clinic for a research related encounter and is admitted to the hospital as a result of complications related to the research study, Vidant Health Finance will need to be notified when the patient is admitted.

- If there are any amendments or revisions in regards to procedures, labs, radiology, drugs, etc **<u>OR</u>** changes in regards to what the sponsor will/will not pay for, it will be necessary to follow up with Vidant Health Finance.

- These forms will be effective **<u>April 1, 2014</u>**. If a study is already in Ancillary Review within ePirate, the old Financial Services Form will be accepted. However, the revised Participants List will need to be used for any notifications after April 1, 2014.