From: OC GCP Questions
To: [redacted]
Subject: Legally Authorized Representative "Snow Birds"
Date: Monday, October 16, 2017 8:52:58 AM
Attachments: [redacted]

Good morning –

This office cannot comment on state laws. We can offer you the following information on LAR.

FDA regulations define a legally authorized representative (LAR) as “an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research” [21 CFR 50.3(l)]. The key point to consider when determining who may serve as an LAR is that the individual (or judicial or other body) must be authorized under applicable law to consent on behalf of the prospective subject. In the United States, the legal authority for who may serve as an LAR is determined by state and local law. If you are uncertain about state and local laws governing who can serve as an LAR, FDA recommends consulting with your legal counsel. Although most, if not all states, have laws that govern who may serve as an LAR for medical decisions in a clinical care context, very few states specifically define who may serve as an LAR for research purposes. Where applicable law exists to determine who is authorized to serve as an LAR to consent to an individual's participation in research, consent must be obtained from an LAR in accordance with this law. In the absence of an applicable law determining who is authorized to serve as an LAR to consent to an individual's participation in research, FDA recommends following state and local law as to who can serve as an LAR to consent for an individual's clinical care.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, October 13, 2017 6:38 AM
To: OC GCP Questions
Cc: [redacted]
Subject: Legally Authorized Representative "Snow Birds"

Dear OC GCP Questions,
We recently had a study team inquire about how to manage the Legally Authorized Representative (LARs) process when encountering snow birds who to go to Florida sites in the Winter and then return home state to their primary site? Or snow birds that go to Florida sites, then return to their home sites out of state for assessments then back to the Florida sites? Are they to be covered under

Florida Law if not residents?

We understand that there is a general consensus on why a subject would be considered vulnerable, slight technical differences in ages for minors, but a bit more differences from local state to state on who is recognized as an LAR. I do not have any previous experience for Snowbirds but would assume the state where the subject signed consent would be the local law that would apply. In my opinion, if a subject is a snow bird and they are a venerable subject that would definitely require an LAR and the PI evaluation of capacity to consent on an ongoing basis, no matter what state they were living, but I am not aware of how state laws apply to snowbirds.

Any references or cases for this that we can review to better understand?

[redacted]

Kind Regards,

[redacted]

[redacted]

[redacted]

[redacted]