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Beginners Guide to Biometric and Forensic Science Human Subjects Research Protections

William Chapman
R. Austin Hicklin
Melissa Taylor

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Melissa Taylor
Forensic Science Research Program
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Author ORCID iDs
William Chapman: 0000-0002-6951-9826
R. Austin Hicklin: 0000-0003-2155-3432
Melissa Taylor: 0000-0002-4204-3864

Contact Information
Melissa.Taylor@nist.gov

Abstract

This document is designed to help researchers in the United States navigate and comply with requirements and best practices for human subjects research, with specific emphasis on biometric and forensic science research. The purpose of this document is to summarize requirements and best practices involved in Institutional Review Board (IRB) approval, consent forms, and data use agreements, when conducting biometric and forensic science research involving human subjects and distributing the resulting data. This document also provides a variety of resources from multiple sources to help navigate the IRB approval process. The process of beginning a human subjects research project requires several considerations to be made to protect the rights of the participants including approval by IRBs; writing, releasing, and collecting consent forms; and collecting, documenting, and using data for the execution of the research and the potential publishing of the findings.

Keywords

Biometrics; forensic science; human subjects, research.

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1. Introduction

Embarking on a project that involves human subjects research requires careful planning to protect the rights of the participants. Several actions must be taken before a human subjects research project can be started: development of plans for the collection, documentation, and use of research data including plans for distribution and publication; development of research subject recruitment and consent processes and forms; and obtaining Institutional Review Board (IRB) approval. This document summarizes the requirements and best practices involved in IRB approval, unique consent considerations, and data use agreements when conducting biometric and forensic science research involving human subjects and distributing the resulting data within the United States. This document also provides a variety of resources to help navigate the IRB approval process.

The U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP), National Institutes of Health (NIH), the World Health Organization (WHO), and the Food and Drug Administration (FDA) provide a wealth of human subjects research information to researchers in fields such as medicine, behavior, food and drug development, or education. While general regulations established by the aforementioned organizations apply to human subjects research in the fields of biometrics and forensic science, there may be specific questions or concerns that arise which are not well documented as these organizations do not specifically address biometric and forensic science research. This document intends to close this gap by offering a variety of guidelines that can be applied to biometric and forensic science research involving human subjects.

This document was written based on publicly available information from multiple sources, as well as from the input of experts in the field of human subjects regulations. This document compiles information from these sources into a single source to serve as a toolkit that:

- Helps the reader navigate the process of setting up, performing, and publishing research involving human subjects;
- Suggests methods for handling and potentially distributing collected data for use by third-party researchers; and
- Provides resources for identifying appropriate IRB processes, preparing IRB documents, developing data use agreements, and licensing data for third-party use.

While this document provides best practices in human subjects research, it is imperative that researchers follow the policies established by their respective institutions as those are the policies the research will be bound by.

2. Key Concepts

It is necessary to understand several concepts when approaching human subjects research. This section explores several terms and phrases used throughout this document. Developing an understanding of these concepts is important in the planning, execution, and follow-up of research involving human subjects.

2.1. The Belmont Report

Regulation of human subjects research in the United States can be traced back to the 1974 National Research Act, which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In 1978, the Commission released its report, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" which is generally referred to as "the Belmont Report." The Belmont Report [1] outlines three basic principles that are central to the ethics of research involving

human subjects and aiding Institutional Review Boards in ensuring the rights and welfare of research participants are protected. The three principles of The Belmont Report are:

- Respect for persons,
- Beneficence, and
- Justice.

2.1.1. Respect for Persons

Respect for persons states that (1) individuals must be treated as autonomous entities and (2) individuals with diminished autonomy (vulnerable populations) must be protected.

Respect for persons demands that subjects enter research voluntarily and with adequate information about the research being performed. This is complicated in cases where subjects could be subtly coerced or influenced (such as prisoners) when they would have otherwise not volunteered. Thus, vulnerable populations must be protected.

2.1.2. Beneficence

Beneficence works to secure the well-being of a subject and to generate knowledge that is scientifically significant and socially important. The two rules of Beneficence are (1) do not harm and (2) maximize potential benefits while minimizing potential risks. Researchers must consider how the benefits of their effort can be maximized while keeping the risks to the human subject at a minimum to avoid physical, emotional, reputational, or other kinds of harm.

2.1.3. Justice

The principle of Justice demands that the burdens and benefits of research be evenly distributed. For example, it would be against this principle to select a group of participants to bear the burdens of the research while another, uninvolved group, reaps the benefits.

The Belmont Report remains one of the leading works concerning ethics and human subjects research. It provides an ethical framework for researchers and should be reviewed and understood prior to embarking on research involving human subjects. The full report can be found online courtesy of HHS [1].

2.2. Federal Policy for the Protection of Human Subjects ('Common Rule')

The current U.S. system of protection for human research subjects is heavily influenced by the Belmont Report. In 1981, HHS and FDA worked to harmonize their existing human subjects regulations under their respective statutory authorities. This effort laid the groundwork for the creation of the Federal Policy for the Protection of Human Subjects or the “Common Rule” that was first published in 1991.

The Common Rule:

- Describes the types of research subject to regulation,
- Defines key terms such as research, human subject and minimal risk,
- Requires a written assurance of compliance with the common rule,
- Sets forth requirements for an Institutional Review Board’s (IRB) membership, authority, review procedures, records and criteria for approval, and
- Lists the general requirements for informed consent.

The initial version of the Common Rule was amended in 2005 and 2009. This 2009 publication is referred to as the "pre-2018 Common Rule." A later revision was published in January 2017, with amendments in 2018 and an effective date of January 2019. The later revision is referred to as the "Revised Common Rule" or the "2018 Common Rule".

20 Federal agencies (including HHS) intend to follow the revised Common Rule. Each of the signatory agencies have incorporated the policy into its own Code of Federal Regulations (CFR). For example, the HHS codification is at Title 45 CFR Part 46 Subpart A (45 CFR §46) and the Veteran Administration including it in Title 38 CFR Part 16 (38 CFR §16). Human subject research conducted or supported by a federal agency is governed by the regulations of that agency. The head of that agency retains final judgment as to whether a particular activity it conducts or supports is covered by the Common Rule.

If an institution seeks guidance on implementation of the Common Rule and other applicable federal regulations, the institution should contact the agency conducting or supporting the research.

2.3. Institutional Review Board (IRB)

An IRB [2,3] is an administrative body, independent of the research effort, established to protect the rights and welfare of human research subjects. It is a collection of individuals from a variety of academic disciplines with both scientific and non-scientific backgrounds. An IRB is tasked with reviewing all projects involving human subjects to ensure compliance with federal regulations; institutional policies; state, local, and federal laws; and ethical principles.

2.3.1. IRB Authority

An IRB has the authority to:

- Approve research
- Disapprove research
- Modify or require modifications of research
- Suspend or terminate approval of research
- Conduct continuing reviews as deemed necessary
- Observe/verify changes to research
- Observe the consent process and research procedures

2.3.2. IRB Composition

The Common Rule (45 CFR §46.107) [4] sets the following requirements for the composition of an IRB. An IRB must:

- Have at least five members with varying backgrounds, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote a complete and adequate review of the research activities commonly conducted by the institution;
- Make every nondiscriminatory effort to ensure gender diversity;
- include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas;
- include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution;

- not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest; and
- have knowledge and experience with vulnerable populations.
    - Note that if a project involves vulnerable populations, the IRB is encouraged to include an individual with knowledge and expertise in working with those populations. Necessary expertise may also be obtained using consultants.

2.4. Research

Research is defined by 45 CFR §46.102 [5] as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

Research does not include the following activities:[a]

- Scholarly or journalistic activities
- Public health surveillance activities
- Activities conducted for criminal justice or investigative purposes (collection and analysis of information, biospecimens, or records)
- Authorized operational activities in support of intelligence, homeland security, defense, or other national security missions

Within the definition of research, there are some additional important phrases to understand, as discussed in the following sections.

2.4.1. Systematic Investigation

A "systematic investigation" is a methodological approach for collecting and analyzing data to answer a scientific question. Such approaches may include surveys and questionnaires, interviews and focus groups, analysis of existing data, evaluations of programs, or approaches specific to the scientific domain in which the research is conducted.

2.4.2. Designed to Develop or Contribute to Generalizable Knowledge

This phrase deals mainly with the intent of the research. Is the intent of the research to produce results that contribute to a larger body of knowledge for the public good? Or is the intent limited to improving your institution's internal procedures (i.e., the results of your research would not have a discernible benefit to other institutions)? The intent to contribute to a general body of knowledge is a key factor in determining whether your efforts meet the definition of research.

2.5. Human Subject

The specific definition of the term "human subject" varies among agencies depending on whether a given agency has adopted the 2018 Revised Common Rule or continues to observe the pre-2018 Common Rule.

The 2018 Revised Common Rule defines a human subject as:

> "a living individual about whom an investigator (whether professional or student) conducting research:

[a] These exclusions are specific to the 2018 Revised Common Rule, which has not been adopted by all Federal agencies: see Sections 2.2 and 3.5.1 for more details.

(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(e)) [5]

In the pre-2018 Common Rule, a 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." (45 CFR §46.102(f), 2009) [6]

The definition of a human subject can be broken down into individual concepts that make it easier to understand, as defined in the following sections.

2.5.1. Living individual

A human subject must be a living individual. Deceased subjects would not meet the definition of a human subject, however, there are other restrictions for deceased subjects that need to be observed (discussed in Section 3.5.3).

2.5.2. About Whom

For the research activity to meet the federal definition of human subject research, the information collected must be about the individual. Your research may require the collection of general information on a topic: How many routine visits occur weekly? How many surgeries are performed monthly? These questions are "about what" rather than "about whom." Conversely, if the collection focuses on information about an individual's opinions, experiences, or background, or if you are collecting biospecimens from individuals, you are collecting information "about whom."

2.5.3. Intervention

Intervention includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

2.5.4. Interaction

Interactions include communication or contact between researchers and subjects. This is not limited to face-to-face contact: a phone call, email or paper mail, online surveys, etc., could be considered interactions.

2.5.5. Identifiable Private Information

According to 45 CFR §46.102 [5], identifiable 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."
- "Information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)."

To meet the definition, the information must also be individually identifiable meaning a single piece of information (e.g., name or social security number) or pairings of information (a subject ID linking to a subject name) could be used to identify the individual.

2.6. Samples and Specimens

In biometrics and forensic science research, you may often use the term "sample" to refer to collected data (e.g., fingerprint sample or fiber sample). As you begin your research effort, you may instead see the term "specimen" used throughout the regulations you will encounter. In these cases, consider "sample" and "specimen" to mean the same thing.

2.7. Personally Identifiable Information (PII)

PII is "any information about an individual maintained by an agency, including

- Any information that can be used to distinguish or trace an individual's identity, such as name, social security number, date and place of birth, mother's maiden name, or biometric records; and
- Any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information." [5]

2.8. Coded Information

There are two parts to the definition of "coded":

1. Identifying information or specimens that would enable an investigator to easily identify a subject have been replaced with a number, letter, or symbol (or combination of any of the three) to create a "code" and
2. A key to decipher the code exists which would enable an individual to be linked to the identifying information or specimen.

Coding systems may be used as a method of deidentifying collected data to both facilitate data analysis and protect the identity of the subjects. OHRP offers guidance on the use of coded data or specimens.

2.9. Investigator

An investigator in a research effort is an individual involved in the collection and analysis of data or the writing of papers or presentations related to the research effort. An individual who simply provides information or specimens in support of the research would not qualify as an "investigator" unless that individual is also involved in the aforementioned activities.

2.10. Informed Consent

Ethical considerations of human subjects research, in addition to Federal/State/Business/Academic regulations, require researchers to obtain informed consent from all human subjects taking part in research studies. The informed consent process includes:

- Providing information about the study in a language the prospective subject can easily understand,
- Answering questions prospective subjects may have regarding the research,
- Providing sufficient time for a prospective subject to consider their decision(s), and
- Obtaining voluntary agreement of the subject's willingness to join the study.

A consent form is typically used as a tool to both communicate pertinent information about the study to the prospective subject as well as obtain documentation of their consent via signature. Other forms of informed consent may be audio or video recordings, as approved by your IRB.

3. Getting Started

This section contains general guidance on what is required to perform human subjects research. These requirements depend, in part, on whether your research is funded by a Common Rule agency[b] as those agencies will have strict federal guidelines on what is necessary. If you are privately funded, the guidelines may not be as strict, though you will still be required to follow policies set forth by the organizations funding your research (either internal or external) as well as any federal, state, or local laws that may exist. Researchers must always work closely with their organization to ensure policies are properly understood and observed.

