



MCW Guidance on Incidental Findings in Research

This document aims to provide guidance for research teams on MCW IRB's expectations relating to incidental findings in research. This document is also in response to an increasing number of incidental findings in projects without a

DEFINITIONS:

Incidental finding: In contrast to the return of general or individual study findings, incidental findings are discoveries of individual-level findings that are unrelated to the study.

1

Actionable incidental finding: A finding meeting the above definition that is also able to be acted upon whether medically or personally.

Validated: Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.² Within the research environment, this likely means FDA approval or CLIA certification.

Types of Incidental Findings

Below are the main categories of incidental findings seen by MCW researchers. This document contains additional recommendations for certain types of findings to assist investigators in planning their research projects.

Imaging

Genetic testing
or laboratory
tests

Suicidal
ideation
and/or abuse

Frequently Asked Questions

Are there barriers to acting on an incidental finding?

If responses or results are anonymous or if there is no plan to review responses/results in a timely manner, this should be described in both the SmartForm and consent form. A rationale may be requested by the IRB for the delay in review depending on the specific project.

What may increase the likelihood of incidental findings?

¹ <https://www.hhs.gov/ohrp/sachrpecommittee/recommendations/attachment-august2-2017/index.html>

² [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=820.3#:~:text=\(z\)%20Validation%20means%20confirmation%20by,use%20can%20be%20consistently%20fulfilled.](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=820.3#:~:text=(z)%20Validation%20means%20confirmation%20by,use%20can%20be%20consistently%20fulfilled.)

Paper surveys or interviews may increase incidental findings since they allow for free text and open discussion, respectively.

Whole brain/body imaging, high resolution assays, broad genetic testing, and blood tests that generally yield actionable results may all increase the likelihood of incidental findings as compared to more specified imaging or testing.

Would disclosure of certain incidental findings place the specific population at a greater risk personally or professionally?

This question should be addressed within the SmartForm. The potential for greater risk may not remove the requirement of disclosing an incidental finding, but it may warrant a more robust plan and disclosure process.

Are incidental findings always considered negative?

Incidental findings do not always need to be viewed in a negative light. Incidental findings may allow someone to seek preventative care when they otherwise would not have done so.

Should researchers consider releasing results in advance of enrolling subjects?

Specific Considerations for Suicidality and Abuse Disclosure in Research Projects

Does the research require responses to sensitive questions in order to meet its aims?

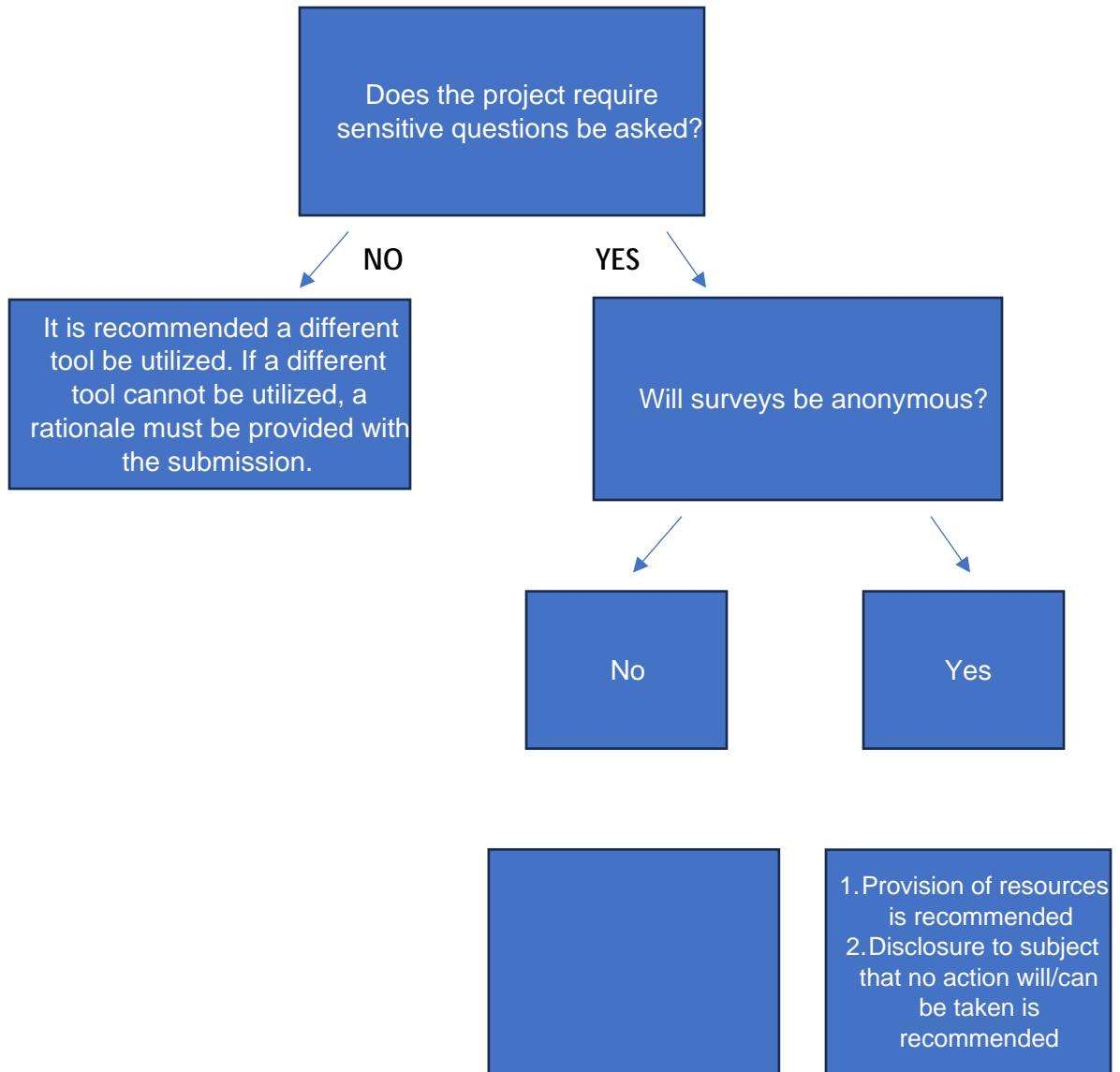
The first question that should be answered in relation to an incidental findings plan for survey research is whether the project requires such questions be asked in order to meet its aims/objectives. If a proposed survey tool happens to contain questions that may disclose suicidal ideation or abuse, yet the project does not require those questions be asked, it is recommended that the tool be modified (with regard for copyright laws) or a new tool be chosen.

Are there certain populations that would trigger an incidental findings plan?

Yes. The MCW IRB has seen an increase of incidental findings when enrolling youth, so it is strongly recommended to have an IRB-approved plan in place for reporting prior to enrollment. For projects involving schools, the plan presented in both the Protocol and consent

In addition, researchers conducting activities outside of MCW (e.g. MPS) should consult with their partners prior to project initiation to determine the partner's process for reporting these types of incidental findings.

Decision Tree for Projects involving Surveys Relating to Emotional or Mental Wellbeing



s callers to the National

eer Crisis Counselor. Twenty-

Instead of...
Committed suicide
Successful attempt
Unsuccessful attempt, suicidal gesture
Suicide ideator or attempter
Completed suicide
Manipulative behavior, cry for help