



Policy: External Regulatory Portals

1. **Purpose:** To describe UAHS RA Regulatory team policy regarding use of external (sponsor-selected) regulatory portals.
2. **Scope:** UAHS RA Regulatory staff and UAHS clinical research staff
3. **Definitions**
 - CRO: Contract Research Organization
 - eReg: Electronic Regulatory Binder
 - RA: Research Administration
 - UAHS: University of Arizona Health Sciences
4. **Procedure**
 - 1) The sponsor/CRO will email the UAHS RA Regulatory team or study team all study documents, to ensure the site has all necessary information on file. The UAHS staff will not enter regulatory information or upload regulatory documents into individual sponsor/CRO portals. All required information will be provided to the sponsor/CRO via email, in-person collection, or through eReg access.
 - 2) Exceptions are made for regulatory portals that are easily accessible and used for multiple studies conducted at UAHS (e.g. StrokeNet trials).
 - 3) If the use of a regulatory portal selected by the sponsor/CRO is mandatory for site participation in a trial, additional funding may be included in the budget to compensate site staff for time required to learn and utilize the external regulatory portal.
 - 4) UAHS RA Regulatory staff will utilize eReg as the institution’s selected electronic regulatory binder. All new UA RA Regulatory studies receiving initial IRB approval on or after January 1, 2023 will be entered into eReg.

Version 1.0 (DATE month/day/year) Revision History Log:

Version Number	Revision Date	Author	Changes
1.0	01/19/2023	Gustavo Cornejo and Kirsten Anderson	Drafted