When beginning a project that potentially involves human subjects research, several questions need to be considered:

1. Is this research?

[b] With the 2018 Common Rule update, organizations may follow the pre-2018 Common Rule or the Revised Common Rule. It is important to defer to your representative organization to know which Common Rule must be observed.

2. Does it involve human subjects?
3. Is an Institutional Review Board (IRB) required?
4. Is a consent form required?
5. What are the relevant regulations?

3.1. Is this Research?

The first question to consider is whether the activities you will be performing fall under the definition of "research." Is it a systematic investigation? Does it involve the development, testing, and evaluation of information or data? Is your intent to contribute to a general body of knowledge for the benefit of science or the public? If you can answer yes to all of these questions, then your project meets the definition of research.

3.2. Does it Involve Human Subjects?

Some organizations have an internal official that is responsible for making the human subjects research determinations while others may use an external body to make such determinations such as an IRB. It is the responsibility of the researchers, specifically the appointed principal investigator, to ensure their research is reviewed by the appropriate individuals. While the final decision of whether your research can be classified as "human subjects research" or not must be made by an authorized representative within your organization, there are some key points that researchers should consider.

One point to understand is how the collection of identifiable or potentially identifiable information can impact the human subjects research determination. For example, researchers may observe the number of individuals that enter a specific site over the course of a week. In this case, the researchers are collecting information about the individuals and the researchers are not interacting or intervening with individuals. This activity would not involve "human subjects" and would likely be determined to not be "human subjects research" classification. Conversely, if the researchers ask these same individuals to provide personal information, the researchers are now interacting with the individuals. In this case, the research would involve human subjects and may be subject to Common Rule (or organizational equivalent) regulations (see Section 3.5.1). Taking this example one step further, if identifiers were collected for one purpose but all data was provided to researchers without the identifiers, this may be considered "Not Human Subjects Research" (NHSR).

In short, determining whether your research involves human subjects requires careful consideration of how data is collected (does it involve interaction or intervention?) and the types of information collected (are you collecting potentially identifiable information from subjects?). As always, it is vital that researchers work with their IRB to ensure the proper classifications are applied to research efforts.

3.3. When is IRB Review Required?

An IRB is an administrative body established to protect the rights and welfare of human research subjects. The IRB has the authority to approve, disapprove, or otherwise monitor research activities that fall within its jurisdiction. In general, any research involving human subjects that does not meet the criteria for one of the exempt categories must be reviewed by the IRB. Some human subjects research may be determined to be exempt from the requirements of the Common Rule and further IRB review, except in cases where a limited IRB review is indicated. The 2018 Revised Common Rule lists the following eight categories of human subjects research as being exempt: (45 CFR §46.104) [7]

1. Research in conventional education settings

2. Research that involves educational tests, survey procedures, interview procedures, or observation of public behavior
3. Research involving benign behavioral interventions
4. Secondary research using identifiable private information or identifiable biospecimens under certain conditions
5. Research or demonstration projects by or for Federal agencies using data collected for or by the federal government under certain conditions
6. Taste and food quality studies
7. Storage or maintenance of identifiable private information or biospecimens collected under broad consent and with limited IRB review
8. Storage or maintenance of identifiable private information or biospecimens collected under broad consent and with limited IRB review or other IRB review

Whether your research is exempt or non-exempt is a decision strictly made by an IRB representative. Even if you think your research may be exempt, a qualified expert in your IRB Office will need to review your research to make the final determination. In the event no IRB exists, your organization may need to consider establishing its own, seeking a partnership with an organization that has an already established IRB, or seeking commercial IRB solutions. See Section 4 (IRB Process) for more information on options for IRB oversight.

3.4. When is a Consent Form Required?

As noted in Section 2.10, the informed consent process includes:

- Providing information about the study in a language the prospective subject can easily understand,
- Answering questions prospective subjects may have regarding the research,
- Providing sufficient time for a prospective subject to consider their decision(s), and
- Obtaining voluntary agreement of the subject's willingness to join the study.

A consent form is typically used as a tool to both communicate pertinent information about the study to the prospective subject as well as obtain documentation of their consent Whether a consent form is required is strictly at the discretion of the IRB reviewing your research effort. Typically, if your research requires IRB oversight, you will need to prepare and distribute a consent form for prospective participants to read and sign. If your research is exempt human subjects research, the IRB will then determine whether a consent form is necessary [8]. It is also possible that the IRB may waive the consent requirement if certain conditions apply. For more information on writing a consent form, see Developing the Consent Form (Section 5).

3.5. What Regulations Apply to My Research?

The relevant regulations that will need to be observed are generally dictated by the organization conducting the research, the agency funding the research, and (in some cases) the state in which the research is being conducted. For example, if your research is funded by, or is being performed within, one of the organizations that observes the Common Rule (see Section 2.2), these regulations will apply to your research. There are a variety of additional regulations that may need to be observed depending on the nature and potential subjects of your research. This section covers several (but not all) regulations that could impact your research depending on the nature of the information to be collected.

3.5.1. The Common Rule, Revised Common Rule, and Agency-Specific Rules and Forms

One of the ways in which the federal research community promotes uniformity among departments and agencies under the Common Rule, is to require that applicants submit the *Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form—Extension* (OMB No. 0990–0263), which exists to help with the process to determine whether a project qualifies as human subjects research. The OMB No. 0990–0263 form helps to "ensure common means of ascertaining institutional review board certifications and other reporting requirements relating to the protection of human subjects in research." Before engaging in non-exempt human subjects research that is conducted or supported by a Common Rule department or agency, each institution must: "(1) Hold an applicable assurance of compliance [Section 103(a)]; and (2) certify to the awarding department or agency that the application or proposal for research has been reviewed and approved by an IRB designated in the assurance [Sections 103(b) and (f)]." [41] This form would be included as a part of a funding application.

While most federal agencies have agreed to observe the 2018 Common Rule (see Section 2.2), it is important to note that some agencies may have agency-specific rules or have chosen to continue to use the pre-2018 Common Rule. Your funding organization or IRB will be able to help you determine whether the 2018 Revised Common Rule is being observed.

In addition to the Common Rule, each of the organizations listed here also has its own set of rules to be observed:

- Agency for International Development (USAID) (22 CFR §225) [10]
- Consumer Product Safety Commission (16 CFR §1028) [11]
- Department of Agriculture (7 CFR §1c) [12]
- Department of Commerce - National Institute of Standards and Technology (15 CFR §27) [13]
- Department of Defense (32 CFR §219) [14]
- Department of Education (34 CFR §97) [15]
- Department of Energy (10 CFR §745) [16]
- Department of Health and Human Services (45 CFR §46) [17]
- Department of Housing and Urban Development (24 CFR §60) [18]
- Department of Justice - National Institute of Justice (28 CFR §46) [9]
- Department of Labor (29 CFR §21) [19]
- Department of Transportation (49 CFR §11) [20]
- Department of Veterans Affairs - Office of Research Oversight - Office of Research and Development (38 CFR §16) [21]
- Environmental Protection Agency - Research and Development (40 CFR §26) [22]
- Homeland Security (6 CFR §46) [23]
- National Aeronautics and Space Administration (14 CFR §1230) [24]
- National Science Foundation (45 CFR §690) [25]
- Social Security Administration (20 CFR §431) [26]

If you take direction or funding from any of the organizations listed above, the Common Rule applies to your research, including any modifications specific to that agency's variation of the Common Rule.

The Food and Drug Administration (FDA) is an agency within the Department of Health and Human Services, but its regulations differ from the Common Rule and FDA is therefore not considered a Common

Rule agency. However, they are required to follow the Common Rule whenever permitted by law. For more information on FDA regulations, see the FDA Code of Federal Regulations Title 21 [27].

Both the Office of the Director of National Intelligence (ODNI) and the Central Intelligence Agency (CIA) are Common Rule agencies under Executive Order 12333 [28] but do not, at this time, have a Code of Federal Regulations that can be cited. Executive Order 12333 (Part 2.10) states "Human Experimentation. No agency within the Intelligence Community shall sponsor, contract for or conduct research on human subjects except in accordance with guidelines issued by the Department of Health and Human Services. The subject's informed consent shall be documented as required by those guidelines." [28] If you work with one of these agencies, speak with your IRB representative to learn more.

If you do not take direction or funding from any organization listed above, your organization may have established its own human subjects research regulations. It is also possible for your organization to observe the Common Rule as a best practice. If you are uncertain, speak to your appointed IRB or human subject research authority to learn about which regulations apply to your research.

3.5.2. Regulations for Vulnerable Populations

Some federal agencies and departments have regulations for the protection of vulnerable subjects; many agencies and institutions follow these regulations as a matter of policy. While there may be some additional policies in place to be observed, these agencies generally use the following regulations:

- Pregnant Women: HHS 45 CFR §46 Subpart B [29] outlines rules regarding pregnant women, human fetuses, and neonates (nonviable and uncertain viability).
- Prisoners: HHS 45 CFR §46 Subpart C [30] outlines rules regarding prisoners.
- Children: HHS 45 CFR §46 Subpart D [31] outlines rules regarding children.

It is important to work with your organization to determine whether additional policies apply to these, or other unlisted, vulnerable subjects.

3.5.3. Research Involving Deceased Subjects

Under federal regulations, research involving deceased subjects is not considered "human subjects research" as the term "human subject" only covers living individuals[c]. Depending on the data being collected, there are other issues researchers need to consider when working with deceased subjects:

- The health information of deceased individuals is protected under federal and state regulations for 50 years after death. If the health information associated with the data is "protected health information" (PHI) — which is the health information protected under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule — then researchers will need to ensure their research complies with the HIPAA Privacy Rule.
- IRB oversight is needed if the information collected from a cadaver will result in an investigator obtaining information about the cadaver's living relatives (e.g., genetic studies). Activities in which a researcher collects private, identifiable information about third parties may meet the definition of human subjects research.
- If the research includes a mix of living and deceased individuals, the research will need to comply with HIPAA regulations and will be subject to IRB oversight.

[c] If OJP-funded biometric or forensic science research involves deceased subjects or samples from deceased subjects, 28 CFR §22 [8] becomes relevant so that a privacy certificate is required to protect the PII.

3.5.4. State Regulations and Other Requirements

In addition to federal regulations, states may have their own regulations that must be observed when performing research involving human subjects. Universities, corporations, and federal agencies may have additional organization-specific requirements. It is important to understand how these regulations and requirements may further impact your human subjects research effort. Your IRB will review your research plans in accordance with your state's regulations, as well as organizational requirements.

3.5.5. Health Insurance Portability and Accountability Act (HIPAA)

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a United States regulation intended to provide data privacy and security provisions for safeguarding individuals' medical information. The HIPAA Privacy Rule [32] establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. Depending on the nature of your research, you may be bound by the HIPAA Privacy Rule, in addition to the regulations set forth by your representing organization.

More on this can be found on the Department of Health and Human Services HIPAA for Professionals webpage [33].

3.5.6. Privacy Act of 1974

The Privacy Act of 1974 "establishes a code of fair information practices that governs the collection, maintenance, use, and dissemination of information about individuals that is maintained in systems of records by federal agencies." [34]

More information can be found on the U.S Department of Justice's Privacy Act of 1974 webpage [34].

3.5.7. Children's Online Privacy Protection Act (COPPA)

In cases where research data may be sought through the internet from children under the age of 13, the Children's Online Privacy Protection Act must be implemented.

More information can be found on the Federal Trade Commission's *Complying with COPPA: Frequently Asked Questions* webpage [35] and COPPA webpage [36].

3.5.8. Family Education Rights and Privacy Act (FERPA)

Research efforts that rely on the collection of education data such as truancy records, grades, disciplinary records, etc., must adhere to the Family Education Rights and Privacy Act.

More information can be found on the U.S Department of Education's FERPA webpage [37].

3.5.9. The Protection of Pupil Rights Amendment (PPRA)

Schools must obtain parental approval for children in grades K-12 to participate in surveys, analysis, or evaluations when the following topics are discussed:

- Political affiliations or beliefs of the student or student's parent;
- Mental or psychological problems of the student or student's family;
- Sexual behavior;

- Illegal, anti-social, self-incriminating, or demeaning behavior;
- Critical appraisals of others with whom respondents have close family relationships;
- Legally recognized privileged relationships, such as with lawyers, doctors, or ministers;
- Religious practices, affiliations, or beliefs of the student or parents; or
- Income, other than as required by law to determine program eligibility.

More information can be found on the U.S Department of Education's PPRA webpage [38].

3.5.10. Paperwork Reduction Act (PRA)

The Paperwork Reduction Act (44 U.S.C. § 3501 et seq.)[39] imposes procedural requirements on federal agencies – or on behalf of federal agencies – seeking to collect information from the public. Before requesting or collecting information from the public, federally funded researchers must obtain the proper Office of Management and Budget (OMB) form to proceed.

