NC Parents Bill of Rights and the IRB

Guidance for Researchers Completing Human Subjects' Research

As a part of our ongoing efforts to support App State researchers completing human subjects research, we wanted to provide you with guidance around completing research activities in North Carolina public schools in context of the new NC Parents' Bill of Rights law. The new law primarily impacts the rights of parents of minors in K-12 public schools, but there are some aspects that affect research with human subjects that the Appalachian State IRB must address.

This guidance provides researchers with basic information about the law and other details regarding roles, responsibilities, the law's effect on human subjects research, and IRB protocol-related action steps.

Brief Overview of NC Parents' Bill of Rights:

This law affects the requirement for parental permission around what occurs in NC public schools with minors including: video/audio recordings, collection of biometric information, survey content, and boundaries around topics for instruction. This law affects all activities within NC public schools, including the human subjects research activities that may take place at public schools in NC.

It is important that Appalachian State University researchers work with the public schools where the research will take place, to discuss the school's expectations for how this law is addressed. Topics should address making materials available for parents to review and preferred methods for seeking parental permission. The information resulting from the school discussion should then be reflected in the design of the research submitted to the IRB for review.

Roles and Responsibilities

To appropriately address this law and its enforcement, clarification of roles and responsibilities is needed. Below is a brief description of obligations

NC Public Schools
are responsible for the implementation of procedures to meet the requirements set forth in this law. This includes ensuring that those who work in the public school know the processes and procedures for carrying out activities subject to this law. Additionally, the specific school is responsible for any and all implementation of this law including parental reporting activities.

App State General Counsel
is available for consultation regarding this law and how it affects the role of App State faculty, staff, and students. They can help navigate difficult questions and let you know what responsibilities lie with you versus partnering schools. They can also help you navigate how this law may affect what you do in the classroom at App State should a minor be enrolled in your class/program.

App State Faculty and Staff
are expected to follow the App State guidance on how to address this law for enrolled students who are also under the age of 18.

App State Researchers Completing Human Subjects Research
are expected to consult with the public school where the research is taking place. This consultation should include expectations around parental permission, information about making study materials available to parents, and any additional requirements the school has set forth. Researchers are also expected to design their research projects to include the requirements from this law. This may also include submitting an amendment to an already approved IRB protocol (check out this guidance document on submitting modification) or accounting for this law in a newly proposed research protocol.

App State Human Research Protections Program (including IRB and IRB Office)
ensures that the federal and university regulations that govern research with human subjects are followed. This includes ensuring that all federal and state laws are followed. They do this by reviewing IRB applications. Neither the IRB nor the IRB Office cannot provide guidance on interpretation of the law nor can they override how an institution has interpreted the law. The IRB staff are responsible for ensuring the following elements are addressed in an IRB protocol: parental permission for video/audio recordings, collection of biometric information, survey content, and some topics used as an instructional intervention.

Resulting Changes that Affect Research with Human Subjects

Complete waivers of parental permission or the use of a parental "Opt Out" form in lieu of prospective parental permission, are no longer available for implementation in NC public schools. Prospective permission is required regardless of IRB review level. Some interventions cannot be implemented in K-4 classrooms at all.

Audio/Video Recording
Any audio or video recording; creation, sharing, or storage of a biometric scan; or creation, sharing, or the storage of blood or DNA, of a child (a person less than 18 years of age who has not been emancipated), requires prior written consent from the child's parent or guardian. This applies regardless of whether research is reviewed by the IRB at the exempt, expedited, and convened full board review levels.

- For research deemed "exempt" by the IRB, this law requires parent or guardian permission for audio or video recording in NC schools.
    - This means that any study approved as exempt without prospective parental permission must submit an amendment to update the study to include parental permission.
- For research reviewed via "expedited" or "full board" procedures where a waiver of parental permission was granted by the IRB, this law makes it a requirement to seek parent or guardian permission for audio/video recording in NC schools.
    - This means that a study that may have qualified for a waiver of consent or parental permission, no longer qualifies for that waiver and an amendment to update the study to include prospective parental permission must be submitted.
- This law may affect how recording can occur. In the past you have been able to create "zones" of recording. This may no longer be feasible, and you will have to discuss how you will record audio and video with the school where the research will take place before applying for IRB approval or before amending an already approved protocol.

