Increasing the Likelihood of Your IRB Application Acceptance

Rebecca Ballard
Research Compliance and Export Control Officer

Welcome!

Course Objectives:

• Understanding the levels of IRB review
• Defining Research
• Defining Human Subjects
Federal regulations gives us various levels of IRB review.

These labels are used to describe the review process the study will undergo.

More extensive the review process

The further down the triangle you go, the greater the review required.

More extensive the review process

Can be reviewed by non-voting member

Reviewed by an experienced voting member

Must be reviewed at a meeting with a majority of members
The study procedures determine which level of review can be performed.

- **Not Human Subjects Determination**: Projects that are not research or does not involve human subjects.
- **Exempt**: Minimal risk + Procedures fit within the exempt categories.
- **Expedited**: Greater than minimal risk studies.

More extensive the review process

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**Why is it important to understand the levels of review?**

A type of study can fall within various levels. Let’s take secondary research as an example.

<table>
<thead>
<tr>
<th>Not Human Subjects</th>
<th>Exempt Category 4</th>
<th>Expedited</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Not Human Subjects" /></td>
<td><img src="image" alt="Exempt Category 4" /></td>
<td><img src="image" alt="Expedited" /></td>
</tr>
</tbody>
</table>
Not Human Subject Determinations

The Common rule applies to research involving human subjects. Projects not fitting within this definition do not require IRB review.

Not Human Subjects Determination

- Projects not involving research
- Projects not involving human subjects

The Common Rule

45 CFR 46

“All research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or Agency.”

45 CFR 46.101(a)

Not Human Subject Determinations

To require IRB review, the project must both be research and involve human subjects.

Research + Human Subjects = IRB Jurisdiction

The Common Rule

45 CFR 46

“All research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or Agency.”

45 CFR 46.101(a)
Not Human Subject Determinations

If the project does not fit the definition of research, IRB review is not required.

Research + Human Subjects = IRB Jurisdiction

Not Human Subject Determinations

Likewise, if the project does not involve human subjects, IRB review is not required.

Research + Human Subjects = IRB Jurisdiction
Defining Research for Non-Clinical Trials

Research means

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

45 CFR 46.102(d)(pre-2018)/45 CFR 46.102(l)(1/19/2017)

Quality Improvement Projects are Often Determined Not to be Research

Quality **improvement projects** are focused on monitoring a process/policy in place to determine if it reaching a target or measurable goal.

QI projects are aimed at promoting adherence to or implementing a best practice.

**Select why quality Improvement projects not considered research?**

1. A QI project does not contribute to generalizable knowledge.
2. A QI project is not a systematic investigation.
3. A QI project does not involve testing.
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**Select why quality Improvement projects not considered research?**

1. A QI project does not contribute to generalizable knowledge.
2. A QI project is not a systematic investigation.
3. A QI project does not involve testing.

That's right!

QI projects are internally focused and may not be transferrable knowledge outside the local setting.

This does not satisfy the “contributing to generalizable knowledge” criteria.

Publishing one’s experience in promoting a best practice alone does not necessarily make a QI project research, requiring IRB review.

Not quite.

QI projects are internally focused and may not be transferrable knowledge outside the local setting.

This does not satisfy the “contributing to generalizable knowledge” criteria.

Publishing one’s experience in promoting a best practice alone does not necessarily make a QI project research, requiring IRB review.

A QI project can be a systematic investigation and can involve testing alternative practices.
The Publication Myth

OHRP has refuted the fact that publication alone makes a project research, requiring IRB review.

“Intent to publish is an insufficient criterion for determining whether a quality improvement activity involves research.

The regulatory definition under 45 CFR 46.102(d) is "Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of research; people seek to publish descriptions of nonresearch activities for a variety of reasons, if they believe others may be interested in learning about those activities.

Conversely, a quality improvement project may involve research even if there is no intent to publish the results.


Certain activities have been long been understood to not be research. Recent changes to the Common Rule now clearly spell out activities in the regulation stating they should not to be deemed research.

Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and sue of information, that focus directly on the specific individual about who the information is collected.

Public health surveillance activities, including collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.

Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
Not Human Subject Determinations

We've reviewed research, now let's turn to the human subjects part of the equation to IRB jurisdiction.

![Image of a flask and people]

Research + Human Subjects = IRB Jurisdiction

Defining Human Subject

The definition for a human subject is multi-faceted. Let's take it step by step.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

45 CFR 46.102(d)(pre-2018)/45 CFR 46.102(e)(1) (1/19/2017)
### Defining Human Subject

First, regulations limit IRB review to those projects with living individuals.