More information on the Paperwork Reduction Act can be found on the Justice Information Sharing [40] site provided by the U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Assistance.

3.5.11. Office of Justice Programs (OJP) Privacy Certificate and Confidentiality Requirements

If human subjects research is funded by any Office of Justice Programs agency within the Department of Justice (DOJ),[d] researchers need to be aware of the OJP policy for protecting the privacy of individuals according to 34 USC 10231(a) [42] and the *Confidentiality of Identifiable Research and Statistical Information* in 28 CFR §22 [8]. These regulations:

1. Protect the privacy of individuals by limiting the use of private, identifiable information for research or statistical purposes.
2. Protect private information provided by individuals from use in any judicial, legal, or administrative process without the individual's prior consent.
3. Improve the scientific quality of NIJ research programs by minimizing the subject's concerns over the use of the data.
4. Clarify for researchers the limitations on the use of privately identifiable information for only research or statistical purposes.
5. Ensure that our understanding and knowledge of the broad criminal justice system will continue to advance by providing individual privacy protections. [43]

See the *NIJ Confidentiality and Privacy Protections* webpage for more information.[43]

3.6. Reporting Incidents

For research under the Common Rule or research under a Federalwide Assurance (FWA),[44] the US Department of Health and Human Services offers guidance on procedures institutions may use to file incident reports with OHRP [45]. For organizations not under the Common Rule or FWA, your organization should have procedures for reporting incidents. For organizations that do not yet have a procedure in place,

[d] Office of Justice Programs agencies include the National Institute of Justice, the Bureau of Justice Statistics, the Bureau of Justice Assistance, the Office for Victims of Crime, the Office for Juvenile Justice and Delinquency Prevention, and the Sex Offender Sentencing, Monitoring, Apprehending, Registering, and Tracking (SMART) Office.

the HHS guidance may serve as a starting point for establishing proper incident reporting procedures. For clarification, incidents are not only situations in which a human subject is harmed or personal information is compromised. One of the most common incidents that can occur is an investigator changes the research activity in some way without prior approval from the IRB. Most institutions require prior approval of study changes regardless of IRB-approval status. Proposed study changes may impact the human subjects determination, so it's imperative that changes are appropriately reviewed and approved prior to initiating the changes, unless the change is being made to avoid an immediate hazard to subjects. When the IRB is separate from the funding agency (i.e., when a separate agency is funding the effort) sometimes the change is approved by the IRB, but the funding agency has not yet been notified. Both need to be aware of the change before you can proceed. Failure to inform your IRB and associated organizations of changes to the protocol can result in fines, suspension of the research effort, and in more severe cases, discontinuation of current and future approvals.

4. IRB Process

This section outlines considerations that should be made for selecting an IRB, preparing necessary application documents, and other potential requirements such as obtaining a FWA or specific training necessary for conducting human subjects research. Before beginning the IRB process, it is recommended that research teams visit *Office for Human Research Protections (OHRP) Database for Registered IORGs & IRBs, Approved FWAs, and Documents Received in Last 60 Days*.[46] This system can help organizations determine whether an OHRP-registered IRB or FWA is on file for a specified organization. Note that this system only includes OHRP-registered organizations and therefore your organization's IRB may not appear in the search.

4.1. Selecting an IRB

Selecting an IRB can be a daunting and frustrating process, especially when an internal IRB is not an option. Todd W. Rice's *How to Do Human-Subjects Research If You Do Not Have an Institutional Review Board* [47] is a great resource for navigating some options for organizations that do not have an IRB or equivalent within their organization. In general, there are three options for identifying an appropriate IRB:

- Internal — If your organization already has an established IRB or an equivalent contact such as a Human Subjects Research Officer, you will want to start by speaking with them to determine what is necessary.
- Partner Organization — If an internal IRB is not available, you may be partnered with an organization that can provide IRB oversight. If you are not already partnered, you may consider partnering with a nearby organization that has an established IRB such as a university, medical facility, or other research organization.
- Commercial IRBs — If working with an internal IRB or a partnered IRB is not an option, seeking help from a third-party, commercial IRB is an option for getting your research reviewed. Citizens for Responsible Care and Research (CIRCARE) have compiled a list of commercial IRB options across the United States. CIRCARE's website [48] also provides additional resources for locating IRBs that are not included on their list.

4.2. Single IRB Requirement

Beginning January 20, 2020, the new Common Rule requires the use of a Single IRB (sIRB) when more than one institution is involved in a research project (i.e., multi-site research studies) funded by a Common Rule organization. Note that this requirement does not affect studies funded by agencies that have not signed

on to the new Common Rule. You can find more information about this requirement from OHRP's Single IRB Exception Determinations website [49] and by speaking with your human subjects protection representative.

4.3. Preparation

Once you have identified the IRB you will work with, there will be a variety of documents that will need to be filled out and submitted for the IRB to begin reviewing your proposed research project. The documents necessary will vary from IRB to IRB but there are a few items to consider that will help prepare you for document submission.

4.3.1. IRB Application

All IRBs will have their own application that will need to be filled out by the principal investigator and, depending on the requirement of the application, the research team. When selecting your IRB, it is important to understand what types of information will be required by the application so your teams can begin preparing as early as possible. Many commercial IRBs post copies of their applications so you can familiarize yourself with the process before applying.

4.3.2. Federalwide Assurance (FWA)

When working with common rule agencies, you may be required to obtain a federalwide assurance for your organization. The FWA is the only type of assurance accepted and approved by OHRP and signifies a commitment by the institution, that it will comply with the requirements set forth by the Common Rule. If an FWA is required by the funding agency or IRB, researchers will need to use the OHRP's Electronic Submission System for FWAs and IRB Registrations [50] to submit, update, and/or renew an organization's FWA and IRB registration.

4.3.3. Training

In certain cases, you may be required to complete specific training before engaging in human subject research activities. The requirement for training will vary by organization but it is a good idea to determine whether training is required before getting started, how long that training will take, and whether there are associated costs. Understanding this information before you begin will help you better plan the schedule, costs, and personnel.

The Office for Human Subjects Research Protections also provides free online education [51] to help IRB members and administrators, investigators, and institutional officials. This is an excellent resource for new researchers wanting to learn more or for researchers who are looking to expand their understanding of human subjects research protections.

4.3.4. Additional Regulations

As outlined in Section 3.5, there are a variety of additional regulations that may apply to your research depending on its goals. Each of these regulations may have its own forms that need to be filled out and submitted to the IRB for approval. Consider all the various regulations that could apply to your research and determine what other forms may be necessary. Your IRB will be able to help identify the specifics but having a basic understanding of what may be required before you begin can help you plan and avoid running into unforeseen roadblocks.

4.4. Continuing IRB Oversight

After the initial approval is received from your IRB, you can begin interacting with human subjects.[e] However, interaction with the IRB is an ongoing process. As outlined in Section 3.6 Reporting Incidents, communication with your IRB is required when protocol changes are proposed or when problems arise with the safety of the human subject and/or the data collected. Additionally, IRBs may require a continuing review, typically every year, to ensure all research is being performed in accordance with the previously approved protocols. If you are using a third-party IRB, consider the length of your research effort to determine expected costs for the initial and any ongoing reviews.

5. Developing the Consent Form

Unless your IRB, or equivalent official, has determined your research does not need a consent form, you will need to prepare and distribute a consent form for every prospective human subject in your study. As outlined in Section 2.10 - Informed Consent, the consent form is used as a tool to both communicate pertinent information about the study to the prospective subject as well as obtain documentation of their consent via signature. This section provides some tips on writing consent forms that comply with federal regulations as well as increasing the likelihood of participation from your prospective subjects.

5.1. Common Rule Required Items

This section provides an overview of the content that should be included in a consent form. Detailed information on these items can be found in HHS Title 45 CFR 46.116 – General requirements for informed consent [52]. In cases where HHS regulations do not apply, it is strongly recommended that the following HHS regulations be used as a best practice.

- A section describing the key information about the study. This may include purpose, risks, benefits, alternatives, etc., described clearly and concisely. In this way, prospective participants will be able to understand the basics of the consent form upfront, before going through the consent form in detail. Note that if the information included here satisfies the elements of informed consent under 45 CFR §46.116(b) and (c), these elements do not need to be repeated in the body of the consent form.
- A statement that the study involves research and an explanation of the purposes of the research.
- The expected duration of participation.
- A description of the procedures to be followed and identification of any procedures that may be experimental.
- A description of any reasonably foreseeable risks or discomforts to the subject. If there are no foreseeable risks or discomforts, note that so it is clear to the reader.
- A description of any direct benefits to the subject (e.g., monetary compensation) or to others that may reasonably be expected to benefit from the research.
- If there are no direct benefits, consider noting what you hope to learn or how learned information will contribute to the related field of study or the general population.
- If applicable, a description of alternative procedures that may be advantageous to the subject. This is often seen in medical studies where differing courses of treatment could be offered. However, if there exist alternate methods by which researchers may obtain the data they need, those methods should be included as alternatives.

[e] If OJP-funded, research activities may not begin until the IRB compliance documents and a privacy certificate have been submitted, reviewed, and approved in the Grants Management System.

- A statement describing how the confidentiality of records identifying the subject will be maintained, if applicable. This description must also consider state-mandated requirements. These requirements vary from state to state so it is important to understand the specific regulations in your area.
- For any research involving more than minimal risk, a description of treatment options and compensation should injury occur. This should also explain where information about those options may be obtained.
- Information about whom to contact with questions about the research and the research subjects' rights, as well as whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary and both refusals to participate or discontinuation of participation will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- A statement regarding whether participants' information or biospecimens collected as part of the current research might be stripped of identifiers and used for other research in the future. The purpose of this is to let participants know that their information may be used in future studies. If prospective participants do not agree to this potential, they may not want to participate in the study.

5.2. Common Rule Optional Items

While these are additional items to be included as appropriate according to the Department of Health and Human Services, the authors of this document recommend the first four bullets be included in any consent form for biometric or forensic science research. As such, those bullets have been italicized for emphasis. Considerations for other elements are encouraged.

- *A statement that the procedure may involve risks to the subject which are currently unforeseeable (i.e., additional risks may come up over the course of the study but are currently unknown, and have no way to be known, by the principal investigator and/or research team)*
- *Anticipated circumstances under which the subject's participation may be terminated by the investigator regardless of the subject's consent*
- *Any additional costs to the subject that may result from participation in the research*
- *The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject*
- A statement that significant new findings developed during the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
- The approximate number of subjects expected to be involved in the study
- The 2018 Revised Common Rule also adds three new items including:
  - A notice about possible commercial profit,
  - A notice about whether clinically relevant research results will be returned to the subjects, and
  - A notice about whether research activities will or might include whole genome sequencing

5.3. Types of Human Subjects in Biometric or Forensic Science Research

When developing your consent form, consider whether there are situations that would apply to some participants and not others (e.g., employees who may serve as research subjects and could be more vulnerable to coercion/undue influence; in such situations ensuring the research lead/principal investigator does not invite anyone who reports to him/her to participate would be critical). Depending on the nature of your research, a single consent form may not serve as a one-size-fits-all solution.

While you may not need separate consent forms for each of these individuals from the perspective of the Common Rule, certain individuals may be more likely to participate in the research effort if they had a

consent form tailored to specific requirements. For example, in a test in which footwear data is collected to test footwear examiners, there may be two different categories of subjects:[f]

- Professional footwear examiners participating in the test want assurances of how this relates to them professionally.
- Volunteers who provide their own footwear want assurances that their property won't be damaged or limits on how their property will be used (e.g., footwear will not be used for official criminal investigation purposes).

Note from this example that the consent forms would need to address three types of possible risk: physical risk, professional risk, and property risk. In the context of the Common Rule, the risk to the human subject is always considered so making these additional considerations would not be necessary.

5.4. Participation vs Release of Data

While participants may be happy to provide their information to primary researchers as part of participating in a research study, those same participants may not want their data to be redistributed. Similarly, subjects may agree to provide their data for immediate research purposes but may not want their data used in the creation of datasets or retained for use in future research efforts by the primary or even secondary research team. Researchers need to consider potential uses of collected data that extend beyond initial collection and analysis and to include those anticipated uses in their consent forms so prospective human subjects can make an informed decision.

Under the 2018 Revised Common Rule, a statement regarding whether participants' information or biospecimens collected as part of the current research might be stripped of identifiers and used for other research in the future is required. The purpose of this is to let participants know that their information may be used in future studies. If prospective participants do not agree to this potential, they may not want to participate in the study.

5.5. Examples of Consent Forms

For an example/template of a consent form, see Appendix A.

