Defining Human Participant Research:

How to determine if your study requires IRB oversight

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Human Participant Research

Research involving human participants are subject to many Federal regulations.

The two main regulatory agencies are:

1. DHHS: Office of Human Research Protections (OHRP)
2. FDA

What do the Regulations Say:

HHS: Office of Human Research Protections (OHRP)

Research is defined as:

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

Human Subject is defined as:

A living individual about whom an investigator (whether professional or student) conducting research obtains

1. Data through intervention or interaction with the individual or
2. Identifiable private information

Upcoming Change to This Definition

- The HHS regulations overseeing Human Participant Research are undergoing sweeping changes. The changes includes a minor modification to the current definition of research and human particpants:

Change to the Definition of Research

The change adds activities that are deemed not to be research:

- Scholarly and journalistic activities
- Public health surveillance activities
- 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.

Change to the Definition of Human Participant

A living individual about whom an investigator (whether professional or student) conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens.
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

What Do the Regulations Say:

U.S Food & Drug Administration (FDA)

FDA has defined *"clinical investigation"* to be synonymous with *"research".*

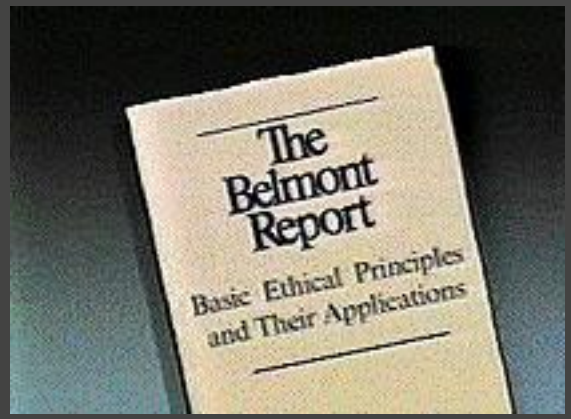
"Clinical investigation" means any experiment that involves a test article **and** one or more human subjects, **and** that either must meet the requirements for prior submission to the FDA…or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

"Human subject"

An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

Origin of the Common Rule Definition

- The National Commission (which published The Belmont Report) was given the task of identifying the basic ethical principles for conducting human subject research, while considering "the boundaries between biomedical or behavioral research involving human subjects and the accepted routine practice of medicine.



The Belmont Report:

Discerning Human Subject Research from the Routine Practice of Medicine

- **"For the most part, the term 'practice' refers to interventions that are designed solely to enhance the well being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals."**

"When a clinician departs in a significant way from the standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is 'experimental' in the sense of new, untested or different, does not automatically place it in the category of research"

The report also recommended that a medical practice committee should consider when a major innovation should become a part of a formal research project.

Is it Quality Improvement?

There are regulatory definitions of research, but no regulatory definition of quality improvement.

- Quality improvement projects are often **systematic investigations**; following a pre-determined plan.
- Also designed to contribute to knowledge that can be useful to the organization's process that the QI project targets.

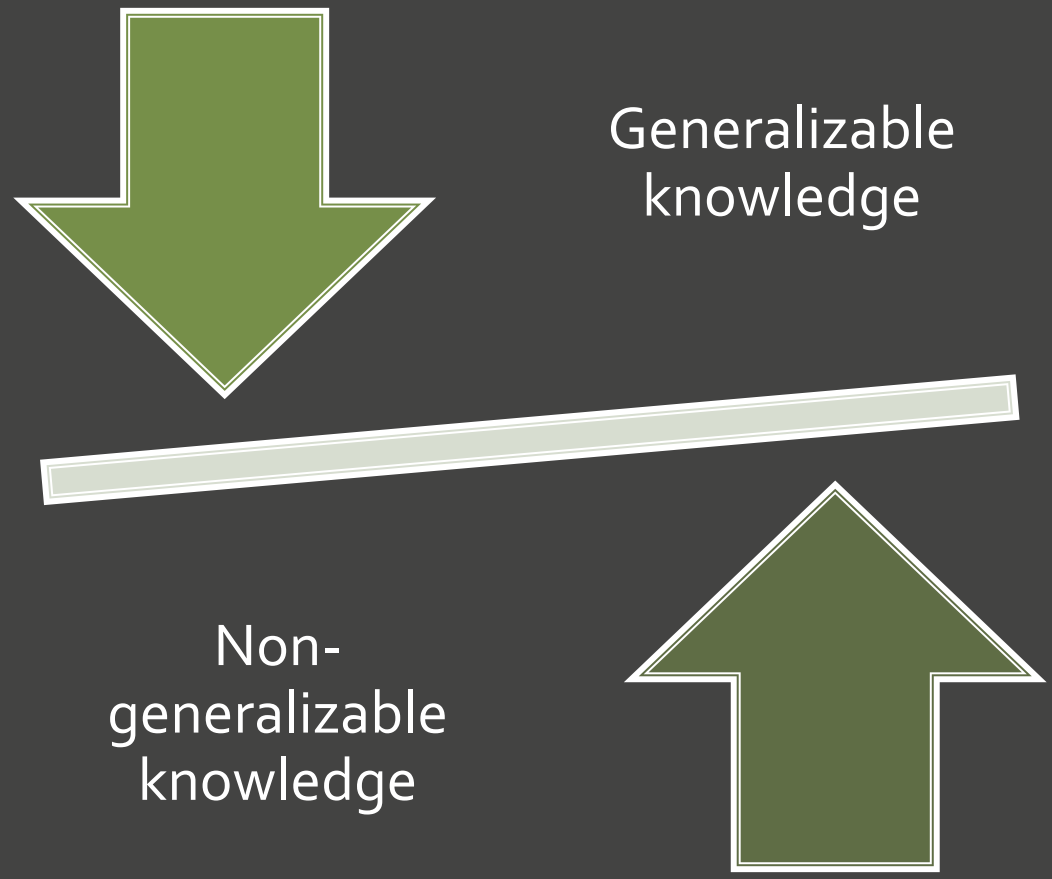
To determine if an activity meets this definition start by looking at the def. of research:

