

**WHY ALL RELIANCE AGREEMENTS MUST PASS THROUGH
THE ORRC/HOWARD UNIVERSITY**

Reliance Agreement - HU Checklist

- **DC local Laws – Related issues**
 - Vulnerable population
 - Age of majority and consent
 - Reporting requirements for STD
 - Reporting requirements for other infectious diseases

- **HU Specific Requirements**
 - Injury language
 - HIPAA language and review (authorization)
 - Other specifics to HU ICF
 - Conflict of Interest (COI) management

- **HU – Availability of needed resources to conduct study**
 - Space
 - Technical
 - Alternative and offsite arrangements

- **HU Biosafety (If related)**
 - Institutional Biosafety Committee (IBC review if relevant)
 - Infectious agents concern

- **HU Animal Care (If related)**
 - Institutional Animal Care and Use Committee (IACUC Review)
 - Mastery in proposed procedures

- **HU Laboratory Safety**
 - Laboratory inspection up-to-date
 - Safety hood and cabinet certification

- **Radiation Safety**
 - Onsite – Review by radiation safety committee
 - Offsite – Offsite certificate of radiation safety

- **Study team qualifications**
 - Lead investigator

- Co-Investigators
- Other key personnel
- Study coordinator

- **HU Required Training CITI (Relevant to study)**
 - **RCR Training:** Responsible conduct of research (RCR) (Required for all)
 - **COI Disclosure:** Conflict of Interest (Required for all)
 - **HIPAA:** If research include accessing/use of medical records
 - **Basic human subject research:** Medical (All - Conducting Human Research in the Medical sciences)
 - **Basic human subject research:** Behavioral (All - Conducting Human Research in the Behavioral sciences)
 - **Good Clinical Practice (GCP):** If working on Clinical Trial (all)
 - **Clinical Research Coordinators (CRC):** If a clinical coordinator on a clinical trial protocol
 - **Working with animals:** If conducting animal studies
 - **Working with IACUC:** If conducting animal studies
 - **Biohazard and Biosecurity:** If working with hazardous materials
 - **Export control:** If study include international component

- **Recruitment:** Availability and ability to recruit needed population

- **Compliance Responsibilities (designation):**
 - Reporting adverse events
 - Protocol deviation
 - Protocol amendments
 - Continuation