

sIRB Flowchart: Determining Engagement of Institutions in Research

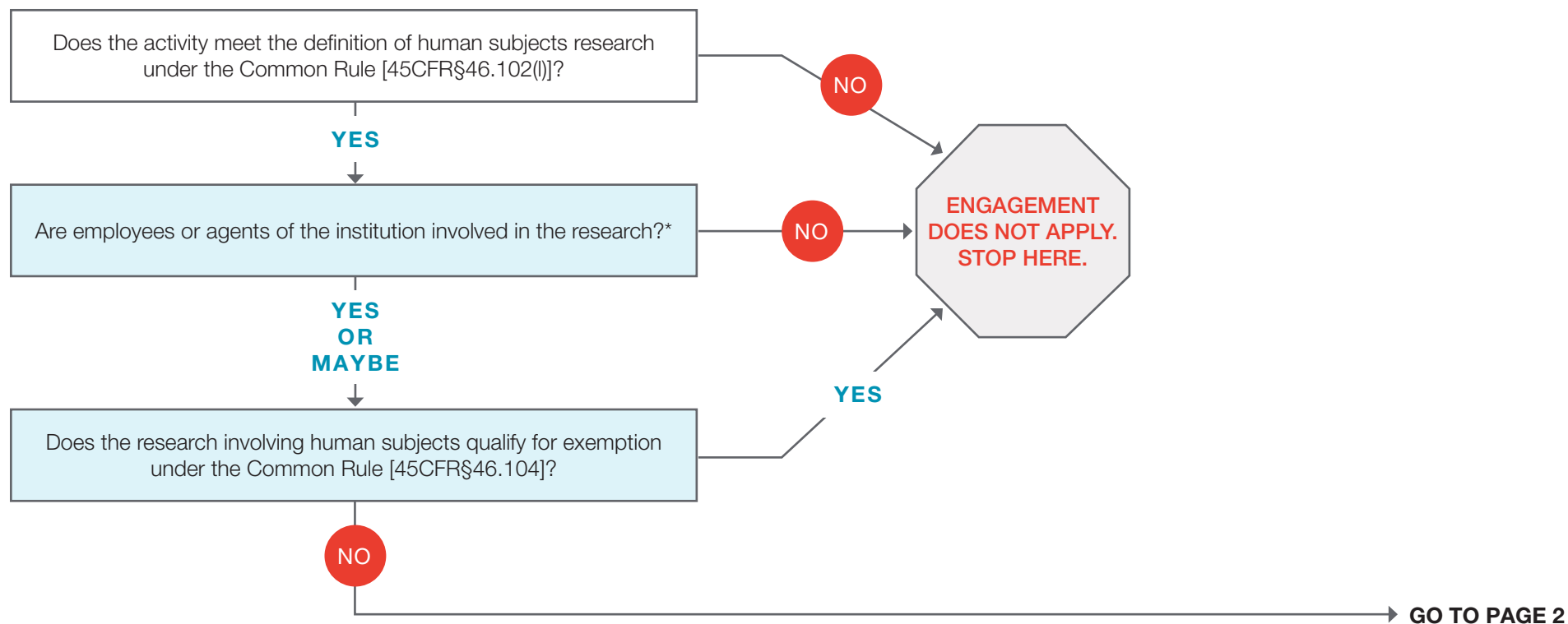
PURPOSE: Assist in determining if activities an institution's employees or agents perform constitute human subjects research as outlined by the Office for Human Research Protections (OHRP)* and thus engage the institution in that research. When multiple institutions are involved, review flowchart separately for each institution.

EXPERTISE NEEDED: Ability to assess -

- who is performing activities,
- where the activities are being performed, and
- the relationship of those performing activities with the institution

LIMITATIONS: Intended only as a tool. Contact IRB/other human research protection program (HRPP) office or research administration for final determination. Consult OHRP resources for additional information.

STEP 1: Confirm the activity constitutes non-exempt human subjects research and that employees or agents of institution are involved.



*Employee/agent defined as individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. "Employees and agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

STEP 2: Determine if institution is engaged in the research