Ask the following questions:

1. Is the planned activity to be conducted in a systematic manner?
   i. Is there a written plan or protocol?
   ii. Is data being collected?
2. What is the intent of the activity?
   i. Would the activity be conducted if there was no possibility of professional recognition such as publishing a paper or earning tenure attached?
3. Will the activity contribute to generalizable knowledge?
   i. Will the information be disseminated outside of the institution?
   ii. Is the goal simply to improve productivity, or will the information be shared with the world?

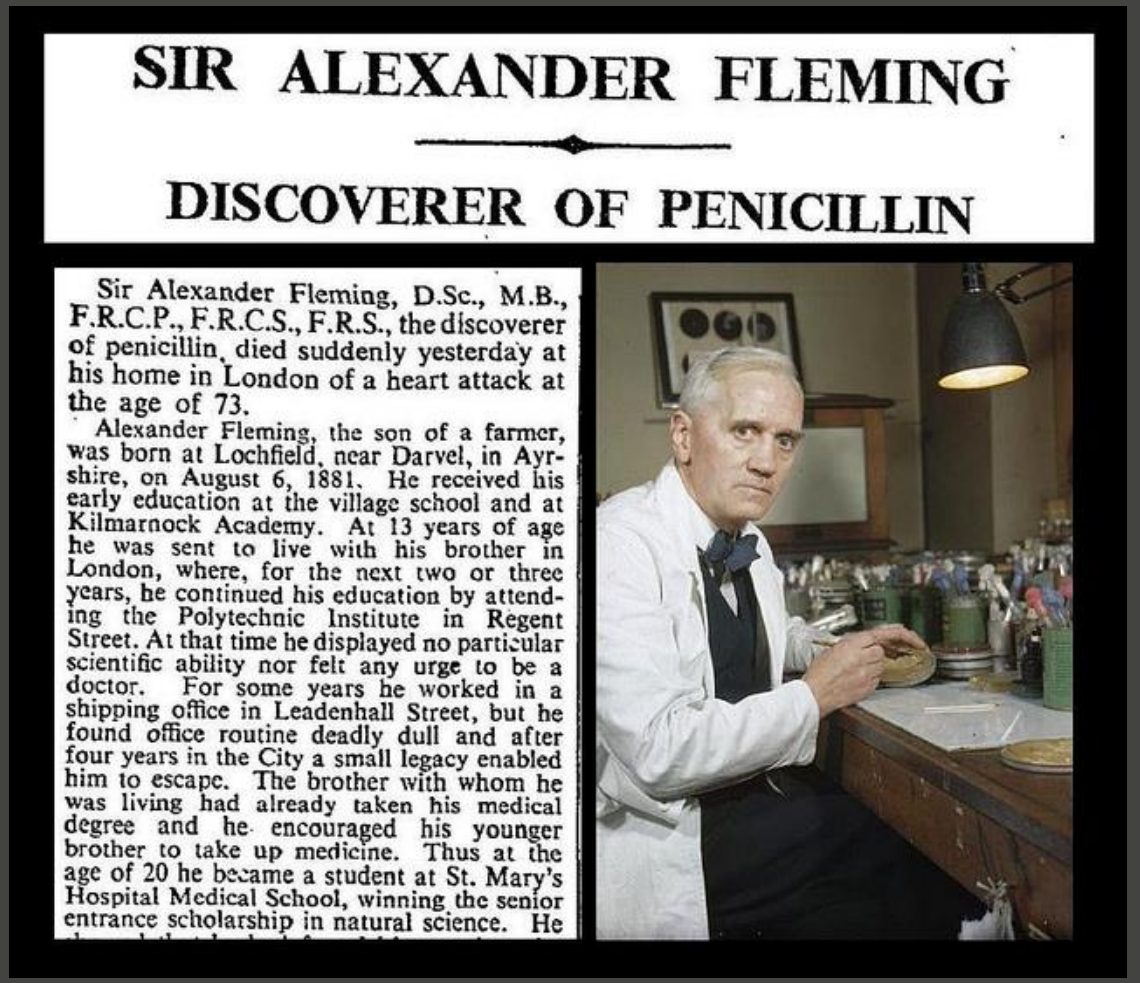
Generalizable versus non-generalizable knowledge

- When we contribute to generalizable knowledge we are making knowledge that is universally applicable =
  - Research
- Non-Generalizable Knowledge is locally applicable i.e. department, or organization that the project is targeting=
  - quality improvement



What about those activities that are not research which add to generalizable knowledge?

