



The Office of the National Coordinator for
Health Information Technology



Legal and Ethical Architecture for PCOR Data

CHAPTER 4:

FRAMEWORK FOR NAVIGATING LEGAL AND ETHICAL REQUIREMENTS FOR PCOR

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Chapter 4

Framework for Navigating Legal and Ethical Requirements for PCOR

INTRODUCTION

Building on Chapters 2 and 3, this chapter presents a visual decision tool that highlights the key considerations associated with the spectrum of data used for PCOR and the nature of the relationships between researchers and other stakeholders. This Framework is built on the data characteristics and types (discussed in the previous chapters) that are critical to navigating legal and ethical requirements that govern use and exchange of data for PCOR.

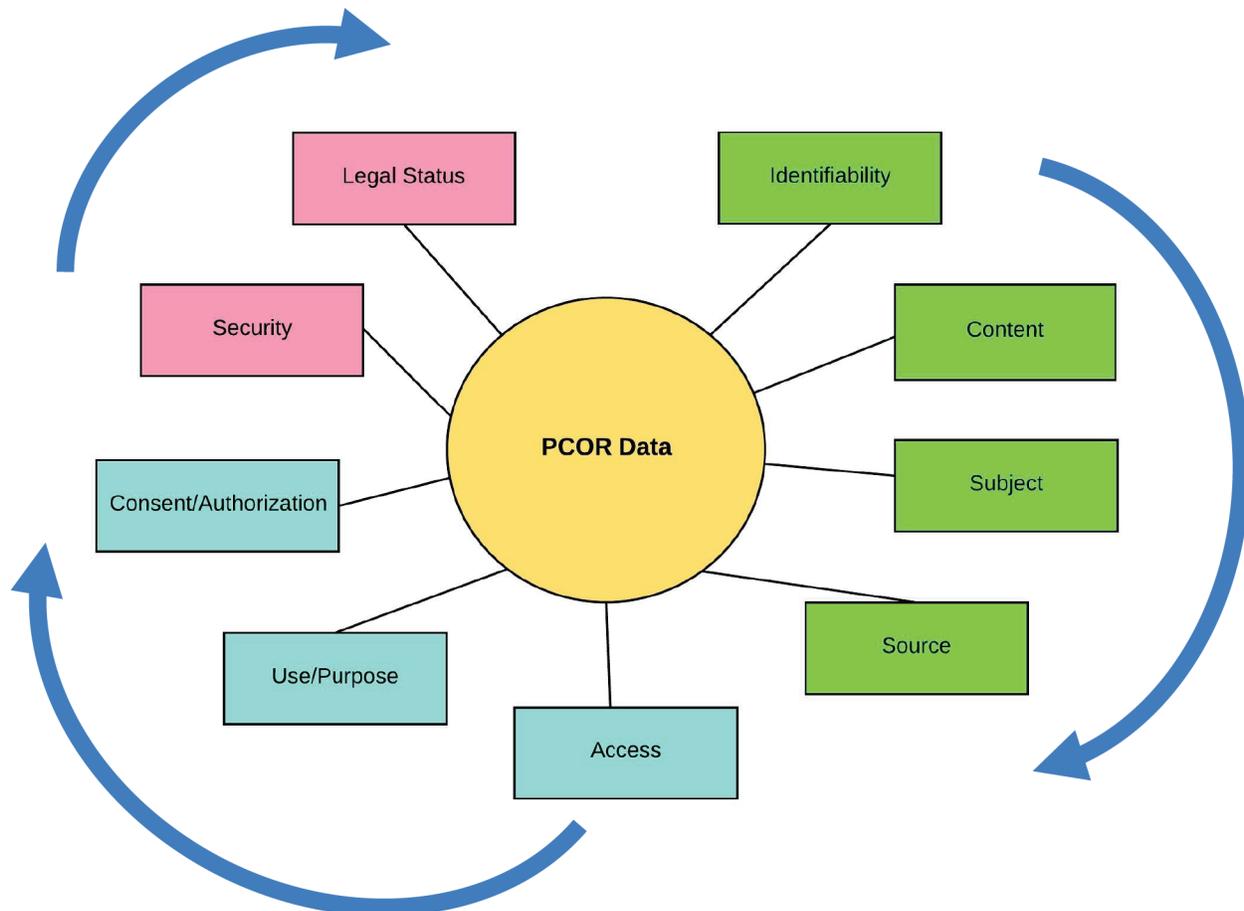
PCOR FRAMEWORK

This Framework is designed to serve as a decision tool for PCOR researchers that addresses the key data characteristics and considerations (previously discussed in Chapter 2) both individually and collectively. While the characteristics presented here are by no means exclusive, they represent the key characteristics of data that determine what legal requirements and ethical principles apply for research use of that data.

- **Identifiability:** Refers to the ability to link information to particular individuals.
- **Content:** Refers to the subject matter or substance of the data.
- **Subject:** Refers to the person or thing that is the focus of the data.
- **Source:** Refers to the person, entity, and/or setting in which the data originated or was collected.
- **Access:** Refers to the ability of a person or entity other than the individual subject(s) of the information to view, create, edit, or share data.
- **Use/Purpose:** The intended use or purpose of the data collection will affect whether and how the data may be collected and used.
- **Consent/Authorization:** Refers to the activities and documentation potentially required of researchers seeking permission to collect, use, or share data about an individual.
- **Security:** Refers to the means by which data is protected from unauthorized use or access.
- **Legal Status:** Refers to rights and responsibilities related to data that may be triggered by ownership rights, agency principles, and/or contractual obligations.

These characteristics are not mutually exclusive, and the considerations that surround them are interconnected and frequently overlapping. For example, ownership of a certain data set under the terms of a contract (which is an aspect of “legal status”) also determines who may access the data; the content and subject characteristics of data affect how it may be used; and identifiability may determine what consent or authorization must be obtained in order to use the data for research. Users are encouraged to review all of the characteristics thoroughly to determine if/how they apply to their research.

As discussed in Chapter 2, answers to key questions related to these characteristics can help researchers understand the legal and ethical significance of different aspects of data used for PCOR. These data characteristics are displayed as the spokes around a wheel, with the center of the wheel representing PCOR data.



For this chapter, the key characteristics are organized into three color-coded groups according to their priority for decision-making by researchers and are organized around the wheel in the order in which a researcher should consider them, starting with “Identifiability” in the top right position and moving clockwise around to “Legal Status.”

Step One: The lime-colored characteristics (Identifiability, Content, Subject, and Source) are the factors that determine whether a statute or regulation applies to the data. A researcher should consider these characteristics first because determinations associated with these characteristics will inform a researcher whether and what statutes and regulations potentially apply and also inform the researcher of the need to move on to the second step for consideration. For example, if a researcher determines that the data in question is identifiable, several statutes and regulations potentially apply, and their requirements will depend on secondary considerations such as Access and Use/Purpose. If a researcher determines that the data is de-identified, then no statute or regulation applies to the data, and the researcher will not need to consider the secondary considerations.

Step Two: The aqua-colored characteristics (Access, Use/Purpose, and Consent/Authorization) are issues that address how a researcher should navigate statutes and/or regulations that apply to the data in question. If a statute and/or regulation applies, the collection or use of the data may be limited or restricted by requirements related to these characteristics.

Step Three: The pink-colored characteristics (Security and Legal Status) involve case-specific determinations relating to data collection and use by a PCOR researcher. For each research protocol, a researcher should consider these characteristics separate and apart from the considerations discussed in steps one and two to the extent they apply. In all cases (as noted at the bottom of each diagram), a researcher should consult with legal counsel (in-house or external), IRB policies and practices, and organizational policies and procedures.

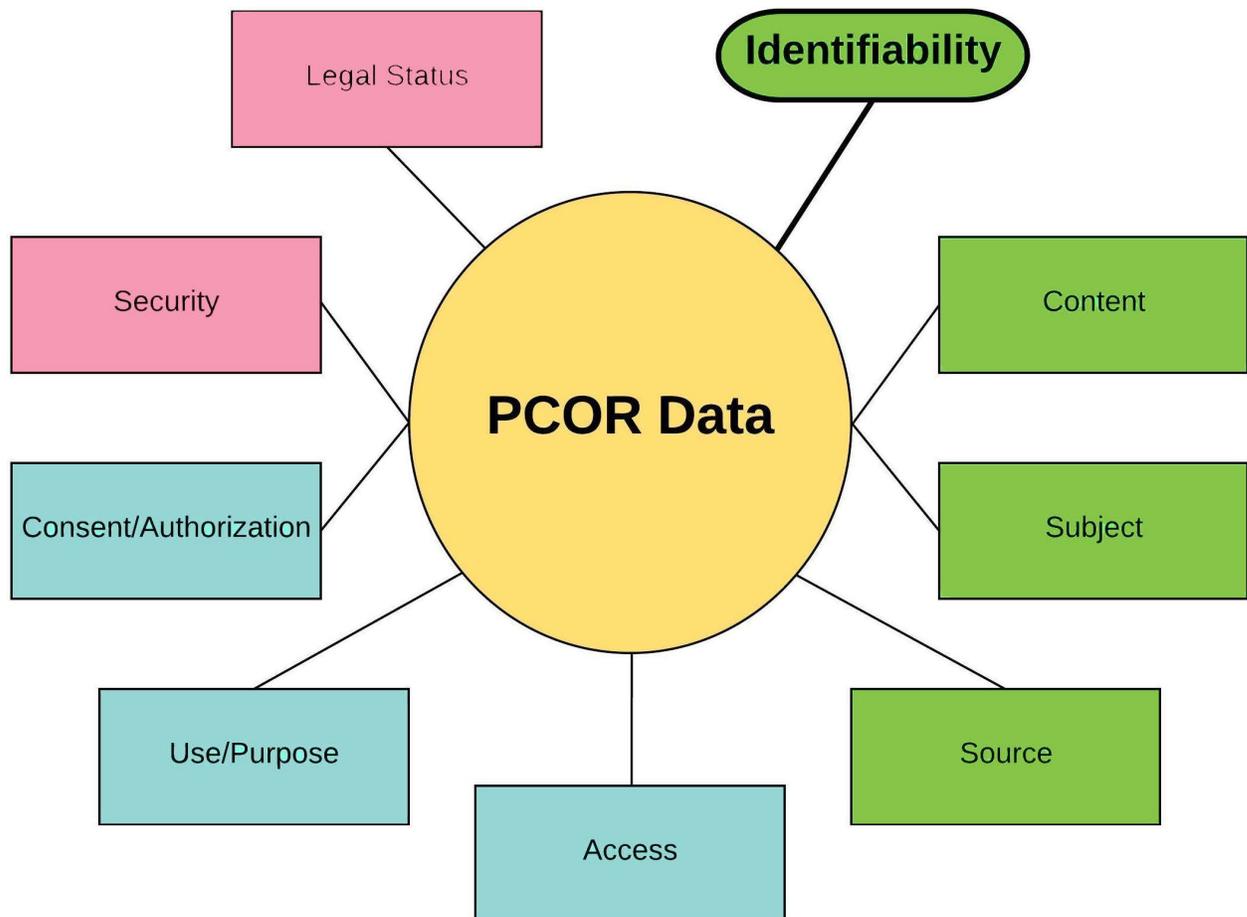
Each characteristic is further explored individually in a decision-oriented structure that illustrates key questions and considerations related to each data characteristic:

- *Key Question:* The content in this column identifies the key questions related to a data characteristic that a researcher must address.
- *What It Means:* The content in this column identifies the meaning and/or interpretation of the key questions related to PCOR.
- *Why It Matters:* The content in this column identifies the legally significant aspects of the issue raised by the question, including identification of any relevant statutes and regulations that are potentially implicated by the issue.
- *Considerations for Next Steps:* The content in this column identifies legal and ethical considerations and activities for PCOR researchers related to each question, including implications for structuring research.
- *General Note:* At the end of each data characteristic's structure are reminders to ensure that research complies with relevant legal and ethical requirements and to identify the parties to consult for further guidance.

