Office of Human Research Protection
Institutional Review Board
701 Grove Rd
ESC158
Greenville, SC 29605

GUIDANCE – sINDs

A **Single-Use Investigational New Drug** (sIND) is used when a physician would like to request an Investigational New Drug (IND) application to use an unapproved drug or other product for a single patient for Compassionate or Emergency Use. Single patient projects can be reviewed via expedited process through Committee Chair review.

Compassionate Use of an investigation drug or device involves several steps, including **prospective** IRB review. Once a physician has identified an experimental treatment to try, the physician will ask the pharmaceutical/biotech company if it will provide its experimental product to the patient outside of a clinical trial. If the company agrees, the proposed treatment plan goes to the FDA for review. The FDA ensures that the proposal relies on sound medical reasoning and will not cause undue harm to the patient, and it makes any necessary revisions to the treatment plan. If the FDA allows the request to proceed, the IRB must approve the plan before the investigational agent can be administered to the patient.

Your IRB submission for a non-emergency, compassionate use project should be made in IRBNet and include:

- Protocol/Treatment Plan
- FDA Acknowledgement Letter
- Sponsor/Drug company Letter of Authorization
- Informed Consent (utilizing the Prisma Health ICF Main Template)
- Drug Brochure/Drug insert
- Please also note that appropriate signatures must be obtained on the package, all study staff should be shared on the project, and appropriate trainings and credentials should be uploaded into each study team member's individual IRBNet user profiles.

Emergency use (EU) is defined as the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102(d)]. The emergency use provision in the FDA regulations [21 CFR 56.104(c)] is an exemption from prior review and approval by the IRB. The exemption, which may not be used unless all of the conditions described in 21 CFR *56.102(d) exist, allows for one emergency use of a test article without prospective IRB review.*

If the strict emergency use requirements are not met, both the physician and the institution may suffer strong sanctions. Physician noncompliance may result in termination or suspension from treating patients in any and all FDA-regulated studies. If the institution fails to provide guidance to physicians and to establish clear procedures, the institution's ability to conduct FDA-regulated research may be restricted.

To help physicians comply with emergency use regulations, the IRB determines whether each use complies. Most often, this is done when the physician discusses the proposed use with an IRB Chair or Vice Chair before the patient is treated. For contact information, please visit our website or reach out to IRB@PrismaHealth.org. Formal submission to the IRB is not required before drug initiation in Emergency Use situations; however, **you will need to obtain IRB Chair concurrence before the use**. Formal IRB submission in IRBNet after drug initiation is

required within *5 business days* of the emergency use. Please include all the items listed under Compassionate Use in your IRBNet submission.

Please Note: Annual Review is required for sINDs.

Please make your Continuing Review Submission in IRBNet at least 30 days prior to expiration. Please note: submission **must** be made to the FDA for their annual review first. In your submission to Prisma Health IRB, please include:

- FDA renewal notification
- Annual progress report as submitted to the FDA by the PI
- CR cover sheet
- Any reportable events not required to be reported promptly
- Please note that only the PI signature is required on Continuing Review submissions; however, CITI training must remain up to date for all study staff.

For more information regarding Expanded Access projects, please visit the FDA website here.