1. Human subject **means a living individual** about whom an investigator (whether professional or student) conducting research:
   
   (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens or
   
   (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Projects reviewing records of deceased persons would not involve human subjects. **No IRB review is required.**

45 CFR 46.102(d)(pre-2018)/45 CFR 46.102(e)(1) (1/19/2017)

### Involving Human Subjects

Human subject **means a living individual.**

Select which would situation would not involve human subjects.

1. The study follows subjects to death and reviews the medical record to record long-term outcome.
2. The study reviews records from state’s online database of death records.
3. Pathology provides de-identified specimens from terminally ill patients.
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**That’s right!**

A research study involving deceased persons do not meet the definition of “involving human subjects research.”

But all subjects must be deceased. A study that includes both living and deceased persons would involve living individuals.

Options 1 and 3 cannot be confirmed that living individuals are not part of the subject population.

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**Not quite.**

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But all subjects must be deceased. A study that includes both living and deceased persons would involve living individuals. Options 1 and 3 cannot be confirmed that living individuals are not part of the subject population.
Defining Human Subject

Next, the definition discusses the level of involvement the research must have with the subject.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

Let’s Apply

Read the description below.

Click thumbs up if activity is an intervention that would involve human subjects.
Click thumbs down if this is not an intervention.

The research adds aromatherapy for students during study sessions to measure its impact on the ability to focus.

Is this an intervention?
Let’s Apply
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Click thumbs up if activity is an intervention that
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The research adds aromatherapy for students
during study sessions to measure its impact
on the ability to focus.

Is this an intervention?

That’s right!
Intervention includes **manipulations of the subject or the subject's environment** that are performed for research purposes.
This would be an intervention.

Not quite.
Intervention includes **manipulations of the subject or the subject's environment** that are performed for research purposes.
Even though this study does not involve a medical procedure, the study would involve an intervention.

Is this an intervention?
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Interaction includes communication or interpersonal contact.

Let’s Apply

Read the description below.

Click thumbs up if activity is an interaction that would involve human subjects. Click thumbs down if this is not an interaction.

The researcher approaches care givers of current patients undergoing treatment for breast cancer and asks the care givers to fill out surveys related to their experience as care givers.

Survey responses are anonymous.

Is this an interaction?
Let’s Apply

Read the description below.

Click thumbs up if activity is an interaction that would involve human subjects.
Click thumbs down if this is not an interaction.

That’s right!

**Interaction** includes communication or interpersonal contact.

Survey procedures involve interaction with the subjects, even if the interaction is short.

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Survey responses are anonymous.

Is this an interaction?

---

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Read the description below.
Click thumbs up if activity is an interaction that would involve human subjects.
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Subjects logins from their home computer and creates an avatar to represent them.

The subject participates in a focus group with researchers and other subjects in an online forum using the avatar. Researchers will not know which subject is represented by which avatar.

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Interaction includes communication or interpersonal contact.

Even though the interaction is not face-to-face, this still involves researcher-to-subject interaction.
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**Is this an interaction?**

Nope.

**Interaction** includes communication or interpersonal contact.

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Defining Human Subject

Regulations go on to define when human subjects are involved even when there is no direct intervention or interaction with the subjects.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

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(ii) Obtains, uses, studies, analyzes, or generates identifiable **private** information or identifiable biospecimens.

3

**Private** information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public.

45 CFR 46.102(d)(pre-2018)/45 CFR 46.102(e)(1) (1/19/2017)
### Defining Human Subject

Another key concept is understanding when information or biospecimens are identifiable.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens or

(ii) Obtains, uses, studies, analyzes, or generates **identifiable** private information or **identifiable** biospecimens.

**Identifiable** means private information or biospecimens for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

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### De-identification

De-identification has been used as a key protective feature in privacy regulations and the Common Rule as a means of protecting subjects.

But scientific, legal, and computer science literature has called into question de-identification as a method providing sufficient protection.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Title</th>
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</table>
"Many commentators expressed the opinion that the existing regulatory framework is adequate.... Commenters noted that, **although it is theoretically plausible to identify a person** based on their biospecimen, the **likelihood remains remote enough to argue against the presumption that the sources of all biospecimens are identifiably** and cited a study showing the risk of re-identification from a system intrusion of databases was only 0.22 percent.”

82 FR 7149, 7166 (1/19/2017)

Many commenters proposed or endorsed alternatives ...[including] developing penalties and sanctions for re-identification of biospecimens and information

82 FR 7149, 7167 (1/19/2017)

Research involving re-identification should undergo IRB oversight.

Commenter suggested that there should also be a prohibition ... against the release or publication of information that would lead to re-identification.