This chapter is designed to be a decision tool for PCOR researchers guiding them through a series of considerations specific to the key characteristics that determine whether laws apply to particular data and if so, what requirements attach to collection and use of the data. Potentially applicable laws are referenced throughout the Framework, and complete summaries of key laws are included in Appendix A.

It is important to note that, by design, this chapter does not delve into the complex legal requirements as do Chapters 1, 2, and 3. Rather, as noted above, this chapter provides a decision guide for PCOR researchers to help them understand both the independence and interconnectedness of the characteristics associated with relevant data and a suggested model for assessing and understanding those issues, their relationship to relevant statutes and regulations, and next steps.

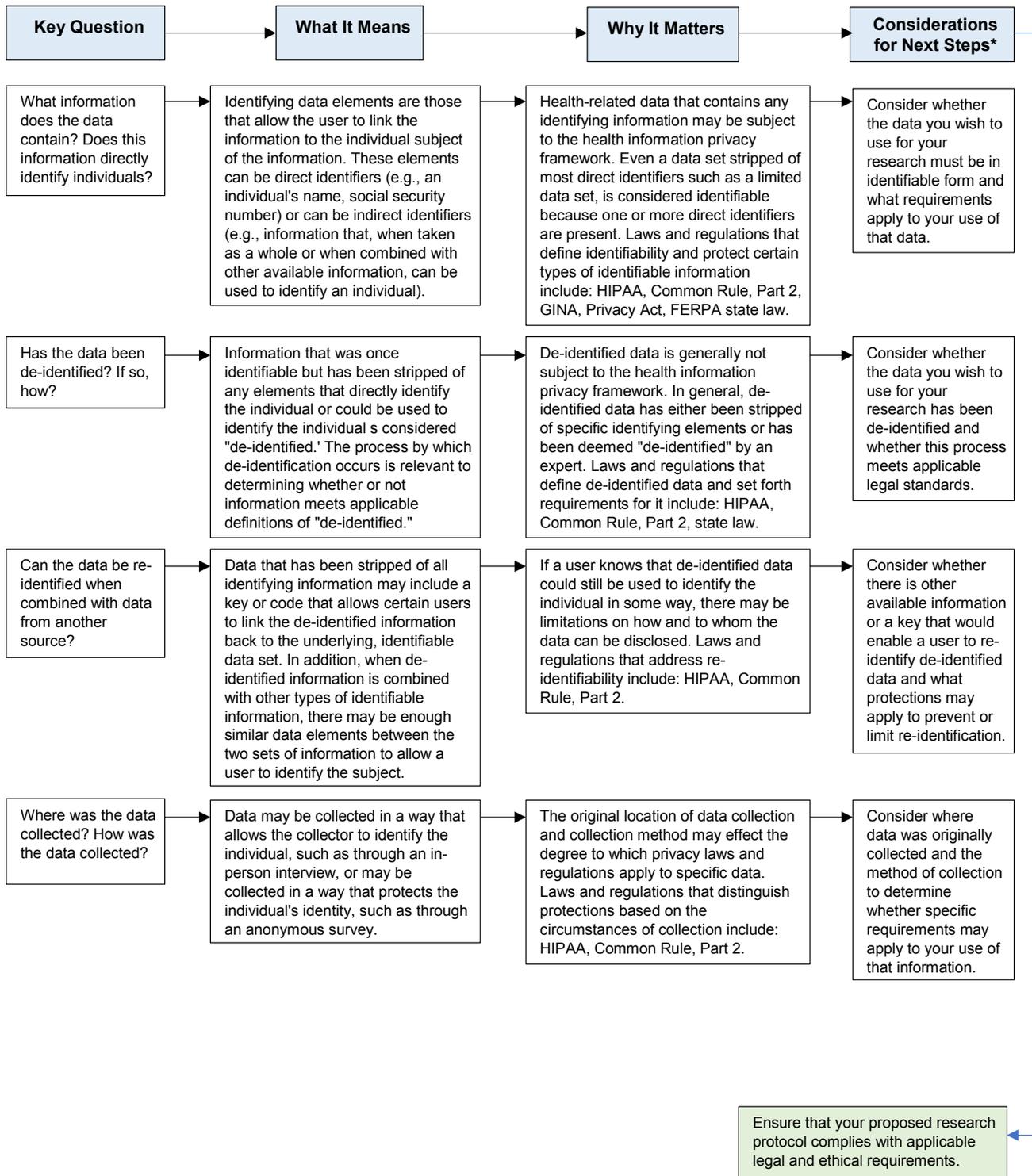
Data Characteristic 1: Identifiability



Identifiability

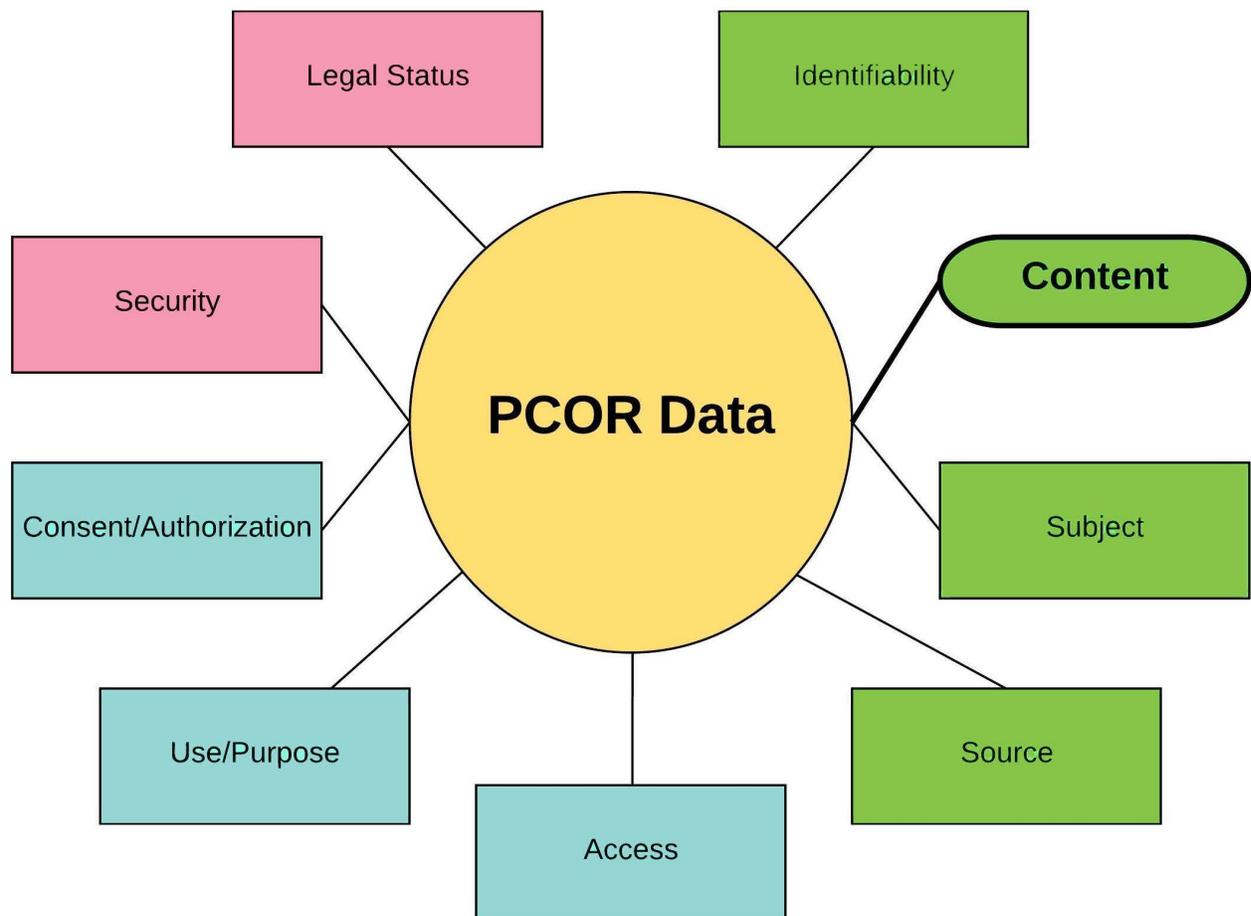
Identifiability refers to the ability to link information to particular individuals.

Identifiability pg. 2



*GENERAL NOTE: In all cases, researchers should consult legal counsel (in-house or external), individual IRB practices, and organizational policies and procedures. Relevant parties may include privacy boards or officers, compliance committees or officers, research managers or contracting personnel, and other legally responsible parties.

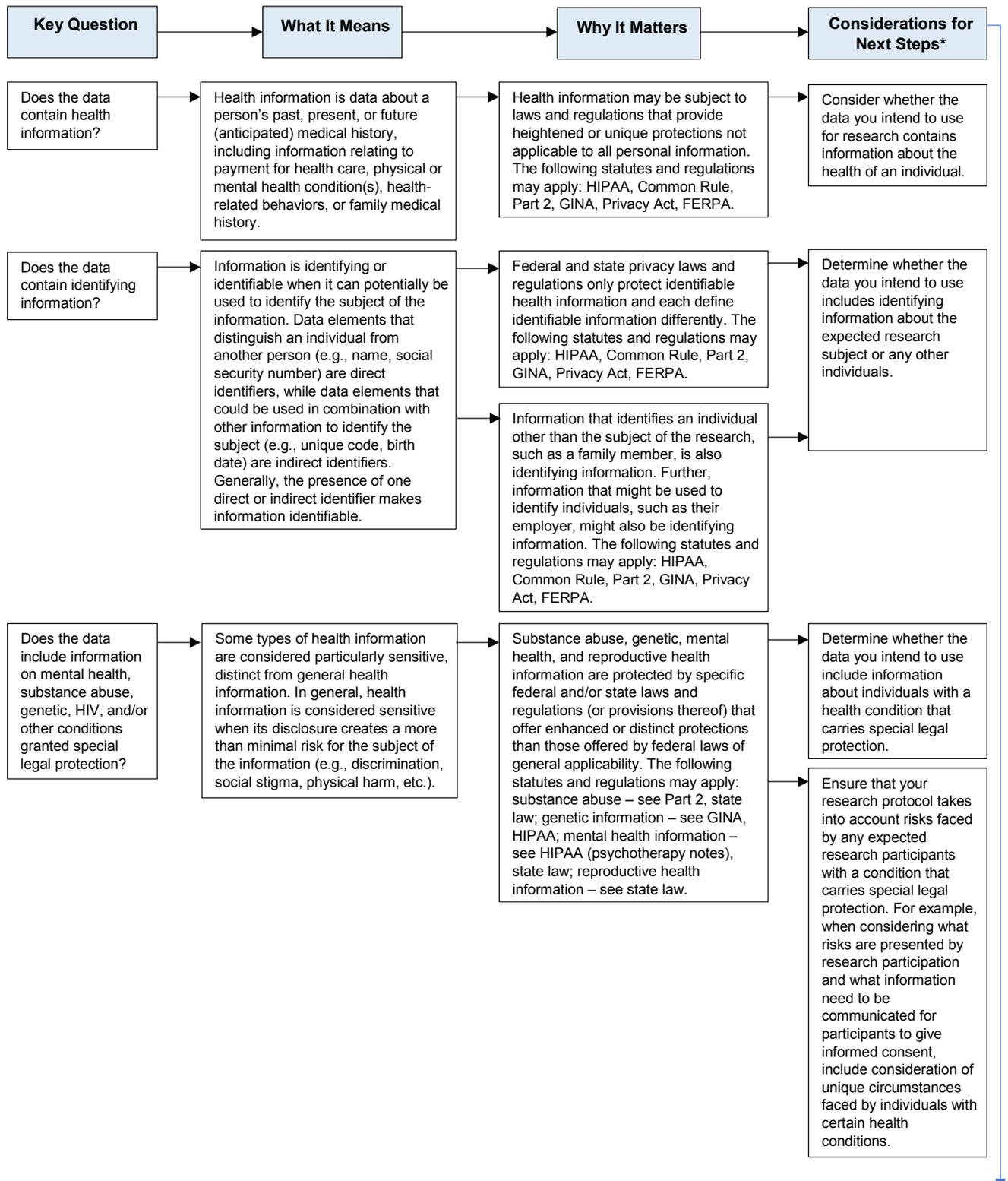
Data Characteristic 2: Content



Content

Content refers to the subject matter or substance of the data.

