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 review/disclosure plan in place, which creates difficult decisions and situations for research teams, subjects, and the IRB Office.

DEFINITIONS:
Incidental finding: In contrast to the return of general or individual study results to subjects, incidental findings are discoveries of individual-level findings that are unrelated to the goals of 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/sachrp-committee/recommendations/attachment-f-august-2-2017/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.

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?
Yes! Even if results may not be clinical quality, investigators should consider the possibility that that an incidental finding may be generated within the project or that subjects may request images, lab results, etc.

What is one of the best ways to prepare for an incidental finding?
While each incidental finding scenario may differ, one of the best ways to prepare is to have appropriate members on the research team who could address the incidental finding according to professional expertise if one arises. For example, a project that includes imaging as a research activity should strongly consider having a member of the research team who clinically reviews such images and advises patients on their implications. At a minimum, these individuals should be consulted for guidance prior to initiating the project.

Are there expectations for how an incidental finding should be shared with a subject?
Each incidental finding may warrant a different method of disclosure based upon the type of finding and its severity. By engaging appropriate individuals as discussed in the above question, a plan for determining an appropriate method of disclosure can be developed.

Consent Expectations

Subjects should be provided with a clear and comprehensive description of what will occur should an incidental finding arise during the research. With consideration to subject population and project procedures, research teams should be prepared for incidental findings.

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 form/informational letter should include a thorough description of the research team's process in addition to the school system's process for acting upon an incidental finding.

Also, trauma survivors, veterans, and those with major depressive disorder are at higher risk for suicide, so special considerations may be warranted for these populations as well.

Are questions related to suicidal ideation accompanied by questions about intent, plan, and/or means?
Consideration should be given to the sensitivity and severity of questions that will be asked. A survey that may expose suicidal ideation is not equivalent to a survey that asks about suicidal ideation, intent, and a plan relating to the ideation.

What should be detailed within the Project SmartForm and/or Protocol?

1. **Timeline for non-anonymous survey research**
   A timeline for review of results must be provided to the IRB (and potentially the subject) whether the survey is administered online or in-person. If the survey is administered in-person, the results relating to suicidality should be evaluated before the subject leaves. If the survey is administered online, a slightly lengthier timeline may be appropriate, but this should be outlined within the Protocol and consent form or informational letter.
2. **Assessment of results**
   A description of how the research team will assess the level and immediacy of risk as well as the interventional steps that will be taken for each scenario.
3. **Mitigating factors**
   If subjects complete the survey online, thought should be given to whether there is a need to collect additional information to alleviate risks (e.g. location).

