



# **THE IRB AND HUMAN SUBJECTS RESEARCH**

**Office of Research Integrity**

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# OVERVIEW

- ❖ What is an Institutional Review Board(IRB)?
- ❖ History of Human Subjects Research
- ❖ IRB Responsibility and Human Subjects Research(HSR)
- ❖ IRB Submission and Review Process
- ❖ IRB Documents
- ❖ Special Topics
- ❖ Common Mistakes & Best Practice



# INSTITUTIONAL REVIEW BOARD(IRB)

- ❑ A compliance committee that reviews research studies to make sure that they follow ethical standards and regulations for research with human being
- ❑ The primary mission of IRB is to protect human subjects who participate in research
- ❑ Composed of at least five members of various backgrounds in order to provide complete and adequate review of human research





# HISTORICAL REASONS FOR PROTECTION OF HUMAN PARTICIPANTS IN RESEARCH

## Past events unearthed research ethics concerns

- Nazi Experiments in Concentration Camps (1939-44)
- Japanese Army Unit 731 (1936-1946)

**The Nuremberg Code (1947):** Nuremberg Doctor's Trial

## In the name of Science, in the name of research...

- Tuskegee Syphilis Study (1932-72)
- Milgram's Obedience study (1963)
- Jewish Chronic Disease Hospital Study (1963)
- Tea Room Trade Study (1970)
- Stanford Prison Experiment (1971)



# HISTORICAL REASONS FOR PROTECTION OF HUMAN PARTICIPANTS IN RESEARCH

## The U.S. Public Health Service Syphilis Study at Tuskegee

- Conducted by the U.S. Public Health Service
- Research Question: How does untreated syphilis progress?
- Initially involved 600 “Poor” Black men – 399 with syphilis, 201 who did not have the disease
- Researchers told the men they were being treated for “bad blood”
- Not informed of their disease
- By 1943, penicillin, a treatment for syphilis, was becoming widely available, but participants were not offered.
- Abuses not revealed until 1972

More information:

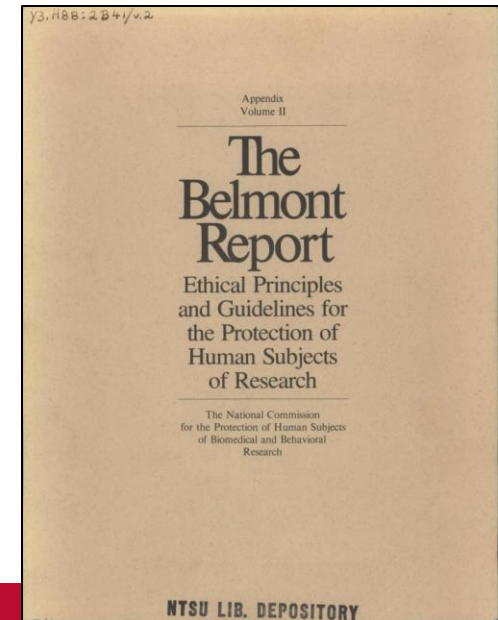
<https://www.cdc.gov/tuskegee/timeline.htm>

•**Result:** 28 participants perished from syphilis, 100 more passed away from related complications, at least 40 spouses had been diagnosed with it and the disease had been passed to 19 children at birth.



# BELMONT REPORT(1978)

- ❑ On July 12, 1974, In response to these historical events and concerns, the National Research Act was signed into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- ❑ In 1979, The National commission published the Belmont report- The Foundation document of the current system of US human subjects protection.
- ❑ The IRB requirements are based on the application of The Belmont Report's three ethical principles.

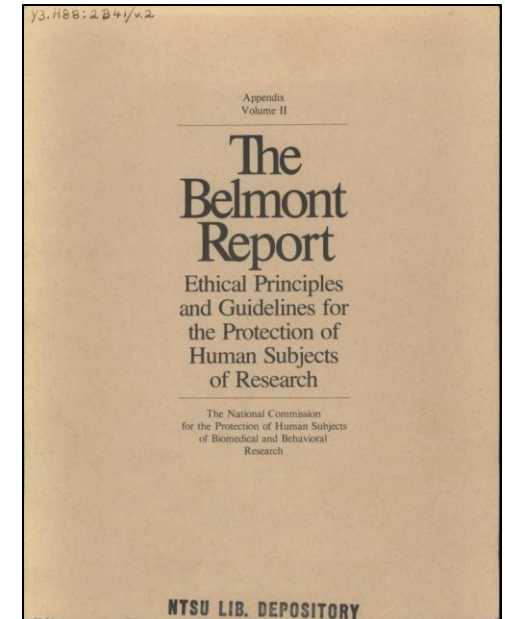


# THE BELMONT REPORT AND ETHICAL PRINCIPLES

**Respect for Persons**: Participants must be fully informed about research before they choose to participate in or not

**Beneficence**: Minimizing risk and maximizing possible benefits

**Justice**: All participants must be treated fairly- Subject populations are not selected because of convenience







# COMMON RULE

- ❑ The Common Rule is a 1981 rule of ethics in the United States regarding biomedical and behavioral research involving human subjects
- ❑ It governed Institutional Review Boards for oversight of human research and followed the 1975 revision of the Declaration of Helsinki
- ❑ The Common Rule is the baseline standard of ethics for all government-funded research in the US and research in nearly all academic institutions regardless of funding
- ❑ The Common Rule Sets all regulations for IRB composition, functions, and review of research with human subjects
- ❑ Revised in 2018

The Declaration of Helsinki is a set of ethical principles regarding human experimentation developed originally in 1964 for the medical community by the World Medical Association (WMA). It is widely regarded as the cornerstone document on human research ethics.