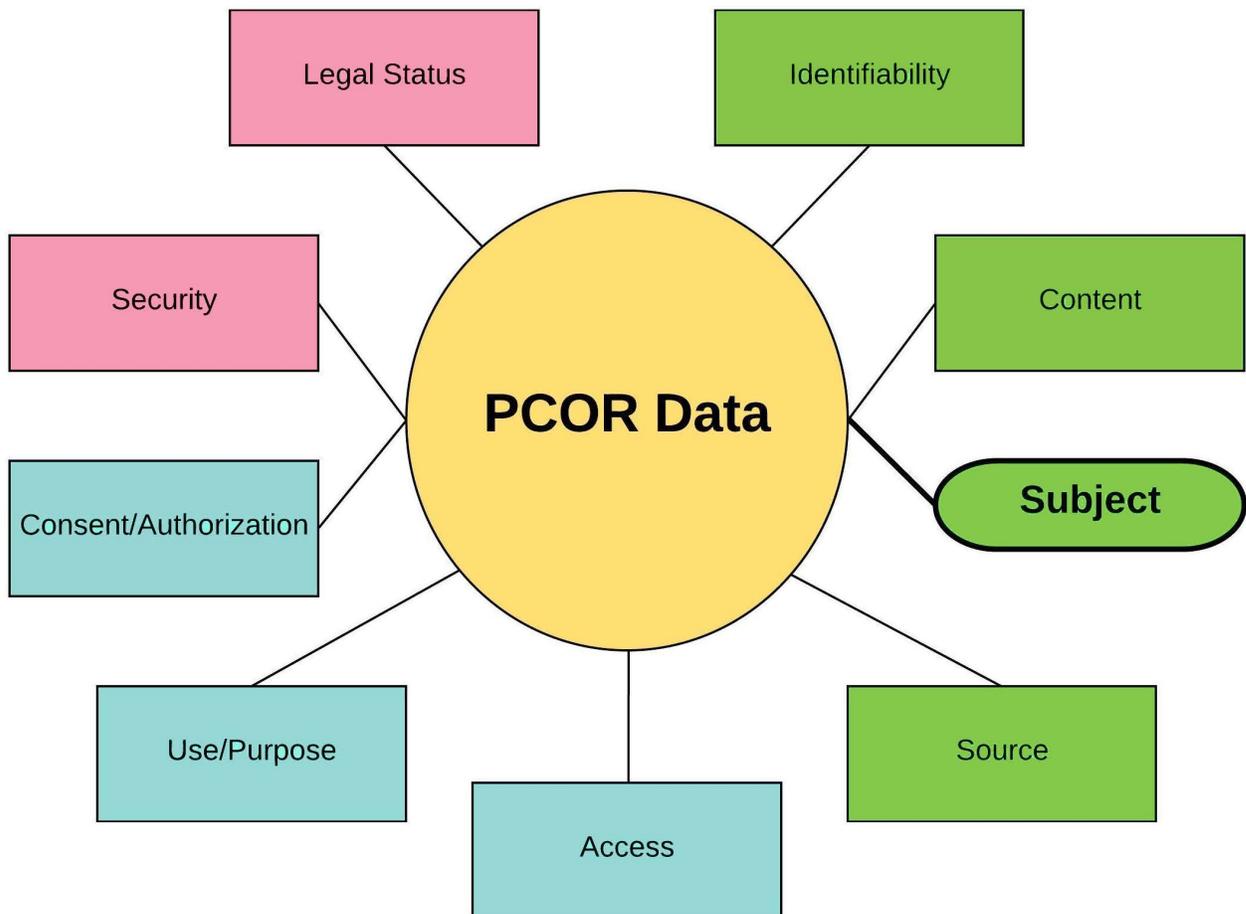
Content pg. 2



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Ensure that your proposed research protocol complies with applicable legal and ethical requirements.

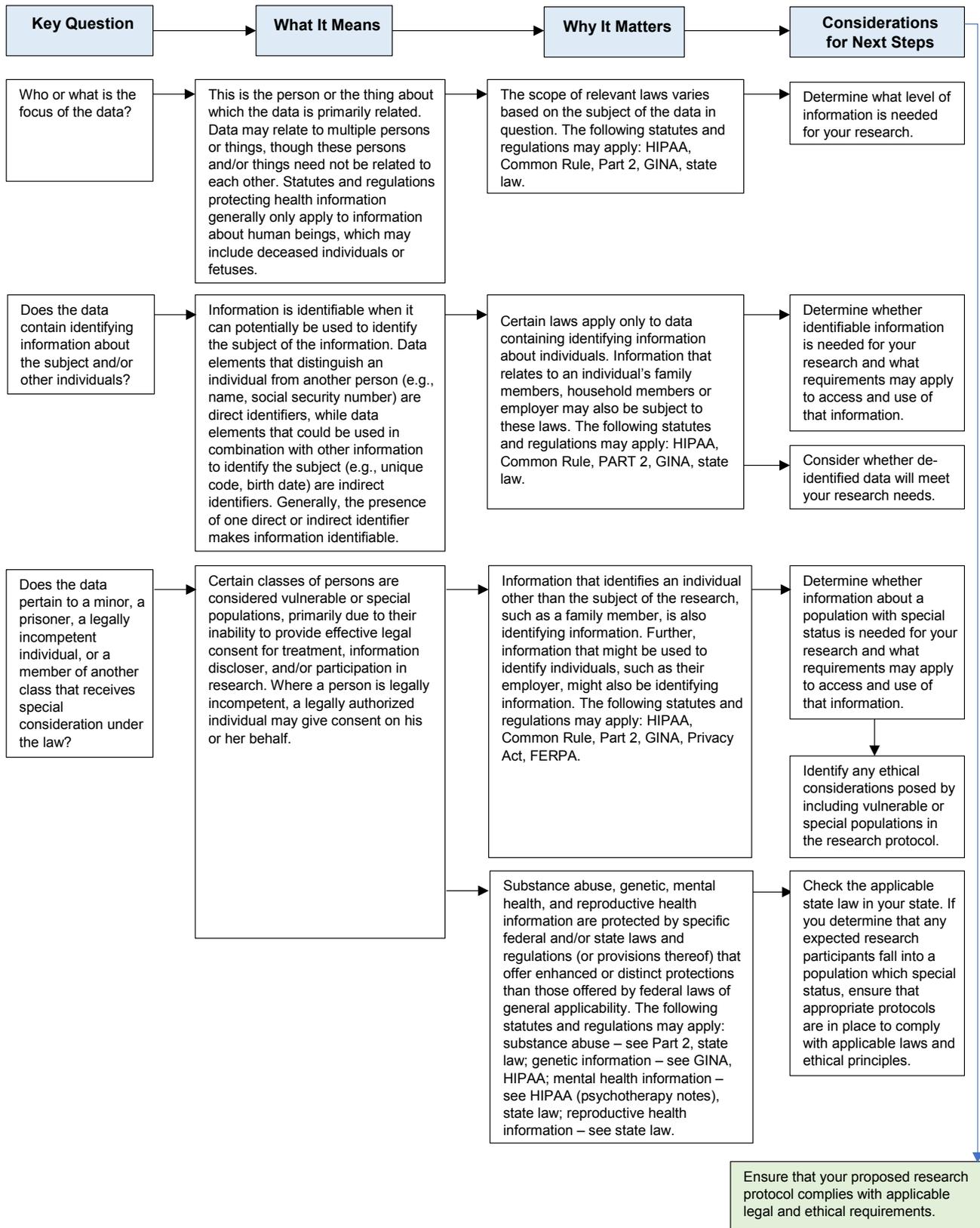
Data Characteristic 3: Subject



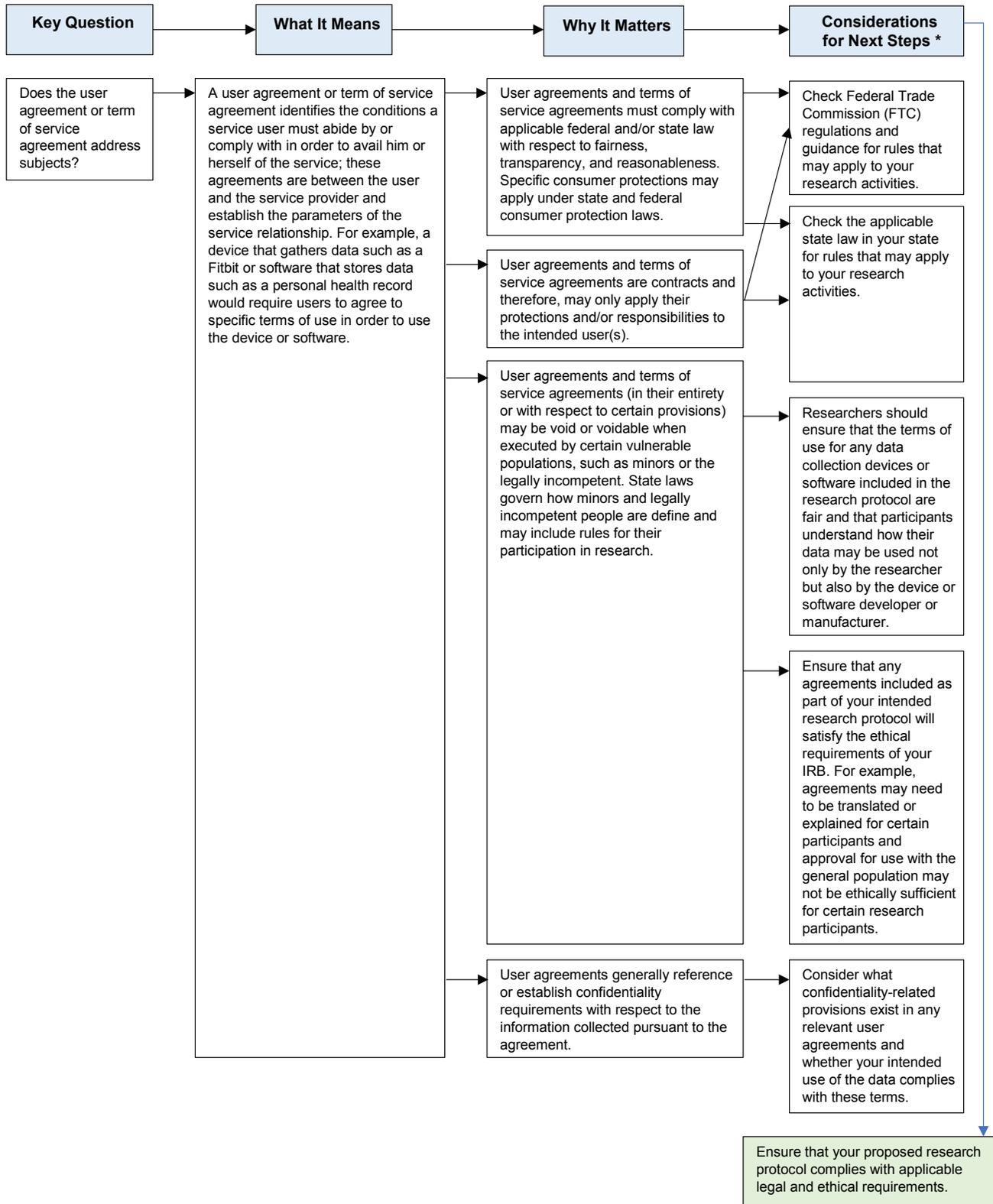
Subject

Subject refers to the person or thing that is the focus of the data.

