Module 7
Protections for Research Participants

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Overview of Module 7: Protections for Research Participants

This section will include:

- Brief History of Research Protections
- Ethical Research Principles
- Role of Institutional Review Boards (IRBs)
- Information on Privacy and Confidentiality

Estimated Time Commitment: *20 to 30 minutes*

Feel free to take breaks along the way – you can do this at your own pace!

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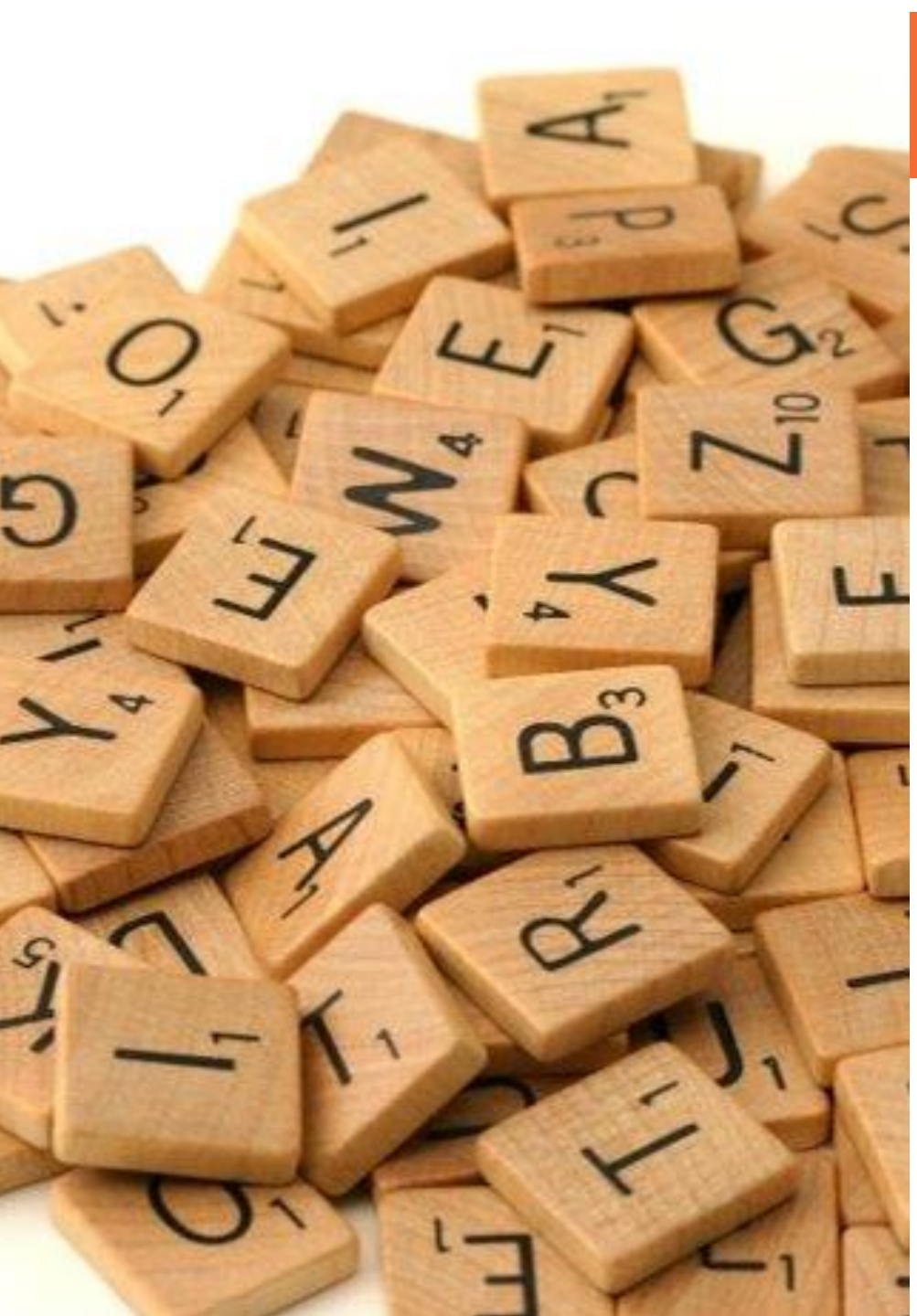

Key Terms Used in this Module

- You will hear a lot of **new terms** during this module that you might not know

- We do **not expect you to know what these terms mean right away or memorize them** – just to familiarize yourself with the words

- Here is a **link to the key terms** used in this module that you can reference as you go through – click here