## Revised Common Rule (2018)

**Allows more flexibility in keeping with today's dynamic research environment.**

- ✓ Revised consent forms must quickly and clearly capture the research study.
- ✓ Less-risky studies will have less paperwork.



# THE RESPONSIBILITIES OF IRB

- ❑ Responsible for protecting the rights and welfare of research participants (Primary mission)
- ❑ Responsible for determining what is (or is not) **Human Subjects Research**
- ❑ Responsible for review and approval of all research involving human subjects before data collection begins
- ❑ Responsible for overseeing the ongoing conduct of research through
- ❑ NOT responsible for protecting the researcher or the institution, though if we all do our jobs right, then all are protected



# HUMAN SUBJECTS RESEARCH(HSR)

Not all research needs to be reviewed by the IRB. IRB only reviews HSR.

## Research

**systematic investigation** (including research development, testing and evaluation) designed to develop or contribute to **generalizable knowledge**

## Human Subjects

**living individual** about whom an investigator conducting research obtains:  
✓ Data through intervention or interaction with individual  
✓ Identifiable private information

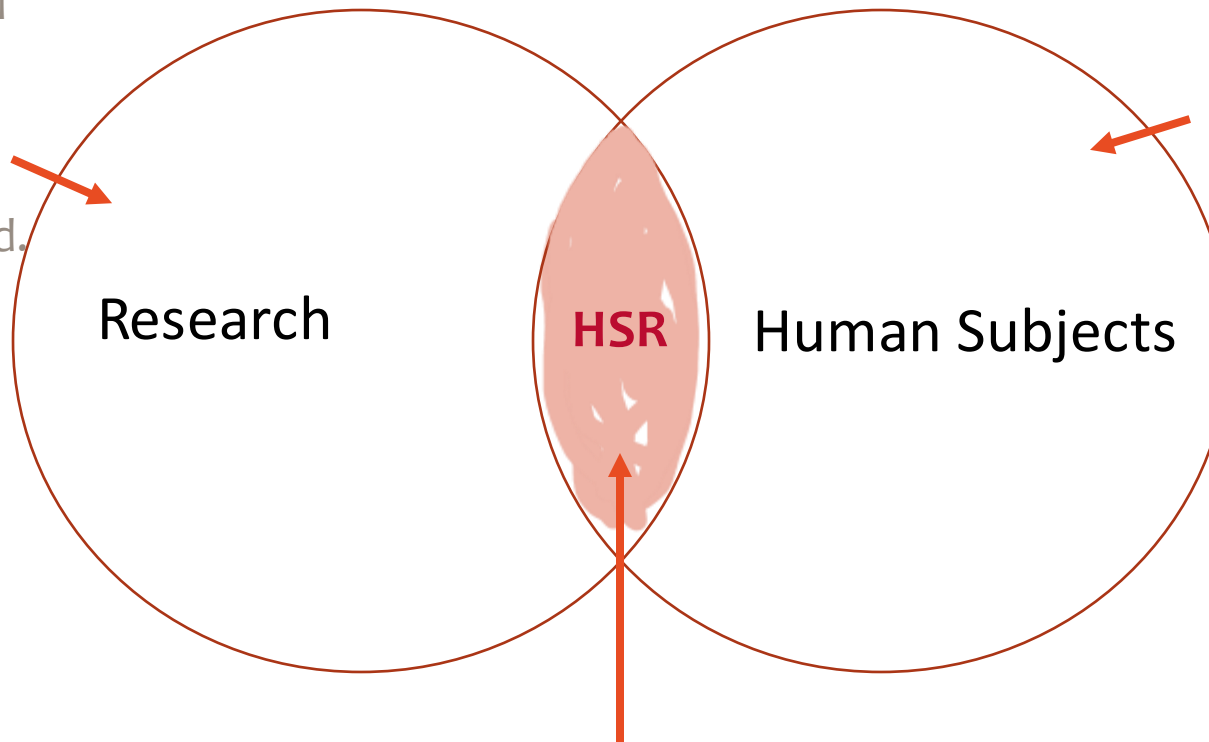
## Examples -not Research:

- Projects that involve quality improvement, case reports, program evaluation
- Marketing and related business analysis
- Surveillance activities

# HUMAN SUBJECTS RESEARCH(HSR)

Meet the federal  
definition of  
research  
But no human  
subjects involved.