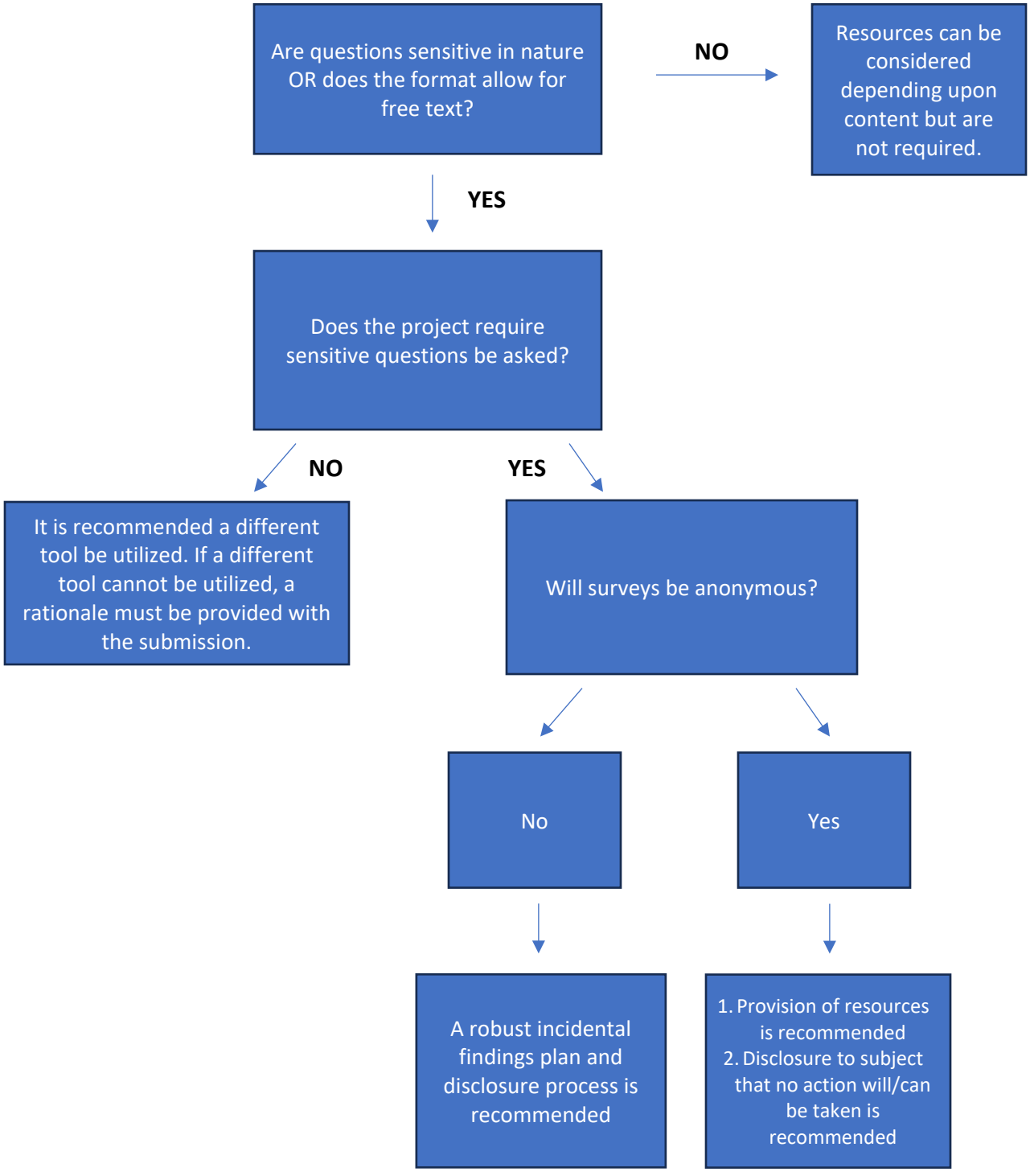
   Any resources or services that will be provided to subjects should be referenced within the Protocol and/or SmartForm.

What steps should the research team take operationally?

When possible, an individual with professional knowledge applicable to an incidental finding of suicidal ideation or abuse should be on the research team. When this is not possible, subject matter experts can still be consulted for details on available resources and/or clinical workflow.

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



Resources

988 Suicide and Crisis Lifeline, a three-digit dialing code that routes callers to the National Suicide Prevention Lifeline
Twenty-four hours a day, seven days a week
https://988lifeline.org/

Crisis Text Line
Text HOME to 741 741 from anywhere in the US to reach a volunteer Crisis Counselor. Twenty-four hours a day, seven days a week
www.crisistextline.org.

The Trevor Lifeline
1-866-4-U-TREVOR (488-7386)
Twenty-four hours a day, seven days a week
The Trevor Project primarily serves young people, ages 13-24
www.thetrevorproject.org

Vocabulary

Say…	Instead of…
Died of suicide	**Committed suicide**
Suicide death	**Successful attempt**
Suicide attempt	**Unsuccessful attempt, suicidal gesture**
Person living with suicidal thoughts or behavior	**Suicide ideator or attempter**
Suicide	**Completed suicide**
Increasing drug/alcohol use; talking about wanting to die/being a burden; self-harm (describe the behavior)	**Manipulative behavior, cry for help**

For further information on appropriate language choice, review information from the Centre for Addiction and Mental Health (CAMH).