6. Data Handling

The data that is collected during research efforts has the potential to be valuable for future research efforts within your organization or even for individuals outside of your organization interested in evaluating similar datasets. The data may also be subject to misuse which could compromise the integrity of your research and the privacy of your human subjects. This section covers precautions researchers should take to safeguard against misuse of collected data.

6.1. Protecting Human Subject Data

Improperly stored data can be compromised, and subjects may be put at risk of harm from a data breach. The development of safeguards for research data is an important aspect of protecting human subjects and their private identifiable information. Careful consideration should be given to deciding the type and amount of data needed to achieve the study goals.

There are four categories of collected data – identifiable, coded, deidentified, and anonymous:

[f] Note that a consent form is not required unless these individuals are also research subjects.

- Identifiable data refers to data that includes direct identifiers such as a subject's name, address, Social Security number, or biometric information. Some identifiable data may require the use of special software, equipment, or knowledge to identify a participant. For example, iris, fingerprint, vein, ear, DNA, and palm data could potentially be used to identify an individual but would require special tools, software, and expertise to do so. Identifiable data may also include indirect identifiers (such as sex, ethnic heritage, educational level, or type of affiliation) if those indirect identifiers provide enough information in the aggregate with other information in the dataset to deduce a study participant's identity. When identifiable data is collected, coding and de-identification are two methods that allow researchers to protect study subjects' privacy and confidentiality.
- Coded data refers to data in which the identifiable and non-identifiable data are separated and a code or other mechanism is used to link them. As discussed in Section 2.8 (

- Coded Information), OHRP considers data to be "coded" when 1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the information or samples pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and 2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or research data. In this case, researchers can unmask study participants because they have access to both the coded data and the key.
- Deidentified data refers to data in which all identifiable information has been stripped from the data, and any codes (for coded data) have been deleted.
- Anonymous data refers to data where identifiers were never collected or recorded. Data collected in this manner can never be used to identify a study participant. No links exist between the data and the subjects that provided them.

The terms "deidentification" and "anonymization" are not always used consistently. While definitions for deidentification may vary, generally it describes the action that one takes to remove identifying characteristics from data. The term "anonymization" may be a term that is used synonymously with deidentification, or it may be used to describe the act of permanently and completely removing personal identifiers from data. Researchers must communicate with their organization's human subjects protection official and/or IRB to understand how these terms are being defined and identify the best approach for your research. In using these terms, please consider the distinctions between these processes, all of which may be described (appropriately or not) as "deidentification":

- Changing a dataset from identifiable to deidentified by permanently deleting all identifiable data
- Creating a derived deidentified dataset from an identifiable dataset by omitting identifiable data in the derived dataset (e.g., for the public release of the derived deidentified dataset while internally retaining the identifiable dataset)
- Changing a dataset from coded to deidentified by permanently deleting all links and cross-references
- Creating a derived deidentified dataset from a coded dataset by omitting links and cross-references in the derived dataset

Understanding how the collected data can be used to potentially identify a subject can help researchers determine if additional restrictions need to be applied to the data use or if the data even needs to be collected in the first place. It is important to consider whether individual pieces of data or a combined collection of data would compromise anonymity. For example, if the data showed that a subject was a female, latent print examiner, between the ages of 45-50, and worked at an unaccredited state lab, the anonymity could be compromised as the combined pieces of information narrows possible results. Alternatively, sex, age, or occupation by itself would not be enough to narrow results so the subject's identity would remain anonymous. There is a burden on the researchers to make sure that the information disseminated does not compromise anonymity. Researchers releasing datasets (or releasing results derived from datasets) should consider the concept of "k-anonymity" [53], in which the indirectly identifying information about the individuals contributing to that dataset is restricted so that samples cannot be associated with identifiers for any unique individuals in the dataset. A k-anonymized dataset limits the indirect identifiers associated with each record so that at least another k -1 (k minus one) other records share any combination of those identifiers. For example, a dataset enforcing 5-anonymity could include sex and educational level for each sample if the smallest combination of sex and education for anyone in the dataset contained at least five subjects, but 5- anonymity would be violated if only three subjects in the dataset were females with PhDs. This removes the ability to link specific information to individuals, while still preserving the data's utility and effectiveness.

6.2. Dissemination of Data

Datasets may be collected with a variety of restrictions imposed by the IRB, the subject's wishes as noted on the consent form, data use agreements/licenses, and the organization that collected/distributed the data. Dissemination restrictions generally fall within these categories:

- Use only in specified test/study
- Sequestered for unlimited use within a specific organization
- Restricted redistribution (e.g., among federal agencies or among law enforcement agencies)
- Public release with restrictions from data use or licensing agreement
- Public release retaining copyright
- Release into the public domain with no restrictions

The combination of IRB, subject's consent, and other restrictions can create somewhat complex dissemination restrictions that must be observed. For example, in one study:

- The data could be used for current and subsequent studies but only within the collecting organization.
- The data, as a whole, could not be redistributed.
- For publication purposes, a subset of subjects is permitted for public use. Another subset of subjects agreed to be contacted for requests for public use (extended previous consent), but many subjects stated that they did not want to be contacted and therefore could not have data used in any publications.
- For requests for data, only aggregates of demographic information could be released to avoid compromising anonymity.

Some organizations may also have data-archiving requirements. For example, NIJ, Bureau of Justice Statistics (BJS), and the Office of Juvenile Justice and Delinquency Prevention (OJJDP) require de-identified datasets to be archived at the National Archive of Criminal Justice Data (NACJD) [54].

Researchers must work with their funding organization, IRB, and related officials to track and observe all possible data dissemination requirements.

7. Alternate Sources for Data Collection

If collecting data directly from primary sources (i.e., human subjects) is difficult or does not satisfy the research requirements, existing data might support your research. Secondary data can be cost-effective since the data collection has already been performed. However, it is important to consider several factors when including secondary sources in your research. This section provides an overview of possible secondary sources and considerations to make when using secondary data sources.

7.1. Collecting Data from Secondary Sources

Secondary data is data that was collected by someone else or collected for a purpose unrelated to the research being considered or conducted. It may be valuable to investigate whether any data already exists before undergoing a biometric or forensic science data collection because the use of existing datasets may eliminate the need to collect samples. Secondary data could also be used to expand the data in your study by providing a comparison dataset for the data you collect.

Although projects involving secondary data may not deal directly with humans, they may still be considered human subjects research if the secondary data includes identifiable private information of living individuals (see the definition of a human subject in Section 2.5). Conversely, secondary data that is de-identified and or coded would likely not be considered human subjects research if the key is not provided and the researchers make no attempt to reidentify the individuals. [55]. Each situation must be analyzed on its own

to determine whether this designation applies. When in doubt, ask your IRB or your organization's authority in the area of human subjects research.

7.1.1. Secondary Data Sources

Secondary data may come from public or private/proprietary sources. Public sources include statistics from government agencies (public datasets), technical reports, scholarly journals, and literature [56]. For example, the NACJD is a secondary source for criminal justice data for research purposes. Private and proprietary sources may be obtained by contacting the owner of the data. Typically, these types of sources contain guidance on whom to contact or how to request data sets for secondary use. These sources of data may be subject to licensing agreements which may prevent you from using the data in the manner that suits the needs of your research. See Section 9.2 (Common Types of Data Licenses) for information on the types of licensing that you may find.

7.1.2. Secondary Existing Data

When using existing data, your research may qualify for exemptions under the Common Rule (45 CFR §46) [57]. One such exemption states that if data sources are publicly available or if the information obtained cannot be used to identify subjects (directly or indirectly), then it may be exempt from human subjects designation. Exemption must be determined by an IRB or equivalent organizational representative.

7.1.3. Research Involving Secondary Public Data

Public data is unlikely to qualify as human subjects research, but each situation must be taken on a case-by-case basis. Public datasets may include those made public by government institutes (e.g., census), social media posts and profiles from internet searches, and publicly accessible forums or articles. When selecting a dataset, be certain you have assurances that the data was not acquired through illicit means to avoid putting your research effort at risk.

7.1.4. Research Involving Private Data

Private data may be human subjects research but must be taken on a case-by-case basis. If private data cannot lead to identification, it may not be considered human subjects research. Purchasing or obtaining datasets, receipt of coded data (depending on whether a code key is available), and private forums, chats, or groups may or may not be human subjects research. Private datasets with individual identifiers would be considered human subjects research.

7.1.5. Operational Data

When looking at the use of operational data – data that is derived from your organization's day-to-day operations also referred to as "real world data"– for research purposes, some considerations must be made. To start, collection of operational data by itself is not considered research and therefore, does not usually fall under human subjects research regulations. However, if the data being collected is designed to develop or contribute to generalizable knowledge (see definition of research – see Section 2.4 Research) and falls under the definition of a human subject (see definition of a human subject in Section 2.5 Human Subject), then the use of operational data could fall under human subjects research. Each research organization must consider the design and original intent of the data being used and consult your IRB representative for clarification on any questions that may arise.

8. Data Use Agreements

The purpose of a data use agreement is to ensure all individuals who have or may have access to collected data will abide by restrictions set forth to safeguard the data from misuse. Data use agreements may or may not apply to your research. Further, data use agreements are intended to set rules on how data may be used when it is transferred from one entity to another. This is not to be confused with "employee confidentiality statements" that are signed by each researcher on a team, pledging that applicable regulations will be observed.

This section covers different applications of data use agreements to protect your data from misuse.

8.1. Distribution and Dissemination

When making collected data available to researchers outside of your organization, a data use agreement can help protect your data from misuse. By limiting the distribution of your data to individuals who have signed a data use agreement, you track who has access to your data and ensure that those individuals have a legal obligation to use that data within the outlined restrictions.

The following items are commonly included in data use agreements:

- Restrictions on redistribution
- Restrictions on reidentification
- Restrictions on modifications
- Restrictions on sale or commercial use
- Licensing of data
- Citation requirements
- Indemnification by user/licensee for claims or litigation arising from improper use of data
- Archival or disposal of data following study completion
- Copyright information

As an alternative to data use agreements for third-party researchers, datasets can be licensed. See Section 9 (Data Licensing) for more on data licensing options.

8.2. Examples of Data Use Agreements

For a list of examples of data use agreements with links to those examples, please see Appendix B.

9. Data Licensing

Whereas data use agreements allow an organization to set rules on how their data may be used by first and third-party users, licensing provides flexible, legally sound terms on how data may be used by a third party. This can reduce uncertainty and ambiguity in how your data will be used as the license tells potential users upfront how your data can be reused, altered, or redistributed. There are a variety of options researchers have when licensing data for third-party use and the license chosen depends on the type of data. This section outlines several different types of licenses researchers can pursue. Keep in mind that the researcher's organization or funding agency may have requirements for data licensing and/or may have a data license ready to be applied to the data. Researchers must contact their organization or agency to determine if this is the case.

Before moving forward with licensing data, consider whether research participants were informed that their data may be licensed and whether those participants agreed to the licensing of the collected data. Section 6.2 (Dissemination of Data) covers, at a high level, considerations that should be made when disseminating

research data. In general, if a participant has not provided consent for their data to be licensed or the potential for their data to be licensed, the collected data cannot be licensed.

9.1. Determining Whether a Data License Should be Used

To determine whether a data license is required or useful, evaluate the biometric or forensic science data by asking the following questions:

- Does my organization/agency require a data license?
- Is the material owned by the researcher? If not, is the researcher authorized to license it? Note that researchers cannot apply a license to material that is not owned or is not authorized to license.
- Did the IRB impose any licensing constraints?
- Is it data that is subject to export controls?[g]
- Is it sensitive data that is controlled by other federal or state legal requirements or policies?
- Is it research data that is subject to sponsor, institution, or lab controls?
- Can the data be anonymized?
- Will the data be shared through a repository that requires a specific license for all data submitted?

9.2. Common Types of Data Licenses

There are a variety of licenses that may be appropriate for your data [58]. If you plan to license your data, consider the following questions:

- What type of data formats do I wish to license: images, audio files, videos, spreadsheets, presentations, etc.?
- Do I want to receive attribution for my data?
- Do I want others to be able to reuse my data?
- Do I want others to be able to build upon my data?
- Do I want to allow others to use my data for commercial purposes?
- Do I want to put my data in the public domain with no restrictions or attribution?

The answers to these questions may help point you towards one or multiple licenses that meet your needs. The types of available licenses can include but are not limited to those summarized in the following sections (9.2.1 through 9.2.7). When determining whether a data license is needed, or deciding which data license is appropriate, it is recommended that you consult with your organization's IRB and/or legal representative.

9.2.1. Public Domain

Datasets dedicated to the public domain waive all rights to the work. Users of the data are allowed to reuse, modify, and redistribute the data without any restrictions, to the extent allowable by law. Datasets released under *public domain* do not require any attribution when used. Creative Commons Zero [59] is an example of a worldwide public domain license.