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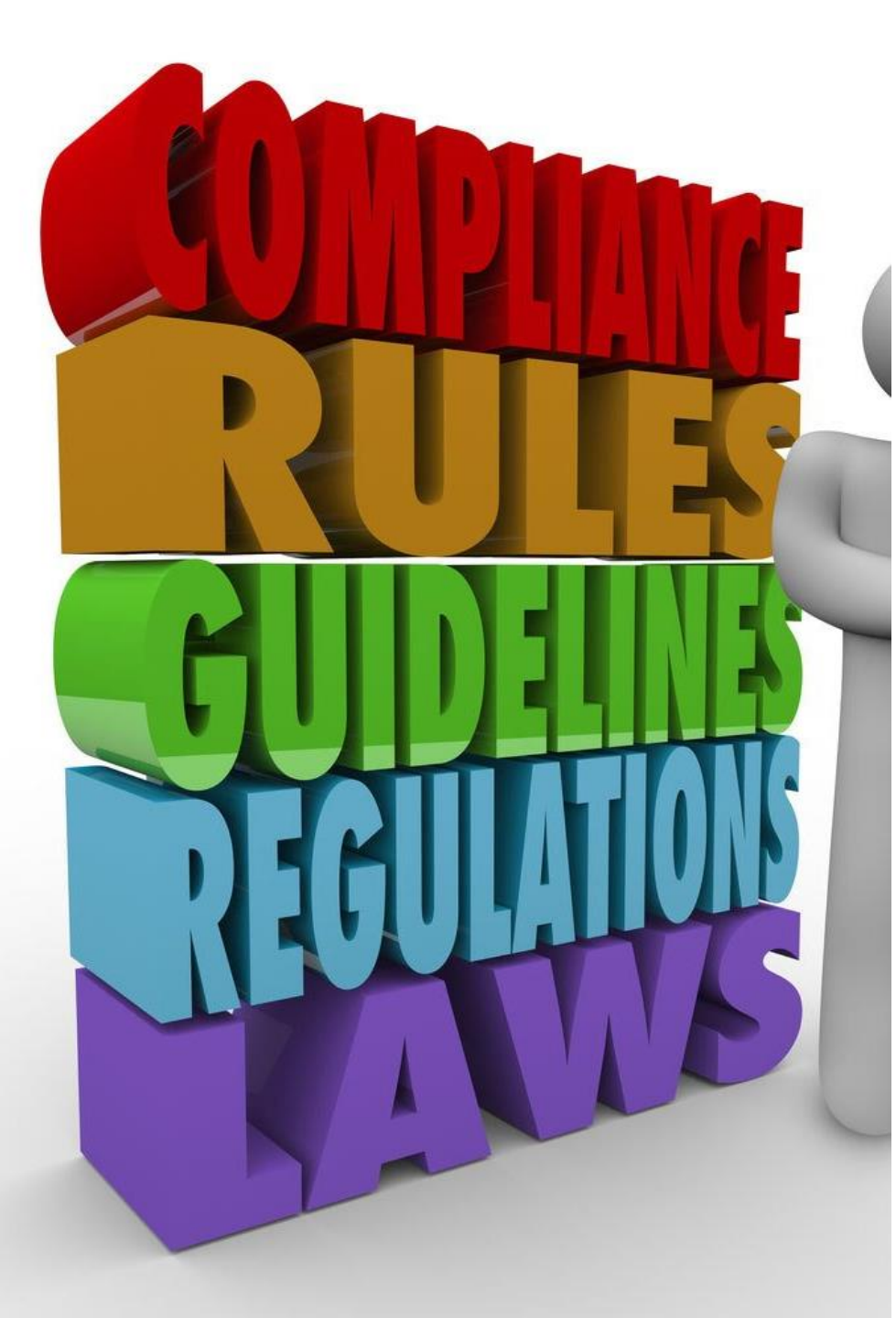

Overview of Research Protections History

- Strong protections and federal regulations for people participating in research are in place today.
- These protections developed over time.
- They were created to make sure past abuses do not happen again.
- The next few slides go through the history and protections that have been put in place

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Overview of Research Protections History

Nazi Experimentation (early 1940s)	Doctors in Nazi concentration camps forced prisoners to take part in dangerous experiments. Examples of unethical experiments were forcing prisoners to be sterilized and be infected with diseases.
Nuremberg "Doctors Trial" (1946-1947)	A U.S. military court in Nuremberg, Germany charged 23 Nazi doctors and officials with war crimes, including unethical medical experiments on concentration camp prisoners. Sixteen Nazis were executed or sent to prison.
Nuremberg Code (1947)	After the Nuremberg Trials, the judges listed important principles of acceptable medical experiments. These principles became known as the Nuremberg Code. Important principles are: • Research participation must be voluntary. • Research participation cannot put people at high risk for disability or death. • Participants can quit a study at any time.

