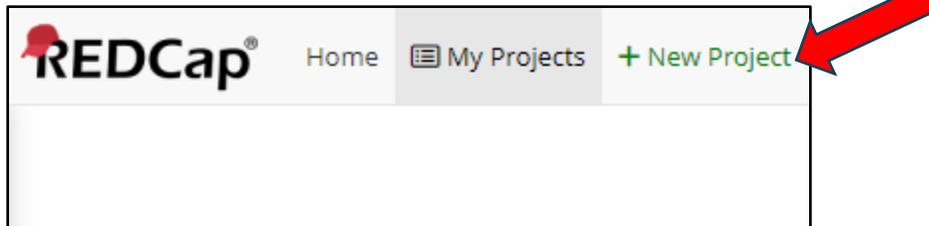


**Follow the process below to create a UTSW 21 CFR Part 11 Compliant REDCap project:**

1. Ensure the project is an FDA regulated research project which requires 21 CFR Part 11 Compliance. You may consult with the IRB Office to confirm.
2. Require all individuals with access to the REDCap project (users) to complete the [REDCap Part 11 training](#).
  - a. Users added to the REDCap project should be named as study team members on the UTSW IRB approved study.
  - b. **NOTE: REDCap admin verifies all Users on project have completed training prior to publishing the project.** *ADDITIONAL users added after the project is live will be required to have training before they are added to the project. Not completing training prior to being added to live projects will be considered noncompliance.*
3. Log in to UTSW REDCap using your UTSW User ID and password.
4. Create a new project by clicking “**New Project**”



- Complete the REDCap Project Creation Form by entering the relevant required information as shown below.

+ Create a new REDCap Project

You may begin the creation of a new REDCap project on your own by completing the form and clicking the Create Project button at the bottom.



The screenshot shows the REDCap Project Creation Form with several red callout boxes highlighting required information:

- You MUST select Research:** Points to the 'Project's purpose' dropdown menu, which is set to 'Research'.
- PI Name Required:** Points to the 'Name of P.I. (if applicable)' fields, which are filled with 'John', 'Doe', and 'MI'.
- STU Number Required:** Points to the 'IRB number (if applicable)' field, which is filled with 'STU-2024-0000'.
- Select appropriate option:** Points to the 'Please specify' section, where the 'Clinical research study or trial' checkbox is checked.
- You MUST enter "Part 11 Project" here:** Points to the 'Project notes (optional)' text area, which contains the text 'Part 11 Project'.

- NOTE:** Study team members (Users) **MUST** enter **Part 11 Project** in the project notes to ensure compliance with 21 CFR Part 11 requirements.
- Create the project as desired.
- Submit to the REDCap Administrator for approval.
- The REDCap Administrator validates the project and confirms all users added have completed the Part 11 training.
- Receive notification that the project is LIVE  
***Don't Forget! Any ADDITIONAL users added after the project is live will be required to have training before they are added to the project. Not completing training prior to being added to live projects will be considered noncompliance. Compliance with training will be monitored by the Office of Institutional Compliance.***