82 FR 7149, 7192 (1/19/2017)

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**TIP**

Be specific about data collection, storage and retention.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| **1** | How is data being collected?  
What is viewed from the source? |
| **2** | What will be extracted and stored in the research record?  
Any identifiers? If yes, can they be minimized? |
| **3** | Where will the data be stored?  
How is it protected while stored?  
- Password protected  
- Encrypted  
- Restrict Access  
How long will it be stored? Minimum 3 years.  
How will you destroy when the time comes? |
Knowledge Check
Which scenario most likely to be viewed as not involving human subjects?

A study is looking at biking to work programs and healthy lifestyles.
Subjects are asked to wear GPS tracking devices. Investigators receive GPS data showing where subjects biked on the map but do not know which map is for which subject.

There is a de-identified copy of research records from previous studies. Identifiers have been removed and dates scrambled according to a de-identification methodology.
Researchers can perform retrospective chart reviews using this tool.

The study is developing an app where parents can take a picture of their child’s rash and send to their doctor. The doctor can give information back to the parent on what to do next.
Instructions in the app tell parents that pictures taken should not include any identifying features of the child.

Next >

Knowledge Check
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Nice.
The clearest of the three scenarios is the de-identified record.
But these questions can be tricky, especially when you need to have a good understanding of what other data may be collected by the technology applications and tools.
IRBs may want to include an IT or data security expert in its membership to help assess these types of scenarios.
Knowledge Check
Which scenario most likely to be viewed as not involving human subjects?

Review
We’ve reviewed a lot of concepts.

Course Objectives:

- Understanding the levels of IRB review
- Defining Research
  - Systematic Investigations
  - Contributing to Generalizable Knowledge
- Defining Human Subjects
  - Research on Living Individuals
  - Defining Interventions or Interactions with Human Subjects
  - Defining Individually Identifiable Private Information/Biospecimens
Exempt

Let’s get an overview of exempt determinations.

Course Objectives:

• Understanding what Exempt Means
• Learning the limits to applying exempt status
• Review the exempt categories pre and post-2018 requirements
• Introducing Limited IRB Review

If you recall, the federal regulations gives us various levels of IRB review.

In this session, we will focus on the exempt and limited IRB review level.
Not Human Subject Determinations

Previously, we described Not Human Subjects Determinations as being outside the definition of the Common Rule.

- Projects not involving research
- Projects not involving human subjects

The Common Rule 45 CFR 46

“All research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or Agency.”

45 CFR 46.101(a)

Exempt Determinations

Unlike projects that qualify for not human subjects determinations, projects that qualify as exempt fits the regulatory definition of research involving human subjects.
Exempt Determinations

Regulators felt that research involving human subjects that met exempt criteria posed such minimal risk to subjects that the Common Rule would not be applied to those studies.

The Common Rule
45 CFR 46

“All research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or Agency.”

45 CFR 46.101(a)

Exempt Determinations

Not Human Subjects Determination

Even though an exempt project meets the definition, an exempt study is an exception to applying the Common Rule to all research involving human subjects.

Limits to Exempt Determinations

It is important to understand the limits to applying exemptions.

All exempt categories are not applicable to children.

Exemptions at (b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research involving children, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.
Limits to Exempt Determinations

It is important to understand the limits to applying exemptions.

Cannot exempt research involving prisoners

Pre-2018
Does not involve prisoners, was not collected from individuals while they were imprisoned or include individuals known to currently be imprisoned.

Post-2018
The research involves prisoners, except for research involving broader subject population incidentally including prisoners.

Tips

QUALITY of LIFE
RESEARCH FOR THE REAL WORLD

Protocol 2003-A: Identification of Physiological Symptoms During the Psychological Stress of Waiting for an Approval Letter.

0-8 Hours
Waiting for the IRB's fax...
Symptoms:
Nervousness & indigestion...

1-3 Days
Should I Call Them?
Increased blood pressure & heart rate; trembling...

3-7 Days
Where's That G###N Letter?
Metamorphosis, adrenaline surge, uncontrollable rage...

After-effects
That's right...
Total nervous breakdown.
Big Picture Changes to Exempt

Why the Change to Exempt Categories?

The proposed revisions to the exemption categories have been modified to better align with their risk profile.

Goal: To allow for more low-risk research studies to be eligible for exemption.