Kaiser B, Thomas G. "Patient Advisor Toolkit 1: Orientation for Patient Advisory Committees (PAT-1)." Wisconsin Network for Research Support, University of Wisconsin – School of Nursing, and Health Innovation Program. 2018; Available at https://www.hipxchange.org/PAT-1

Overview of Research Protections History continued…

Willowbrook Study (1963-1966)	Willowbrook was a home for children with mental disabilities in New York City. Researchers deliberately injected children with hepatitis to learn about the disease. Risk not fully explained to parents.
Declaration of Helsinki (1964)	The World Medical Association, meeting in Helsinki, Finland, approved principles for ethical research. Important principles are: • Research plans should be reviewed by an independent committee, such as an institutional review board (IRB). • Research participants must give their "informed consent" to be in a study. • Risks of being in a study should not outweigh benefits.
Tuskegee Syphilis Study (Ended 1972)	Starting in 1932, doctors from the U.S. Public Health Service studied African-American men in Alabama with syphilis. Medications to treat syphilis were available, but doctors wanted to study long- term effects of the disease. Doctors did not give men the medications they needed, and dozens of men died of syphilis or its complications. The study did not end until 1972 when details about it became public.

Kaiser B, Thomas G. "Patient Advisor Toolkit 1: Orientation for Patient Advisory Committees (PAT-1)." Wisconsin Network for Research Support, University of Wisconsin School of Nursing, and Health Innovation Program. 2018; Available at https://www.hipxchange.org/PAT-1

Overview of Research Protections History continued…

National Research Act (1974)	The act did two major things to stop unethical research on people: • It required the U.S. government to create rules to protect people in research studies. • It created a national committee to develop guidelines for ethical research. These guidelines are in the Belmont Report.
Belmont Report (1979)	The report listed three basic principles for the ethical treatment of people who participate in research: • **Respect** • **Beneficence - "Doing good" not harm** • **Justice** Examples of the three principles are: *Respect*: People must have a choice about what happens to them. *Beneficence - "Doing good"*: The risks of a study cannot outweigh the possible benefits. *Justice*: The benefits and risks of research should be fairly shared across society.

Kaiser B, Thomas G. "Patient Advisor Toolkit 1: Orientation for Patient Advisory Committees (PAT-1)." Wisconsin Network for Research Support, University of Wisconsin – School of Nursing, and Health Innovation Program. 2018; Available at https://www.hipxchange.org/PAT-1

Overview of Research Protections History continued…

- With the National Research Act in 1974 and the Belmont Report in 1979, strong protections based on the 3 principles of Respect, Beneficence (doing good, not harm) and Justice were put into place.

- Federal laws are in place for how research should be done:
  - *Protecting people in studies*
  - *Informing people before they decide to join studies*
  - *Reviewing research before it moves forward and while it is going* on

- The rules were created for everyone doing human subjects research – there are no exceptions

Role of Institutional Review Boards

Institutional review boards (IRBs) – created in 1974 with the National Research Act – are the organizations responsible for reviewing, approving and monitoring research and enforcing the rules:

- All research **must be reviewed and approved by an IRB** before starting
- The goal is to ensure that people joining studies will be **protected from unknown harm or risks**
- **IRBs weigh risks vs. benefits**, look at what protections are in place and if people in the study are informed about all the key pieces of the study before they decide to join

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Role of Institutional Review Boards continued…

- Once a study is approved, any changes in the study must be reviewed by the IRB before they are put into place
- IRBs conduct yearly reviews of all studies
- Any unexpected or serious study issues must be reported to the IRB
- People in the study can call the IRB if they are concerned about something with the study

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Informed Consent Document & Obtaining Informed Consent

As you learned in Module 6 about different types of study documents, the informed consent document:

- Must be approved by the IRB before being used to recruit people into a study
- The **informed consent document:**
  - Describes what will happen in the study
  - What is being asked of people who join the study
  - What the potential risks are
  - Information on privacy and confidentiality
  - What the person's rights are in the study including the right to stop at any time
  - Provides contact information for the study team and the IRB
  - Must be written in clear language that anyone could understand
- It is not a contract, it is a voluntary agreement
- A person can stop participating in the study at any time and does not have to give a reason

