

# Does My Project Need IRB Review?

START

Is my project  
**RESEARCH?**

**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)  
[Click here for more guidance](#)

If *any doubt* submit [Determination of Human Subject Research - Application to the IRB](#)

YES

Does my project involve  
**HUMAN SUBJECTS?**

**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](#)

YES

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

**[Submit a protocol application](#) to the IRB**  
via web-based [eProtocol](#) application - requires SUNet ID

\* GUI-42 [Research Funded by Other Agencies - Additional Requirements](#)