Fleming and Newton were not conducting research when they discovered penicillin and gravity, however they were able to identify unintended results of their accidents, and create generalizable knowledge without intending to so. Their actions would not meet today's HHS definition of research



SIR ALEXANDER FLEMING

DISCOVERER OF PENICILLIN

Sir Alexander Fleming, D.Sc., M.B., F.R.C.P., F.R.C.S., F.R.S., the discoverer of penicillin, died suddenly yesterday at his home in London of a heart attack at the age of 73.

Alexander Fleming, the son of a farmer, was born at Lochfield, near Darvel, in Ayrshire, on August 6, 1881. He received his early education at the village school and at Kilmarnock Academy. At 13 years of age he was sent to live with his brother in London, where, for the next two or three years, he continued his education by attending the Polytechnic Institute in Regent Street. At that time he displayed no particular scientific ability nor felt any urge to be a doctor. For some years he worked in a shipping office in Leadenhall Street, but he found office routine deadly dull and after four years in the City a small legacy enabled him to escape. The brother with whom he was living had already taken his medical degree and he encouraged his younger brother to take up medicine. Thus at the age of 20 he became a student at St. Mary's Hospital Medical School, winning the senior entrance scholarship in natural science. He

Systematic Investigations to Follow

- Although Newton and Fleming's discoveries were not intentional and systematic investigations, they did pave the way for future systematic investigations that were intended to contribute to generalizable knowledge to change our understanding of the universe, and how we treat infection.
  - Newton's research following his initial discovery did not involve human participants
  - Fleming's research following his initial discovery was tested on humans, and was therefore human participant research, which today would be subject to OHRP and FDA regulations.

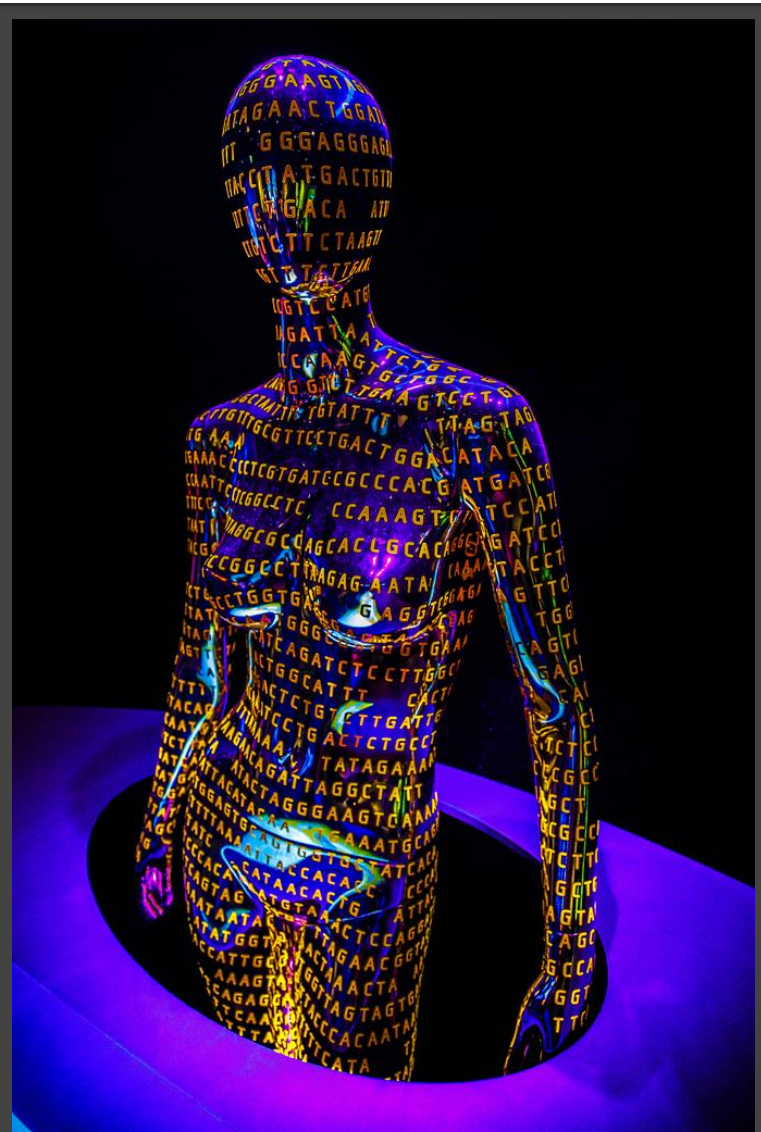
Research Conducted With Intended Outcomes Adding to Generalizable Knowledge

Human Genome Sequence

- Plans to map and sequence the human genome were made in 1988 by the US National Academy of Sciences. It was developed through a series of five year plans.

