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Special Edition Newsletter
Aurora Research Subject Protection Program (RSPP)
Institutional Review Board (IRB)

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The Aurora RSPP Office will be publishing several Special Editions of our newsletter to discuss the regulatory changes included in the revised Federal Policy for the Protection of Human Subjects (aka the HSS "Common Rule"). The changes included in the revised Rule are scheduled to go into effect on January 21, 2019.

This Special Edition will discuss changes to **Exempt Review**.

Exemptions under the Revised Common Rule

Research that is exempt will continue to have to be 1) no greater than minimal risk and 2) all research activities must fall into one of the categories for exemption specified in the federal regulations. The categories for exemption under the Revised Common Rule have been expanded.

Ongoing IRB oversight is not required of research qualifying for exemption; however, an exempt determination does ***not*** lessen an investigator's ethical obligation to subjects as articulated in the Belmont Report and in disciplinary codes of professional conduct.

While the type of research projects falling within an exemption category has been expanded, several of the exemptions now require a limited IRB review. This limited review is beyond the review to ensure exemption criteria are met, and the specifics of the limited review depend on the research being considered.

The revised regulations expanded the categories for exemption from 6 to 8. This included merging one previous category and adding three new categories. Each category has specific conditions for eligibility. See the published final rule for the full description of all exempt categories and their criteria. A summary table of all categories has been provided at the end of this newsletter. In *summary*, the three new categories include:

- Benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording of the subject with prospective agreement.
- Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use (broad consent required). ****

- Secondary research involving the use of identifiable private information or identifiable biospecimens (broad consent required). ****

****Aurora has decided not to adopt the categories requiring broad consent at this time. Studies falling under these categories would receive an Expedited Review by the Aurora IRB.

The FDA's acceptance of the revised common rule: Note that the FDA has not commented on the implementation of the revised common rule for FDA regulated studies. The only exempt category that applies to Food and Drug Administration (FDA) regulated research is category 6 (see table at the end of the newsletter for explanation of categories).

Limited IRB Review

The revised regulations also incorporate an additional review requirement for studies otherwise qualifying for exemption but working with **identifiable information** or **identifiable biospecimens**. In these circumstances, an IRB member must conduct a limited IRB review to determine that the research design includes adequate provisions to protect participant privacy and maintain confidentiality of data.

New Exempt Review Process with the Aurora IRB

As the Federal Office of Human Research Protections (OHRP) guidance recommends that the investigator should not be the one making the exemption determination, exempt determinations will continue to be issued by the Aurora IRB at this time.

The Aurora IRB has created a new Exempt form that is designed to solicit the information necessary to assess the criteria for exemption, including the information needed to conduct a limited IRB review. The process incorporates an investigator self-assessment followed by verification of exempt eligibility by the Aurora IRB.

If the study appears to qualify for exemption, the investigator submits completed materials to the Aurora RSPP office for review and an exempt determination. If additional information is needed to make an exempt determination or the study does not qualify for exemption, the RSPP office staff will guide investigators to further submit. When required, the RSPP will route applicable studies for limited IRB review. Once the RSPP issues a formal letter of exempt determination, human subject research activities may commence.

Changes in study design and investigators/key personnel will need to be submitted. To request a change in study design/conduct or personnel working on the study, the PI/research team member will use the Change in Approved Research form found on the RSPP website/Cyber IRB library. Substantive changes that alter the exempt research determination will result in the researcher needing to submit a new submission application to the IRB for expedited/convened IRB review. Note that IRB approval of the proposed changes must be issued before the revisions can be implemented. See the *Exempt Research* guidance on the RSPP website from more information.

Studies determined to be exempt will not require an annual Continuing Review. To close the protocol, investigators need to submit a Final Report.

