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# Human Subjects Research in Education

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TEACHxWSU

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# Introductions

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Over the past thirty years he has worked in academic research administration and conducted research in areas including pharmacology, microbiology, biochemistry and molecular/evolutionary biology.



**HEATHER BRACKETT**

She has been with the HRPP since 2018 and has been interested in the intersection of education and policy since she graduated from WSU (for the first time) in 2005.



**SYDNEY WIRKKALA**

A proud cougar alum, Sydney is a compliance specialist for the Human Research Protection Program (HRPP) in the Office of Research Assurances

# Historical Background and Context



# Education as a field of study

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Psychology or philosophy?

G. Stanley Hall's "The Contents of Children's Minds" (1883)

Educational psychology

- William James
- John Dewey
- Jean Piaget
- Edward Thorndike

# Evolving research fields and pedagogy

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## **Inquiry-based learning**

Introduced in the 1960s, this approach to learning stressed the importance of active learning activities opposed to memorization or direct instruction.

## **Trauma-informed teaching**

Incorporating principles of safety; trustworthiness and transparency; peer support; collaboration and mutuality; empowerment, voice and choice; and cultural, historical, and gender issues into teaching practice and the learning environment.

## **Critical pedagogy**

Recognizing that issues like social justice, power structures, and inequality shape teaching and learning. Education is a tool to dismantle or deconstruct oppression.

## **Universal design**

Providing multiple means of engagement, representation, action & expression into teaching practice.

# Ethics vs. Morality

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## **Morals refer to personal belief codes and values of right and wrong**

- Based on individual upbringing, culture, and religion
- Can vary widely between individuals and societies
- Can be influenced by emotions and personal biases
- Often deal with issues of character and virtue

## **Ethics refer to larger societal standards that govern behavior**

- Based on a code of conduct or rules
- Generally consistent within a profession or organization
- Should be objective and impartial
- Often deal with issues of responsibility and accountability

# Ethical Frameworks

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1947

## NUREMBURG CODE

Clearly articulated  
voluntary and  
informed consent

1964

## DECLARATION OF HELSINKI

Respect for the  
individual

1978

## BELMONT REPORT

Beneficence, respect  
for persons, and  
justice are unifying  
principles in human  
subjects research

# Nuremberg Code & the Declaration of Helsinki

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- Directed at medical professionals engaging in research with human participants
- Research should be conducted by qualified personnel
- Informed consent must be freely given and participation is always voluntary
- Individuals are allowed to make informed decisions regarding participation in research
- Participant's welfare takes precedence over laws and regulations
- Vulnerable participants require additional protections



# Belmont Report

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## Respect for persons

- Participation should be voluntary, and consent treated as an ongoing process
- Clear, accurate information should be provided regarding study procedures
- Vulnerable participants require additional protection

## Justice

- Research opportunities, risks, and benefits should be equally distributed

## Beneficence

- Maximize benefits and minimize risks or harms to subjects
- Risk to benefit ratio is evaluated during IRB review

# Methodologies and Review Categories



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# Research Methodologies

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Qualitative Research	Quantitative Research
Observations	Experimental design
Oral history	Surveys/Interviews
Case Studies	Correlational studies
Ethnographic Research	Single Subject design

# Not Human Subject Research

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- Projects that do not meet the federal definition of **Human Subject** or **Research** (must meet both to qualify for review) do not require IRB review.
- **Human Subject** – A living individual about whom an investigator conducting research:
  - *Obtains information through interaction or intervention with the participant or*
  - *Obtains, studies, analyzes, generates identifiable private information or identifiable biospecimens*
- **Research** – A systematic investigation designed to develop or contribute to generalizable knowledge

# Not Human Subject Research, Cont.

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- Examples of projects that may not meet the definition of human subject research:
  - Course evaluations
  - Class activities done for instructional purposes
  - Oral history projects
  - QA/QI projects
  - Case studies
  - Obtaining course grades from another instructor that do not include any student information that could lead to identifiability (names, student ID #)

**Not designed to  
be generalizable**

**Not identifiable information  
about the individual**

# Exempt Review

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- Minimal risk research that falls under one of six exempt categories under 45 CFR 46.104(d):
  - 1. Research conducted in established educational settings
  - 2. Surveys, focus groups, interviews, public observations
  - 3. Benign behavioral interventions
  - 4. Secondary research for which consent is not required
  - 5. Research conducted or supported by a Federal department or agency
  - 6. Taste and food quality evaluations/consumer acceptance tests