Subject pg. 2

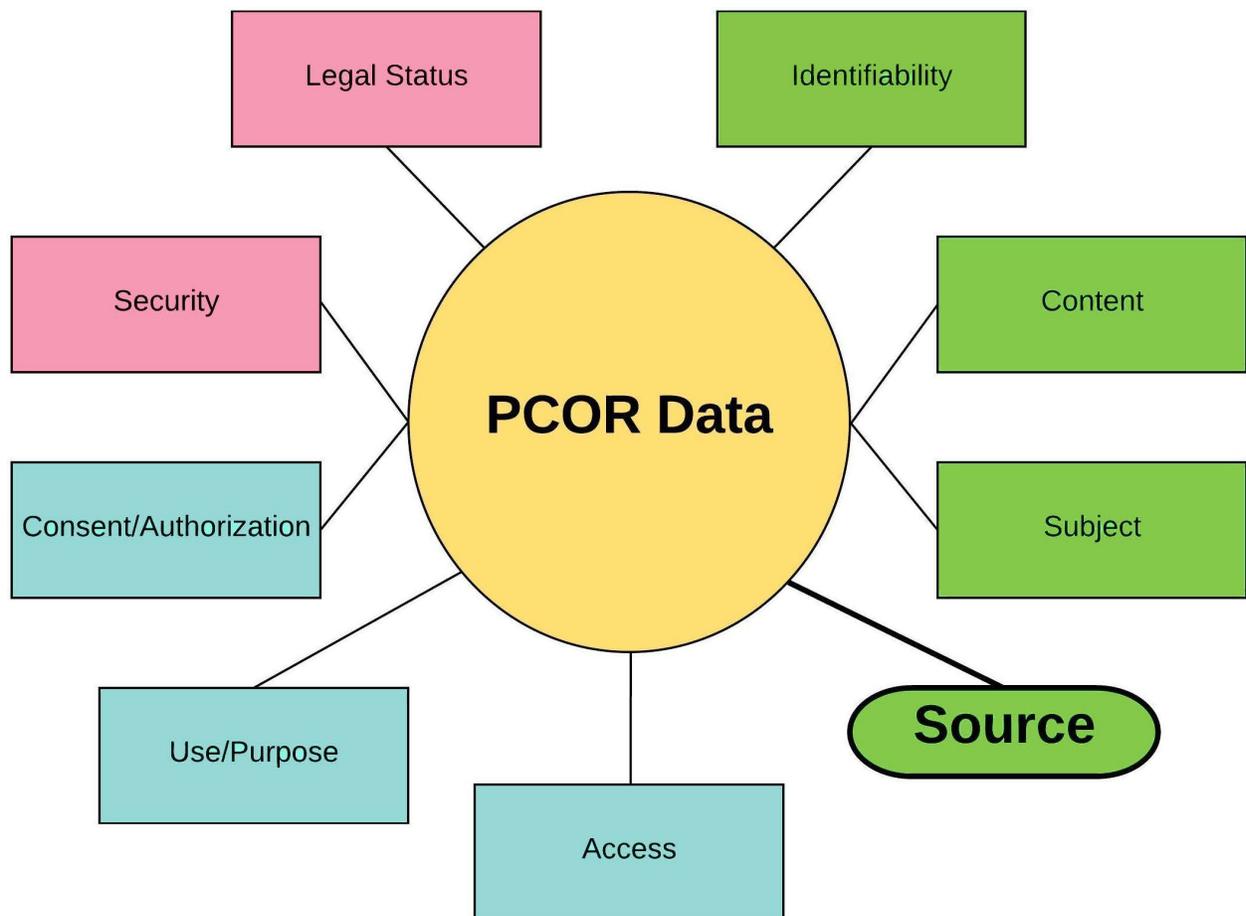


Subject pg. 3



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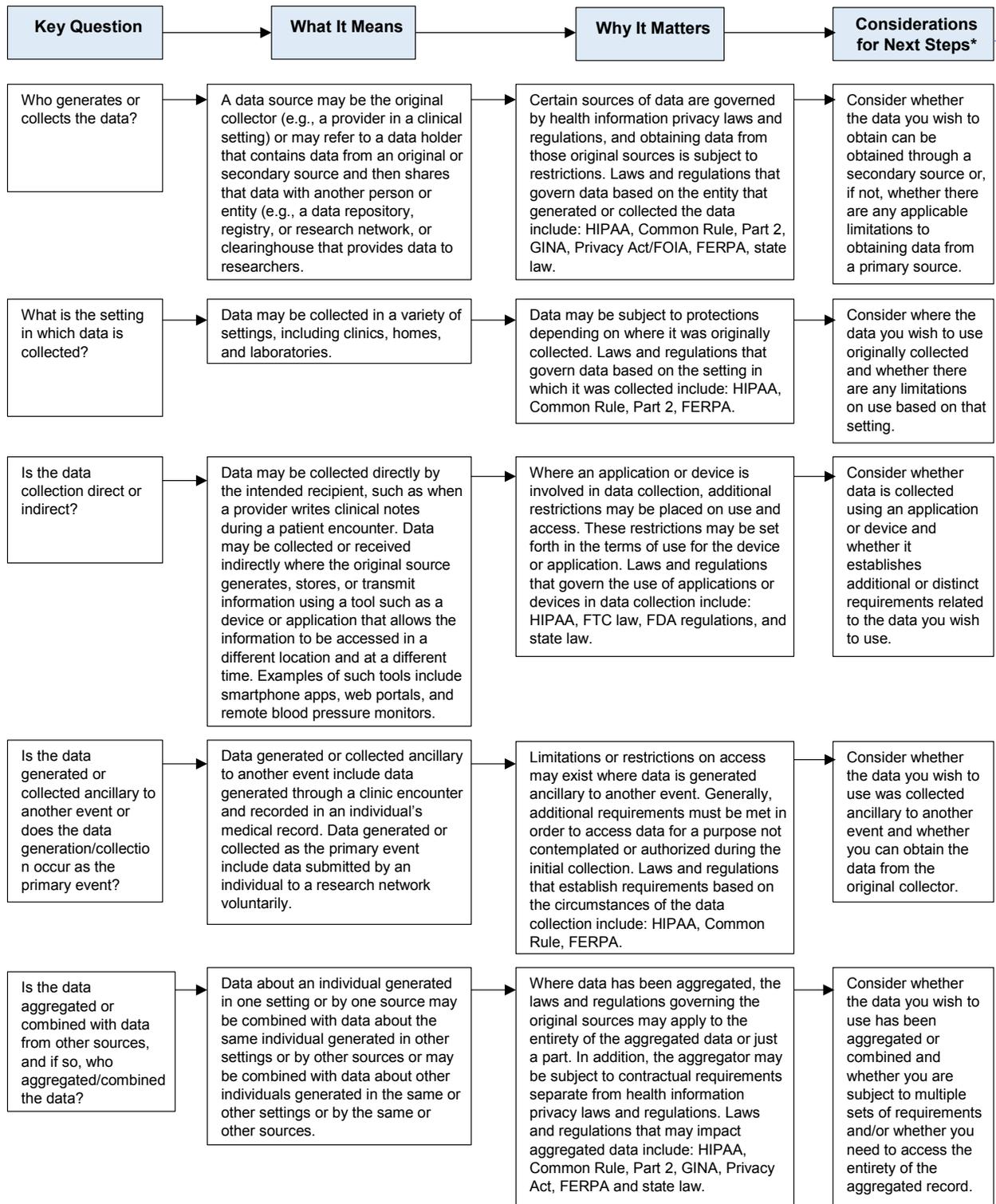
Data Characteristic 4: Source



Source

Source refers to the person, entity, and/or setting in which the data originated or was collected.

