A.L.C.O.A.C CHECKLIST

This checklist reflects the International Council for Harmonisation (ICH) Integrated Addendum To ICH E6(R1): Guideline For Good Clinical Practice E6(R2), and is available as a tool for discretionary use with quality reviews of study records by clinical site staff conducting DMID-supported human subjects research.

A	**ATTRIBUTABLE – the documentation clearly shows** ☐ Each data element is traceable to a person, date, and subject visit; ☐ Who created a record, and when it was created; ☐ Who made a change to a record, and the reason for the change.
L	**LEGIBLE** ☐ The information is readable and easily understood. ☐ The information is recorded permanently on durable medium. ☐ Changes to source data do not obscure the original entry.
C	**CONTEMPORANEOUS** ☐ Study evidence/results are recorded when observed (real-time). ☐ All signatures/initials are attached to a date indicating when the signature was added to a document.
O	**ORIGINAL – the first place where data is recorded** ☐ The source information is accessible, and preserved in its original form. ☐ Changes to source data are traceable.
A	**ACCURATE – the source accurately reflects the observations** ☐ The source data recorded and reported is without error, and collected in accordance with the approved protocol. ☐ No discordant data is recorded elsewhere.
C	**COMPLETE** ☐ The trial data are complete, verifiable, and reliable. ☐ Documents are compliant with applicable regulations and meet recordkeeping/retention requirements*.

* 21CFR312.62 (c) and 812.140 (d)