# Exempt Review, Cont.

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- Minimal risk research that falls under one of six exempt categories under 45 CFR 46.104(d):
  - **1. Research conducted in established educational settings**
    - K-12, college, Girl/Boy Scouts, trade school, driver's education
    - Cannot negatively impact a student's opportunity to learn
    - Ex: Comparing one approved pedagogy to another pedagogy
  - **2. Surveys, interviews, focus groups, observations of public behavior**
    - Cannot include children under 18 unless the researchers do not intervene in study procedures
    - Note that school settings, including public schools, are not considered "public behavior"

# Exempt Review, Cont.

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- Minimal risk research that falls under one of six exempt categories under 45 CFR 46.104(d):
  - **3. Benign behavioral interventions**
    - Must be brief, painless, non-invasive
    - Children under age 18 must not be included in this category
    - Ex: Reaction tests (IAT, etc.), anagram/puzzle tasks, short videos
  - **4. Secondary research for which consent is not required**
    - Secondary data that is publicly available or recorded in a way that is not readily identifiable
    - Protected health information also included in this category



# Expedited Review

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- Minimal risk research that falls under one or more of the expedited review categories in 45 CFR 46.110(a)
  - 1. Drugs or medical devices
  - 2. Collection of blood samples
  - 3. Collection of biospecimens (ex: urine, saliva)
  - 4. Collection of data through non-invasive procedures routinely employed in clinical practice (ex: EEG, exercise tests)
  - 5. Materials collected for non-research purposes (ex: medical records, documents, artifacts)
  - 6. Data from voice, video, digital, image recordings for research purposes
  - 7. Research on individual or group characteristics or behavior (surveys, interviews, focus groups)

# Expedited Review

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- Minimal risk research that falls under one or more of the expedited review categories in 45 CFR 46.110(a)
  - **5. Materials collected for non-research purposes (ex: medical records, documents, artifacts)**
    - Student coursework
    - Grades (subject to FERPA)
  - **6. Data from voice, video, digital, image recordings for research purposes**
    - Photovoice data
    - Video diaries

# Expedited Review

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- Minimal risk research that falls under one or more of the expedited review categories in 45 CFR 46.110(a)
  - **7. Research on individual or group characteristics or behavior (surveys, interviews, focus groups)**
    - Parent permission and assent required for research with children unless a waiver has been approved
    - Ex: A researcher implements a new teaching method or curriculum and then conducts one-on-one interviews with the students about the new curriculum.

# Full Board Review

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- Research that does not fall under expedited review categories in 45 CFR 46.110(a) and/or research that is **greater than minimal risk**.
  - Board meets twice a month, members review and vote on the protocol
  - Greater than minimal risk = probability and magnitude of risk is greater than harm encountered in daily life
  - Ex: assessment of program aimed at preventing sexual violence for youth

# Special Considerations For Developing Your Research Plan



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# Developing Your Research Plan

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- Regulatory Considerations: FERPA, PPRA, Funding Agency
- Research Location and Topic
- Informed Consent: Respect for Persons
- PI and Instructor Roles
- Managing Risk
- Other Topics and WSU Resources

# FERPA

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- Family Educational Rights and Privacy Act
  - Parents have the right to access their children's educational records and have them amended and;
  - The right to some control over disclosure of personally identifiable information from education records
  - When a student turns 18, these rights transfer to the student which may impact informed consent in longitudinal studies
- Main impact on research: Specific consent requirements (covered later)
- Only impacts classroom research if it involves student records

# PPRA

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- Protection of Pupil Rights Amendment
- Applies to any institution that receives funding/support from the Department of Education (ED)
- May not collect “sensitive” information from students without documented prior consent (parental permission)
- Also, may not conduct certain physical examinations, testing, treatment or marketing surveys without documented parental permission
- Parents have the right to access the instructional materials used in a research or experimentation program
- As with FERPA these rights transfer to the student at age 18, this has an impact on informed consent for some longitudinal studies



# PPRA

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- In the context of PPRA, sensitive means:
  1. political affiliations or beliefs of the student or the student's parent;
  2. mental or psychological problems of the student or the student's family;
  3. sex behavior or attitudes;
  4. illegal, anti-social, self-incriminating, or demeaning behavior;
  5. critical appraisals of other individuals with whom respondents have close family relationships;
  6. legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers;
  7. religious practices, affiliations, or beliefs of the student or student's parent; or
  8. income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

