

News from the **RESOURCE HUB**

Expand your clinical research word power with the new SOM Clinical Research Glossary!

Whether you are new to clinical research or an experienced member of the research team, mastering the highly specialized vocabulary of clinical research and using it effectively in scientific communication can be challenging.

Take a moment to test your word power with this imaginary scenario:

An [IND](#) for a [phase 2, randomized, multisite, clinical trial](#) is initiated to evaluate the [safety](#) and [efficacy](#) of a novel [investigational drug](#) for the treatment of hypertension. A [commercial IRB](#) is selected as the [IRB of record](#) and the study is approved. An [SIV](#) is conducted at which time the [CRA](#) meets with the [PI](#) and [SC](#) at one of the sites involved in the study. The site is approved to start after the local [IRB](#) approves the study.

Participants with essential hypertension are recruited based on the [I/E criteria](#) in the [protocol](#). These participants are randomized into a treatment and a [control group](#). During the trial, one of the participants in the treatment group develops a stroke. The [IB](#) does not describe the [risk](#) of stroke. The PI recognizes this as an [SAE](#) and immediately reports it to the [sponsor](#). The SAE is also reported to the IRB as an [UPIRSO](#) because the investigator assesses the [adverse event](#) as both unexpected in nature and possibly related to the investigational agent. A [CRC](#) documents the SAE in the adverse event log and the [CRF](#).

To facilitate clinical research communication in the SOM and beyond, the CRSO has created a comprehensive clinical research glossary that aligns with industry and regulatory standards and is clear, concise, and organized.

[Click to Access the
SOM Clinical Research Glossary](#)

Coming up!

The SOM Clinical Research Glossary is intended to be a living and interactive resource for UNC SOM clinical research teams. We are currently working on adding buckets of related words for each entry and other features to maximize utility of the glossary.

If you have suggestions for how to make the glossary work better, new terms, or clarifications that are key to your clinical research communications, please [let us know](#).