[g] Export controls are U.S. laws and regulations that regulate and restrict the release of critical technologies, information, and services to foreign nationals, within and outside of the United States, and foreign countries for reasons of foreign policy and national security. More information on export controls laws and regulations impact researchers can be found at https://research-compliance.umich.edu/principles-definitions.

9.2.2. Attribution

Attribution requires that users give the licensor appropriate credit when data is distributed, displayed, or used (either for existing work or used to derive new work). Attribution also requires that users provide links to relevant licenses and indicate if changes were made. Attribution does not imply the licensor endorses the researcher or the research.

An issue that can occur with this type of licensing is attribution stacking. This occurs when people do not state all sources of their work and may occur, for example, when work is derived from a long chain of contributors requiring acknowledgment.

9.2.3. Share-Alike

Share-alike is a copyright licensing term used to describe agreements that require copies or adaptations of the work to be released under the same license as the original. If the data is changed in any way (updating existing data, removing data, building upon existing data), the new dataset including the primary researchers' contributions must be distributed under the same license as the original.

9.2.4. Non-Commercial

The main intent of a non-commercial license is to prevent the licensee from profiting from the work performed by others. These can sometimes be found in multi-license situations where a non-commercial license prohibits commercial use, and a second license permits commercial use so long as the licensors are paid.

9.2.5. Database Only

Databases can include a variety of different types of data: images, videos, sounds, documents, etc. A Database Only license would cover the database as a whole but place no regulations on the individual items within the database. Thus, the contents of the database could be removed, altered, changed, and re-used in other databases. It is therefore recommended to seek additional licensing to protect the content of the database when using a database-only license.

9.2.6. No Derivatives

If the data is changed in any way (updates to existing data, removal of existing data, building upon existing data), the modified dataset is not allowed to be distributed. This license will restrict the reuse of the data and will protect the original work of the primary researchers.

9.2.7. Dual or Multiple Licensing

If no one type of licensing meets the needs of the researcher, two or more types of licenses can be used.

9.3. Pre-Made Data Licenses

Many websites provide ready-to-use licenses that can be used if a researcher does not want to create their own. Some examples are Open Data Commons [60] and Creative Commons [61]. Creative Commons also provides a "License Chooser" that helps identify which license, or licenses, are appropriate for the data in question [62]. These and others are available to the public on the internet.

9.4. Applying Data Licenses

Once a type of license has been selected, the researcher decides whether to use an already-made license or create their own. The license is attached to the data by adding a statement that the data is available with a particular license. In addition, the owner of the data provides a way to access the full license. For example, your data may have a statement that reads:

- [This database is/These data are/<name of dataset> is] made available under [License Name] whose full text can be found at: [license URL].

When adding a license, make sure it is prominently displayed before the data is presented.

10. Decision Trees

This section includes decision trees that may help your organization make decisions regarding human subjects research:

- In Section 10.1 you will find decision trees accessible from the U.S Department of Health and Human Services website. These are a series of interactive decision trees that help researchers identify the needs for their research. These trees may contain decisions outside of the typical biometric and forensic science disciplines (such as handling medical information/specimens) but are provided as general guidance for getting started. These can be accessed directly from the HHS website [63].
- Section 10.2 contains a decision tree provided by the U.S Department of Justice (DOJ) Office of Justice Programs (OJP).

While these decision trees are valuable resources, all final decisions must be made in accordance with your managing and funding organization as well as your IRB.

10.1. U.S. Department of Health & Human Services (HHS) Office for Human Research Protections (OHRP) Decision Charts

HHS OHRP provides decision trees to assist in determining whether an activity is human subjects research that must be reviewed by an IRB. These charts are included, verbatim, from the Human Subject Regulations Decision Charts website [64] and are current at the time of writing.

The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.

Note that the decision charts included in this document are relevant to the 2018 Revised Common Rule. For pre-2018 requirements, see the Pre-2018 Human Subject Decision Charts [65].

The charts address the following questions:

- Chart 01: Is an Activity Human Subjects Research Covered by 45 CFR §46?
- Chart 02: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR §46.104(d)?
- Chart 03: Does Exemption 45 CFR §46.104(d)(1) for Educational Practices Apply?
- Chart 04: Does Exemption 45 CFR §46.104(d)(2) for Educational Tests, Surveys, Interviews, or Observation of Public Behavior Apply?
- Chart 05: Does Exemption 45 CFR §46.104(d)(3) for Benign Behavioral Interventions Apply?
- Chart 06: Does Exemption 45 CFR §46.104(d)(4) for Secondary Research that Does Not Require Consent Apply?
- Chart 07: Does Exemption 45 CFR §46.104(d)(5) for Public Benefit or Service Programs Apply?

- Chart 09: Does Exemption 45 CFR §46.104(d)(7) Storage for Secondary Research for Which Broad Consent Is Required Apply?
- Chart 10: Does Exemption 45 CFR §46.104(d)(8) for Secondary Research for Which Broad Consent Is Required Apply?
- Chart 11: Is Continuing Review Required Under 45 CFR §46.109(f)?
- Chart 12: Waiver or Alteration of Informed Consent in Research Involving Public Benefit and Service Programs Conducted by or Subject to the Approval of State or Local Government Officials (45 CFR §46.116(e))
- Chart 13: When Can Informed Consent Be Waived or Altered Under 45 CFR §46.116(f)?
- Chart 14: Can Documentation of Informed Consent Be Waived Under 45 CFR §46.117(c)?

Chart 8 is not included in this list because it relates to food taste and acceptance studies, and therefore is out of scope for this document.

10.1.1. Chart 01: Is an Activity Human Subjects Research Covered by 45 CFR §46?

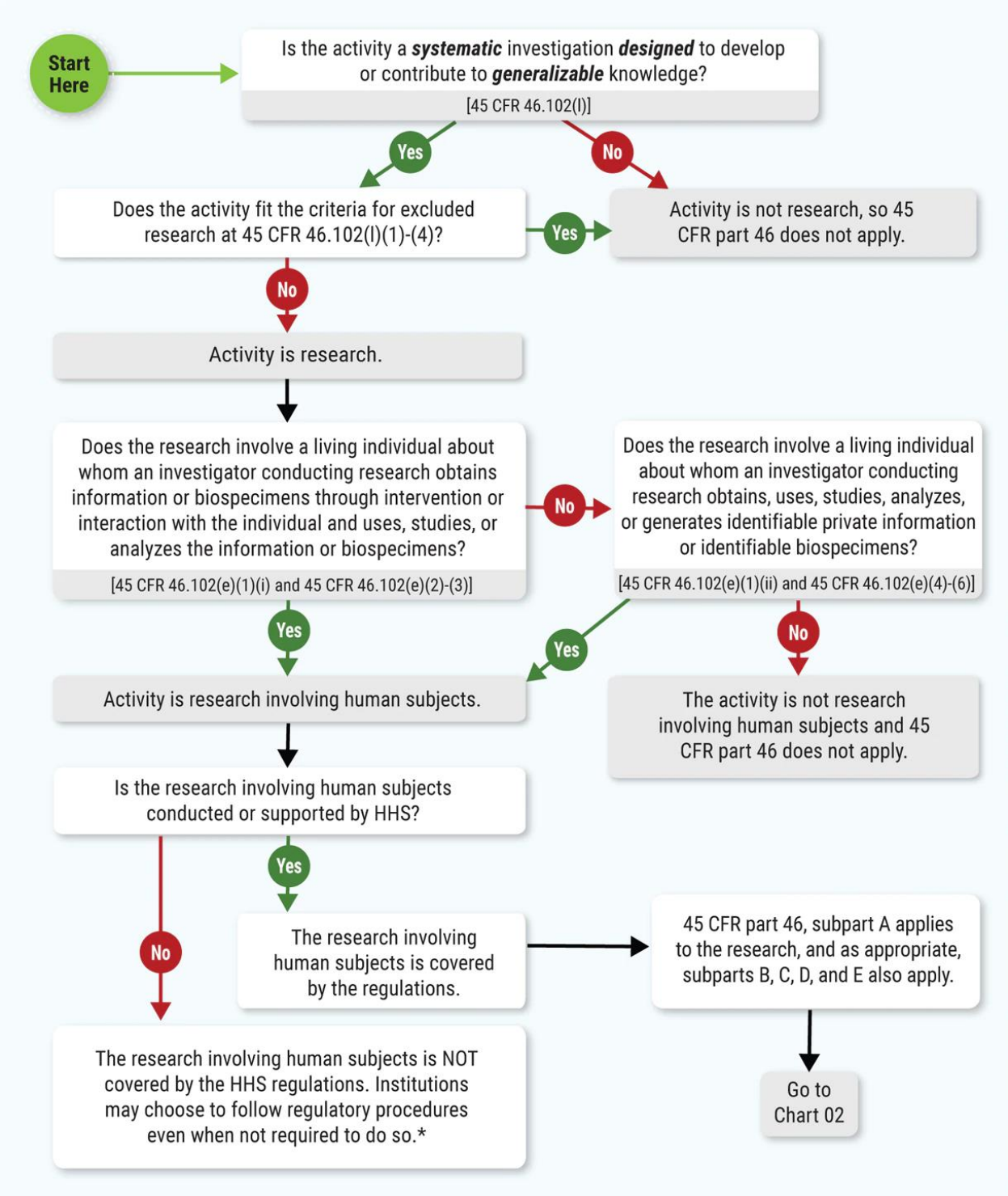

Figure 1: Is an Activity Human Subjects Research Covered by 45 CFR §46?(From the Human Subject Regulations Decision Charts website [64])

10.1.2. Chart 02: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR §46.104(d)?

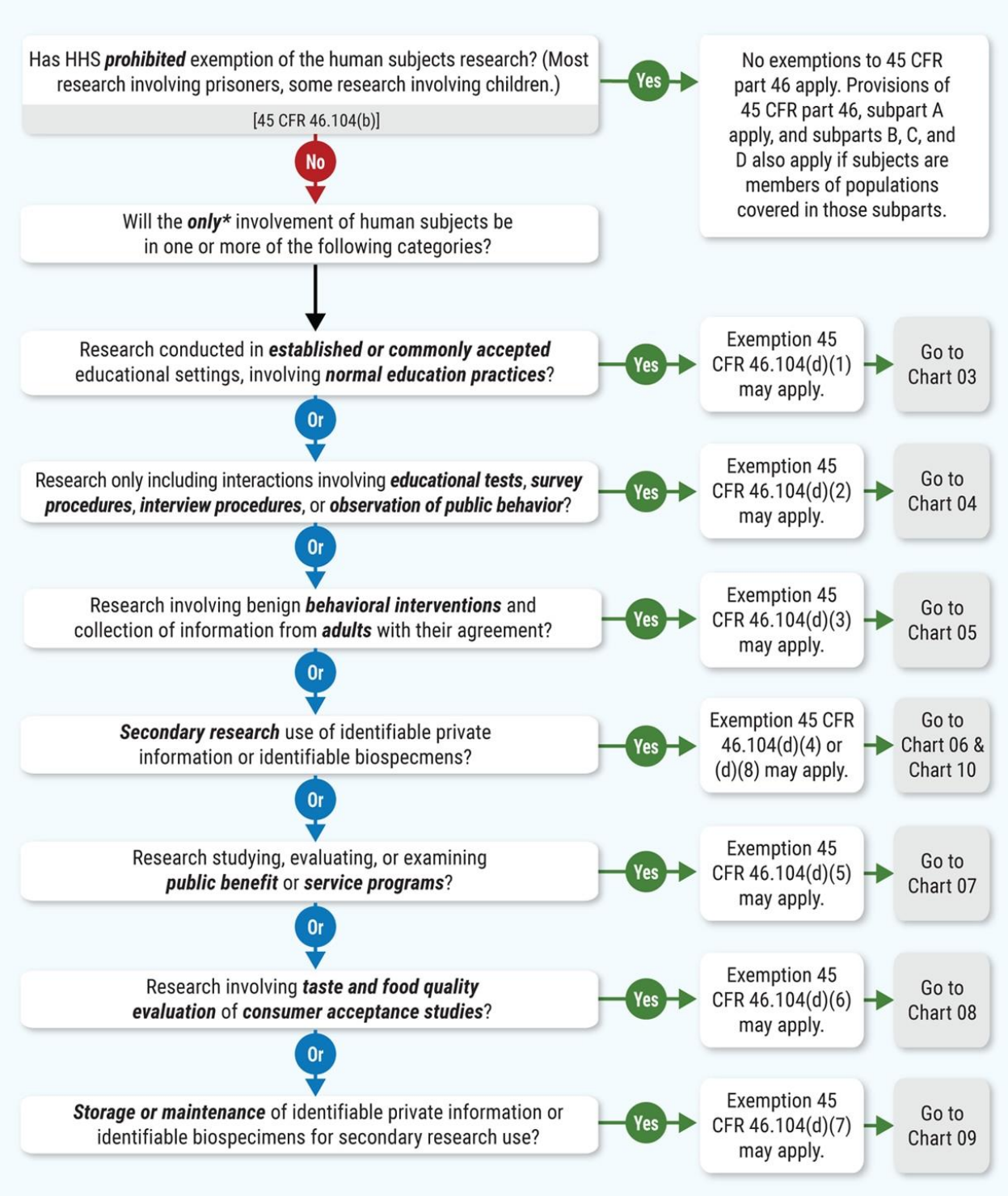

Figure 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR §46.104(d)? (From the Human Subject Regulations Decision Charts website [64])