# Funding Agency Policy

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- NIH Policy requires equitable inclusion, as required by federal law (42 USC 289a-2) as do other state and federal policies
- Proposals “must address inclusion of women, minorities and children”
- IRB approval criteria already require that the PI address “equitable selection of subjects”
  - Those who most stand to benefit from the research should share the burden of the risk
  - This also means that convenience sampling is not appropriate for research that is more than minimal risk or slightly more than minimal (children)
  - To improve equity and inclusion consider applying inclusive teaching strategies and principles to your research design when appropriate

# Research Location

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- Location can impact eligibility for exemption1:
  - Must be conducted in “established or commonly accepted educational settings”
  - Commonly accepted for the content being taught, so this does not mean traditional classrooms only
- Certain locations require permission to conduct research (IRB may ask for documentation of permission for non-exempt)
  - Schools, treatment facilities, juvenile detention centers but also;
  - \*Tribal leadership council of elders, local authorities
  - \*Be aware of WSU EP41 (Tribal Engagement Policy), Even for NHSR
- Different states/countries have different laws and customs, so the location in combination with the topic of the research may impact your research plan

# Research Topics

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- Research requiring use of certain technology may be contrary to inclusiveness (e.g., limited internet access), a research plan may need to address how this might be circumvented to ensure equitable inclusion of subjects
- Sensitive topics such as teen pregnancy or issues impacting LGBTQIA+
  - May be difficult to ensure adequate protection of participants in some locations (e.g., Not just international research, but also states that have unfavorable laws regarding gender or abortion)
  - NIH funded projects include automatic certificate of confidentiality (CoC), but these should be requested for sensitive research that is not NIH

# Informed Consent

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- Respect for persons
- FERPA and PPRA impacts
- LAR or parent permission
  - Child assent
  - Opting in vs opting out (failure to refuse)

# Respect for Persons

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- Informed consent (or permission and assent) is derived from the ethical principle of respect for persons
- Research subjects are to be given the opportunity to choose what will or will not happen to them (autonomy)
- Requires that information be adequate to facilitate understanding
- Presented in language the anticipated participant pool will understand
- Based on degree of capability (assent and permission vs. consent)
- Inclusion and exclusion criteria listed in consent must be justified
  - Research purpose, methodology or impracticality of recruitment vs.
  - Inconvenience to the researcher

# FERPA and Informed Consent

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- Family Educational Rights and Privacy Act Informed Consent Requirements
  - Consent form **must be signed and dated** (no waivers of documentation)
  - Consent form **must specify which records will be disclosed** and;
  - The purpose of the disclosure (research purpose usually covers this)
  - Specifically **identify whom the records may be disclosed to** (if you plan to share them with collaborators, they must be listed)
  - Should also state **how long** the records disclosed will be in use
- For longitudinal studies, there must be a plan for re-consenting students after they turn 18 (parental permission is not considered valid after this)

# PPRA and Informed Consent

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- Protection of Pupil Rights Amendment
  - Does not have the same specific list of informed consent requirements
  - Documentation of signed consent/parental permission is implied
  - As with FERPA, for any longitudinal study, there must be a plan for obtaining consent from students who turn 18



# Parent or LAR Permission

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- Legally Authorized Representative (LAR, e.g., Parent or Guardian) is the individual who can legally provide permission (consent) on behalf of a child (or anyone else who lacks the legal capacity to consent).
- Permission must be specific to an individual: For example, a state representative who is an LAR should not provide blanket permission to work with multiple wards of the state
- Opt in permission/consent is preferable over opt out (failure to respond). Schools may use opt out permission when informing the parents is all that is really needed, but this option when done by researchers is not usually acceptable as there is no “affirmative agreement” to participate

# Child Assent

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- Best practice: Approach the Parent or LAR first
- Assent must be presented in age-appropriate language (and/or pictures)
- Children should be told what will be shared with their parent or LAR and about mandatory reporting requirements for child abuse
- Best practice: If the research presents the prospect of a likely direct benefit to children and the parental permission will dictate participation regardless of the child's wishes, a waiver of assent is appropriate
- If a child does not assent their wishes should be respected just as if the parent has not provided permission
- [WSU Child Assent Guidance](#)