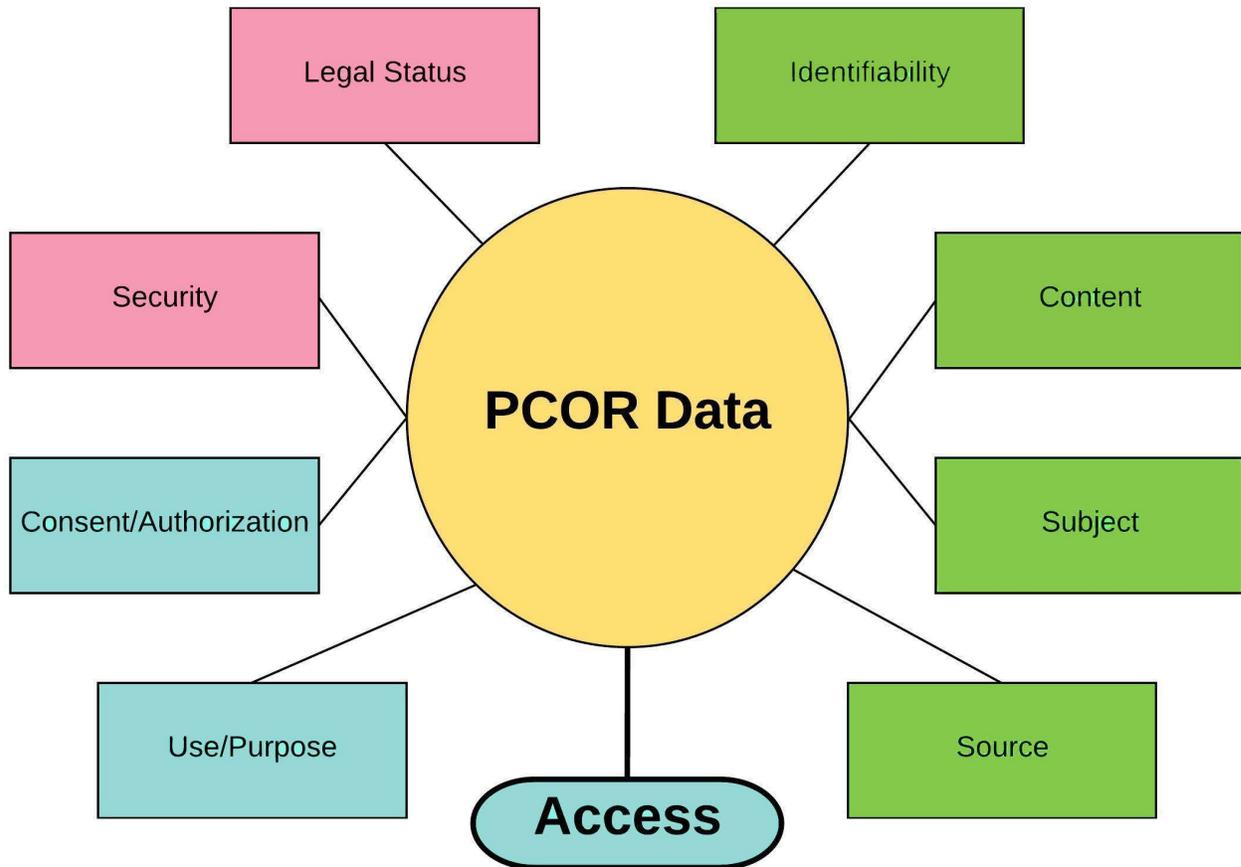
Source pg. 2



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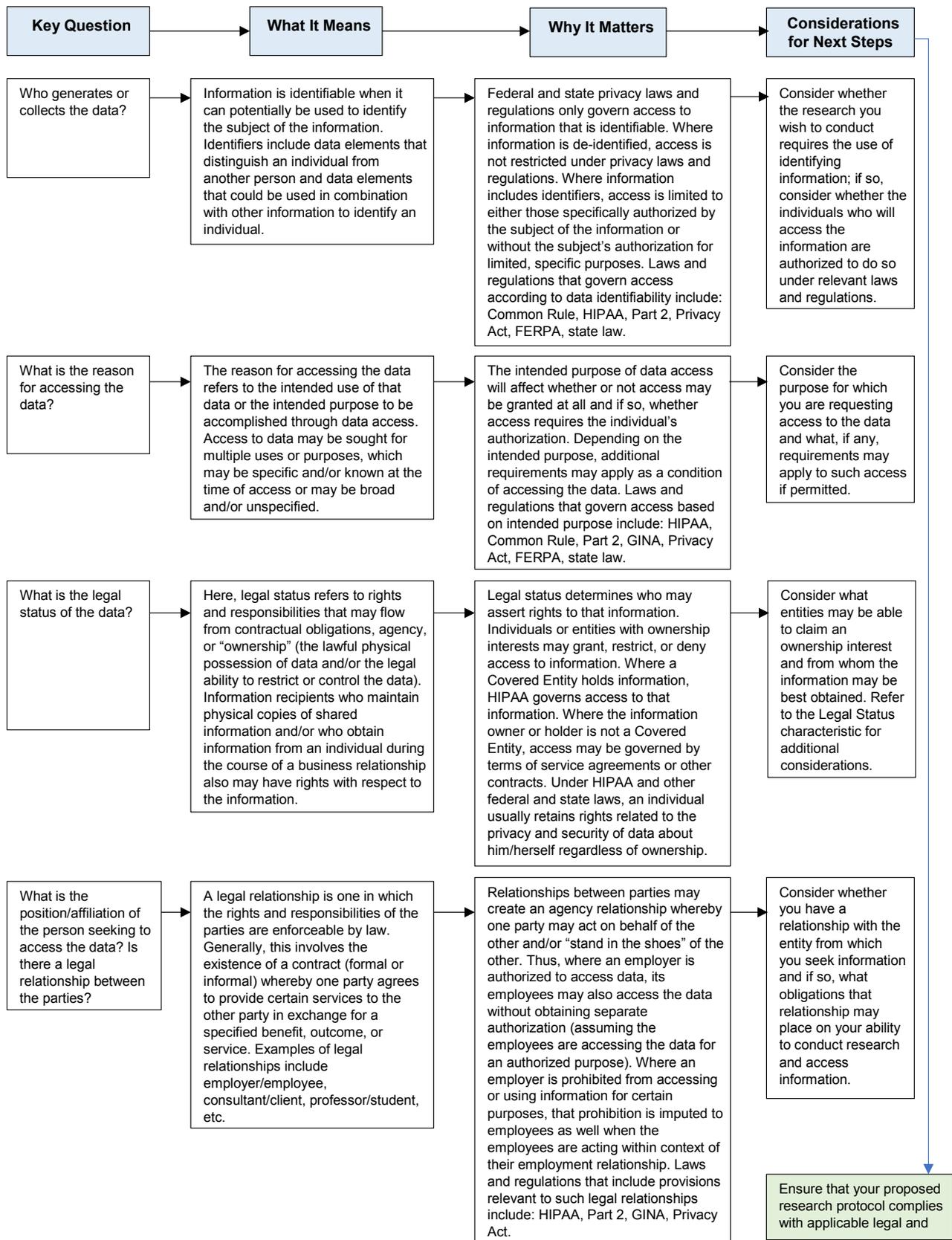
Data Characteristic 5: Access



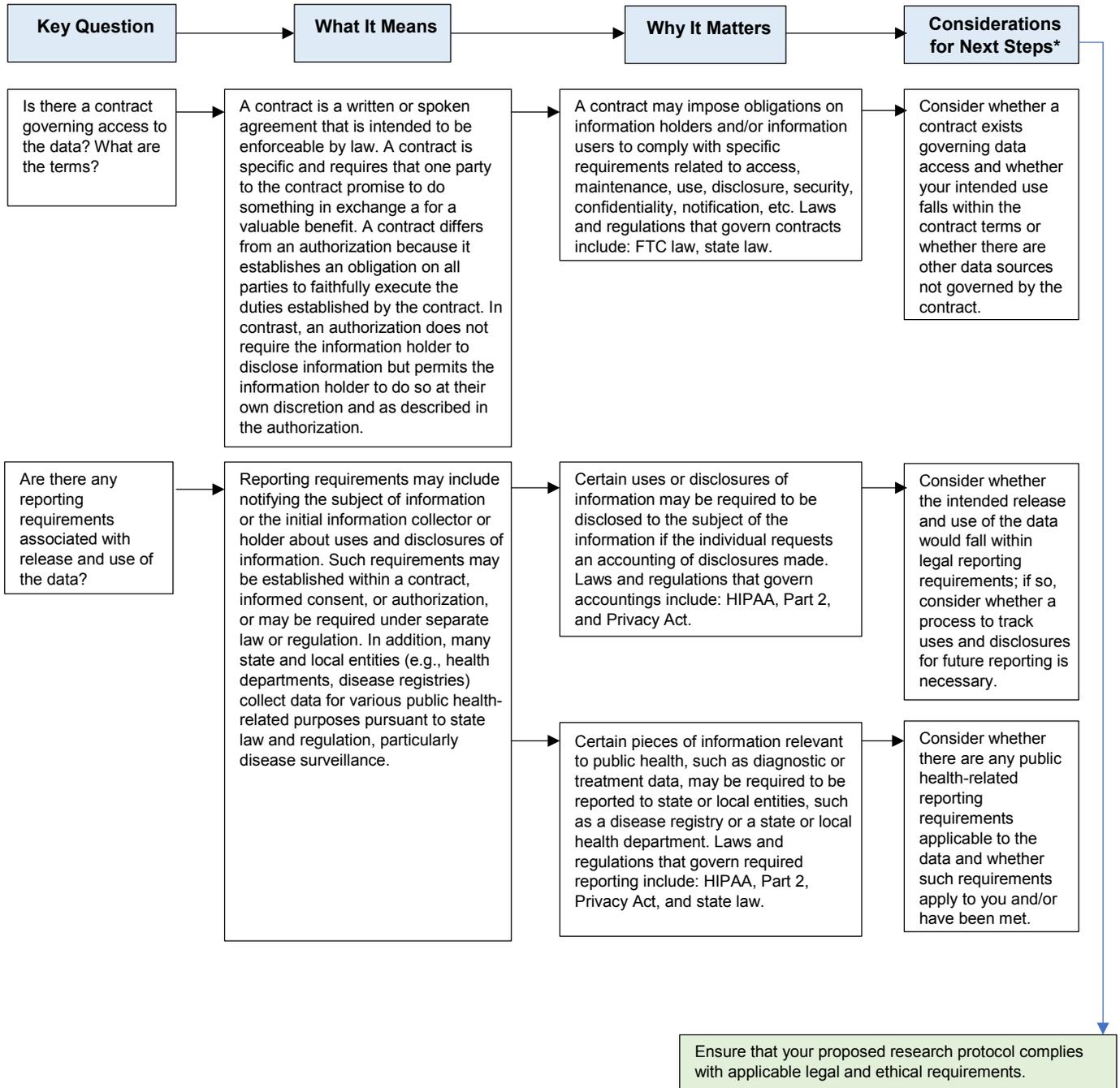
Access

Access refers to the ability of a person or entity other than the individual subject(s) of the information to view, create, edit, or share data.