↓  
**NOT HSR**



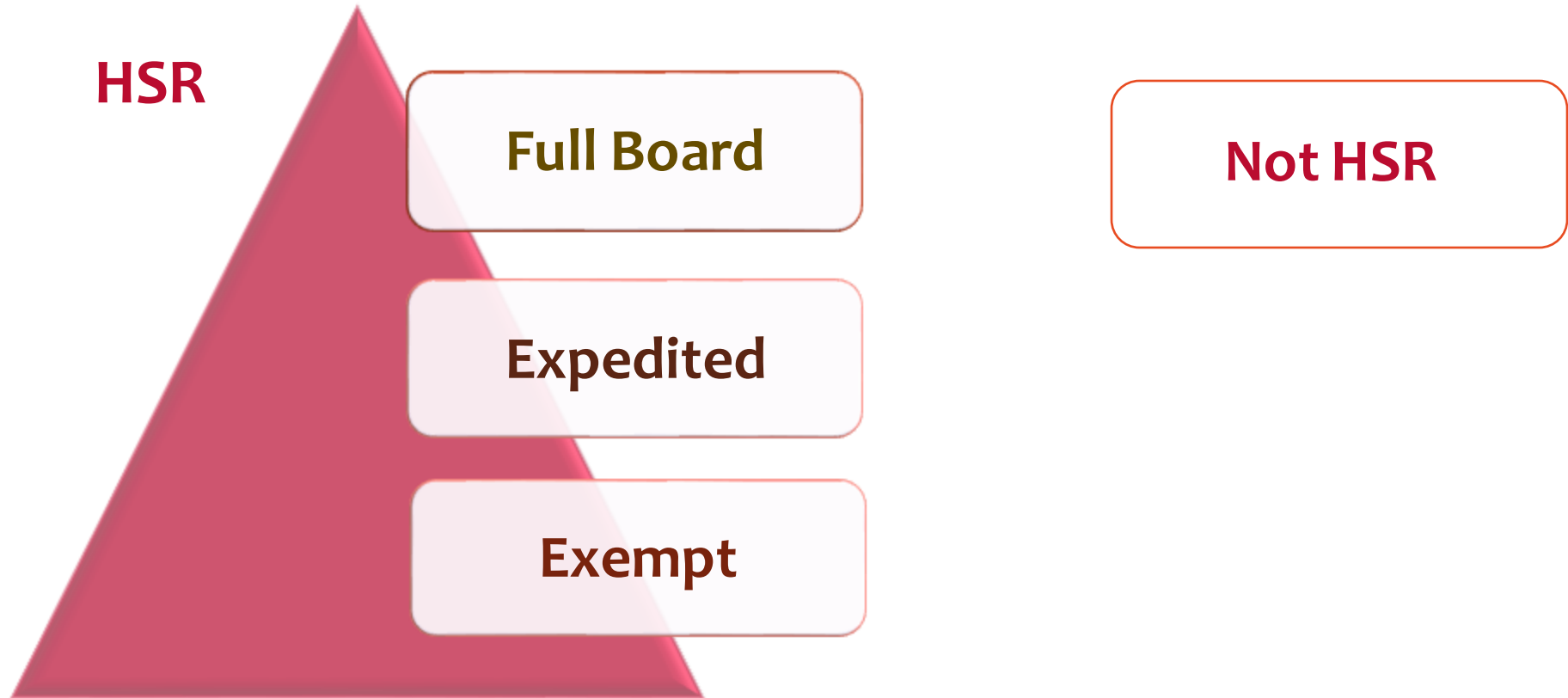
Human subjects  
involved, but the  
project does not  
meet the federal  
definition of  
research

↓  
**NOT HSR**





# LEVELS OF IRB REVIEW



**NOTE: ORI staff and/or a designated reviewer will determine the level.**

# LEVELS OF IRB REVIEW – CRITERIA

## **Risk Assessment :**

No more than minimal risk or Greater than minimal risk?

“Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

## **Protected (vulnerable) Populations**

Who will be recruited? Any protected populations recruited?

- Children/Minors (under age 18)
- Prisoners
- Pregnant women (involved in some types of research)
- People with diminished capacity to give consent
- Mentally or physically challenged individuals
- Students/ Employees

## **Sensitive information**

Sensitive information collected with identifier?

