Study Review using Revised Common Rule Exempt Categories[1]

Staff Designated Reviewer may consult with or have the review routed to a faculty reviewer if additional expertise is needed.

Category and new citation	Exemption Category Description	Limited IRB Review	Conditions/Allowances/Limitations	Who can review?[2]
D1 - 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	Staff Designated Reviewer
D2- 104(d)(2)	Research only includes Educational Tests, Surveys, Interviews, Public Observation if at least ONE of the following criteria met:	Data Collection Only; May include visual or auditory recording; May NOT include Intervention		
	(i) Recorded information cannot readily identify the subject (directly or indirectly/linked); OR	N/A	Surveys & Interviews: Educational Tests or Observation of Public Behavior: Can Only include Children When Investigators Do Not Participate in Activities being Observed	Staff[2]
	(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: Educational Tests or Observation of Public Behavior: Can Only include Children When Investigators Do Not Participate in Activities being Observed	Staff
	(iii) Information is recorded with identifiers & IRB conducts Limited Review[3]	Privacy and Confidentiality Review	No Children	If the study involves any sensitive topic (e.g. use of illicit drugs, mental health issues, sexual preferences) or could put participants at any risk of liability (e.g. criminal activities, studies affecting employability, studies conducted at abortion clinics, needle exchange or distribution), the study should be reviewed by a **Faculty member**. If the above considerations do not apply, a Staff Designated Reviewer can review.
D3- 104(d)(3)(i)	Research involving Benign Behavioral Interventions (BBI) through verbal, written responses, (including data entry or audiovisual recording) from adult subject who prospectively agrees and ONE of following met:	No Children; May Not include Medical Interventions; Subject prospectively agrees; (ii) BBI must be Brief in Duration; Painless/Harmless; Not Physically Invasive; Not Likely to Have a Significant Adverse Lasting Impact on Subjects; Unlikely that Subjects Will Find Interventions Offensive or Embarrassing. (iii) No deception unless participant prospectively agrees		

[1] Adapted from University of Kentucky Office of Research Integrity Exempt Category document.

[2] "Staff" means IRB staff who have been authorized by the Director to conduct Exempt reviews, based on experience and expertise

[3] From https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01058.pdf, page 7189: "This exemption has been expanded to include research using the same methods involving identifiable private information that might be sensitive or potentially harmful if disclosed, so long as the investigators adhere to the limited IRB requirements outlined in § ll.111(a)(7), and the research is not subject to Subpart D"

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	A. Recorded information cannot readily identify the subject (directly or indirectly/linked): OR	N/A		Staff Designated Reviewer
	B. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational reputation); OR advancement,	N/A		Staff Designated Reviewer
	C. Information is recorded with identifiers & IRB conducts Limited Review	Privacy and Confidentiality Review		Staff Designated Reviewer
D4-104(d)(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 following criteria met:	No Primary Collection from subjects for the research; Allows Both Retrospective and Prospective Secondary Use		
	(i) Biospecimens or Information is Publicly Available; **OR**	N/A	Must be publicly available	Staff
	(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		Staff
	(iii) **(USE F5 instead for studies conducted at Emory)** 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; HIPAA protections include authorization or waiver of authorization. **Cannot be used at Emory but can be used at AVAMC or Grady studies.**	Staff Designated Reviewer- **Need to use F5 instead for Emory studies due to Emory's HIPAA privacy policy**
	(iv) Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities	N/A	HIPAA still applies; HIPAA protections include authorization or waiver of authorization.	Staff Designated Reviewer
D5-104(d)(5)	Research and demonstration projects supported by a Federal Agency/Dept. AND Designed to study, public benefit or service programs.	N/A	If research generates identifiable private information it is subject to specified federal privacy laws. Must be posted on a Federal Web Site.	Staff
D6-104(d)(6)	Taste and Food Quality	N/A		Staff

D7-104(d)(7)	Storage or Maintenance of Identifiable Private Information or Identifiable Biospecimens for Secondary Research for Which Broad Consent Is Required	Not applicable at Emory	If an investigator states in their protocol or eIRB submission that they want to obtain broad consent from subjects, include the following language in the list of changes: **"Our institution is not implementing Broad Consent at this point. We do not count with the IT infrastructure to track refusals of consent during the lifetimes of the individuals participating in human subjects' research. If you have any questions, please contact our staff leadership via email".**	N/A
D8-104(d)(8)	Secondary research involving use of Identifiable Private Information or Identifiable Biospecimens for Which Broad Consent was Required	Not applicable at Emory		N/A

Expedited Categories: Which studies should keep an expiration date?

Category	Expiration date?
F1	Yes (FDA regulated study)
F2	No (if not DOJ)
F3	No (if not DOJ)
F4	No (if not DOJ)
F5	No (if not DOJ)
F6	No (if not DOJ)
F7	No (if not DOJ)[4]
F8	No, if not FDA or DOJ
F9	Yes, until in DAO or LTF (if not DOJ)

[4] F7 would be used in research with children when identifiers are utilized or if the researcher is participating in observation of public behavior (otherwise the study can be reviewed under exempt category D2).