10.1.3. Chart 03: Does Exemption 45 CFR §46.104(d)(1) for Educational Practices Apply?

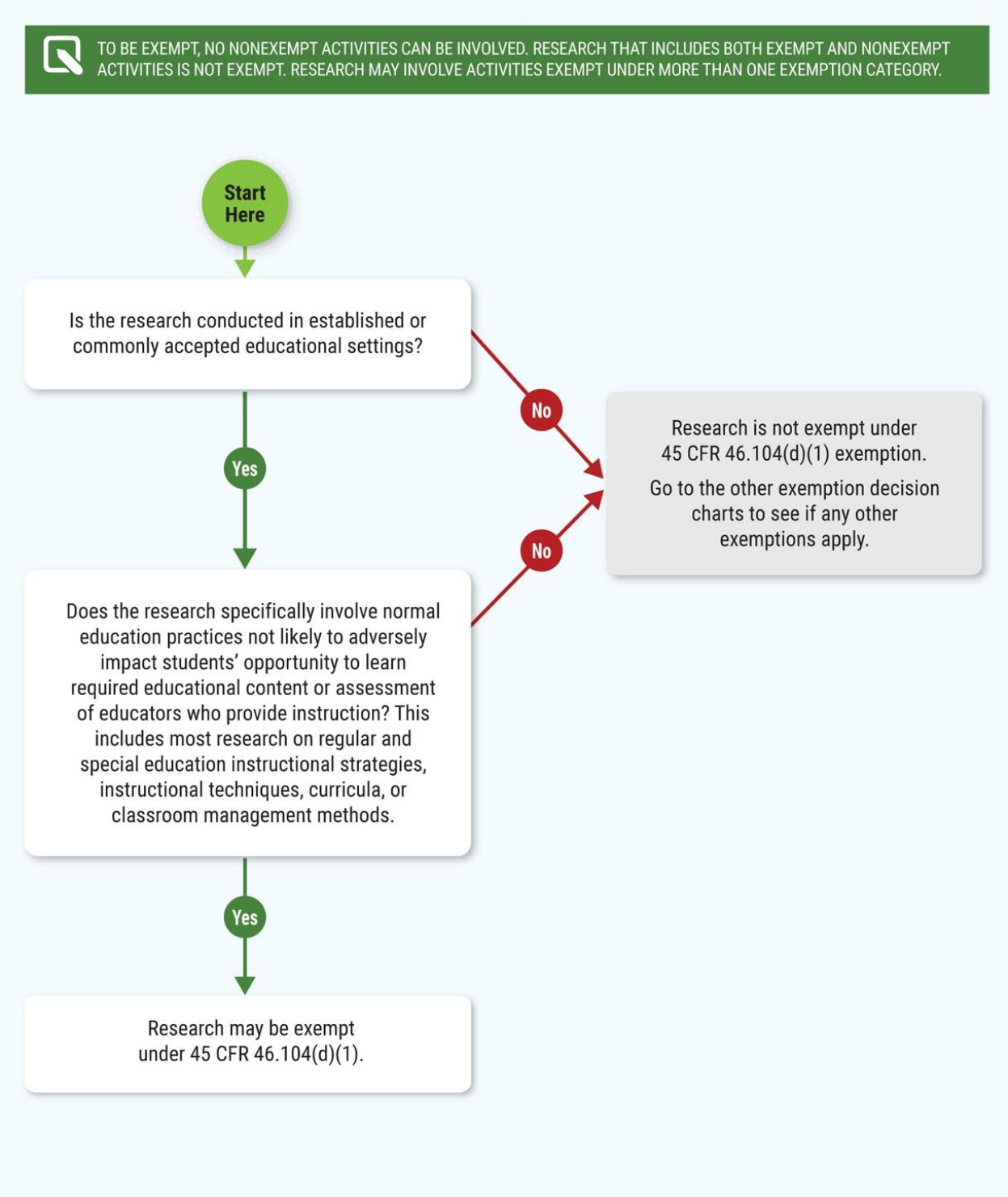

Figure 3: Does Exemption 45 CFR §46.104(d)(1) for Educational Practices Apply? (From the Human Subject Regulations Decision Charts website [64])

10.1.4. Chart 04: Does Exemption 45 CFR §46.104(d)(2) for Educational Tests, Surveys, Interviews, or Observation of Public Behavior Apply?

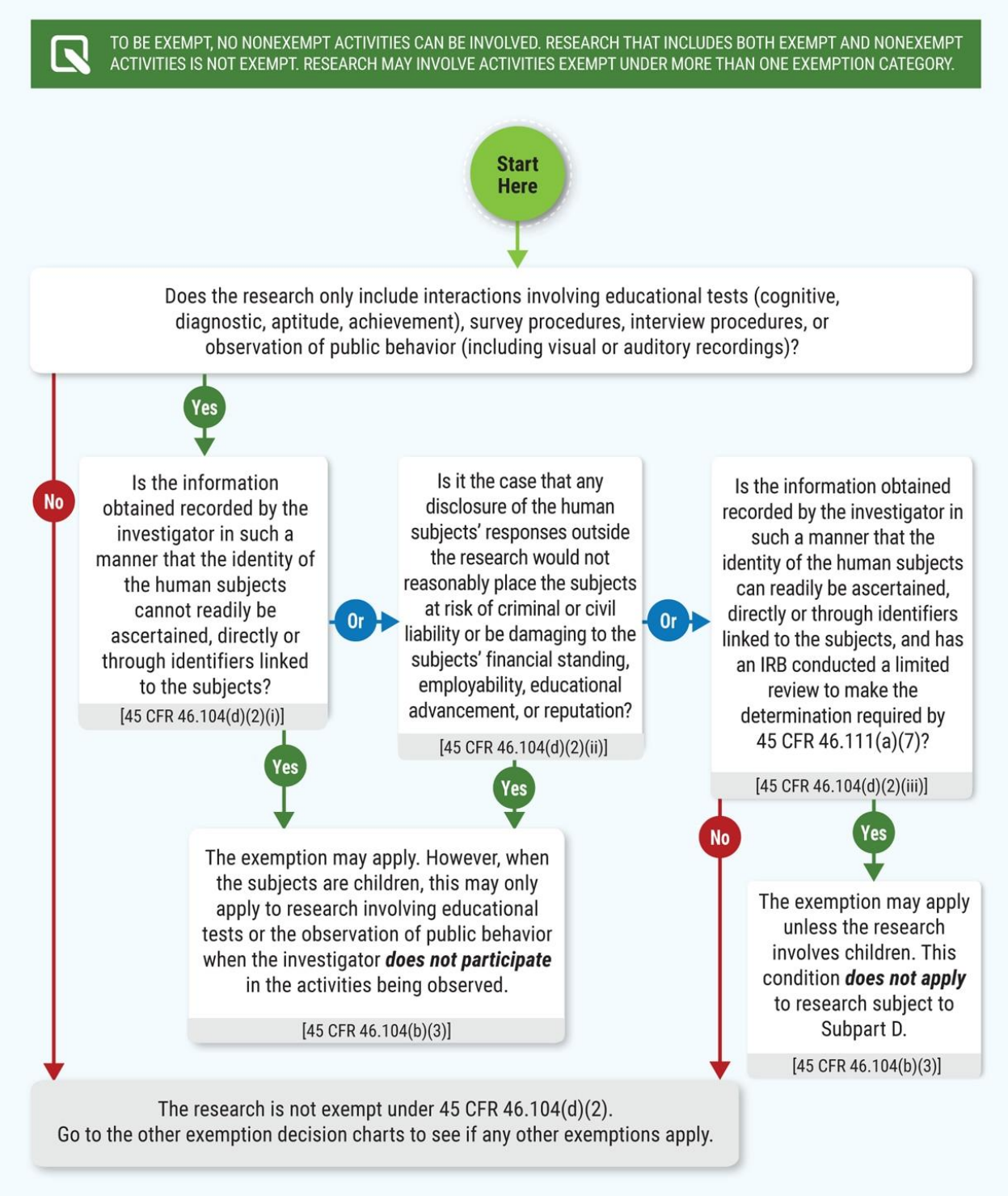

Figure 4: Does Exemption 45 CFR §46.104(d)(2) for Educational Tests, Surveys, Interviews, or Observation of Public Behavior Apply? (From the Human Subject Regulations Decision Charts website [64])

10.1.5. Chart 05: Does Exemption 45 CFR §46.104(d)(3) for Benign Behavioral Interventions Apply?

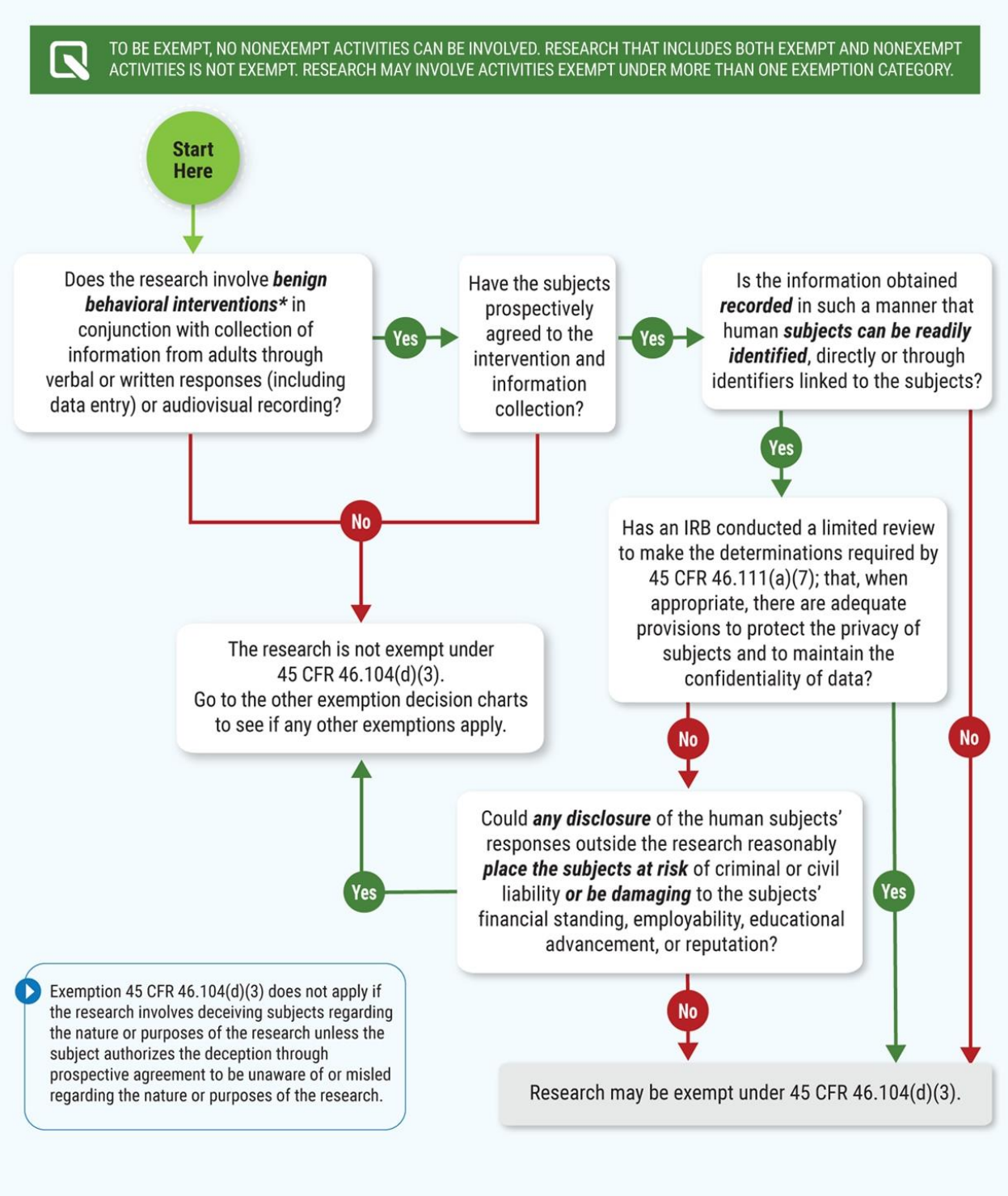

Figure 5: Does Exemption 45 CFR §46.104(d)(3) for Benign Behavioral Interventions Apply? (From the Human Subject Regulations Decision Charts website [64])