One of the biggest changes in the revised Common Rule that will affect much research conducted at Aurora is that most studies that currently qualify for an expedited Medical Records/Database Review (expedited categories 5 or 10) will qualify for an exempt determination (category 4 below) under the revised common rule. The current Medical Records Review Submission Form application will no longer be in use after the implementation of the revised common rule. Please work with the RSPP office if there is an application that you have already started and intend to submit after the New Year. The new Exempt form will be available on the RSPP website and in Cyber. Please note that submissions received on the new form will not be processed until after the 1/21/19 implementation of the revised common rule. This may add additional time to the review process. The Aurora IRB will assess currently approved Medical Record Review studies at the time of Continuing Review and may transfer studies to the regulations under the revised common rule. If your study is transferred to the revised common rule continuing review will no longer be necessary.

Exemption Categories under revised Common Rule

Category	Exemption Category Description	Limited IRB Review	New Citation	Conditions/Allowances/Limitations
2	**Research only includes Educational Tests, Surveys, Interviews, Public Observation if at least ONE of the following criteria met:**	N/A	**104(d)(2)**	**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: No Children;** Educational Tests or Observation of Public Behavior: Can Only include Children When Investigators Do Not Participate in Activities being Observed
	(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: No Children;** Educational Tests or Observation of Public Behavior: Can Only include Children When Investigators Do Not Participate in Activities being Observed
	(iii) Information is recorded with identifiers & IRB conducts Limited Review	Privacy and Confidentiality Review		NO Children
	Research involving Benign Behavioral Interventions (BBI) through verbal, written responses, (including data entry or audiovisual recording) from adult subject who prospectively	N/A	**104(d)(3)(i)**	**NO Children; May Not include Medical Interventions; Subject prospectively agrees;**

3	**agrees and ONE of following met:**			**(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**
	A. Recorded information cannot readily identify the subject (directly or indirectly/linked): **OR**	N/A		
	B. 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		
	C. Information is recorded with identifiers & IRB conducts Limited Review	Privacy and Confidentiality Review		
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:**		**104(d)(4)**	**No Primary Collection from subjects for the research;** **Allows Both <u>Retrospective and Prospective</u> <u>Secondary Use</u>**
	(i) Biospecimens or Information is Publically Available; **OR**	N/A		Must be publically 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		
	(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; HIPAA protections include authorization or waiver of authorization;
	(iv) Research information collected by or on behalf of federal government using government generated or collected information obtained for non-	N/A		If research generates identifiable private information it is subject to specified federal privacy laws (see iv for list)

	research activities			
1	**Research in Established or Commonly Accepted Education Settings that Involves Normal Educational Practices**	N/A	**104(d)(1)**	**Not Likely to Adversely Impact Students' Opportunity to Learn or Assessment of Educators**
5	**Research and demonstration projects supported by a Federal Agency/Dept. AND Designed to study, public benefit or service programs.**	N/A	**104(d)(5)**	**Must be posted on a Federal Web Site**
6	**Taste and Food Quality**	N/A	**104(d)(6)**	
7 Aurora is not using this Category	**Storage or Maintenance of Identifiable Private Information or Identifiable Biospecimens for Secondary Research For Which Broad Consent Is Required**	-Broad consent is obtained --Documented or documentation waived - If there is a change made for research purposes in the way material stored or maintained, Privacy and confidentiality review	**104(d)(7)**	**All requirements for Broad Consent Met;** **MUST TRACK REFUSALS –as the IRB may not waive consent for use of identifiable material for any individual who refuses**
8 Aurora is not using this Category	**Secondary research involving use of Identifiable Private Information or Identifiable Biospecimens for Which Broad Consent was Required**	-Privacy and confidentiality review & -research is within the scope of the broad consent & -PI does not plan to return research results	**104(d)(8)**	Privacy and Confidentiality protections adequate; Broad consent was obtained**;** Documented or documentation waived **No plan to return research results;** **MUST TRACK REFUSALS as the IRB may not waive consent for use of identifiable material for any individual who refuses**

- Subpart B: Studies Involving Pregnant Women, Fetuses & Neonates are Eligible for Exempt Under All 8 Categories
- Subpart C: Exemptions Do Not Apply to Research Involving Prisoners Except "for Research Aimed at Involving a Broader Subject Population that Only Incidentally Includes Prisoners"
- Subpart B: Children are allowed in categories 1,4,5,6,7, & 8; Limitations & Exclusion of Children in Category 2 & 3