# PI Roles

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- Instructor as the PI (may impact recruitment/consent and COI disclosures)
- Instructor as research team member (recruitment, consent)
- Instructor as instructor: Is it QA/QI for your class or HSR?
- In defining your role related to the research:
  - It is important to distinguish research from practice (teaching)
  - What activities would you be doing anyways if the research did not take place?
  - Research involving activities that are not done solely or primarily for research purposes may qualify for exemption as secondary research

# Instructor as the PI: Research in your own class

- Management of potential conflicts of interest
  - Do you as the instructor have an interest in the outcome of the research (financial or otherwise). If yes, even if it is not significant, the interest should be disclosed via informed consent.
  - For example, if you plan to utilize software in your classroom and you will be compensated by the software company for conducting research to evaluate software impact on learning, you should disclose this.
  - If the financial interest is significant (over \$5,000) you should consult with ORSO to determine the need for a management plan:  
<https://research.wsu.edu/resources-researchers/operations-support/coi/>
  - If the interest is not significant, the IRB/HRPP can help you determine if disclosure is appropriate

# Instructor as the PI: Research in your own class

- Management of undue influence (or coercion)
  - As the instructor, you are in a position that may unduly influence your students to participate in your research
  - Participation must be voluntary, absent undue influence or coercion
  - To ensure this, it is often best practice to have another member of the research team (not the TA from your own class) carry out recruitment and consent activities involving your own students
- Coercion is a less common concern, but to avoid the appearance of coercive recruitment avoid any recruitment activity that indicates students would be treated less favorably if they do not participate
- Concerns regarding coercion make it even more important to delineate between required classroom activity (“practice”) and research

# PI Roles

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- If you are either the PI or part of the research team
  - Minimize undue influence
  - Plan for those students who decline to participate in a way that does not negatively impact their opportunity to learn (required for Exemption 1)
  - Be flexible where possible to maximize inclusivity
- If you are an instructor evaluating your own teaching methods, instruments, exam content etc. that you employ in your own class
  - This type of QA/QI is almost always Not Human Subjects Research (NHSR)
  - If you plan to use student materials (e.g., graded examinations) from a class for your research, FERPA may still apply, and you should consider an appropriate process for disclosure/consent even if FERPA does not apply

# Managing risks

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- Data Management Plans, Data Use Agreements, Data Security
- Appropriate training for the research team
- Inclusiveness in research strengthens research outcomes, but there is need for awareness that some marginalized populations may be vulnerable to topic specific risks, be prepared to address and manage these risks
  - LGBTQIA+ legal landscape
  - Evidence of childhood abuse (past or ongoing) and required reporting
  - Teenage pregnancy, impacts of state and international law
  - Substance use disorders (SAMSHA compliance, evidence of illegal activity)

# General Data Security Concepts

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- Minimize collection and storage of identifiable data
  - Data breaches are the most likely risk to impact education researchers and their participants
  - Protect participants by:
    - Collecting only the identifiers that are essential to your research question
    - Retaining identifiable information for only as long as you need it (e.g., for analysis, verification or longitudinal comparisons)
    - Be aware that general demographic information may or may not be “identifiable” depending upon factors like population size and composition



# Training

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- The PI ensures appropriate training of all members of the team
  - The funding source can impact required training
  - WSU policy, by default, requires the most commonly required funding agency trainings for all key personnel (e.g., IRB, RCR, GCP)
  - Non-WSU personnel covered by WSU IRB under reliance agree to comply with WSU policy, and that includes training
  - Fairly simple to provide and track training for WSU personnel (CITI)
  - Providing training for non-WSU collaborators (e.g., school employees who assist with consent, assent or permission) can be more challenging
  - WSU provides access to CITI for non-WSU collaborators
  - Type and documentation of training required by the IRB depends on the role of the specific personnel and the review level of the research

# Current Topics

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- Use of AI and WSU policy
  - Guidance is available from ITS and Compliance and Risk Management
  - WSU workgroup is currently working on policy
  - The concept you should be most aware of is that **any data shared with Open AI can no longer be controlled or retrieved.**
  - Be aware that existing policy, particularly data security policy impacts the acceptable use of Open AI like ChatGPT (EP8, BPPM 87.01)
  - Ethics in Public Service Act RCW 42.52, WSU EP45 (University Ethics Policy) applies to appropriate uses of WSU resources including data
  - Contact ITS to request a [Security Assessment](#) and get written authorization from WSU [System Privacy Officer](#), especially for Protected Health Info.