Access pg. 2

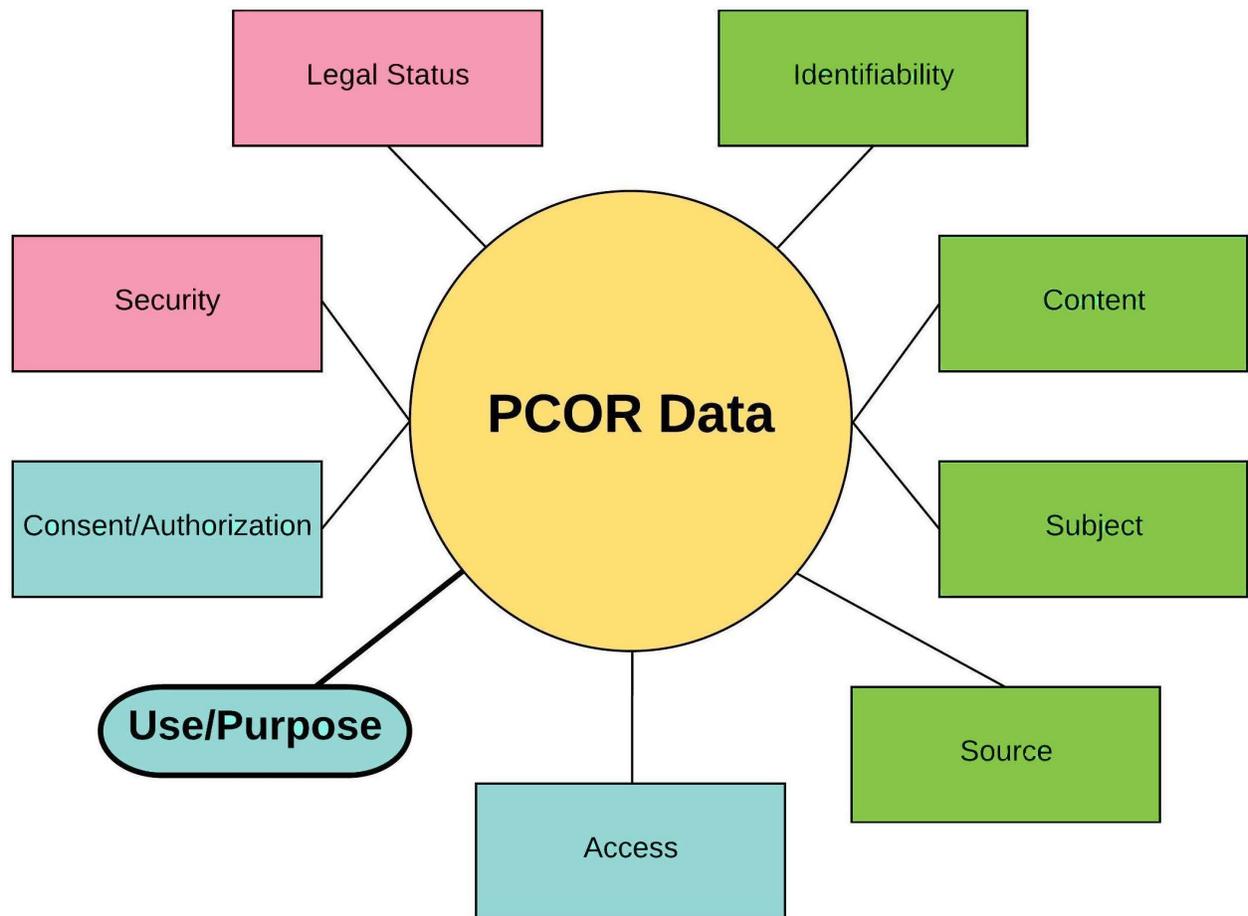


Access pg. 3



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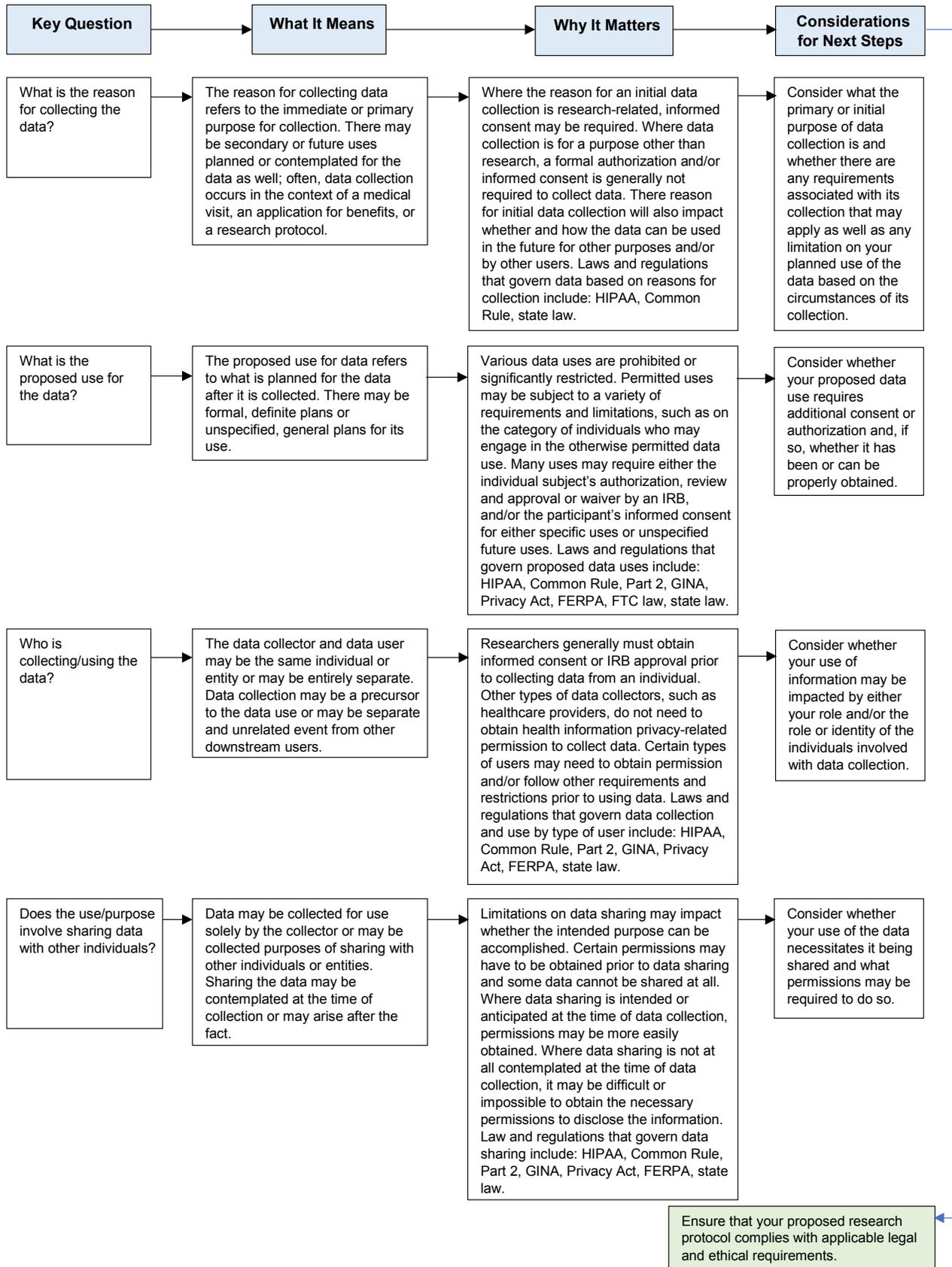
Data Characteristic 6: Use/Purpose



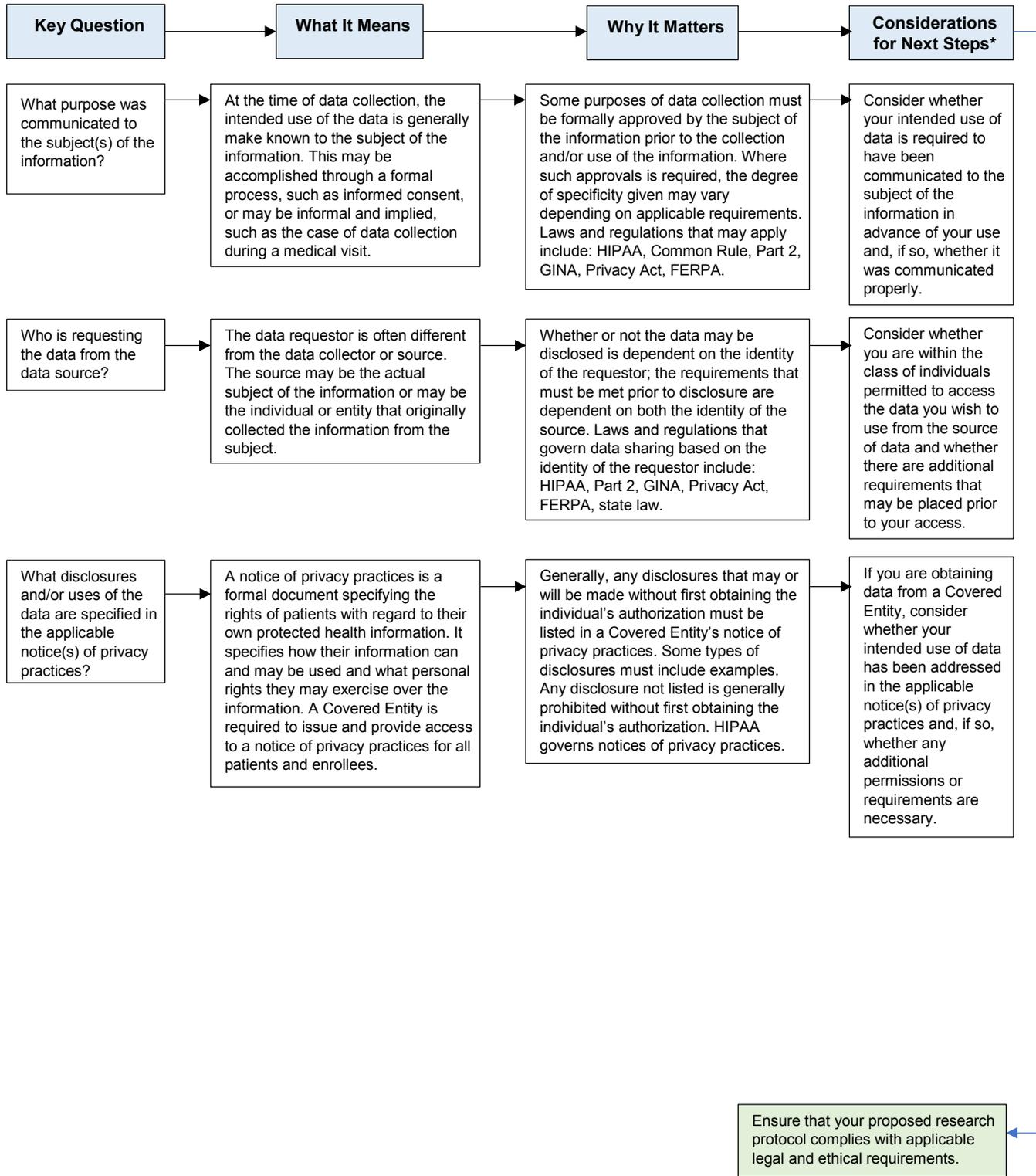
Use/Purpose

The intended use or purpose of the data collection will affect whether and how the data may be collected and used.

Use/Purpose pg. 2

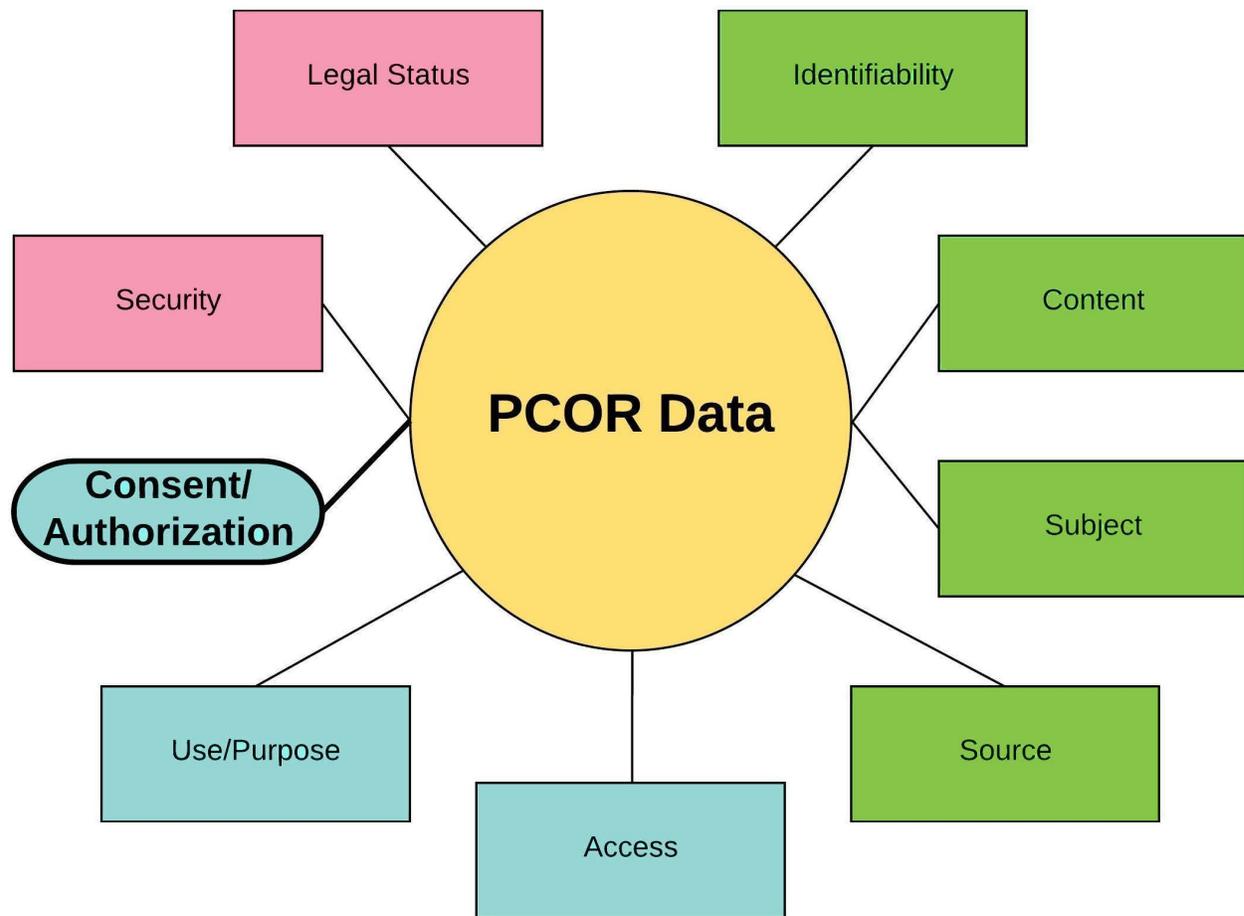


Use/Purpose pg. 3



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Data Characteristic 7: Consent/Authorization



