## **4.2 Outcome Measures**

A close up of a sign

Description automatically generated

***Guidelines***

1. *Required for clinical trials only*
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 255 characters for Name and Time Frame, and 999 characters for Brief Description***
  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. *Minimum 1 required, Maximum 50 allowed*
   2. *Complete for all Primary, Secondary and other important measures*
   3. ***Name:*** *Must be unique within each Study Record*
   4. ***Type:*** *Choose from drop-down options*
      1. ***Primary:*** *Measures specified in the protocol that are of great importance (typically the outcome(s) used in the power calculation)*
      2. ***Secondary:*** *Measures specified in the protocol that are of lesser importance*
      3. ***Other:*** *Additional measures used to evaluate the intervention*
   5. ***Time Frame:*** *Indicate all times when a measure will be collected for analysis (e.g. baseline, post-treatment)*
      1. *Must be specific to the outcome measure*
      2. *Note: The specific duration of time over which each participant is assessed is usually not the overall duration of the study*
   6. ***Brief Description:*** *Describe the metric used to characterize the outcome, if not already included in the name*
2. *When form is complete:*
   1. *Remove this box*
   2. *Verify character limit for each field has not been exceeded*
   3. *Save file as “4.2 Outcome Measures”*

**Outcome 1:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Click on Outcomes below to add additional outcomes.**

**djfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffafaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffafaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffaskdjfklsadjhfkljasdlffask**

**Outcome 2:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 3:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 4:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 5:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 6:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 7:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 8:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 9:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 10:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 11:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 12:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 13:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 14:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 15:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 16:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 17:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 18:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 19:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 20:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 21:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 22:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 23:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 24:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 25:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 26:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 27:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 28:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 29:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 30:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 31:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 32:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 33:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 34:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 35:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 36:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 37:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 38:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 39:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 40:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 41:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 42:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 43:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 44:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 45:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 46:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 47:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 48:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 49:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |

**Outcome 50:**

|  |  |
| --- | --- |
| **Name**  (255 characters) |  |
| **Type** | Choose Type |
| **Time Frame**  (255 characters) |  |
| **Brief Description**  (999 characters) |  |