**Study Title**

We are conducting this research study to find out (purpose of study and other background information in lay terms)

**# of cycles and/or time on treatment**

[Type here]

**Drug dosing and administration**

[Type here]

*Include both how the drug(s) will be administered (by mouth, injected, topical, IV, etc.), how often (once, daily, every two weeks) and where the administration will take place/who will administer (home, clinic, self, study staff)*

**Tests/procedures performed**

[Type here]

*(Such as blood draws, radiographic studies, biopsies, etc.)*

**Days between administration and testing** *(if applicable)*

[Type here]

**Follow-up Procedures**

[Type here]

*(List significant procedures and/or time commitment)*

**Randomization/Assignment to Groups**

[Type here]

*(Example: Some participants will receive treatment A, some will receive treatment B* ***OR*** *all participants will receive active drug)*

**Screening**

*(List any significant screening procedures)*

[Type here]

**Reason(s) for exiting dosing cycle**

[Type here]

*(Such as disease progression, completion of x cycles, etc.)*

 ***Example Text/Guidance in Purple***

|  |
| --- |
| **Risks or discomforts** |
| List risks and discomforts that are likely to be experienced during participation |
|  |
|  |
|  |

|  |
| --- |
| **Potential Benefits**  |
| List any potential benefits or state that there are no expected benefits for the participant |
|  |
|  |
|  |

|  |
| --- |
| **Alternative treatments available** |
| List alternatives to study participation; these may include standard treatment and/or no treatment |
|  |
|  |
|  |