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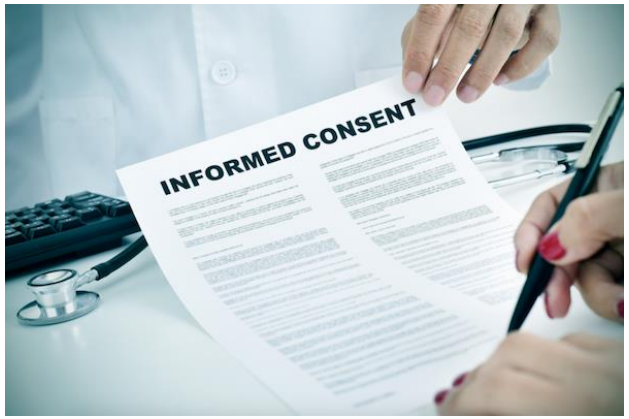
Informed Consent Document & Obtaining Informed Consent continued…

Obtaining informed consent from a person:

- Must be **reviewed** and **explained before** a person can do any **study activities**
- Must be **given freely** – a person can **change their mind at any time**
- Must **not be forced** and ensure the person has enough **time to think** before agreeing to join the study
- **Usually requires a written signature** on the informed consent document
  - In some cases, consent can be obtained verbally if approved by the IRB
  - In special cases can be provided by the person's legal representative



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Privacy and Confidentiality

Privacy and confidentiality for people in a study must be respected at all times. How one's privacy and confidentiality will be protected must be written in the informed consent document and, also in the protocol that the IRB reviews and approves.

Privacy–applies to the person	Confidentiality—applies to the data
• An understanding that **information an individual provides will not be shared with others without their permission**. • Involves the **methods and setting used to collect information** from study participants to ensure the information will remain private and **patients' wishes will be respected.**	• Involves **a person's identifiable information and the security in place** on who can see the information. • Involves the **procedures in place to ensure that only *authorized* individuals see the information**—in other words, only seen by people involved in running the research study or other approved people *(regulatory people such as the Food and Drug Administration or the National Institutes of Health).* • **All information is considered confidential**.

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Health Insurance Portability and Accountability Act (HIPAA)

The Health Insurance Portability and Accountability Act (HIPAA) was signed into law in 1996.
It had 3 main focuses:

- **Protect health care insurance coverage for individuals when they lose or change jobs.** (Portability)
- **Address fraud, abuse and waste in health care** insurance and the delivery of health care.
- **Ensure the security and confidentiality of patient information.** (Accountability)

HIPAA required that the U.S. Department of Health and Human Services create **"Privacy and Security Rules"** that health care organizations and insurance companies must follow.

The Privacy Rule: defined protected health information (PHI) as "any information held by a covered entity which concerns health status, the provision of health care, or payment for health care that can be linked to an individual." It also set national standards for how this information can be used and disclosed.

The Security Rule: describes the safeguards that must be in place to protect the confidentiality, integrity, and availability of *electronic* protected health information (ePHI)

The Breach Notification Rule: requires insurance companies or health care organizations notify you if your protected health information has been shared in an unsecure way.

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The Common Rule

The **Common Rule** is the short name for the **Federal Policy for the Protection of Human Subjects** that was published in 1991, recently updated in 2019 and is based on the 1979 Belmont Report (slide 7).

The Common Rule is the **minimum standard of ethics that all government funded research in the United States is held to** and is codified in the Health and Human Services (HHS) regulations, 45 CFR part 46, which includes four subparts:

- Subpart A, also known as the Federal Policy or the "Common Rule";
- Subpart B, additional protections for pregnant women, human fetuses, and neonates;
- Subpart C, additional protections for prisoners; and
- Subpart D, additional protections for children.

Each government agency includes in its chapter of the Code of Federal Regulations [CFR] section numbers and language that are identical to those of the HHS codification at 45 CFR part 46, subpart A.

**Should you be matched to a study, the research team will ask you to complete more in-depth training on Human Protections at which point you will learn more about the Common Rule.*

Module 7: Review Questions

- The next few slides have some questions to help you review and remember what we have presented in this Module.

- This is not a graded test and is meant to only help you retain the information from this Module. There is an answer key at the end.