- Sexual attitudes, preferences, or practices
- Use of alcohol, drugs, or other addictive products
- Information pertaining to illegal conduct
- Information that, if released, could reasonably damage an individual's financial standing, employability, or reputation within the community
- Health and medical information contained in a medical record, chart, or insurance file (HIPAA)
- Psychological, psychiatric, or mental health information about a specific individual
- Student's academic records information (FERPA)
- Genetic Information

# LEVELS OF IRB REVIEW

## Exempt Review

- ❑ Minimal or low risk study
- ❑ Does not involve identifiable sensitive information or protected populations
- ❑ Reviewed on a “rolling basis”

## Expedited Review

- ❑ Minimal risk study
- ❑ May involve a protected population group and/or sensitive information
- ❑ Review is conducted by an IRB Subcommittee (weekly)

## Full Board Review

- ❑ Greater than minimal risk studies
- ❑ Involves protected populations and identifiable, sensitive information
- ❑ Invasive procedures
- ❑ Not covered under expedited categories
- ❑ Review is conducted by the Full IRB Committee (monthly)



**Full Board**

**Expedited**

**Exempt**

# IRB SUBMISSION STEPS

Complete the Collaborative Institute Training Initiative (CITI)



Register with IRBNet



Upload All Study Documents



Submit Project



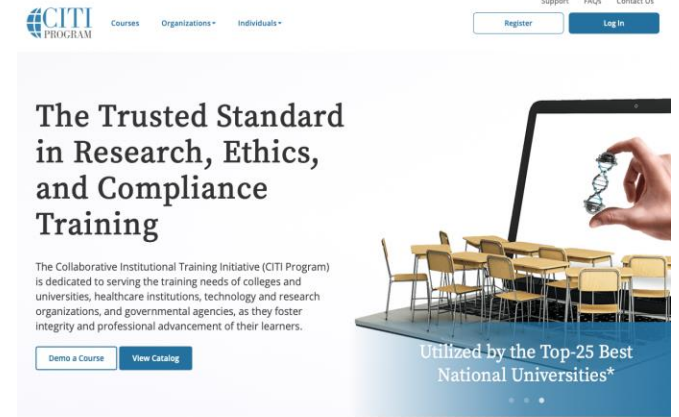
Review process begins





# CITI TRAINING

- ❑ Register and affiliate yourself with Ball State
  - Use BSU email
- ❑ PI and **ALL** research team members must complete either:
  - A Social and Behavioral Research-Basic/Refresher Course; or
  - A Biomedical Research-Basic/Refresher Course
- ❑ Responsible Conduct of Research (RCR)
  - Take this course only if the research is federally funded or required by a granting agency, federal official, or BSU
- ❑ This Certification is good for three years



# IRBNET

**IRBNet** Innovative Solutions for Compliance and Research Management

Login:  Username  Password

[New User Registration](#) | [Forgot Your Password?](#)

[Home](#) | [The IRBNet Difference](#) | [Demo](#) | [Contact Us](#) | [FAQ](#)

## Comprehensive Solutions

**The Industry's Most Complete Solution**  
IRBNet's unmatched suite of electronic solutions drives compliance and productivity for your Administrators, Committee Members, Researchers and Sponsors. These powerful research design, management and oversight tools support your IRB, IACUC, IBC, COI and other Boards with a unified solution.

**Flexible, Intuitive and Easy to Use**  
Your own forms. Your own processes. Your own standards. Powerful reporting and performance metrics. The data you need. From electronic submissions to form wizards, to agendas, minutes, and more. Our easy to use, web-based tools are rapidly launched and backed by our best practices expertise and the industry's leading support team.

**Secure, Reliable and Cost-Effective**  
IRBNet's secure web-based solution is accessible to your research community anytime, anywhere. Our enterprise-class technology is cost-effective and designed to accommodate institutions of any size.

[Try the demo and see for yourself!](#)

**Test Drive IRBNet**  
See for yourself...

### Satisfied Members

"Our first electronic meeting went so smoothly! It was over so fast the members didn't know what to do. They just sat there for a few minutes in disbelief."

- Bruce Day  
Director, Office of Research Integrity  
Marshall University

[Next](#)

### 2020 Events - Join Us

- Annual AAHRPP Conference  
Baltimore MD, May 19 - 21
- PRIM&R Advancing Ethical Research Conference  
Seattle WA, November 7 - 10

- ☐ The IRBNet is a submission system.
- ☐ Wizard form (Launched on July 15<sup>th</sup>)
  - The IRBNet Wizard Application form uses a logic-tree design that prompts researchers to enter information that is relevant to their specific study and needed to facilitate the IRB review process.
  - The old form (PDF application) will be accepted until **September 30, 2021**. After then, researchers must submit their IRB application using wizard system (Wizard form).

<https://www.irbnet.org/release/index.html>





# IRBNET

<https://www.irbnet.org/release/index.html>

New forms, guidance documents, and updated IRBNet manual are available on **IRBNet Forms and Templates.**

**IRBNet**

Welcome to IRBNet  
Sena Lim

**Submission Manager**  
Agendas and Minutes  
My Projects  
Create New Project  
My Reminders (65)

**Other Tools**  
Track Training (8) (288)  
**Forms and Templates**  
Library Manager

Your "My Projects" workspace shows projects that you have created and projects that have been users. Use Reminders, Tags and Archiving to help organize your workspace and keep it running.