1. Prospectively and
2. Intentionally

Designed to contribute to generalizable knowledge



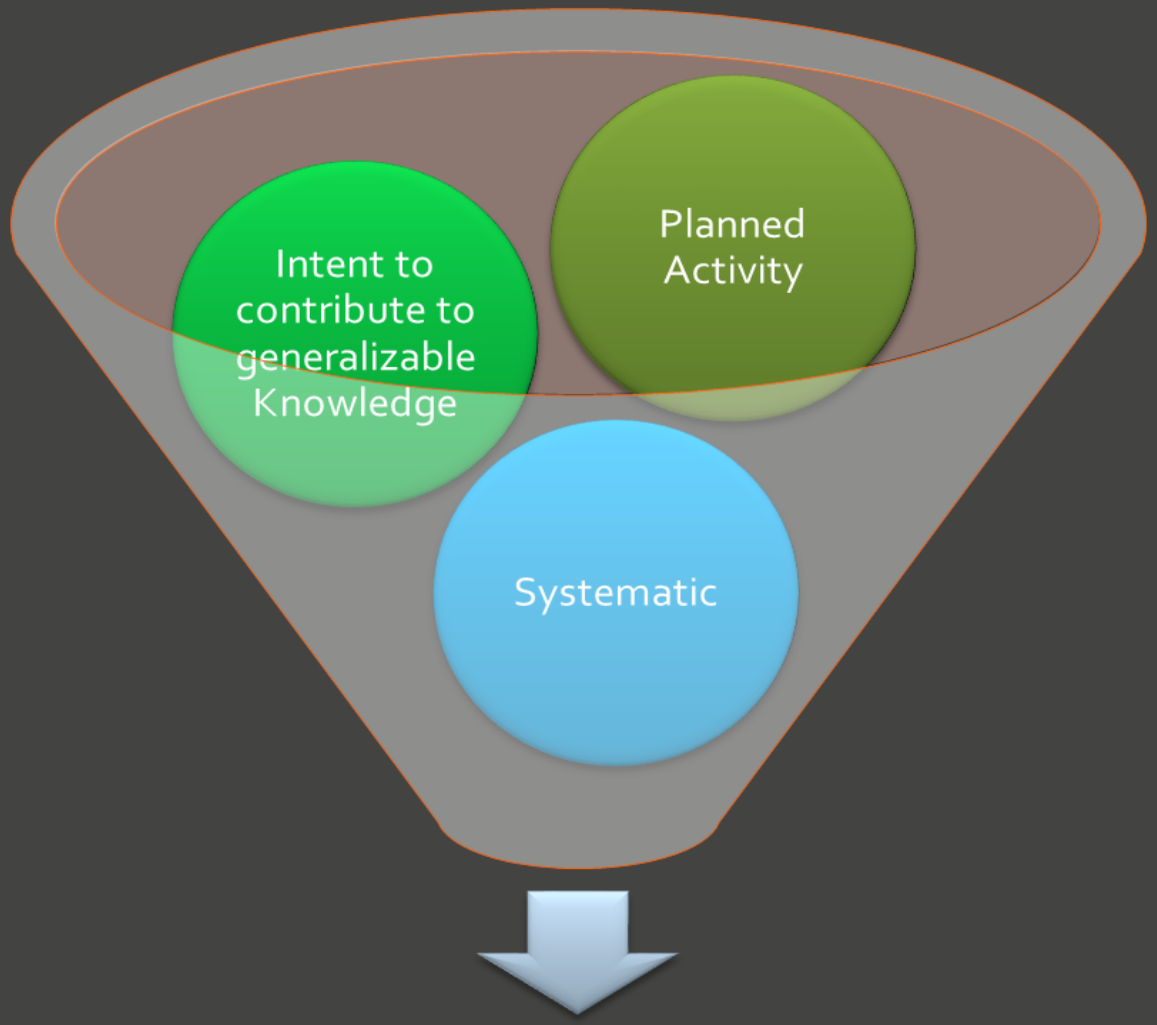
It's all about the *DESIGN* and *INTENT*

- The difference between Fleming's discovery of Penicillin and the Discovery of the complete Human Genome Sequence is all in the intent and design.

