If your research involves UF Health Shands patients and visitors, please note the following:

- PIs or research staff with no clinical relationship with patients are not permitted to enter patient rooms or approach patients in the outpatient clinics for research purposes unless the treating clinician/clinic staff have approached them first to establish that the patient is interested in hearing more about a study.
- Shands patients and visitors can only receive compensation in the form of food, coffee, or gas cards with value of less than $15, per the DHHS Office of Inspector General.

If you have questions, please contact UF Health Shands Compliance Services at (352) 627-9050.

Unaffiliated Investigator Agreements (UIAs) and Visiting Residents Process

Is the non-UF researcher affiliated with an institution that has an IRB (i.e., are they at another university, or at someplace like Baptist that has an IRB)?

1. If yes, then one of the following should happen:
   a. Obtain IRB approval from their own IRB to cover their activities
   b. We negotiate an Institutional Authorization Agreement (IAA) for our IRB to cover their activities (or vice versa).
   c. Rarely, if they are engaging only in minimal risk research as an outside activity (not affiliated with their home institution, but on their own personal time), then we could cover them with a UIA. However, we need documentation from their home institution that they don’t want to cover them or do an IAA, and if they publish results they cannot sign the publication with their institution. Please also note that greater than minimal risk studies are excluded from this provision.

2. If no, (they are in private practice, unemployed, not an active student, etc.), then we can:


**IRB Education Opportunities**

**Brown Bag Series**

**October 11, 2017**

“The UF Health Cancer Center (UFHCC) Scientific Review and Monitoring Committee (SRMC) Process”

Alison Ivey
SRMC Associate Director

and

Timmy Guinn
SRMC Coordinator

**October 25, 2017**

“AAHRPP Accreditation”

Gailine McCaslin
AAHRPP Project Coordinator

Objectives: TBA

RSVP: Ivana Simic, IRB Educator

isimic@ufl.edu

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- **a.** Cover them under a UIA if it is a single individual on a single study.
- **b.** Cover them under an IAA if
  - i. They are an institution (i.e., private practice) and we don’t want to sign multiple UIAs because:
    1. Multiple people engaging in research, and/or
    2. Engaging in multiple research projects
  - ii. They will need to get FWA, name an institutional official, and negotiate the IAA with us.

1. Any correspondent student (defined as a non-local student enrolled in a UF run distance learning class or program) are prohibited from serving as the PI.

2. Adjunct Faculty may only be a PI with written approval from the Institutional Official or designee (i.e., Dr. Norton).

Please refer to the Qualifications of a Principal Investigator & Student Roles in Conducting Human Research for more information.

3. If the IRB has requested changes to your revision or continuing review in myIRB, please have the PI or approved PI Proxy submit the changes.

“Hold still, Mrs. Brown while I draw your blood.”