10.1.6. Chart 06: Does Exemption 45 CFR §46.104(d)(4) for Secondary Research that Does Not Require Consent Apply?

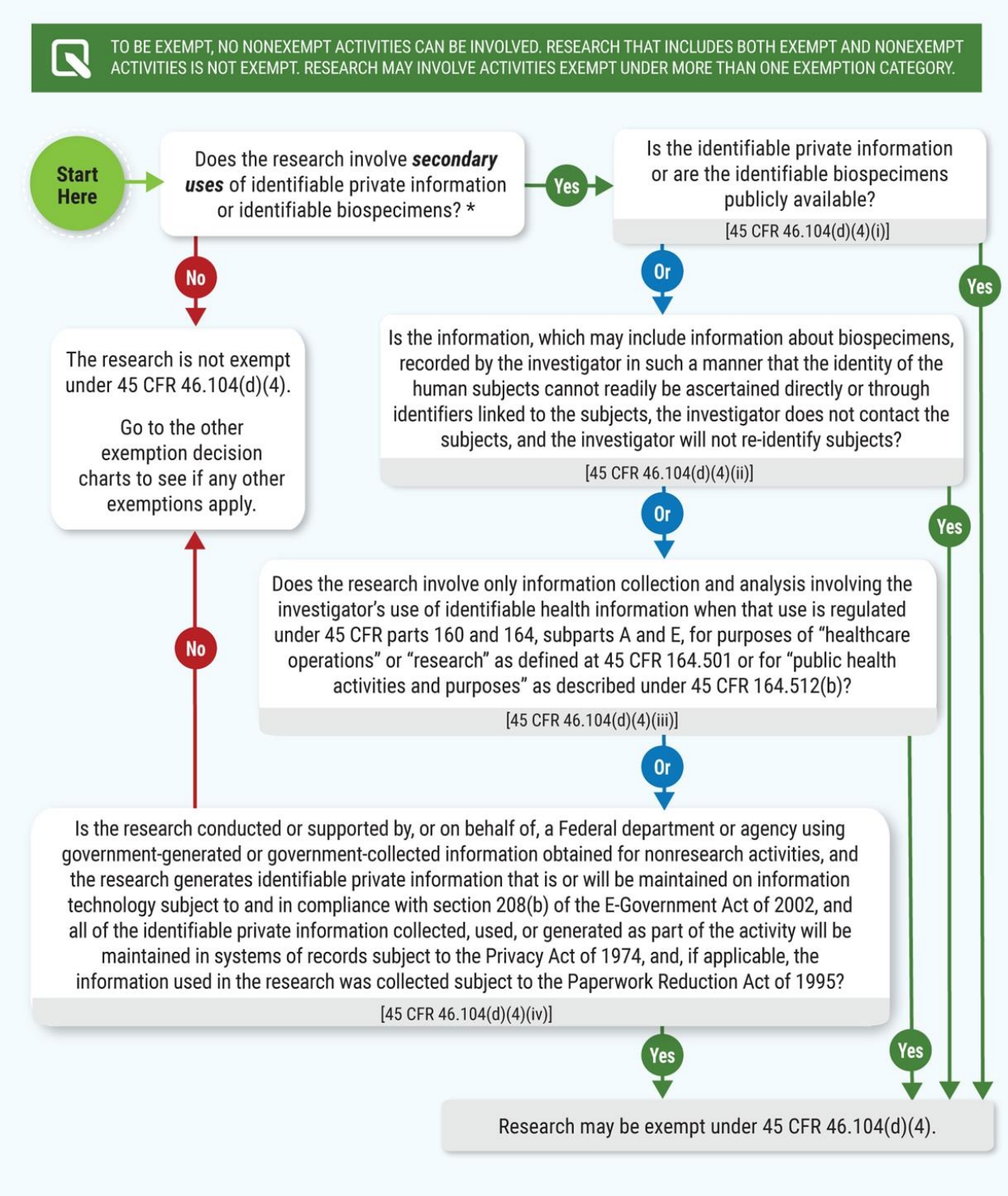

Figure 6: Does Exemption 45 CFR §46.104(d)(4) for Secondary Research that Does Not Require Consent Apply? (From the Human Subject Regulations Decision Charts website [64])

10.1.7. Chart 07: Does Exemption 45 CFR §46.104(d)(5) for Public Benefit or Service Programs Apply?

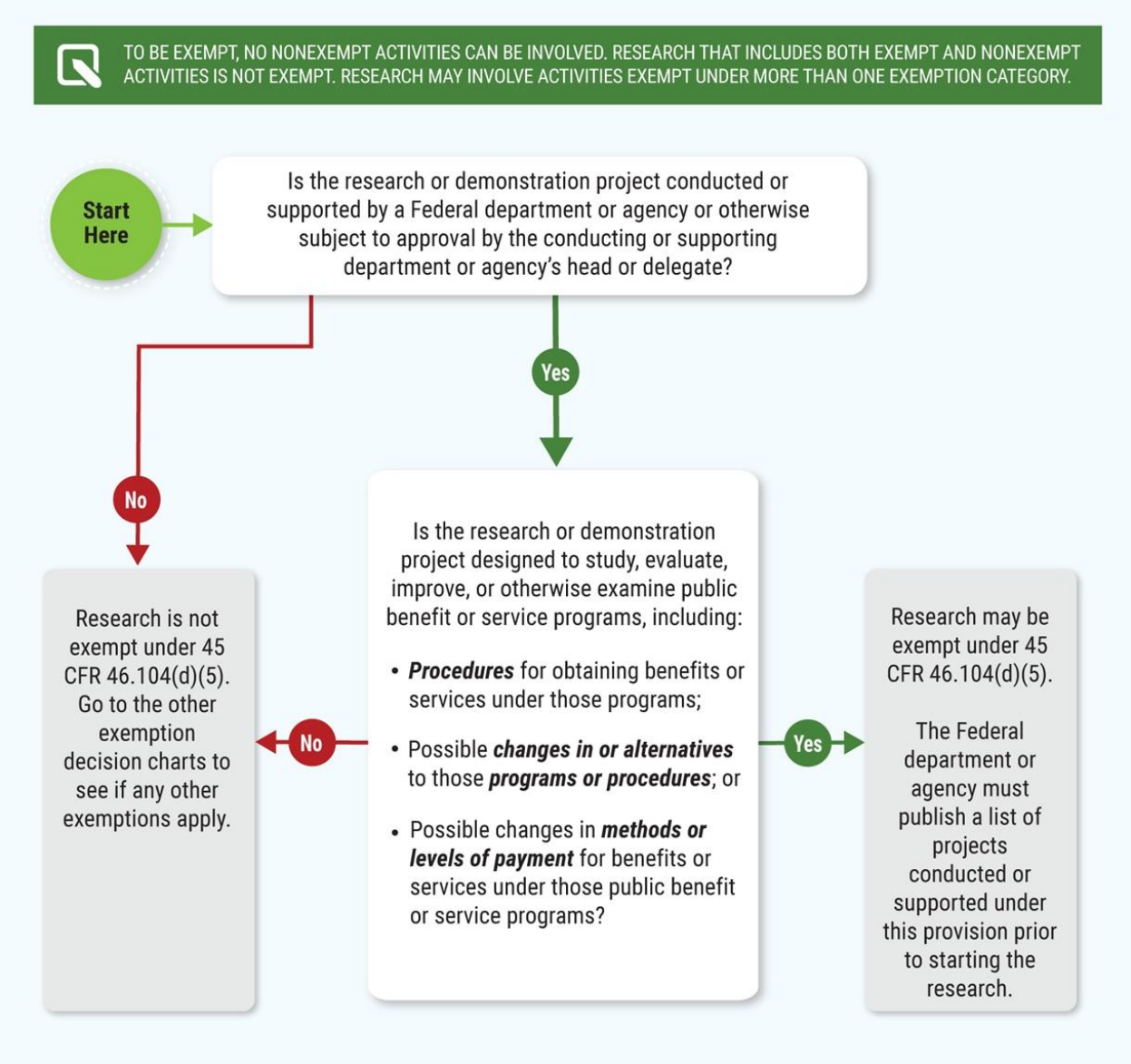

Figure 7: Does Exemption 45 CFR §46.104(d)(5) for Public Benefit or Service Programs Apply? (From the Human Subject Regulations Decision Charts website [64])

10.1.8. Chart 09: Does Exemption 45 CFR §46.104(d)(7), Storage for Secondary Research for Which Broad Consent Is Required, Apply?

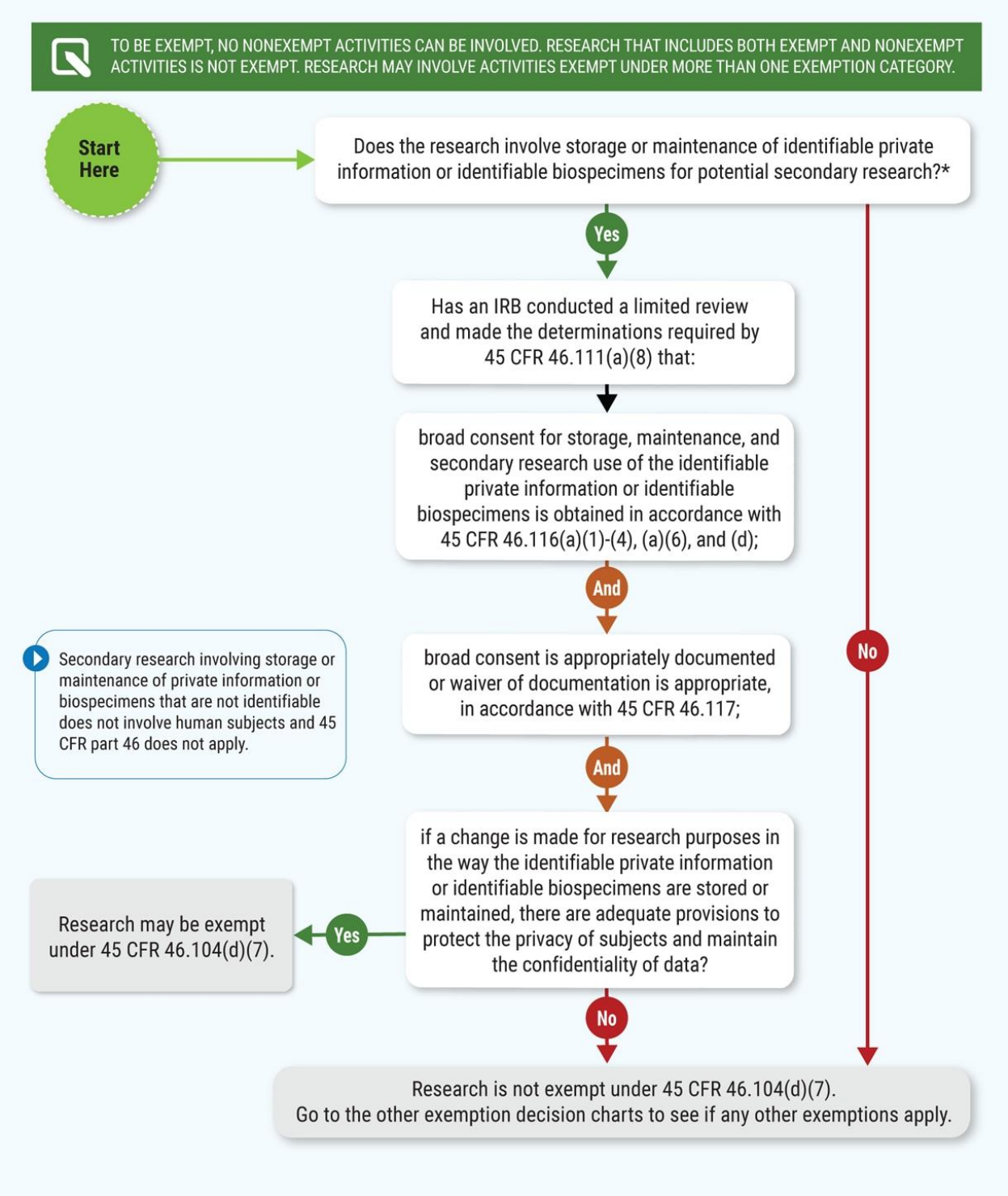

Figure 8: Does Exemption 45 CFR §46.104(d)(7), Storage for Secondary Research for Which Broad Consent Is Required, Apply? (From the Human Subject Regulations Decision Charts website [64])

