All research submitted to **New_Study@trihealth.com**

Hatton Regulatory Coordinator performs the following regulatory tasks:

- Verifies TriHealth employment/affiliation of researchers
- Verifies researcher credentials and performs follow-up on any missing CV, CITI, License, and Annual Conflict of Interest Questionnaires
- Assigns Hatton/IRB #
- Coordinates creation of TriHealth study regulatory folder (if applicable, if not already created)

Hatton Regulatory Coordinator submits the following projects to the **IRB** for review:

- Non-Interventional & Non-Sponsored Studies,
- Non-Sponsored Exempt Projects

IRB performs **Human Subject Protection Review** (or Exempt Evaluation, as applicable) and provides IRB approval documents to researchers

MISSION COMPLETE!

Hatton Regulatory Coordinator submits the following projects to **Hatton Leadership** for review:

- Sponsored Projects
  - For example, studies receiving pharmaceutical/device company funding, Non-TriHealth hospital or institution funding, and/or government funding)
- Interventional Studies (regardless of sponsorship)

Hatton Leadership performs review using "Hatton Leadership Checklist" and evaluates submission for:

- **Potential risk to TriHealth/institution**
- **Financial feasibility**
- **Contractual obligations**

Hatton Leadership/designated Hatton Regulatory Coordinator submits project, including Hatton Leadership Checklist, to **IRB** for review

IRB performs **Human Subject Protection Review** and provides IRB approval documents to researchers

MISSION COMPLETE!