

## ***When to use the Information Sheet for Caregivers***

The use of an **Information Sheet for Caregivers** is appropriate when a Caregiver is assisting or facilitating a research subject's participation during a Study. In these situations, the Caregiver would not be considered a research subject since no research is actually being performed on the Caregiver, and no data specific to the Caregiver is being collected. In these scenarios, the Caregiver does not need to sign this document or provide informed consent. The Caregiver is simply assisting the research subject with some research specific functions, such as bringing the subject to study visits and helping the subject with his/her study diary. This Information Sheet for Caregivers should be given to Caregivers to help them understand their role as it relates to the study subject.

Some examples of when to use the Information Sheet include, but are not limited to:

1. Attending study visits with the subject
2. Giving information about the subject to the study doctor and study staff, including the completion of the study diary to keep track pertinent study information
3. Telling the study doctor or study staff if the subject shows or tells the Caregiver about any unexpected or unusual symptoms, physical changes, behavior, or other signs of changes
4. Providing information about how long the subject will be enrolled and how many times the subject is expected to come to the study center

## ***When to use an Informed Consent form for Caregivers***

The use of an **Informed Consent Form for Caregivers** is appropriate when a Caregiver is actually participating in the research study as a research subject. Intervention or interaction with the Caregiver is taking place with the intent of collecting research-related data. In these scenarios, the Informed Consent Form template should be completed specific to the research activity involving the Caregiver, and the Caregiver should undergo the Informed Consent Process. It may be appropriate to edit the Informed Consent Form specific to the Caregiver's role in the research study.

*For any questions on when these forms should be used, please contact the RSPP Office at 414-219-7744.*