**Decision Making Tool for Exempt Research\***

1. Research studies involving pregnant women, Fetuses and Neonates are eligible under all eight new common rule exempt categories.
2. Exemptions under the new Common Rule do not apply to research involving prisoners unless for “Research Involving Broader Subject Population”. This means, Prisoners are not the primary focus of research; however, when prisoners are only incidentally included.
3. Exempt categories does not allow children to be included in the study in Exempt Categories 2 (i) and (iii) **[Regulation 104(d)(2)(i) and (iii)]** and

3 **[Regulation104(d)(3)(i)]**.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Category** | **Exempt Category Description**  | **Permissible Conditions/Allowances/Limitations** | **Review Requirement** | **CIRB Application Process** |
| 1 | Research in established or commonly accepted education setting that involves normal educational practices [**(104(d)(1)]** | 1. Research is not likely to adversely impact students’ opportunity to learn or assessment of educators providing instruction
 | IRB administrative review using the same process used before the implantation of new common rule.  | Submit CIRB application for exempt review by selecting exempt category 1. |
| 2 | Research only includes interactions involving educational tests, surveys, interviews, public observation if at least One of the following Criteria is met **[(104 (d)(2)]:** | 1. Does NOT include any type of intervention
2. Purpose is only for data collection
 |  |  |
|  | 1. Information recorded in such fashion CANNOT readily be ascertain the subjects identity (directly or indirectly/linked); Or
 | 1. Includes surveys and interviews, children are excluded
2. Includes educational tests or observation of public behavior
3. May include children when investigators do not participate in activities being observed
 | IRB administrative review using the same process used before the implantation of new common rule. | Submit CIRB application for exempt review by selecting exempt category 2(i)  |
|  | 1. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement reputation); Or
 | 1. Includes surveys and interviews. Children are excluded
2. Includes educational tests or observation of public behavior
3. May include children when investigators do not participate in activities being observed
 | IRB administrative review using the same process used before the implantation of new common rule. | Submit CIRB application for exempt review by selecting exempt category 2(ii)  |
|  | 1. Information is recorded with identifiers or codes linked to identifiers and IRB conducts limited review
 | 1. Children are excluded
 | Requires IRB review under Expedited Review | Submit CIRB application by selecting appropriate Expedited Review category. Generally research Expedited Category 7 applies here |
| 3 | Research involving benign behavioral interventions through verbal, written responses (including data entry or audiovisual recording) from adult subjects who prospectively agrees and one of the following criteria is met **[(104 (d)(4)]:**1. Recorded information cannot readily identify the subject (directly or indirectly/linked); Or
2. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (Criminal, civil liability, financial, employability, educational advancement, reputation); Or
3. Information is recorded with identifiers and IRB conducts limited IRB review by an IRB member.
 | 1. Children are excluded
2. Does not include medical interventions
3. Subjects prospectively agree to participate
4. Intervention should be brief in duration
5. Painless and harmless
6. Not physically invasive
7. Not likely to have a significant effect or lasting impact on subjects
8. Unlikely that subjects will find interventions offensive or embarrassing
9. Excludes deception unless participant prospectively agrees
 | Categories A and B are reviewed under exempt reviewCategory C requires IRB review under Expedited Review.  | Categories A and B: Submit CIRB application for exempt review selecting category 3 A or 3 BCategory C: Submit CIRB application by selecting appropriate Expedited Review category. Generally research Expedited Category 7 applies here |
| 4 | Secondary research for which consent is NOT required: Use of identifiable information or identifiable biospecimen that have been or will be collected for some other “primary” or “initial activity”, if one of the following criteria is met **[104 (d)(4)]**:  | Primary collection of identifiable information or identifiable biospecimen is not permitted | IRB administrative review using the same process used before the implantation of new common rule. |  |
|  | 1. Biospecimen or information is publicly available; Or
 | Biospecimen must be publicly available | IRB administrative review using the same process used before the implantation of new common rule. | Submit CIRB application for exempt review by selecting exempt category 4(i) |
|  | 1. Information recorded so subject cannot readily be identified (directly or indirectly/linked); investigators does NOT contact subjects and WILL NOT re-identify the subjects or re-identify the subjects; Or
 | Investigators cannot contact subjects or investigators will not re-identify subjects | IRB administrative review using the same process used before the implantation of new common rule. | Submit CIRB application for exempt review by selecting exempt category 4(ii) |
|  | 1. Collection and analysis involving investigators use of identifiable health information when use is HIPAA “health care operations” or “research” or “public health” activities and purposes”; Or
 | 1. HIPAA regulations apply
2. HIPAA protection include authorization or waiver of authorization
3. Does not include biospecimens (only protected health information
4. Federal guidance is not available on how to apply this criteria is not available at this time. Stay tuned
 | Requires IRB review under Expedited Review | Submit CIRB application by selecting appropriate Expedited Review category. |
|  | 1. Research information collected by or on behalf of federal government- generated or –collected information obtained for non-research activities
 | If research generates identifiable private information, it is subject to specified federal privacy laws. Guidance is not available from OHRP at this time. | Not currently reviewed at Rowan at this time. | Not currently reviewed at Rowan at this time.  |
| 5 | Research and demonstration projects supported by a federal agency/department and designated to study……improve……public benefit or service programs **[104 (d)(5)]** | Must be posted on a federal web site | IRB administrative review using the same process used before the implantation of new common rule. | Contact IRB office. Generally this does not apply to Rowan Investigators.  |
| 6 | Taste and food quality **[104 (d)(6)]** | No changes are made | IRB administrative review using the same process used before the implantation of new common rule. | Submit CIRB application for exempt review by selecting exempt category 6 |
| 7 | Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research for which a broad consent is required **[104 (d)(7)]** | 1. There are stringent requirements that needs to be met
2. Investigators must track refusals so subjects are not re-approached
3. IRB will not waive consent for use of identifiable material (biospecimens) for any individual who has refused to give his/her material (biospecimen)
 | 1. Proper consent is obtained and documented or consent and documentation of consent is waived
2. If there is change made for research purposes in the way the material stored or maintained, IRB must approve the change
 | Submit CIRB application to obtain identifiable private information or identifiable biospecimens. Expedited review category required. Contact IRB for guidance |
| 8 | Secondary research involving use of identifiable private information or identifiable biospecimen for which a broad consent was required **[104 (d)(8)]** | 1. Assure privacy and confidentiality protection is adequate
2. Proper consent is obtained
3. Consent is documented or waived
4. No plans to return research results to subjects
5. Investigators must track refusals so subjects are not re-approached
6. IRB will not waive consent for use of identifiable material (biospecimens) for any individual who has refused to give his/her material (biospecimen)
 | Requires IRB review at an appropriate level  | Submit CIRB application to use identifiable private information or identifiable biospecimens. Expedited review category required. Contact IRB for guidance |

\* We sincerely thank University of Kentucky for allowing us to use their Research Integrity Categories tool for Exempt Research