DOES YOUR STUDY NEED TO BE SUBMITTED TO OCR? (applicable to EU faculty or EHC employees/PIs)

- Does study have human subjects?
  - Yes: CRC/RAS submit study to OCR for PRA OCR Submission Form (2)
  - No: No OCR Submission or ERMS entry.

- Does study have EHC or Grady billable items and services (1)?
  - Yes: CRC/RAS submit study to OCR for budget development and negotiation OCR Submission Form (2)
  - No: Is study federal (2)?
    - Yes: Is OCR developing the budget?
      - Yes: CRC/RAS submit study to OCR for budget development and negotiation OCR Submission Form (2)
      - No: No OCR Submission. OCR invoicing will contact you if the study requires ERMS entry for OCR invoicing.
    - No: Is the study a clinical trial - NIH Clinical Trial Definition?
      - Yes: CRC submits an ERMS activation form to OCR after IRB approval ERMS Activation Form.
      - No: After eNOA issued (3), CRC adds subjects and tracks visits in ERMS.

Notes:

1. EHC billable items and services include professional and technical charges billed by EHC using CPT/CDM codes.
2. Required study documents include: OCR submission form, final version of protocol, Emory draft consent, clinical trial agreement (CTA) or contract award if federally funded, sponsor budget, investigator effort calculation form, and most recent FDA communications, e.g. IND or IDE letter.
3. The electronic Notice of Award needs to be issued before study is activated in ERMS and patients enrolled.