- Here is a link to the key terms that might help as you go through the review questions: click here

- If you have any questions, please email BRIDGE@copdfoundation.org

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Module 7: Review Questions

Match the historical moment in research protections with the correct description

1. Nazi Experimentation (early 1940s)	**a**. A congressional act which did two major things to stop unethical research on people: • It required the U.S. government to create rules to protect people in research studies. • It created a national committee to develop guidelines for ethical research
2. Nuremberg Code (1947)	**b.** A home for children with mental disabilities in New York City. Researchers deliberately injected children with hepatitis to learn about the disease. Risk not fully explained to parents.
3. Willowbrook Study (1963-1966)	**c.** After the Nuremberg Trials, the judges listed important principles of acceptable medical experiments. • Research participation must be voluntary. • Research participation cannot put people at high risk for disability or death. • Participants can quit a study at any time.
4. Declaration of Helsinki (1964)	**d**. A report that defined three basic principles for the ethical treatment of individuals participating in research: *Respect*: People must have a choice about what happens to them. *Beneficence : "Doing good"* The risks of a study cannot outweigh the possible benefits. *Justice*: The benefits and risks of research should be fairly shared across society.
5. Tuskegee Syphilis Study (Ended 1972)	**e**. The World Medical Association, meeting in Finland, approved principles for ethical research: • Research plans should be reviewed by an independent committee, such as an institutional review board (IRB). • Research participants must give their "informed consent" to be in a study. • Risks of being in a study should not outweigh benefits.
6. National Research Act (1974)	**f.** Doctors in Nazi concentration camps forced prisoners to take part in dangerous experiments. Examples of unethical experiments were forcing prisoners to be sterilized and be infected with diseases.
7. Belmont Report (1979)	**g.** African-American men in Alabama with syphilis were not given available treatments because doctors wanted to study long- term effects of the disease. Dozens of men died of syphilis or its complications. The study did not end until 1972 when details about it became public.

Module 7: Review Questions continued...

8. Please select the answer below that is NOT a role of the institutional review board

a. Reviews and approves all research before the study begins.
b. Ensures that people joining studies will be protected from unknown harm or risks.
c. Weighs risks versus benefits, looks at what protections are in place and if people in the study are informed about the study before they decide to join.
d. Conducts yearly reviews of all studies.
e. Any unexpected or serious study issues must be reported to the IRB.
f. Serves as a place for individuals participating in the study to share their concerns or complaints about the study.
g. Implements the study and reports the results.

9. True or false: The informed consent document explains what will happen in the study and what is being asked of people who join the study.

a. True
b. False

10. True or false: The informed consent document is a binding contract and once participants begin a study they must continue it until the study is complete

a. True
b. False

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Module 7: Review Questions continued...

Which of the descriptions below is about Privacy (P) and which is about Confidentiality (C)?	"P" or "C"
11. An understanding that information an individual shares will not be shared with others without their permission.	
12. Involves a person's identifiable information and the security/procedures in place to ensure that only authorized individuals see the information.	
13. Applies to the person	
14. Applies to the information	

15. Which of the answers below best describes the Health Insurance Portability and Accountability Act (HIPAA)?

a. It protects health care insurance coverage for individuals when they lose or change jobs.
b. It addresses fraud, abuse and waste in health care insurance and the delivery of health care.
c. It ensures the security and confidentiality of patient information.
d. All of the above

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Module 7: Review Questions Answer Key

1. f
2. c
3. b
4. e
5. g
6. a
7. d
Explanation: See slides 5-8 for a review of these important historical milestones in Research Protections

8. g
Explanation: An institutional review board is *not* involved with the implementation or results reporting of a study, but rather serves as an independent group that reviews the study plans, ensures that participants' will be protected from harm, weighs risks versus benefit and serves as a place for reporting serious issues or concerns and complaints about the study.

9. a-True
Explanation: The informed consent document explains in clear language to study participants what will happen in the study, what is being asked of them, potential risks, their individual rights and contact information for the study team and the institutional review board.

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Module 7: Review Questions Answer Key continued...

10. b-false
Explanation: The informed consent document is a *voluntary agreement* between the participant and the study team—it is not a contract and a participant has the right to *stop participating in a study at any time.*

11. P (privacy)
12. C (confidentiality)
13. P
14. C
Explanation: See slide 13 for a review of privacy and confidentiality

15. d
Explanation: All of these answers describe the Health Insurance Portability and Accountability Act.

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Links to Key Resources for Module 7

Below is a table with links to key resources and information that you might find useful

Takeaway Documents	• **Glossary of Key Terms: click here** • **Module 7 Review Questions with Answers and Explanations: click here** • **Module 7 Summary Document: click here** • **Summary of Research Ethics Milestones link: click here**

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Next Steps

Congratulations! You have completed Module 7!

Please go on to ***Module 8 – Overall Assessment***

You don't have to do this right away – you can do it when you have time.

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