"When I woke up just after dawn on September 28, 1928, I certainly didn't plan to revolutionize all medicine by discovering the world's first antibiotic, or bacteria killer. But I guess that was exactly what I did." –Sir Alexander Fleming

(Markel, 2013)

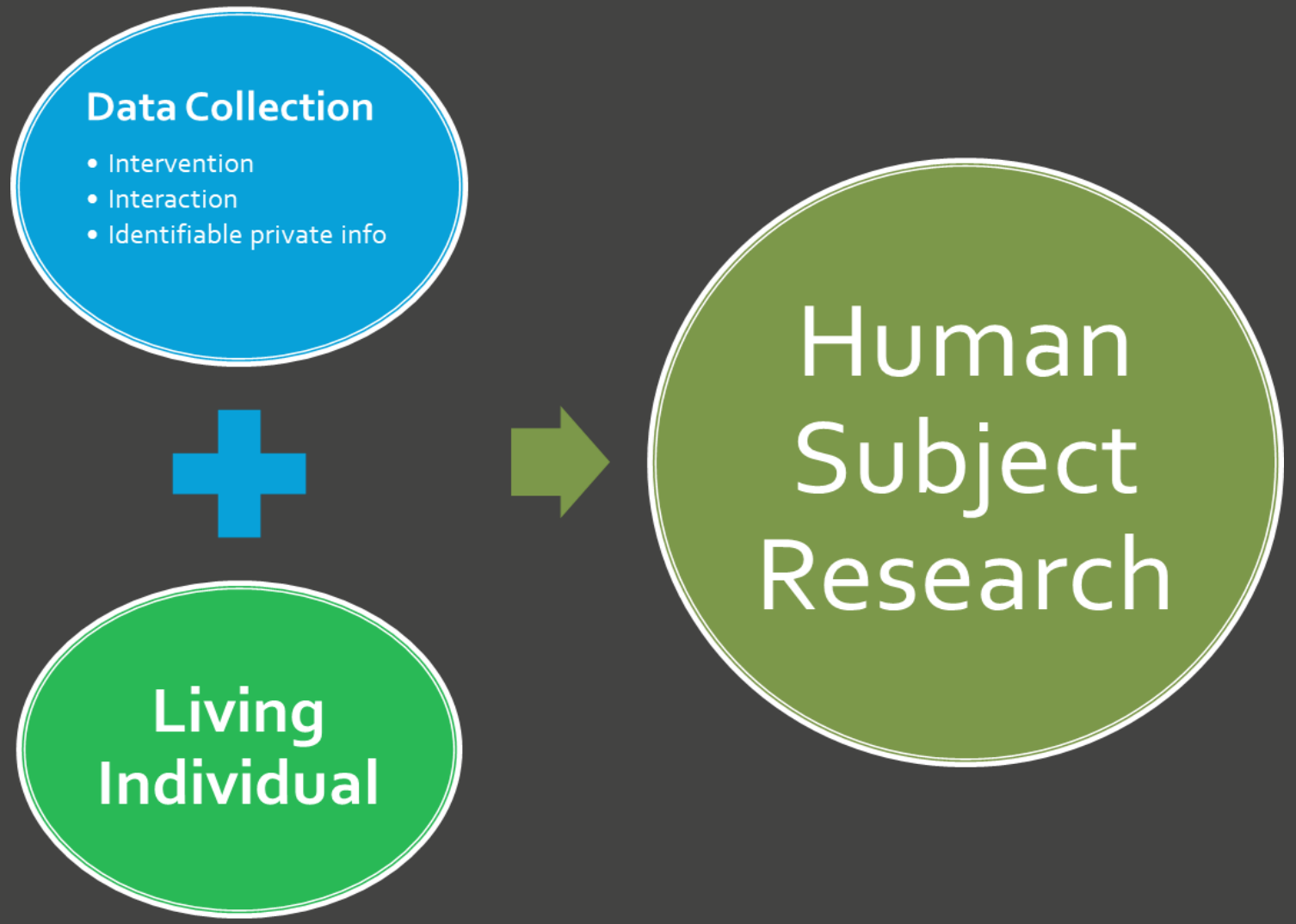
- While the design of a QI project may be systematic, the ***intent*** is to contribute to non-generalizable knowledge; To benefit knowledge locally.


Intent to contribute to generalizable Knowledge
Planned Activity
Systematic

Research

Then go on to the Definition of Human Participants:

- A human participant is "a living individual about whom an investigator (whether professional or student) conducting research obtains data through:
1. **intervention or interaction** with the individual, or
2. **identifiable private information**"



What if I want to Publish the results?

- The intent to publish alone does not mean that your project requires IRB review.

Observations from projects that do not aim to contribute to generalizable knowledge can be highly relevant to promoting learning in their respective fields.

- Healthcare especially is becoming more reliant on "best practices" where rather than re-inventing the wheel to meet the mandatory quality outcome measures, they learn from what other similar institutions are doing.

Is it Research with Human Participants?

Case Study?

Case studies involving up to three similar unique clinical presentations in which the only activity involved is a retrospective record review is not considered Human Research, and therefore does not require IRB review.