Surveys implemented in a public K-12 classroom in NC
Surveys implemented in a K-12 classroom in a public NC school require parent or guardian permission for a "Protected Information Survey," as described in section 115C-76.65(a)(2), to be implemented. A "protected information survey" is any survey, analysis, or evaluation that reveals information concerning any of the following:

- Political affiliations or beliefs of the student or the student's parents.
- Mental or psychological problems of the student or the student's family.
- Sexual behavior or attitudes.
- Illegal, antisocial, self-incriminating, or demeaning behavior.
- Critical appraisals of other individuals with whom respondents have close family relationships.
- Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.
- Religious practices, affiliations, or beliefs of the student or student's parents.
- Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such a program.

This applies to human subjects research at the exempt, expedited, and convened full board review levels.

- For research deemed "exempt" by the IRB, this law makes it a requirement to seek parent or guardian permission for implementation of a survey in NC schools that addresses the above content, including demographics.
    - This means that any study involving this type of survey that was approved as exempt

without parental permission, must submit an amendment to update the study to include prospective parental permission.

- For research reviewed via “expedited” or “convened full board” procedures where a waiver of parental permission was granted by the IRB, this law makes it a requirement to seek parent or guardian permission for implementation of a survey in NC schools that addresses the above content.
    - This means that a study that involves this type of survey that may have qualified for a waiver of consent or parental permission, no longer qualifies for that waiver and an amendment to update the study to include prospective parental permission must be submitted.
- Note: The law requires that "the full text of protected information surveys must be made available to parents at least 10 days prior to administration of the protected information survey." As a result, you should work with the public school where the project will take place to plan your research accordingly.

Surveys implemented in a K-3 classroom in a public NC school that address student well-being or serves as a health screening

Surveys implemented in a K-3 classroom in a public NC school that address student well-being or serves as a health screening as described in section 115C-76.45 have additional responsibilities including:

- For research deemed exempt by the IRB, this law makes it a requirement to obtain prospective parent or guardian permission for implementation of a survey in NC schools that addresses student well-being or serves as a health screening
- For research reviewed via expedited or convened full board procedures where a waiver of parental permission was granted by the IRB, this law makes it a requirement to obtain prospective parent or guardian permission for implementation of a survey in NC schools survey in NC schools that addresses student well-being or serves as a health screening
- Though not an IRB requirement, you should prepare to provide a copy of the blank survey to school officials or parents of the location where the research will take place.

Classroom intervention or interaction that includes students in grades K-4 in an NC public school, where the intervention or interaction addresses gender identity, sexual activity, or sexuality, and can be considered instruction.

- This law may affect researcher’s gatekeeper permission to do the intervention or interaction in the school. The IRB has no control over this.
- The IRB suggests that you reach out to the schools where the proposed intervention would take place and ask the school officials what expectations you must now follow, as this new law prohibits any instruction on gender identity, sexual activity, or sexuality in grades kindergarten through fourth grade.

Minors at Appalachian State University

This law may affect minors who attend Appalachian State University. To understand how the law affects your current or future research with App State students who are also minors, please contact please contact the App State General Counsel

Researchers completing research with App State lab schools should default to the process in that lab school.

Researchers completing surveys with App State students should ensure that the requirements to complete the survey include being 18 years of age or older, and that that requirement is clearly communicated to the potential participant at recruitment and in the consent information on the survey. You may also use survey logic to reroute people to the end of the survey should they enter an eligible age.

Researcher Action Items

- Contact the NC public school where your project is taking place and discuss how they are addressing this law. Discuss whether you can continue your research in the schools and if so, what you need to do to continue your research.

- Regardless of approval level, submit an amendment to each IRB protocol to make the necessary changes. These may include amendments such as:
    - Adding a parent or guardian permission form and process where there was not one before, even if the study qualified for a waiver of parental or guardian permission.
    - Revising surveys or interventions to remove content (if you do not want to seek parent or guardian permission).
    - Restructuring "zones" of audio/video recording to something else determined appropriate after consultation with each school where the research will take place. The IRB would need to be provided information about the change, how it was changed, and if permission for the new "setup" was granted from each school.
    - Any other changes based on the conversation you had with the school such as reporting obligations.

- Regarding the amendment to be submitted to the IRB, the IRB suggests using the language below in the new or amended application to avoid having to submit future amendments regarding this issue:

    - If only doing research in NC public schools: "Due to the law change regarding the 'NC Parents' Bill of Rights,' this study will _____."

    - If doing research in NC public schools and other schools: "Due to the change in the law known as the 'NC Parents' Bill of Rights,' this study will _____ for NC public schools and ____ for schools not subject to this law."

Available Resources

App State University General Counsel: Parents Bill of Rights PPT Slides/Training

For questions about the law, please contact the App State General Counsel. For questions about an IRB protocol affected by this law, please contact the IRB office at irb@appstate.edu.