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### Summary of Changes in Exemptions from Pre-2018 to Revised Common Rule

<table>
<thead>
<tr>
<th>Pre-2018 Rule (Current)</th>
<th>Revised Common Rule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exemption 1</td>
<td>Restrictions added</td>
</tr>
<tr>
<td>Exemption 2</td>
<td>Expanded</td>
</tr>
<tr>
<td>Exemption 3</td>
<td>Removed and replaced with a new exemption 3</td>
</tr>
<tr>
<td>Exemption 4</td>
<td>Expanded, and added new</td>
</tr>
<tr>
<td>Exemption 5</td>
<td>Expanded with changes</td>
</tr>
<tr>
<td>Exemption 6</td>
<td>No change</td>
</tr>
<tr>
<td></td>
<td>✓ New exemption 7</td>
</tr>
<tr>
<td></td>
<td>✓ New exemption 8</td>
</tr>
<tr>
<td></td>
<td><em>(Also new - limited IRB review)</em></td>
</tr>
</tbody>
</table>
To be considered exempt, the research project must fit within one of the exempt categories spelled out in the regulation.

45 CFR 46.101(b)(1) Pre-2018

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
(i) research on regular and special education instructional strategies, or
(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
Exempt Category 1: Educational Practices

This exemption applies to commonly accepted educational settings.

Commonly accepted educational settings includes:

- K-12 schools
- College classrooms
- After school programs
- Alternative educational programs
- Sites where educational activities regularly occur there.

Exempt Category 1: Educational Practices

This exemption also requires normal educational practices.

Normal educational practices include established teaching methods, curriculum content, commonly accepted classroom management techniques that are planned and implemented by the classroom teacher, and, on a case-by-case basis, projects conducted with teachers for professional development purposes.

Normal educational practices are activities that would occur regardless of whether the research is conducted.
To be considered exempt, the research project must fit within one of the exempt categories spelled out in the regulation.

45 CFR 46.101(b)(1) Pre-2018

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
(i) research on regular and special education instructional strategies, or
(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

45 CFR 46.101(b)(1) Post-2018

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction.

45 CFR 46.101(b)(2) Pre-2018

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
(ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

45 CFR 46.101(b)(2) Post-2018

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
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To be considered exempt, the research project must fit within one of the exempt categories spelled out in the regulation.

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Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:
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2. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

### 45 CFR 46.101(b)(2) Post-2018
Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
2. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.

### Expanded & Level of Review

<table>
<thead>
<tr>
<th>Category 1</th>
<th>Category 2</th>
<th>Category 3</th>
<th>Category 4</th>
<th>Category 5</th>
<th>Category 6</th>
</tr>
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To be considered exempt, the research project must fit within one of the exempt categories spelled out in the regulation.

### 45 CFR 46.101(b)(3) Pre-2018
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
1. The human subjects are elected or appointed public officials or candidates for public office; or
2. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

### Expanded & Level of Review

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3/5/2018
To be considered exempt, the research project must fit within one of the exempt categories spelled out in the regulation.

45 CFR 46.101(b)(3) Pre-2018

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter.

45 CFR 46.101(b)(3) Post-2018

No equivalent

To be considered exempt, the research project must fit within one of the exempt categories spelled out in the regulation.

45 CFR 46.101(b)(4) Pre-2018

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
**Exempt Category 4: Research involving existing records.**

Warning letters clearly show that the exemption can only be applied if the records are in existence at the time of IRB submission.

“HHS regulations at 45 CFR 46.101(b)(4) exempt research that only involves the collection or study of existing data, documents, records, pathologic specimens, or diagnostic specimens. *in this case the records did not exist at the time the research was proposed.*”


**Exempt (b)(4) does not apply to prospective collection of such materials.**


To be considered exempt, the research project must fit within one of the exempt categories spelled out in the regulation.

45 CFR 46.101(b)(4) Pre-2018

Research involving the collection or study of existing data, documents, records, pathologic specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

45 CFR 46.101(b)(4) Post-2018

A whole new exemption for performing secondary research.
Post 2018
Secondary Research 45 CFR 46.104(d)

Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
(i) The identifiable private information or identifiable biospecimens are publicly available;
(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
(iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or
(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

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**Applying the Common Rule**

- **Is it research?**
  - Yes → **Does it involve human subjects?**
    - Yes → **Is it exempt?**
      - No → Proceed to IRB review
      - Yes → Proceed to limited IRB review
    - No → Activities deemed not to be research
  - No → STOP

- **Does it involve exemptions 2(iii), 3(i)(C), 7, or 8?**
  - No → Proceed to IRB review
  - Yes → Proceed to limited IRB review

STOP
Other Tips: Know your Study and Levels of Review Options

Other Tips: Make sure the application is complete
Other Tips: Write it Down

Actually, just the treadmill was in my protocol... the rest of it was the IRB's idea!

Other Tips: Think through all risks

See? He chose the safe, cuddly puppy... again. I don't understand why the IRB thought that this is a "high risk" study design!
Other Tips: Don’t Forget Risk of Confidentiality

Other Tips: Ask For Help

Office of Research Compliance

Rebecca Ballard, Director of Research Compliance and Export Control Officer

rebecca.ballard@tamucc.edu

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