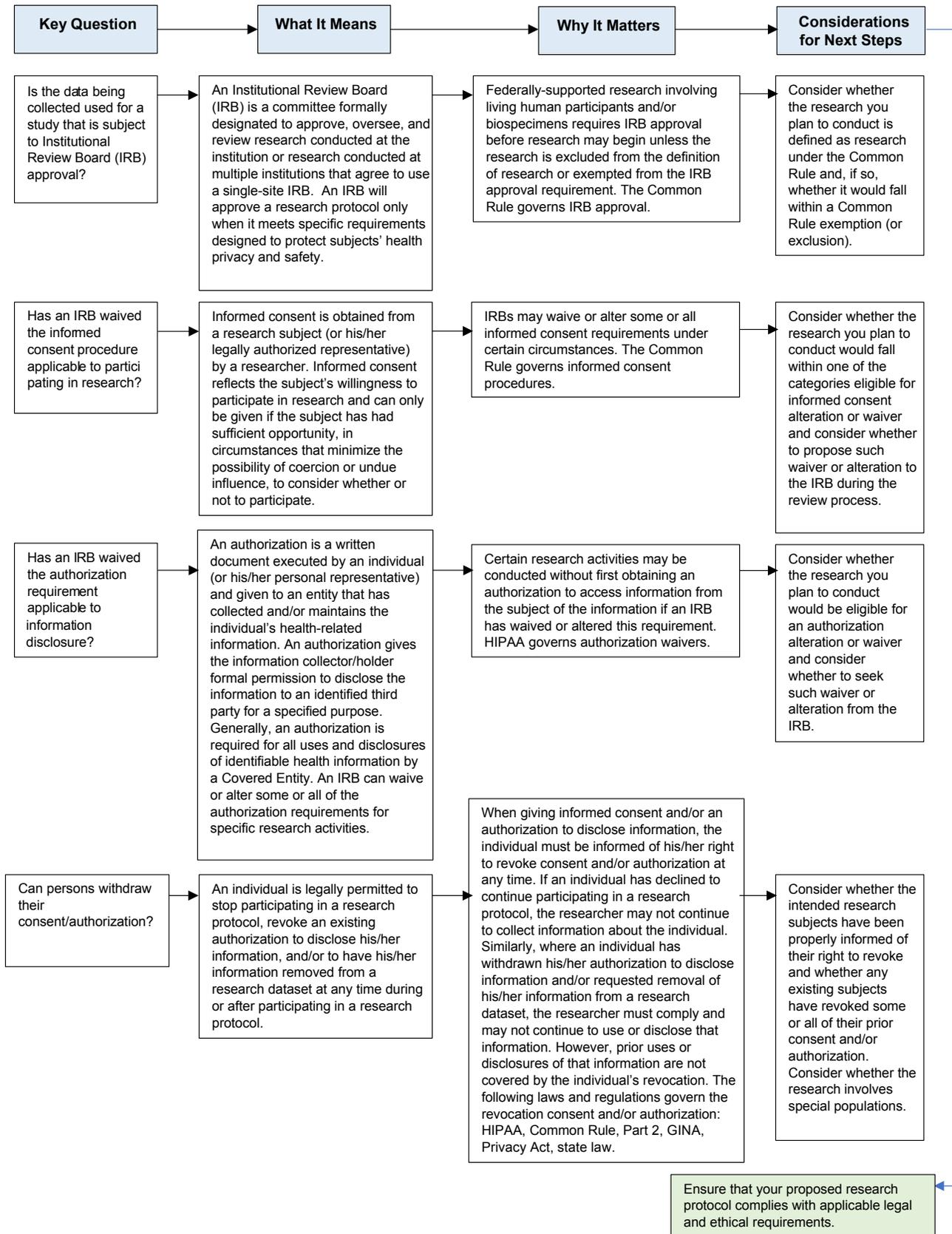
Consent/Authorization

Consent/Authorization refers to the activities and documentation potentially required of researchers seeking permission to collect, use, or share data about an individual.

