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)

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

Click here for more guidance

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.

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

Click here for more guidance

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