## Delayed Onset Study(ies) Justification

A close up of a sign

Description automatically generated

***Guidelines***

1. *Required for human subject studies where specifics of the study cannot be determined at the time of submission*
2. ***Format:***
   1. *No page limit*
   2. *Margins min. 0.5”*
   3. *NIH-recommended fonts: Arial, Georgia, Helvetica, Palatino Linotype*
3. ***Content:***
   1. *Provide Study Title (600 characters)*
   2. *Provide justification explaining why human subjects study information is not available at the time of application*
   3. *For multiple delayed onset studies in a single application, address all studies in a single justification*
   4. *Follow all instructions below*
4. *When the form is complete:*
   1. *Remove this box*
   2. *Save file as “Delayed Onset Justification”*

**Instructions:**

1. Explain why human subjects study information is not available at the time of application.
2. Acknowledge that all PHS requirements will be met before the start of any study.
3. Acknowledge GCP requirements and verify all personnel participating in the research will meet requirements before start of any study.
4. If sIRB policy will apply to your study (i.e. domestic multi-site studies), include information regarding how the study will comply with the sIRB requirement prior to initiating any multi-site studies.
5. If study will meet the definition of a clinical trial, include the dissemination plan here.