# University of Iowa Exemption Categories Tool

## Institutional Review Board and Human Subjects Office

Research may qualify for an exemption if it is no more than minimal risk and all of the research procedures meet one or more of the exemption categories outlined in the Federal regulation, 45 CFR 46.104.

| Category | New Citation | Exemption Category Description | Limited IRB Review | Conditions/Allowances/Limitations |
|---|---|---|---|---|
| 1 | **104(d)(1)** | **Research in established or commonly accepted education settings that involves normal educational practices** | N/A | • Not likely to adversely impact students' opportunity to learn or assessment of educators providing instruction |
| 2* | **104(d)(2)** | **Research only includes interactions involving educational tests, surveys, interviews, public observation if at least ONE of the following criteria met:** | N/A | • Data collection only<br>• May include visual or auditory recording<br>• May NOT include intervention<br>• Only includes interactions |
| | | (i) Recorded information cannot readily identify the subject (directly or indirectly/linked); **OR** | N/A | Surveys & interviews<br>• Does not include children (can only include children when Investigators do not participate in activities being observed)<br>• Educational tests or observation of public behavior |
| | | (ii) Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); **OR** | N/A | Surveys & interviews<br>• Does not include children (can only include children when Investigators do not participate in activities being observed)<br>• Educational tests or observation of public behavior |
| | | (iii) Information is recorded with identifiers or code linked to identifiers & IRB conducts limited review | Privacy and confidentiality review | • Does not include children<br>Consider:<br>• Is data identifiable or de-identified?<br>○ Can de-identified information be re-identified<br>• How will the information collected as part of the research be used?<br>• Who will it be shared with?<br>○ Shared or transferred to a third party?<br>• How long will the data be retained?<br>• What security controls are in place to protect the confidentiality and integrity of the information? (UI ITS Standards)<br>• Is there a potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the intent of the research? |

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| 3* | **104(d)(3)(i)** | **Research involving benign behavioral interventions (BBI) through verbal, written responses, (including data entry or audiovisual recording) from adult subject(s) who prospectively agree and ONE of following criteria are met:** | N/A | • Does not include children<br>• May not include medical interventions<br>• Subject prospectively agrees<br>• No deception unless participant prospectively agrees<br><br>Benign behavioral interventions must be:<br>• Brief in duration<br>• Painless/harmless<br>• Not physically invasive<br>• Not likely to have a significant adverse lasting impact on subjects<br>• Unlikely that subjects will find interventions offensive or embarrassing<br><br>Consider:<br>• Is data identifiable or de-identified?<br>  ○ Can de-identified information be re-identified<br>• How will the information collected as part of the research be used?<br>• Who will it be shared with?<br>  ○ Shared or transferred to a third party?<br>• How long will the data be retained?<br>• What security controls are in place to protect the confidentiality and integrity of the information? (UI ITS Standards)<br>• Is there a potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the intent of the research? |
| | | (i) Recorded information cannot readily identify the subject (directly or indirectly/linked): **OR** | N/A | |
| | | (ii) Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); **OR** | N/A | |
| | | (iii) Information is recorded with identifiers & IRB conducts limited review | Privacy and confidentiality review | |
| 4 | **104(d)(4)** | • **Secondary research for which consent is not required**<br>• **Use of identifiable information or identifiable biospecimen that have been or will be collected for some other 'primary' or 'initial' activity, if ONE of following criteria are met:** | N/A | • No primary collection from subjects for the research<br>• Allows both <u>retrospective and prospective secondary use</u> |
| | | (i) Biospecimens or information is publicly available; **OR** | N/A | • Must be publicly available |
| | | (ii) Information recorded so subject cannot readily be identified (directly or indirectly/linked); Investigator does not contact subjects and will not re-identify the subjects; **OR** | N/A | • PI does not contact<br>• Will not re-identify |

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| 4 | **104(d)(4)** | (iii) Collection and analysis involving Investigators Use of Identifiable Health Information when use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes"; **OR** | N/A | • HIPAA still applies<br>• HIPAA protections include authorization or waiver of authorization<br>• Does not include biospecimens (only PHI)<br>• Federal guidance still needed on how to apply this criterion |
| | | (iv) Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities | N/A | • If research generates identifiable private information, it is subject to specified federal privacy laws (see iv for list) |
| 5 | **104(d)(5)** | **Research and demonstration projects supported by a federal agency/dept. AND designed to study/improve/public benefit or service programs** | N/A | • Must be posted on a federal website |
| 6 | **104(d)(6)** | **Taste and food quality** | N/A | |
| 7 | **104(d)(7)** | **Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research for which broad consent is required** | N/A | • The University of Iowa has elected not to apply this exemption criteria<br>• Studies conducted at Iowa are not eligible for broad consent |
| 8 | **104(d)(8)** | **Secondary research involving use of identifiable private information or identifiable biospecimens for which broad consent was required** | N/A | • The University of Iowa has elected not to apply this exemption criteria<br>• Studies conducted at Iowa are not eligible for broad consent |

*Category 2(iii) and 3: Limited IRB review guidance has not been released by OHRP as of 1/1/19. No changes to the current exemption review will occur based on how these categories are reviewed. University of Iowa IRB will continue to review this exemption request under limited IRB review in the same manner as all other exemption categories.

- Subpart B: Studies involving pregnant women, fetuses & neonates are eligible for exempt review under all 8 categories
- Subpart B: Children are allowed in categories 1,4,5,6,7, & 8; limitations & exclusion of children in category 2 & 3
- Subpart C: Exemptions do not apply to research involving prisoners except "for research aimed at or involving a broader subject population that only incidentally includes prisoners"