Search By Tag:

Create and Manage Tags | Show Archived Projects (1) |

IRBNet ID	Project Title	Principal Investigator	Submission Type	Bo
1801112-1	Test study	Kotewicz	Other	Per
1790685-1	TEst	Lim	Work in progress (Not submitted)	
1786605-1	test wizard	Lim	New Project	Res HSI
1784612-1	test	e	Work in progress (Not submitted)	
1749303-1	Test	Lim	Work in progress (Not submitted)	
1739340-1	test	Lim	Work in progress (Not submitted)	

These libraries have been made available to you by your Boards so that you can easily download blank forms, document templates and reference materials to assist you in your work.

Select a Library: Ball State University IRB, Muncie, IN - Documents for Researchers

Documents in this Library:

Document Description	Last Updated
Form A: IRB Application	03/07/2017 02:48 PM
Form E: IRB Human Subjects FERPA Release Form v. 1	04/23/2014 08:32 AM
Form F: Media Permission Form (with BSU Release)	04/20/2011 03:18 PM
Form G: Media Permission Form (without BSU Release)	04/20/2011 03:18 PM
Form I: IRB Modification/Amendment Form	08/19/2013 05:56 AM
Form J: IRB Continuing Review Form	12/04/2014 08:56 AM
Form K: IRB Adverse Event Form	08/19/2013 05:58 AM
Form L: IRB Research Related Incident Report Form	08/19/2013 05:59 AM
Form M: IRB Final Report	08/19/2013 05:57 AM
Form P1: COVID-19 Safety Plan	08/18/2021 04:24 PM
Form Q1: Human Subjects Research Determination Form	07/24/2021 01:36 AM
Form Q2: Reliance Agreement Request	07/24/2021 01:40 AM
Form Q3: PI Exception Form	07/24/2021 02:00 AM
Form S1: Data security and storage plan	07/24/2021 12:46 AM
Form S2: Informed Consent Form Template	07/24/2021 02:08 AM
Form S3: Parental Permission Form ( template and sample)	07/24/2021 02:10 AM
Form S4: Child Assent Form Template	07/24/2021 02:11 AM
Form S5: Letter of Support (Guideline and Sample)	07/24/2021 02:11 AM
Form S6: International Study	07/24/2021 01:48 AM
Form S7: Recruitment Message Sample	07/24/2021 02:13 AM
Form S8: Flyer Template	07/24/2021 01:57 AM
Form S9: Debriefing Statement Template	07/24/2021 02:08 AM
Form: ORI- Individual Investigator Agreement (IIA)	11/05/2015 03:37 PM
Guidance A1: New Submission Guide for Wizard Form	07/24/2021 02:18 AM
Guidance P1: Covid-19 related guidance for in-person HSR	08/18/2021 04:25 PM
Guidance: collaborative study with non BSU researchers	08/27/2021 09:48 PM

# IRB DOCUMENTS

What documents you need to submit?

- ▶ IRB Application Form/ Wizard Form
- ▶ Informed Consent form – Child assent/parental permission
- ▶ Data Security and Storage Plan
- ▶ Recruitment materials-recruitment email, flyers, advertisements
- ▶ Survey Questionnaires/ Test instruments
- ▶ Interview scripts
- ▶ Stimulus
- ▶ Letter of support
- ▶ Debriefing (if deception occurs)
- ▶ Amendment / Modification Form (if modification requested)
- ▶ Other documents related to your project



# WIZARD FORM

- ❑ PLEASE READ IRBNet User Manual (2021) and New Submission Guide for Wizard Form before you begin your application.
- ❑ Answer all questions if related to your study.
- ❑ At the end of form, the list of supplementary documents will be provided.
- ❑ Provide enough detail that someone who has never heard of your project could read the application and do your study for you, every step of the way.
- ❑ Pay particular attention to the Recruitment Section and the Methods & Procedures section

Package: ▼ 1811217-1 Work in progress (Not submitted)

[Click to add a package description or notes.](#)

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**Step 1:** [Hide Form Libraries](#)  
Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library: Ball State University IRB, Muncie, IN

Select a Document: Form A: IRB Application

[Download](#)

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**Step 2:**  
Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. [Learn more](#)

Documents in this Package:

*There are no documents in this package.*

There are no Training & Credentials records linked to this package. [Link / Un-Link Training Records](#)

[Start a Wizard](#) OR [Attach New Document](#) [\(When should I do this?\)](#)

BSU - IRB Application Form - [1811217-1] IRB application

To get started you can either create a new wizard from scratch or you can clone one of your existing wizards.

**What would you like to do?**

☐ Create a new wizard from scratch.

☐ Clone one of my existing wizards.

[Continue](#) [Cancel](#)



# INFORMED CONSENT DOCUMENT

## Why Informed consent is important?

- ❑ A process, not just a form
- ❑ Obtaining informed consent is a basic ethical obligation and a legal requirement for researchers
- ❑ Informed consent is an ongoing educational interaction between the investigator and the research participant that continues throughout the study
- ❑ Potential participants must be provided with information about the research project that is understandable and that permits them to make a voluntary decision about whether or not to participate.

