Does My Project Need IRB Review?

START

Is my project RESEARCH?

YES

Does my project involve HUMAN SUBJECTS?

YES

Examples of what might not be research under 45 CFR 46 or 21 CFR 50, 56

- QA/QI
- Pilot projects
- Research practicum
- Case studies (approx. 3 to 5)
- Oral histories
(See guidance GUI-42* for other federal agency examples of “not research”)

If any doubt submit Determination of Human Subject Research - Application to the IRB

Examples of “not human subject”

- Cadaver
- Data or specimens when no access to code or link that could allow identification of the individual
- Data generated from medical record and received by investigator without individually identifiable information.

Click here for more guidance

If any doubt submit Determination of Human Subject Research - Application to the IRB

Project is Human Subject Research – you must submit protocol for IRB review

Submit a protocol application to the IRB via web-based eProtocol application at https://hs.stanford.edu/ - requires SUNet ID

* GUI-42 Research Funded by Other Agencies - Additional Requirements