What Incidents Should Be Reported to OHRP?

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Did the incident occur in non-exempt human subjects research, and is it;
an unanticipated problem,
or
serious or continuing noncompliance,
or
suspension or termination of IRB approval?

— **No** → No need to submit an incident report to OHRP*

↓ **Yes**

Did the incident occur in research that is HHS supported or conducted?

↓ **No**

Is the research conducted or supported by a Federal Agency that has adopted the Common Rule?

— **Yes** → **Has the Federal Agency approved a separate assurance, other than the FWA, for the research?**

↑ **Yes** (to "No need to submit an incident report to OHRP*")

↓ **No** (from Federal Agency separate assurance → Report the incident)

↓ **No** (from Common Rule)

Is the research conducted at an institution with an OHRP approved assurance?

— **No** → No need to submit an incident report to OHRP.*

↓ **Yes**

Does the assurance apply to all research regardless of funding?

— **No** → No need to submit an incident report to OHRP.*

↓ **Yes**

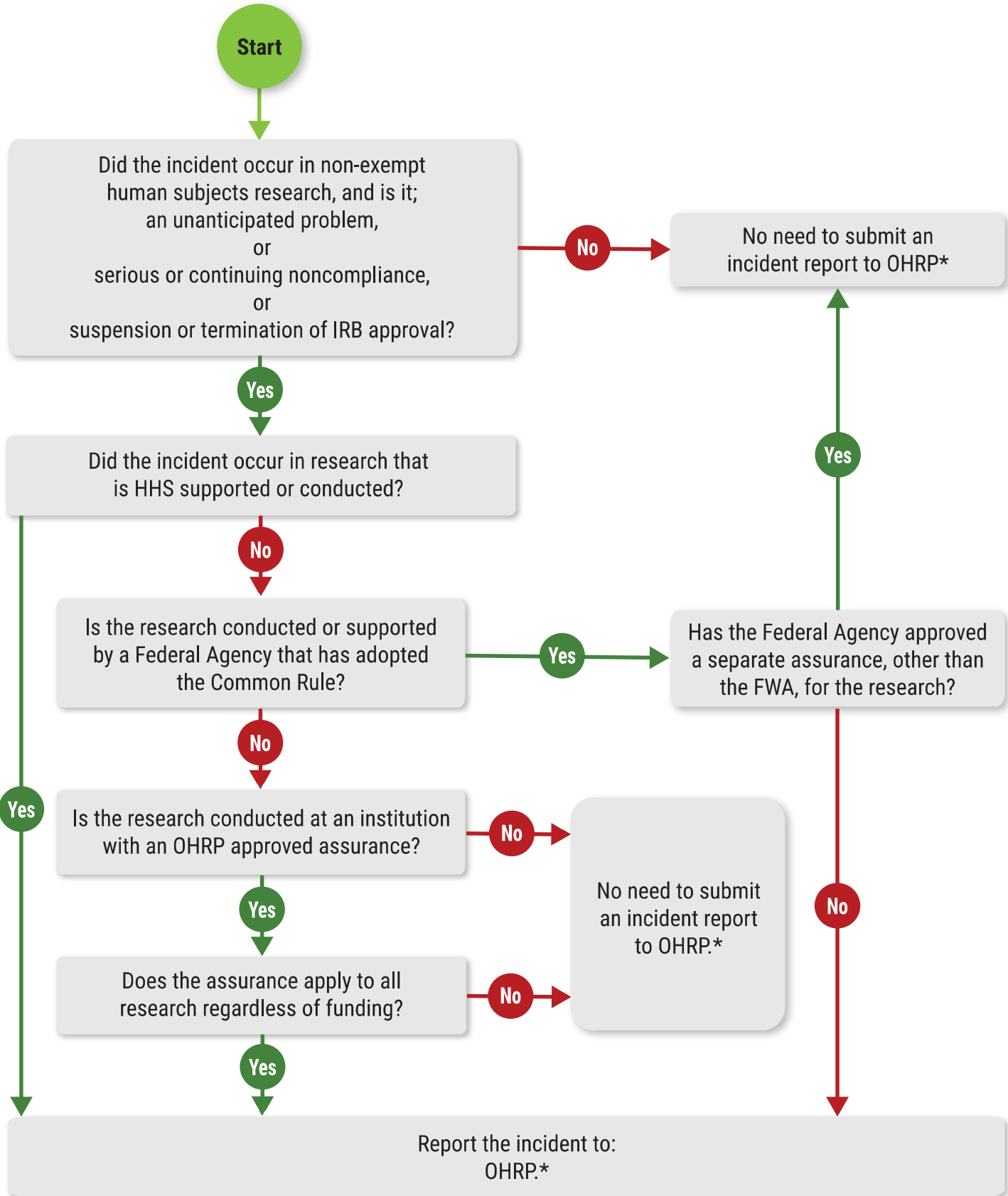(left side **Yes** branch from "Did the incident occur in research that is HHS supported or conducted?")

**Report the incident to:
OHRP.***

* Other reporting requirements may apply, whether or not a report to OHRP is required.