**To help potential participants make meaningful decision about whether to participate**



# ELEMENTS OF INFORMED CONSENT

- ❑ Study Title/ IRB number
- ❑ Study Purpose and Rationale
- ❑ Inclusion/Exclusion Criteria
- ❑ Participation Procedures and Duration
- ❑ Audio or Video Recordings (if applicable)
- ❑ Data Confidentiality or Anonymity
- ❑ Storage of Data
- ❑ Risks or discomforts
- ❑ Who to contact if experience any negative effects from participating in this study
- ❑ Benefits
- ❑ Voluntary Participation Statement (**This is MANDATORY**)
- ❑ IRB Contact Information
- ❑ Consenting/Signatory Area
- ❑ Principal Investigator/Faculty Advisor Contact Information

## Voluntary Participation

Your participation in this study is completely voluntary and you are free to withdraw your permission at any time for any reason without penalty or prejudice from the investigator. Please feel free to ask any questions of the investigator before signing this form and at any time during the study.





# HOW TO WRITE INFORMED CONSENT?

- ❑ Informed consent documents should be written in plain language at a level appropriate to the subject population.
- ❑ Use the second person (you) not third person (the participant) to increase personal identification.
- ❑ Reading level must be at either:
  - The 6-8th grade level; or
- ❑ Use straight forward language that is understandable
  - Spell out acronyms
  - Avoid technical jargons or complex terms
- ❑ Keep paragraphs short and limited to one idea: Write short, simple, and direct sentences.
- ❑ The consent form must be consistent with what is described in the IRB application.



# PARENTAL CONSENT(PERMISSION)/ CHILD ASSENT

- ❑ If you plan to recruit any children/minors (<18 years old), you are required to have Parental Consent and Child Assent
- ❑ Parental Consent has the same information as an adult consent, but uses the phrase “your child will...” rather than “you will...”
- ❑ Child Assent is a separate document
  - Child Assent must be written age-appropriately
  - Children 5-17 should assent
  - Children younger than 5 may give their verbal consent, but a script must be written.



# RECRUITMENT/ ADVERTISEMENTS

- ❑ Any paper or electronic way of advertising your study/recruiting subjects must be approved by the IRB prior to posting them
- ❑ If you plan to recruit participants verbally, the IRB will need to see the script you are using.
- ❑ Include: your project's name & IRB protocol number, your name & contact info, who can participate, what task(s) the participant will do, how long it will take, where the research is being conducted, and how much the participant will be compensated, if applicable.
- ❑ Compensation is meant to offset time and inconvenience of participation rather than used as a means of incentive.
- ❑ Do not include any gambling language and inappropriate images