# Current Topics Guidance

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- [WSU LGBTQ2IA Research Guidance](#)
- [WSU IRB Forms and Guidance Sheets](#) ([irb.wsu.edu/forms](http://irb.wsu.edu/forms))
  - Cannabis research
  - Clinical trials registrations
  - Informed consent/assent
  - Recruitment and Advertising
  - Working with Public Data Sets
  - Research with American Indian or Alaska native Persons
  - Research with Pregnant Persons

Note: WSU forms also now have embedded guidance to assist researchers

# WSU Services for Researchers

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- Institutional Research (ir.wsu.edu)
  - Student data
  - Employee data
  - To obtain identifiable data, evidence of IRB review may be required
- Translation Services (School of Languages, Cultures, and Race)
  - Interpretation services (cost depends on travel and complexity)
  - Translation services (typically a 10+ day processing time, cost increases for rush requests of less than 10 days)
  - <https://slcr.wsu.edu/translation-services/>

# WSU Services for Researchers

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- ORSO: <https://orso.wsu.edu/>
  - Data Use/Sharing Agreements (DUA, DSA, DTA)
  - Proposal submission and compliance with funding agency
  - COI management
- ORSO/ITS
  - Regulated Data Environment (RDE)
  - <https://research.wsu.edu/centers-facilities-capabilities/rde/>
- Library: <https://libraries.wsu.edu/research-assistance-from-librarians/>
- Center For Interdisciplinary Statistical Education and Research (CISER):  
<https://ciser.wsu.edu/>
- Social and Economic Sciences Research Center (SESRC):  
<https://sesrc.wsu.edu/about/>

# Preparing to Submit Your Protocol

## Forms and Timelines



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# Tips for Writing an IRB Application

- Be consistent with word choice when describing procedures
  - Survey vs. questionnaire
  - Interview vs. focus group
- Focus on participant expectations, types of data that will be collected, and potential risks
- Avoid using acronyms and jargon specific to your field
- For more complex procedures, consider visual aids
  - Bullet points, tables, graphs
- Consider separating phases into different IRB protocols
- Focus on the research procedures separate from the educational component

Time Point	Length of Visit	Payment Amount
Week 1	20 minutes	\$5
Week 3	50 minutes	\$20
Week 4	10 minutes	\$0
Week 6	50 minutes	\$20
Week 8	15 minutes	\$5

# Tips for Writing an IRB Application

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Don't	Do
Use specific dates in the application or consent (“On January 25 <sup>th</sup> you will complete the first interview”)	Use timeframes instead (“During the first week of the semester, you will complete the first interview”)
Reference researchers by name in the application (ex: “John Smith will obtain consent from participants”)	Reference the researcher role that will be responsible for procedures (ex: “The PI and Co-PI will obtain consent from participants”)



# Getting Ready to Submit to IRB

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## Email materials to [irb@wsu.edu](mailto:irb@wsu.edu):

- Application (Exemption Determination Application or Non-Exempt Application)
- Addendums *\*if applicable*
  - ✓ Addendum - Research with Children or Wards of the State (for non-exempt research involving children)
- All participant-facing materials:
  - ✓ Recruitment materials
  - ✓ Informed consent/assent/parent permission forms
  - ✓ All study tools/measures for data collection and analysis
- **Letters of support (if conducting research in a classroom) *\*if applicable***
  - *School district approvals take time, and this should be factored into your planning*

# Getting Ready to Submit to IRB

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## Guidance Sheets and Templates for Educational Research:

- Child Assent Templates
  - Ages 7-10, 11-14, 15-17
- Parent Permission Form Template
- Assent Guidance
- Exempt 1 Guidance

<https://irb.wsu.edu/forms>

# IRB Review Timeline



- **Develop your research project/prepare your materials**  
*(As early as possible)*



- **Submit for review**  
*(Recommend 2-3 months prior to start date (1 month for exempt applications))*



- **HRPP Processing/notice of reviewer assignment**  
*(Up to 5 business days)*



- **Receive required and recommended changes**  
*(6-10 business days after review assignment notice)*



- **Submit revisions** (ASAP)



**Re-review/HRPP Processing** *(3 - 10 business days)*



- **Receive review determination** (exemption status or approval)