**Database Theory and Applications for Biomedical Research and Practice (BMIN 502/EPID 635)**
**Spring 2019**

**Assignment 5: Implementing a clinical trial database for ABIC**

Scenario: You are the informatician at a clinical site participating in the CRASH-3 study, a well-known clinical trial of tranexamic acid to reduce intracranial bleeding in those with traumatic head injury. A detailed description, in plain English, is provided at http://crash3.lshtm.ac.uk/index.php/about/

Your job is to design and implement a REDCap database to support the CRASH-3 protocol at your site. Here are some important details:

1. First, read the protocol summary, taking care to understand the purpose of the study, who is eligible to participate, what is done during the study, and the outcome measures. The protocol summary is at http://crash3.lshtm.ac.uk/files/1914/9157/4617/Protocol_summary_v2_for_translation_FINAL.pdf

2. Every patient admitted to the Neurological Intensive Care Unit with a traumatic brain injury is a potential candidate for the trial, as long as they were admitted within three hours of injury.

3. Note when and how the study drug (tranexamic acid) or placebo is given

4. Specific to REDCap
    a. You will implement this database as a longitudinal project, *without* randomization. Please name it: **yourlastname_BMIN502_19_5.**
    b. This might seem counterintuitive, but do *not* set this up as a two-arm study. In REDCap, multiple arms are used only when different instruments are assigned to different arms in the study, and that is not what is happening here.
    c. You will need to allow for multiple days of observation, up to and including the 28th day of admission. In the interest of keeping busy work to a minimum, please repeat the data collection instrument at Days 1, 2, 3, 4, 5, 6, 7, 14, 21, and 28.
    d. For the purposes of this assignment, you should assume that the ABIC registry database (which you modeled for Assignments 1 and 2) do not link to the clinical trial database. In other words, you are going to create a new REDCap project that is specific to the clinical trial.
    e. You will need the following two instruments:
        i. Subject enrollment form (Subject ID, Date and time of head injury Date and time of enrollment, Eligibility criteria (>17 years of age, any intracranial bleeding or GCS <12, no significant extracranial bleeding, calculated time elapsed between enrollment and injury), Eligible for CRASH-3, based on responses to eligibility criteria, and date/time loading dose TXA or placebo given, date/time maintenance dose TXA or placebo given.
        ii. Daily follow-up form (Date of follow-up, GCS (3-15), status (Myocardial infarction, Pulmonary embolism, Deep vein thrombosis, Stroke, Seizure, Neurosurgical intervention, Death)
    f. Add a couple of subjects to the database.

5. That's it! I've kept the assignment simple this week, but we will discuss it in detail in class next time, along with an alternative way of handling this so that the clinical data collected for ABIC can be used automagically for the trial. Please be sure to submit by 9am 2/26.