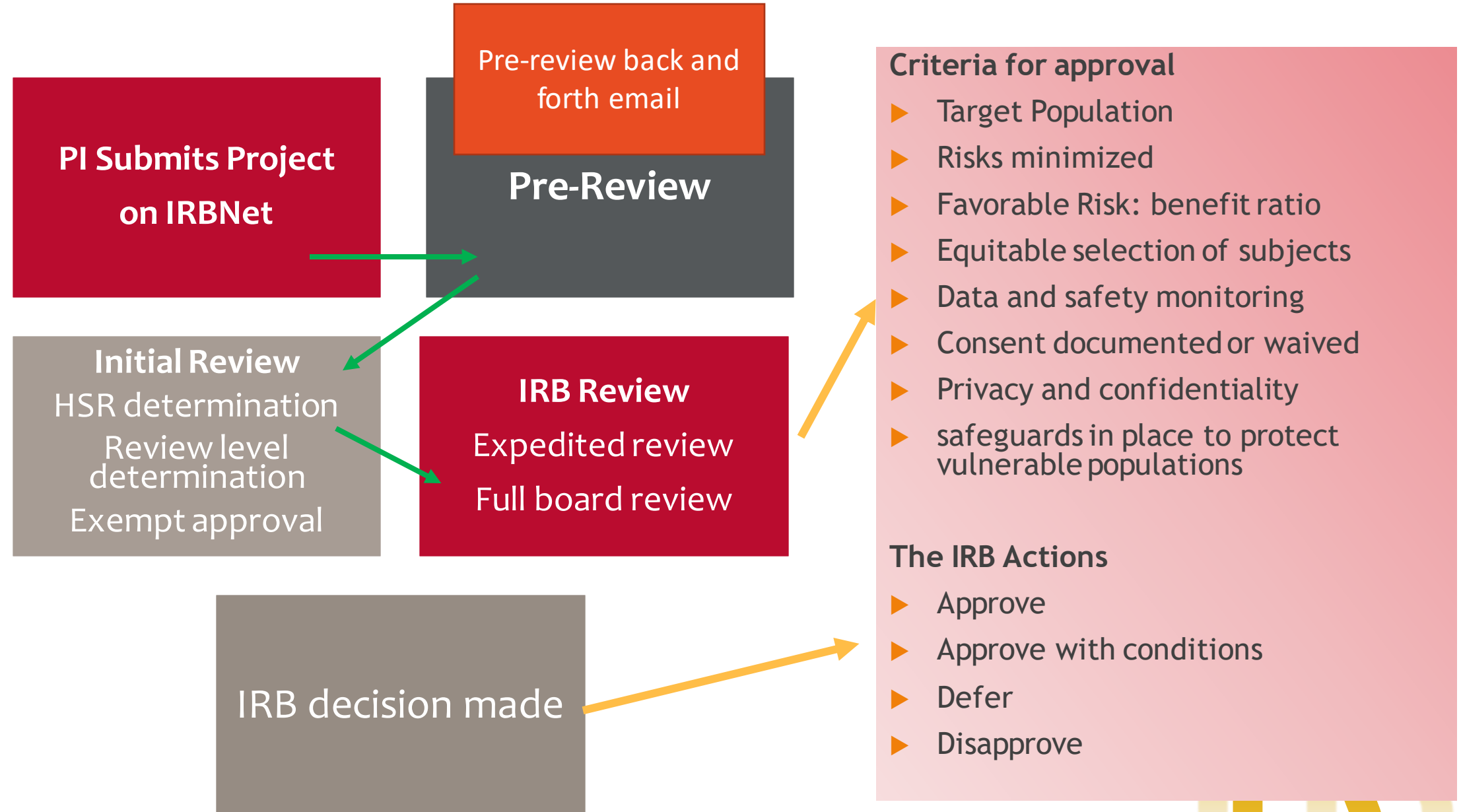


# LETTERS OF SUPPORT

- ❑ Letters of Support/Permission are letters from schools or organizations permitting research to be done at that location
- ❑ They need to indicate in these letters that they are aware you are there for RESEARCH purposes in addition to any other reason you may be there.
- ❑ Letters must be on the school/organizational letterhead
  - ✓ Emails may NOT be accepted
- ❑ Letters must be signed by the school/organization's director, manager, principal, or superintendent
- ❑ Letters must be uploaded on IRBNet prior to IRB review (**not after**)



# AFTER SUBMITTING YOUR PROJECT



### Amendment/ Modification

- ❑ If there are ANY changes to your research study, you are required to submit a Modification Request on the IRBNet for all approved studies
  - Changes of study title
  - Changes of PI/Faculty Advisor
  - Add/Delete Key Personnel
  - Change in number of participants
  - Procedural changes
- ❑ Documents required
  - Modification Form
  - Revised Highlighted Documents
  - CITI Certificates (if you are adding members to your research team)
  - PI & Faculty Advisor E-Signature on IRBNet

## AFTER APPROVAL

### Annual Continuing Report

- ❑ Full Board Projects Only
- ❑ Full Board Projects are approved for one year from the last approval date
- ❑ If the expiration date passes, the project will be closed and PI will need to re-submit as a new study
- ❑ Required Documents
  - Annual Continuing Review Form
  - PI/Faculty Advisor E-Signature on IRBNet



## AFTER APPROVAL

### Any adverse events happen after approval?

- ❑ **Adverse Event(AE) = unexpected or unanticipated problem related or possibly related to participation in the research**
  - AE may result from protocol deviations, participant or personnel minor injury, lost or stolen data, loss of multiple personnel, higher than expected participants withdraw rate, abnormal results, etc.
  - AEs must be submitted to the ORI within 5 business days
- ❑ **Serious Adverse Events(SAEs) = serious event that was unexpected or unanticipated during the research study**
  - SEAs must be reported to the ORI within 24 hours of the event

**NOTE:** During pandemic, you need to report adverse events related to COVID-19. If any research members or participants test positive during study, You need to report adverse events to the IRB.

#### Examples of SAEs include:

Death / Hospitalizations  
Permanent damages  
Suspicious findings  
Birth defects  
Congenital anomaly  
Overdose of drugs  
Adverse pregnancy  
Loss or stolen identifiable  
information/records

# SPECIAL TYPES OF DATA- HIPAA / FERPA

Under HIPAA, **protected health information** is considered to be individually identifiable information relating to the past, present, or future health status of an individual that is created, collected, or transmitted, or maintained by a HIPAA-covered entity in relation to the provision of healthcare, payment for healthcare services, or use in healthcare operations (PHI healthcare business uses).

Under FERPA, **Personally identifiable information for education records** is referring to identifiable information that is maintained in educational records and includes direct identifiers, such as a student's name or identification number, indirect identifiers, such as a student's date of birth, or other information which can be used to distinguish or trace an individual's identity either directly or indirectly through linkages with other information.

- Both are federal regulations that protect private information, who has access to it, and how it can be used.
- In most cases, signed authorizations are required to use protected information.
- Each institution will have their own policies on these. You will need to follow them.
- Both typically require higher levels or reviews.
- Both require additional safeguards and data protection practices.



