

## SECTION 12. DEVIATIONS FROM ASSIGNED TREATMENT

### 12.1 Intercurrent Illnesses

#### 12.1.1 Short-term Illness

A short-term illness is defined as an intercurrent illness that persists for less than 4 weeks. Examples include lower respiratory or gastrointestinal infections, cholecystectomy, herniorrhaphy, as well as any cause of hospitalization or disability for less than 4 weeks.

Antihypertensive regimen during the short-term illness should reflect standard medical care. Participants should resume their study antihypertensive regimen within 4 weeks or less. No protocol follow-up visits should be held during a short-term illness. Because protocol visits are not held, data are not collected. Measurements will be made after the illness if it is within the window for that measurement. Missed GFR measurements will be made up after the illness even if they are outside the window. Reasons for the missed visit will be noted on Missed Visit Form #11.

#### 12.1.2 Long-term Illness

A long-term illness is defined as an intercurrent illness that persists for more than four weeks. Examples include chronic infection, congestive heart failure, inflammatory bowel disease, stroke with a residual deficit etc., as well as any cause of hospitalization or disability that lasts for more than four weeks. Therapy should reflect standard medical practice. Follow-up protocol visits are held during a long-term illness. GFR will be assessed according to Protocol, if not medically contraindicated. If a long-term illness requires a permanent change in antihypertensive therapy so that the assigned therapy can no longer be prescribed, this is a Stop Point.

### 12.2 Adverse Events

Adverse events related to drug therapy should be indicated on Protocol Visit Form #11 unless they are serious.

"Serious" adverse/clinical events must be recorded on Serious Clinical Events Form #42. "Serious" is defined as death, permanent disability, overdose, congenital anomaly, cancer or requiring hospitalization.

### 12.3 Action Items

An action item is defined as an event that occurs after enrollment and prompts a change in the antihypertensive regimen, the blood pressure goal, or the frequency or timing of a visit or measurement. This section contains a summary and detailed explanation of action items. (Stop Points and Action Items are described in detail in the Protocol).