HIPAA considerations to be made with covered entity.

Testing outcomes of new validated pain assessment tool?

Program evaluation. Not designed to contribute to generalizable knowledge, not a systematic investigation. Not Human Research, and therefore does not require IRB review

Is it Research with human participants?

Retrospective record review looking at sepsis outcomes to find a common thread among patients with poor outcomes, such as high BMI, or hypertension

This is a systematic investigation designed to contribute to generalizable knowledge using **individually identifiable** and **private information**. This is research and does require IRB review

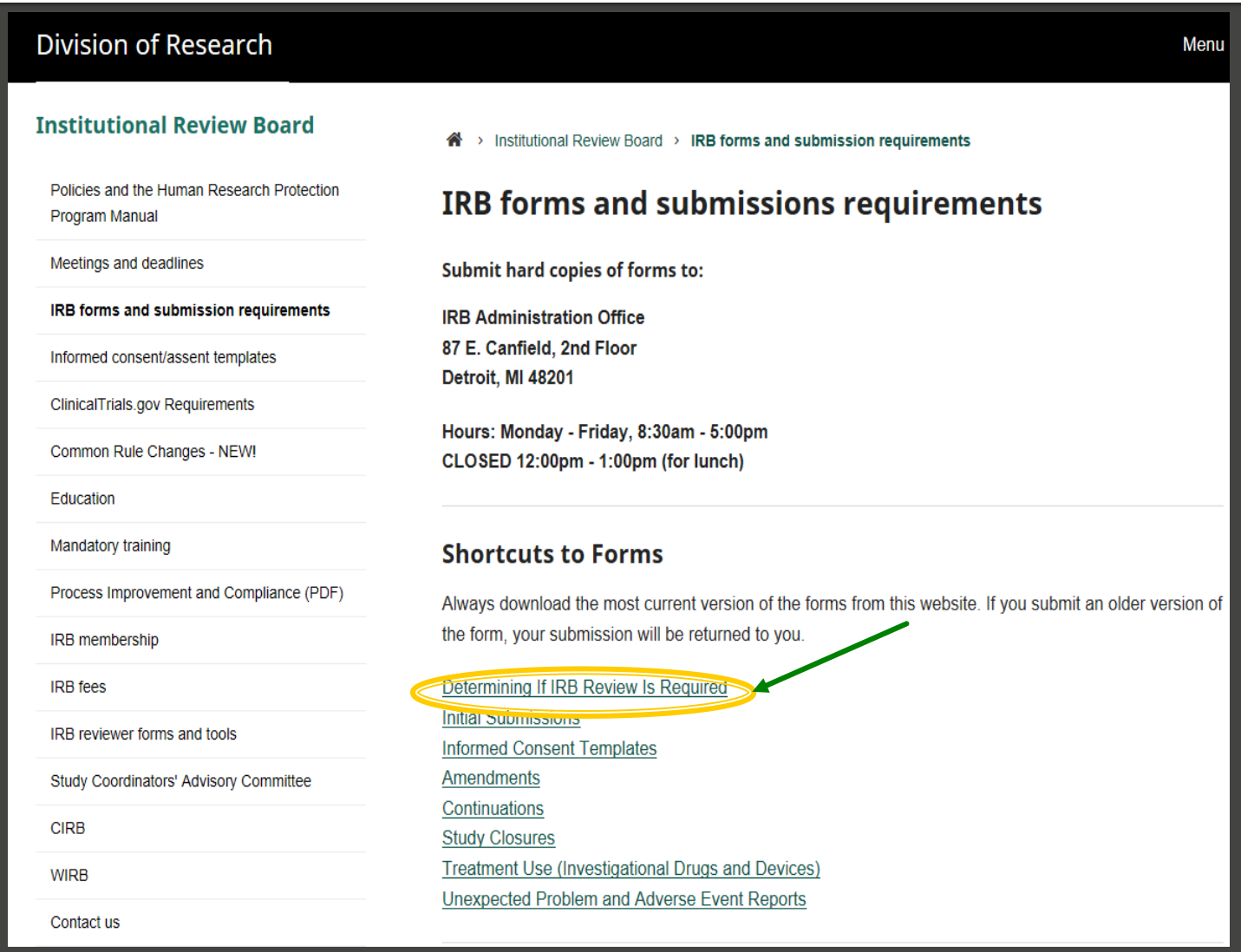
Test wearable fitness monitors to see if heart rate monitors is helpful in providing a reliable clinical history needed to diagnose AFIB

This is a systematic investigation designed to contribute to generalizable knowledge using intervention, interaction with the individual.
Use of **test article**: Subject to FDA Research Regulations

Our HPR Determination Tool:

For assistance with the Human Participant Research (HPR) determination:

- Complete the Human Participant Research Determination Tool available on our website, and turn it in to the irbquestions@wayne.edu e-mail address.
- An IRB member will review your completed HPR tool, and send you an official IRB determination that you can keep on file in case a journal asks for an official IRB determination letter.