# HIPAA AND RESEARCH

- ❑ In general, research involving PHI requires signed authorization from patients.
- ❑ If the research involves human participants or their identifiable information, then the Institutional Review Board (IRB) will generally review the research protocol.
- ❑ The IRB review and approval process may require additional safeguards and security measures.
- ❑ The IRB will ask questions about HIPAA during the protocol review; however
- ❑ IRB approval ≠ HIPAA compliance.
- ❑ Information provided directly by the participant, even if health/medical related, is not covered by HIPAA.
- ❑ **Just because you have access to protected health information (PHI) in your official capacity, does not mean you have access to it as a researcher!**



# PROTECTED HEALTH INFORMATION (PHI)

- Health and medical record information
- Addresses, phone #s, e-mail addresses, etc.
- Patient demographic information
- Any type of medical scan or test result
- Discharge and/or readmission information
- Billing records
- Diagnostic codes
- Insurance information

**\* When generated and/or created by a Covered Entity (CE)**

# IN-PERSON HSR DURING PANDEMIC

The guidance and COVID-19 Safety Plan are available on the ORI website and the IRBNet Forms and Templates library.

- ❑ Researchers need to submit the Safety Plan with their IRB application or IRB modification form via IRBNet.org.
- ❑ All research team members who will have in-person contact with participants are strongly encouraged to be fully vaccinated.
- ❑ All research team members who will have in-person contacts with participants are required to wear protective masks regardless of vaccination status.
- ❑ If participants who are deemed to be at increased risk for severe illness are fully vaccinated, they may be allowed to participate in the in-person HSR projects.
- ❑ If researchers are not fully vaccinated, it should be addressed in the consent document.



# COMMON MISTAKES

Researchers submit a wrong CITI certificate.

- BSU IRB requires social/behavioral basic/refresh course or biomedical research-basic/refresh. Please submit either one.

Not all questions have been answered.

- All applicable questions should be answered in the application and supplementary forms. Review all documents before you submit them.

Researchers do not provide enough details regarding recruitment procedures and data collection procedures for a complete review.

- Recruitment procedures and methods and procedures of data collection need to be written in a detailed manner. It should be written like a recipe. The IRB should be able to conduct your research project based on the amount of detail provided.

Researchers often do not describe the same processes in the application and consent form.

- Review both your application and your consent document to be sure that both describe the same processes.

# COMMON MISTAKES

The informed consent form hasn't been altered in accordance with the study.

- Be sure that, when using the sample in the IRBNet library, you have to make changes to fit your study. Don't use our sample(template) as it is.

Describe compensation as a benefit(s).

- Do not add any compensation under the benefits section both in the application and the consent form. If your study doesn't have any direct benefit(s) to participants, please say no benefits. While a benefit statement is required, it is perfectly fine to say there is no direct benefit(s) to the participant.

A student researcher is listed as a principal investigator(PI) of the record.

- The student should contact the faculty advisor or a faculty/staff member with whom the student is working and correct all documents as the faculty or staff member serves as a PI of the record.



# COMMON MISTAKES

Researchers do not upload a complete package in IRBNet with the documents in the correct format. The documents most commonly missing are recruitment materials such as fliers, emails, and phone scripts.

- Refer to the last page of the Wizard form or use the Submission Checklist to see what documents are needed and in what format.

PI and/or co-PI(s) haven't signed the package in IRBNet.

- Before you submit your package, please sign electronically in IRBNet and have co-PI(s) sign the package.

PI forgets to re-lock the project after making revisions.

- After addressing all requests, be sure to click "Mark Revisions Complete" to re-lock the project. If the project is not re-locked, The IRB and ORI staff will not be notified that it is ready for review.
- One tip to avoid delaying the process: Email the ORI staff when the edits have been made. The ORI staff may check the protocol is re-locked and send a reminder email if the project has not been re-locked.

# BEST PRACTICES

- ❑ Need to address how to **Protect Human Subjects**
  - ✓ Privacy
  - ✓ Data Security
  - ✓ How to minimize risks/discomforts
- ❑ Explain exactly how you plan on carrying out each of these processes in detail. Do not assume what the board know about your study
- ❑ Include all documents – recruitment materials, instruments, surveys, and measurements
- ❑ Prepare early: takes up to two months for review

PLEASE BE FAMILIAR WITH IRBNET MANUAL AND FIRST SUBMISSION GUIDE!

PLEASE USE the CHECKLIST!



# OFFICE OF RESEARCH INTEGRITY

If you have any questions, please feel free to contact us!

- **Chris Mangelli**, Director of Research Integrity & HIPAA Privacy Officer  
765-285-5070 / [cmmangelli@bsu.edu](mailto:cmmangelli@bsu.edu)
- **Jim Klenner**, Associate Director of Research Integrity & Lab Safety Officer  
765-285-5213 / [jwklenner@bsu.edu](mailto:jwklenner@bsu.edu)
- **Sena Lim**, Human Research Protection Program Manager  
765-285-5034 / [slim2@bsu.edu](mailto:slim2@bsu.edu)
- **Adam Kriska**, Responsible Conduct of Research  
765-285-6510 [akriska@bsu.edu](mailto:akriska@bsu.edu)
- **Sandra Currie**, Administrator  
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- **Meghan Haser**, Graduate Student Employee  
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