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

Click here for more guidance

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

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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

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