HPR Tool:

Determining If IRB Review Is Required

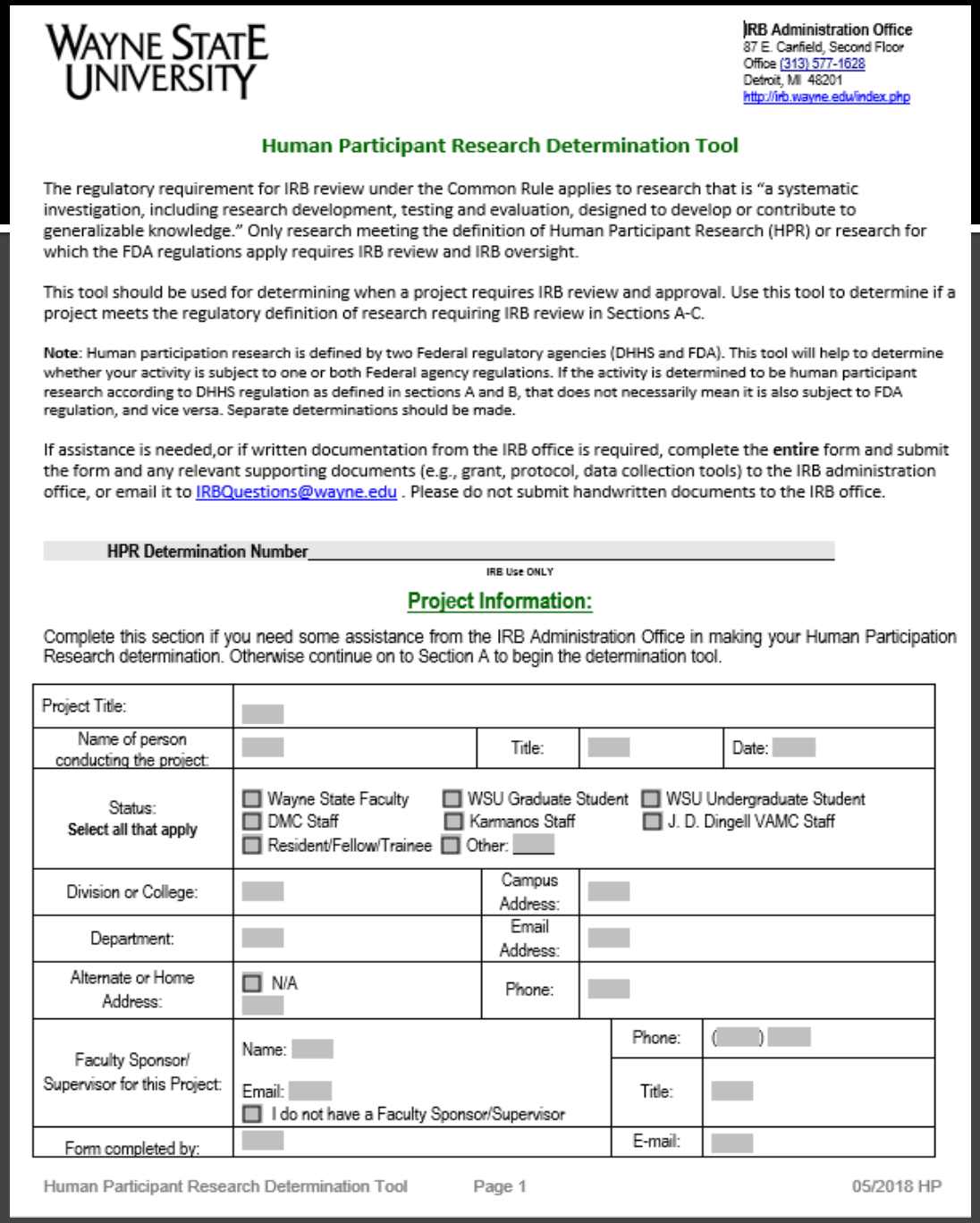
If you are not sure that a project requires IRB review, use the following tool to describe the project and email to IRBQuestions@wayne.edu for assistance. Also, send any written proposal or data collections tools, if available.

Human Participant Research (HPR) Determination Tool (4/2018)

For information regarding activities that **are not** considered Human Participant Research please view the HPR Guidance Tool.

Follow instructions on the tool. If it is clear that your study does not meet the definition of Human Participant Research, then you can keep the completed tool with your study records.

If you are unsure after completing the tool, send it to irbquestions@wayne.edu for an official IRB determination.



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Human Participant Research Determination Tool

The regulatory requirement for IRB review under the Common Rule applies to research that is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Only research meeting the definition of Human Participant Research (HPR) or research for which the FDA regulations apply requires IRB review and IRB oversight.

This tool should be used for determining when a project requires IRB review and approval. Use this tool to determine if a project meets the regulatory definition of research requiring IRB review in Sections A-C.