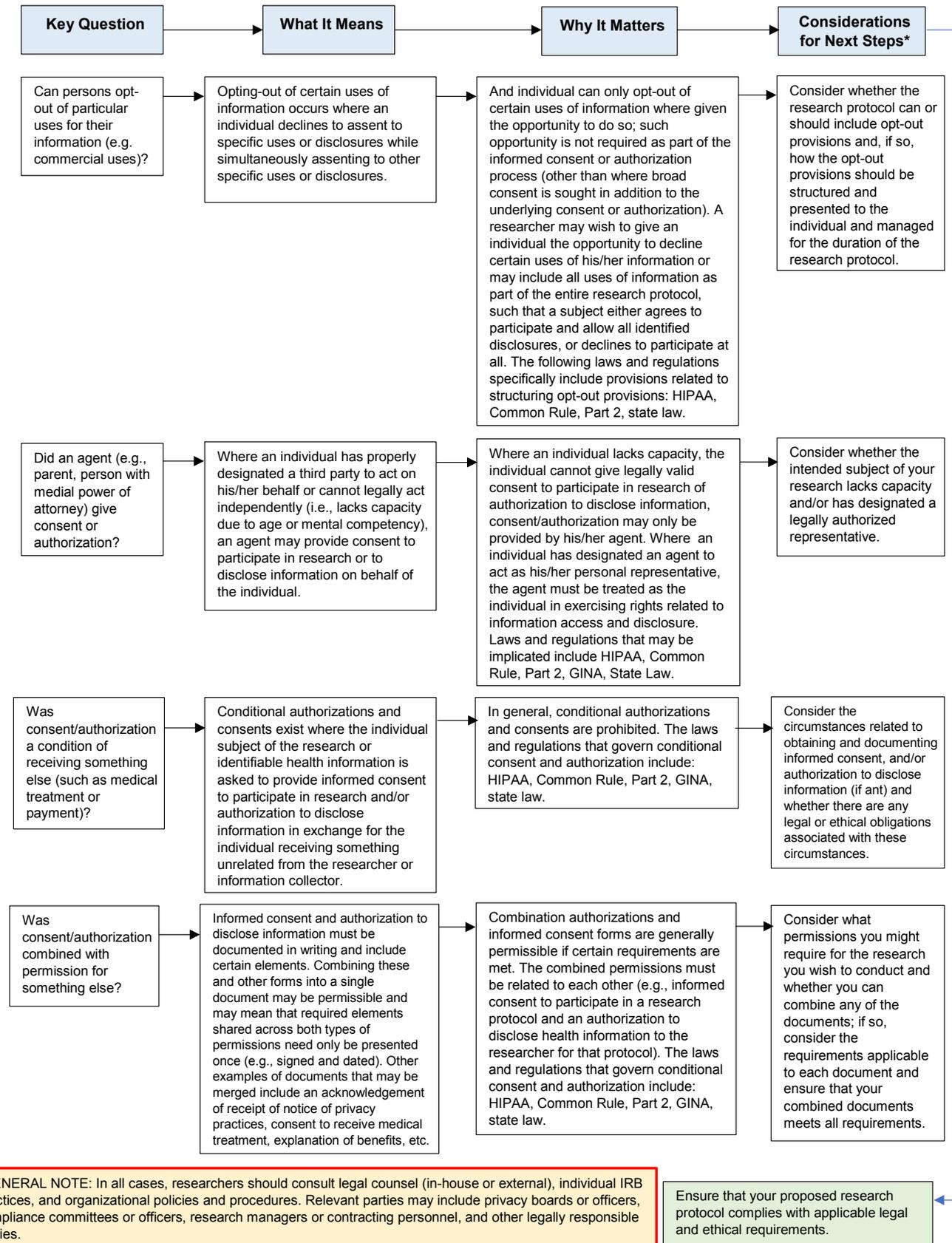
Consent/Authorization pg. 2



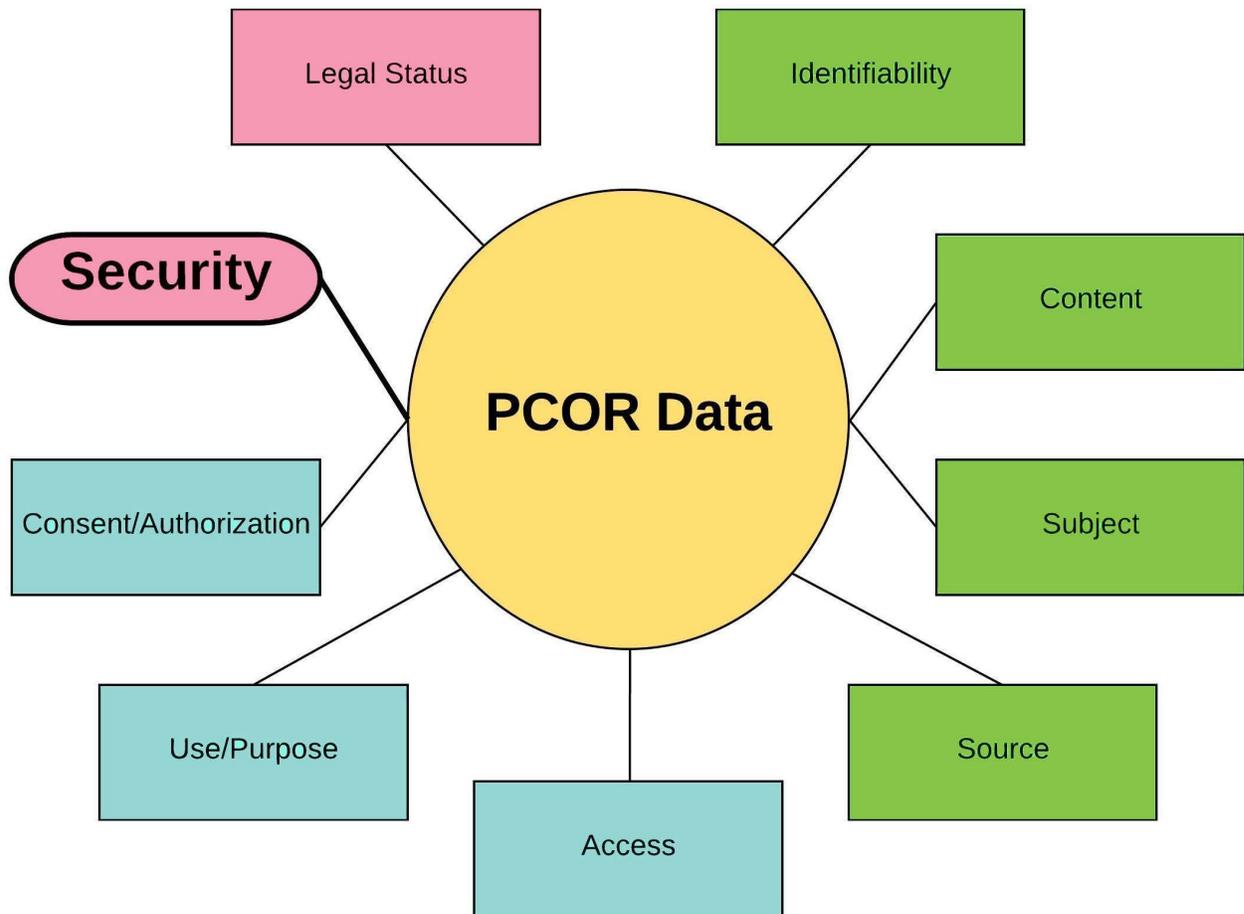
Consent/Authorization pg. 3



Consent/Authorization pg. 4



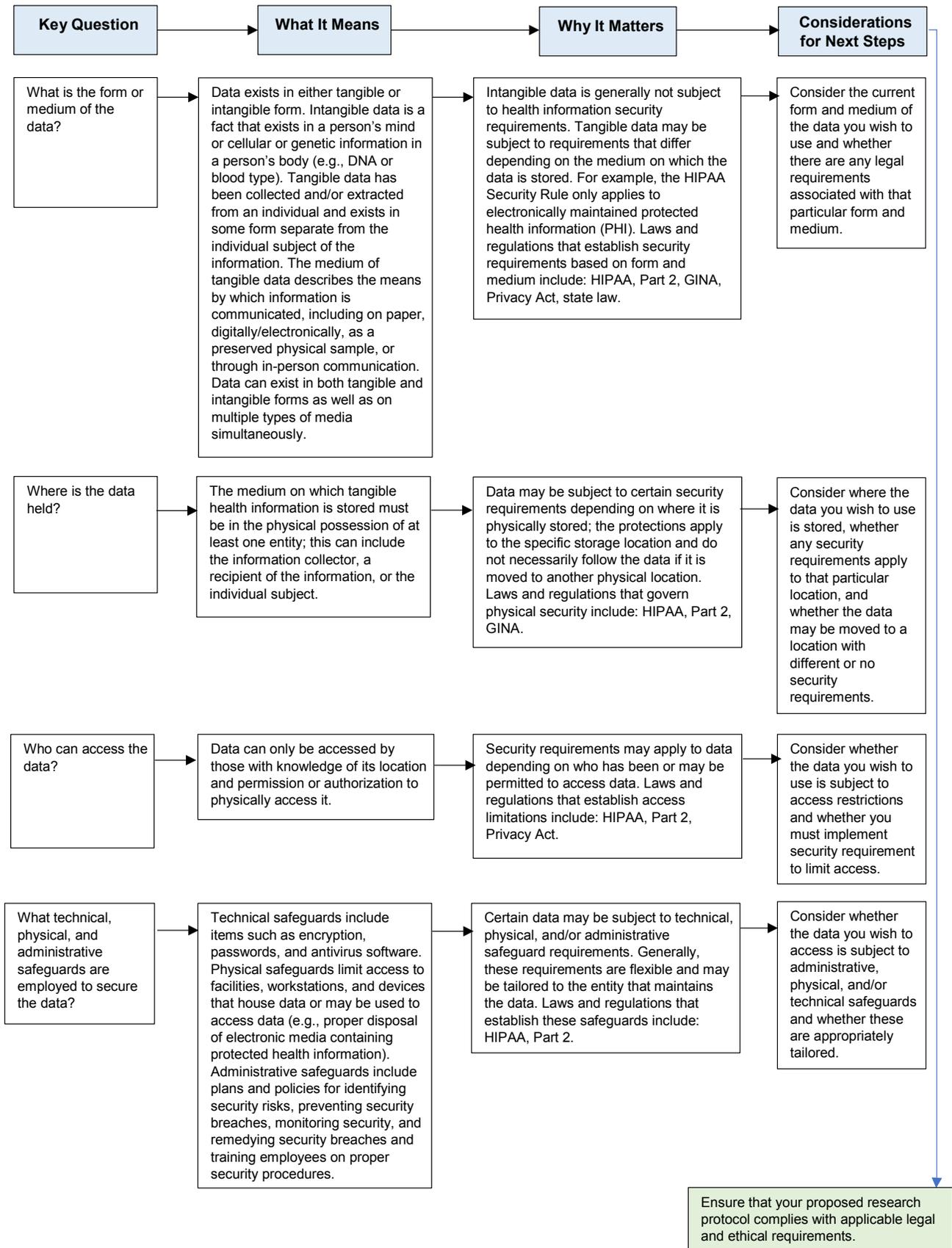
Data Characteristic 8: Security



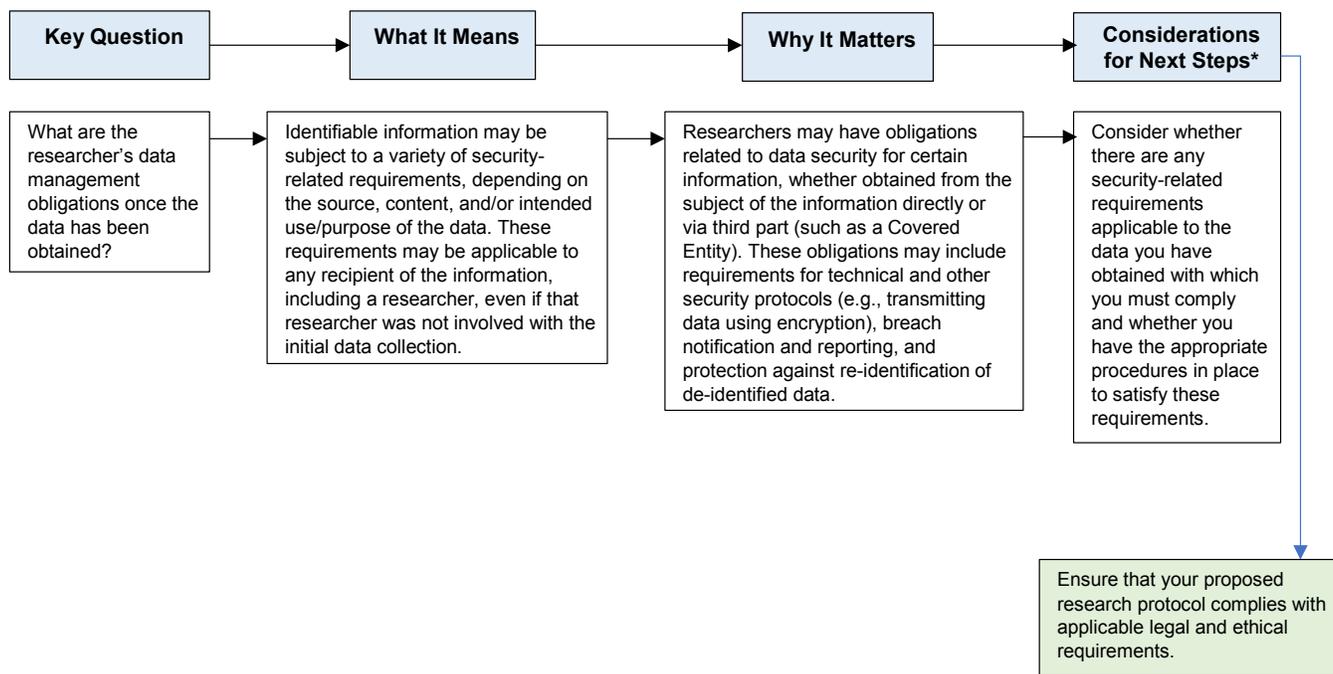
Security

Security refers to the means by which data is protected from unauthorized use or access.

Security pg. 2

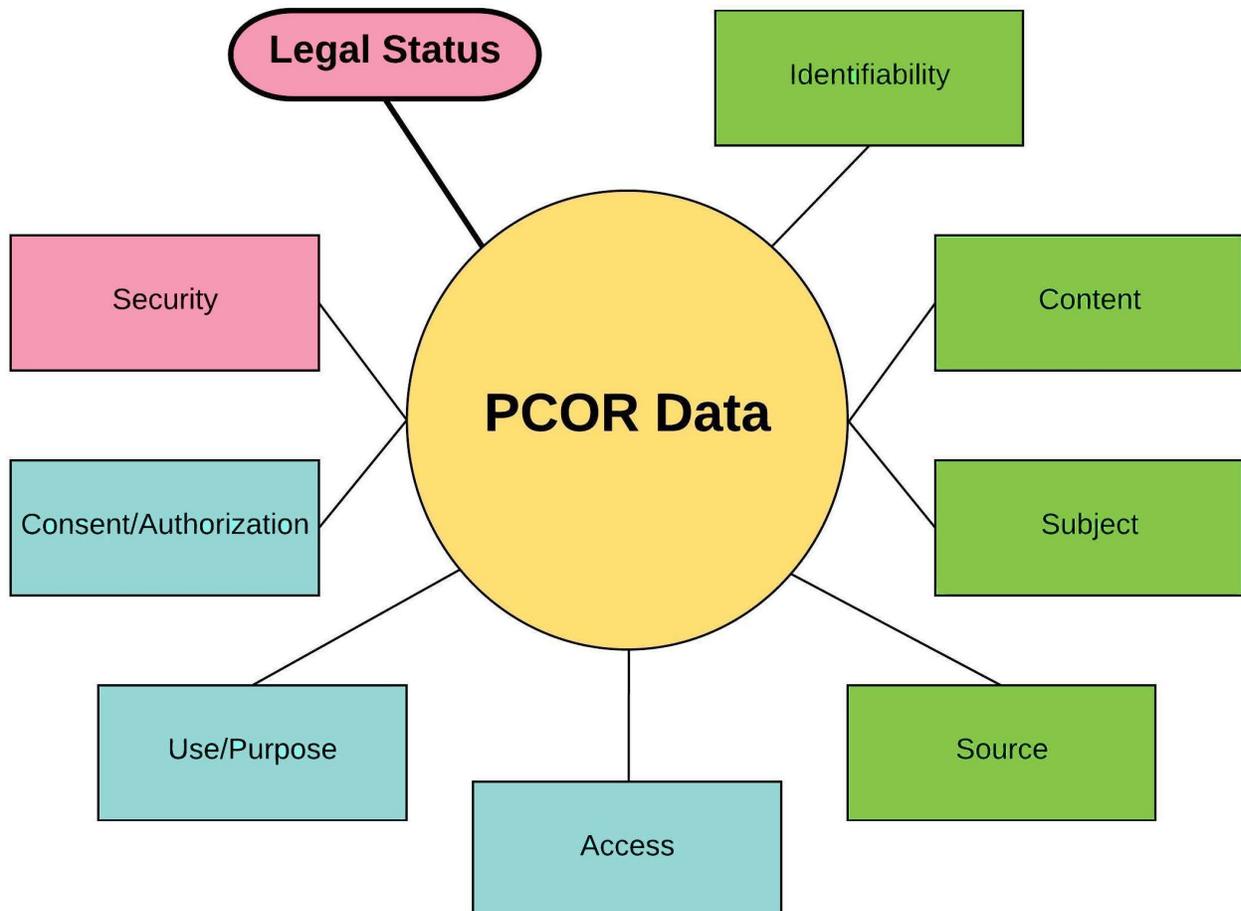


Security pg. 3



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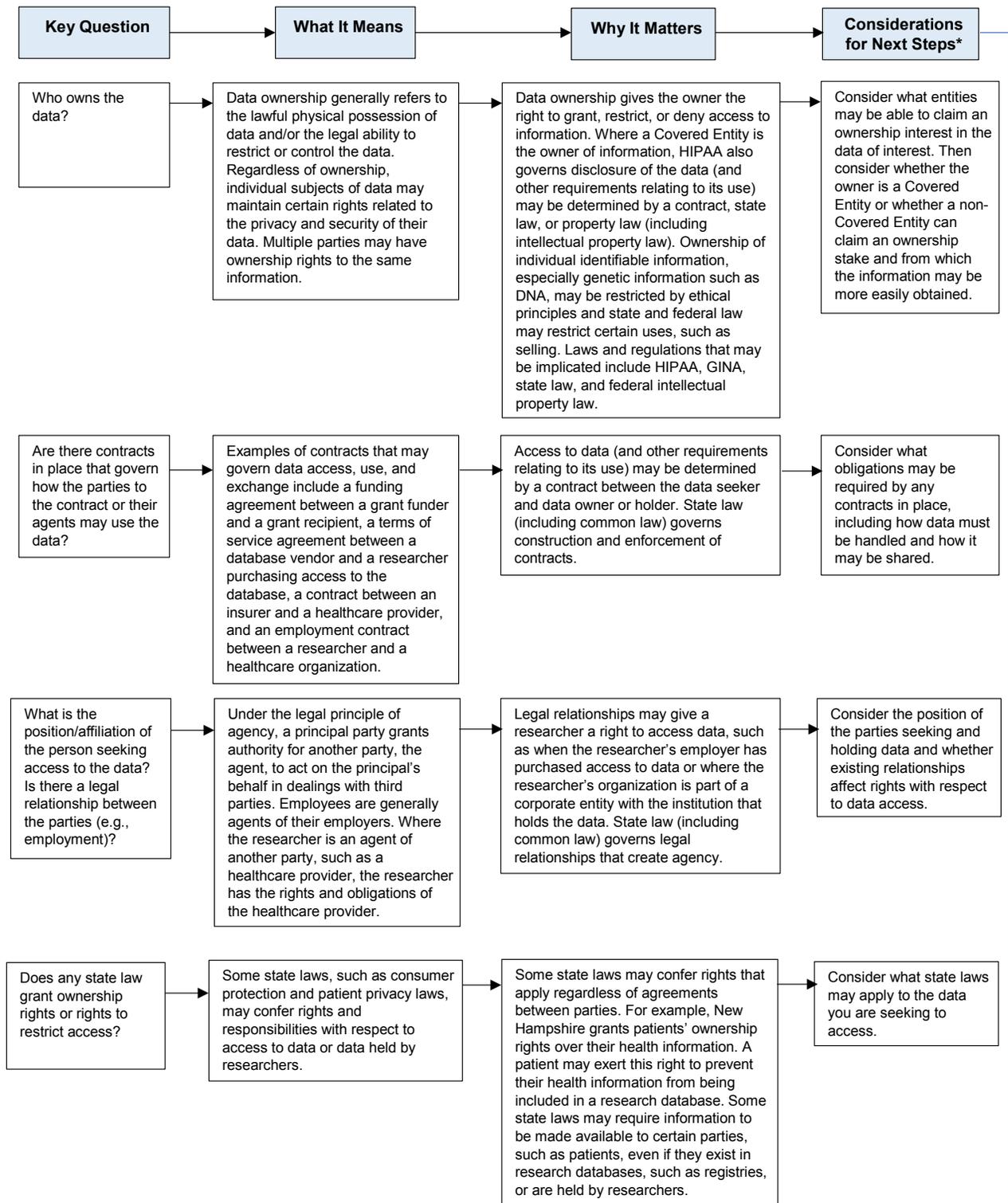
Data Characteristic 9: Legal Status



Legal Status

Legal Status refers to rights and responsibilities related to the data that may be triggered by ownership rights, agency principles, and/or contractual obligations.

Legal Status pg. 2



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