## 4.1.a Detailed Description

A close up of a sign

Description automatically generated

***Guidelines***

1. *Required for clinical trials*
2. ***Format:***

*This data will be entered into a Text Field on the PHS Human Subjects and Clinical Trials Information Form. Text Field rules apply:*

* 1. ***Limited to 32,000 characters***
  2. *Allowable/Unallowable Characters*
     1. *Unicode, with UTF-8 encoding (i.e. Plain text only)*
     2. *Do NOT use smart/curly quotes or Em/Long Dash*
     3. *Do NOT use proprietary fonts or special characters*
  3. *Do NOT use formatting (font, bolding, bullets, subscript, superscript)*
  4. *Do NOT include tables, graphics, figures*
  5. *To format paragraph spaces, include a blank line between paragraphs*
  6. *To format bulleted lists, use “list item” characters such as hyphen (-) or asterisk (\*), followed by a space and then the item list*

1. ***Content:***
   1. *Enter a narrative description of the protocol, including more technical information*
   2. *Do NOT include the entire protocol*
   3. *Do NOT duplicate information elsewhere (i.e. Eligibility Criteria, Outcomes)*
   4. *Describe your plans for assignment of participants*
   5. *Describe your plans for delivery of interventions*
   6. *Show that your methods for sample size and data analysis are appropriate given those plans*
   7. *For trials that randomize groups or deliver interventions to groups, special methods are required*
   8. *See* [*https://researchmethodsresources.nih.gov/*](https://researchmethodsresources.nih.gov/) *for additional guidance*
2. *When form is complete:*
   1. *Remove this box*
   2. *Verify character limit has not been exceeded (32,000 incl. spaces)*
   3. *Save file as “4.1.a Detailed Description”*