Note: Human participation research is defined by two Federal regulatory agencies (DHHS and FDA). This tool will help to determine whether your activity is subject to one or both Federal agency regulations. If the activity is determined to be human participant research according to DHHS regulation as defined in sections A and B, that does not necessarily mean it is also subject to FDA regulation, and vice versa. Separate determinations should be made.

If assistance is needed,or if written documentation from the IRB office is required, complete the **entire** form and submit the form and any relevant supporting documents (e.g., grant, protocol, data collection tools) to the IRB administration office, or email it to IRBQuestions@wayne.edu . Please do not submit handwritten documents to the IRB office.

HPR Determination Number_____
IRB Use ONLY

Project Information:

Complete this section if you need some assistance from the IRB Administration Office in making your Human Participation Research determination. Otherwise continue on to Section A to begin the determination tool.

Project Title:				
Name of person conducting the project:		Title:		Date:
Status: **Select all that apply**	☐ Wayne State Faculty ☐ WSU Graduate Student ☐ WSU Undergraduate Student ☐ DMC Staff ☐ Karmanos Staff ☐ J. D. Dingell VAMC Staff ☐ Resident/Fellow/Trainee ☐ Other:			
Division or College:		Campus Address:		
Department:		Email Address:		
Alternate or Home Address:	☐ N/A	Phone:		
Faculty Sponsor/ Supervisor for this Project:	Name: Email: ☐ I do not have a Faculty Sponsor/Supervisor		Phone: ( )	
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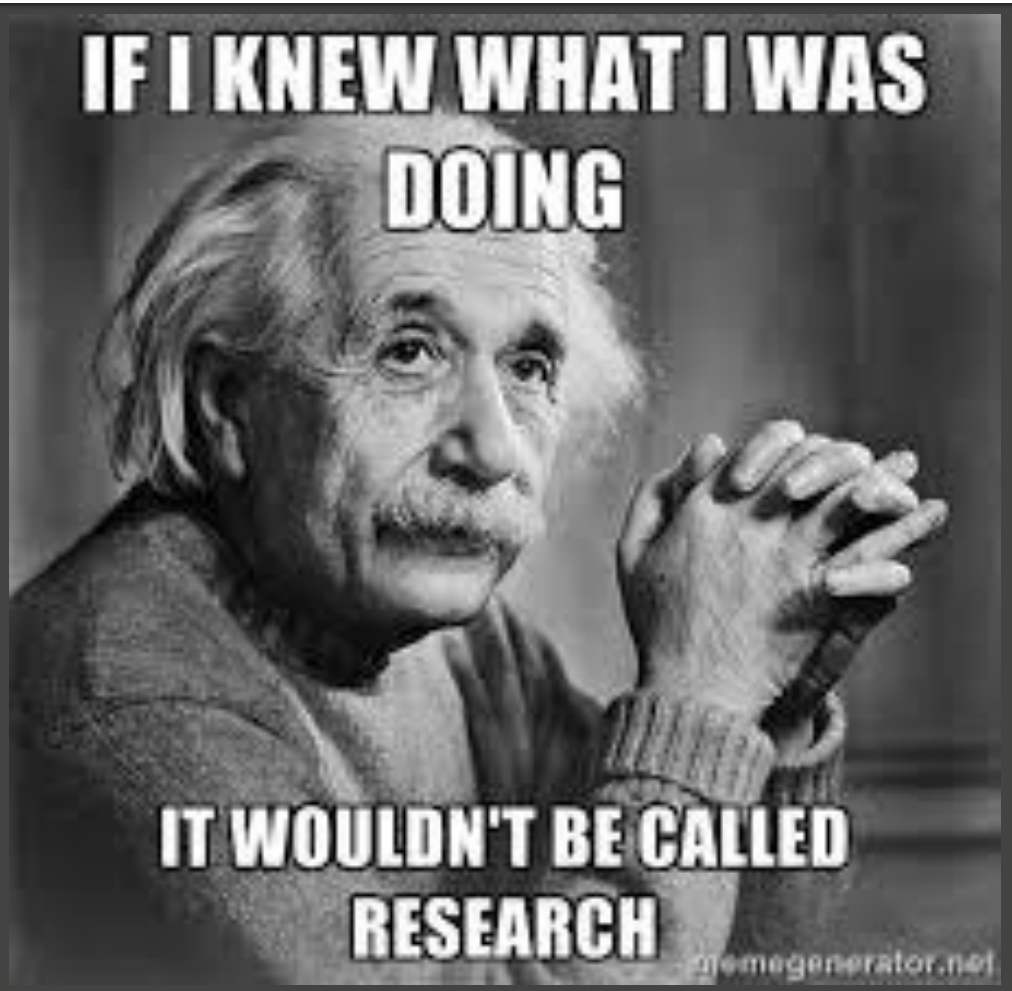
Form completed by:			E-mail:	

Questions??



You can also e-mail your questions to irbquestions@wayne.edu

References

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