10.1.9. Chart 10: Does Exemption 45 CFR §46.104(d)(8) for Secondary Research for Which Broad Consent Is Required Apply?

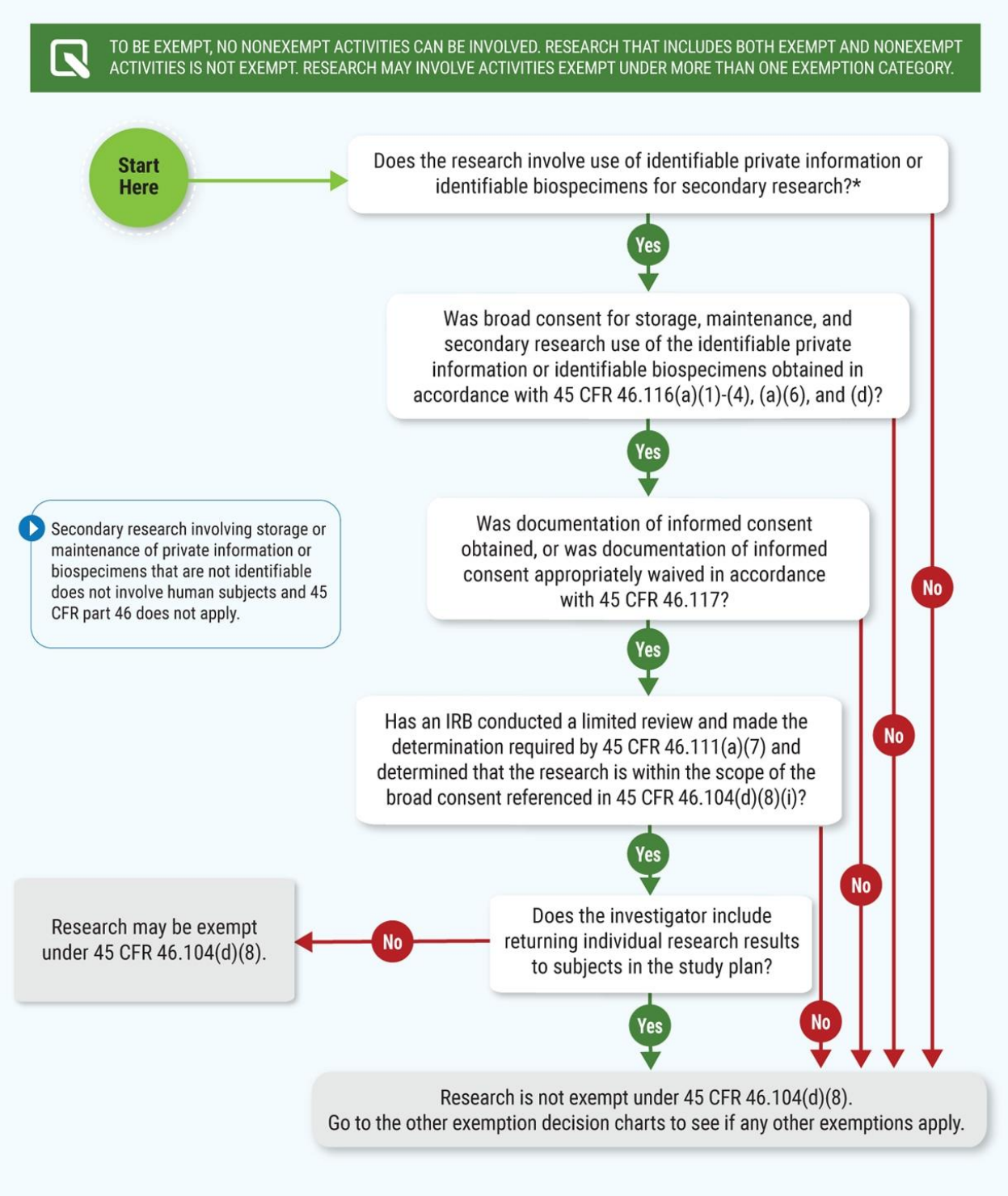

Figure 9: Does Exemption 45 CFR §46.104(d)(8) for Secondary Research for Which Broad Consent Is Required Apply? (From the Human Subject Regulations Decision Charts website [64])

10.1.10. Chart 11: Is Continuing Review Required Under 45 CFR §46.109(f)?

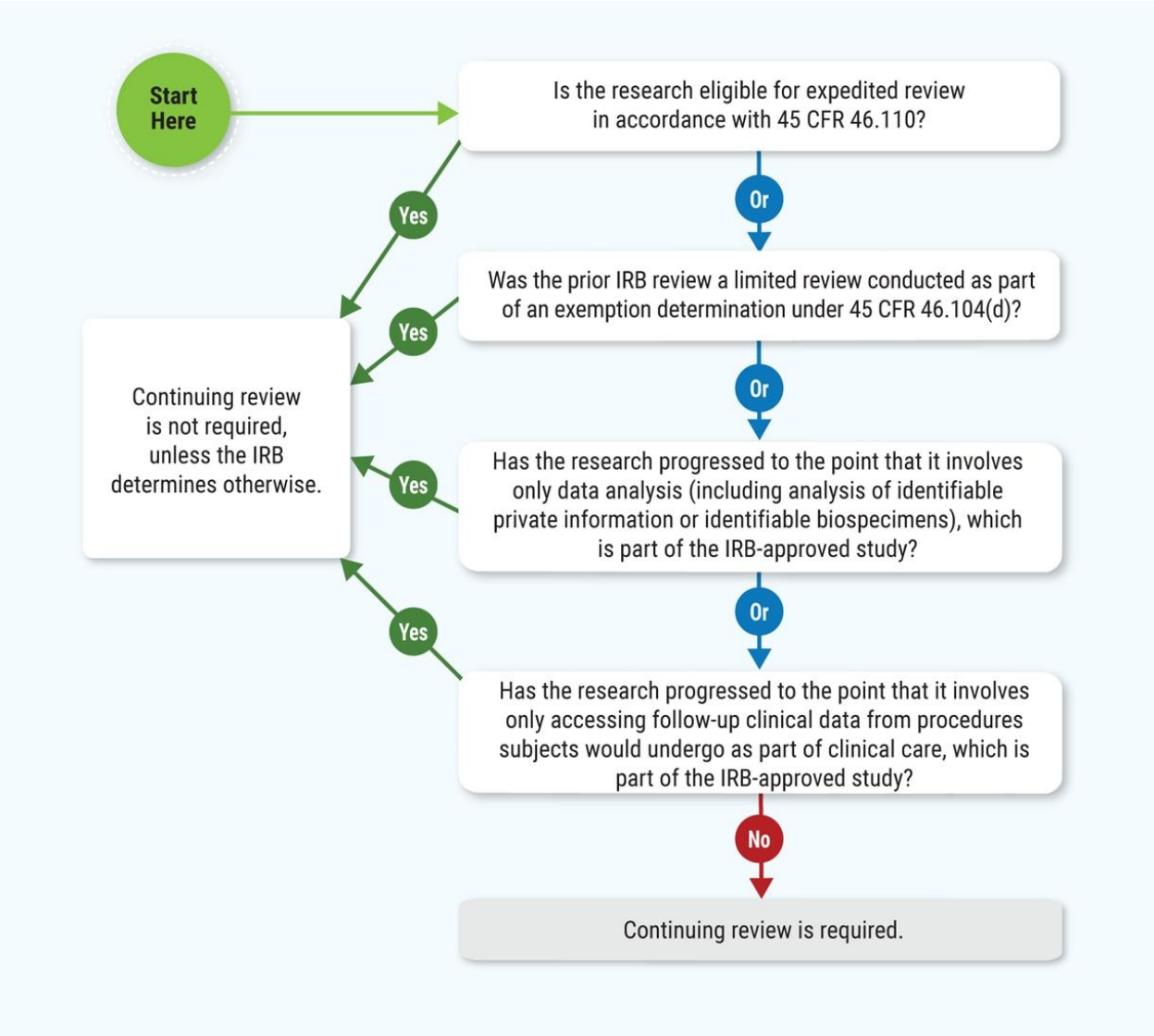

Figure 10: Is Continuing Review Required Under 45 CFR §46.109(f)? (From the Human Subject Regulations Decision Charts website [64])

10.1.11. Chart 12: Waiver or Alteration of Informed Consent in Research Involving Public Benefit and Service Programs Conducted by or Subject to the Approval of State or Local Government Officials (45 CFR §46.116(e))

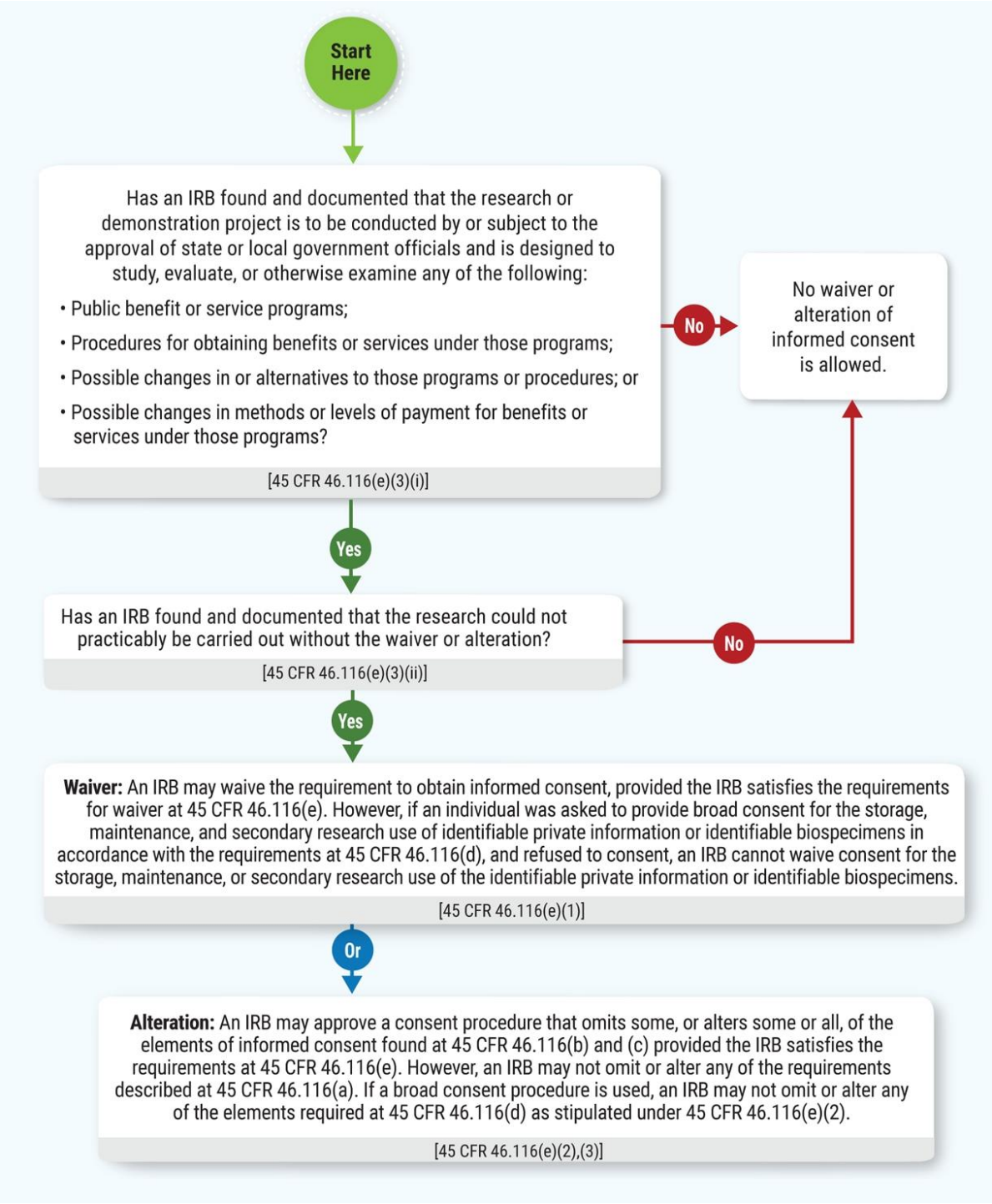

Figure 11: Waiver or Alteration of Informed Consent in Research Involving Public Benefit and Service Programs Conducted by or Subject to the Approval of State or Local Government Officials (45 CFR §46.116(e))? (From the Human Subject Regulations Decision Charts website [64])

10.1.12. Chart 13: When Can Informed Consent Be Waived or Altered Under 45 CFR §46.116(f)?

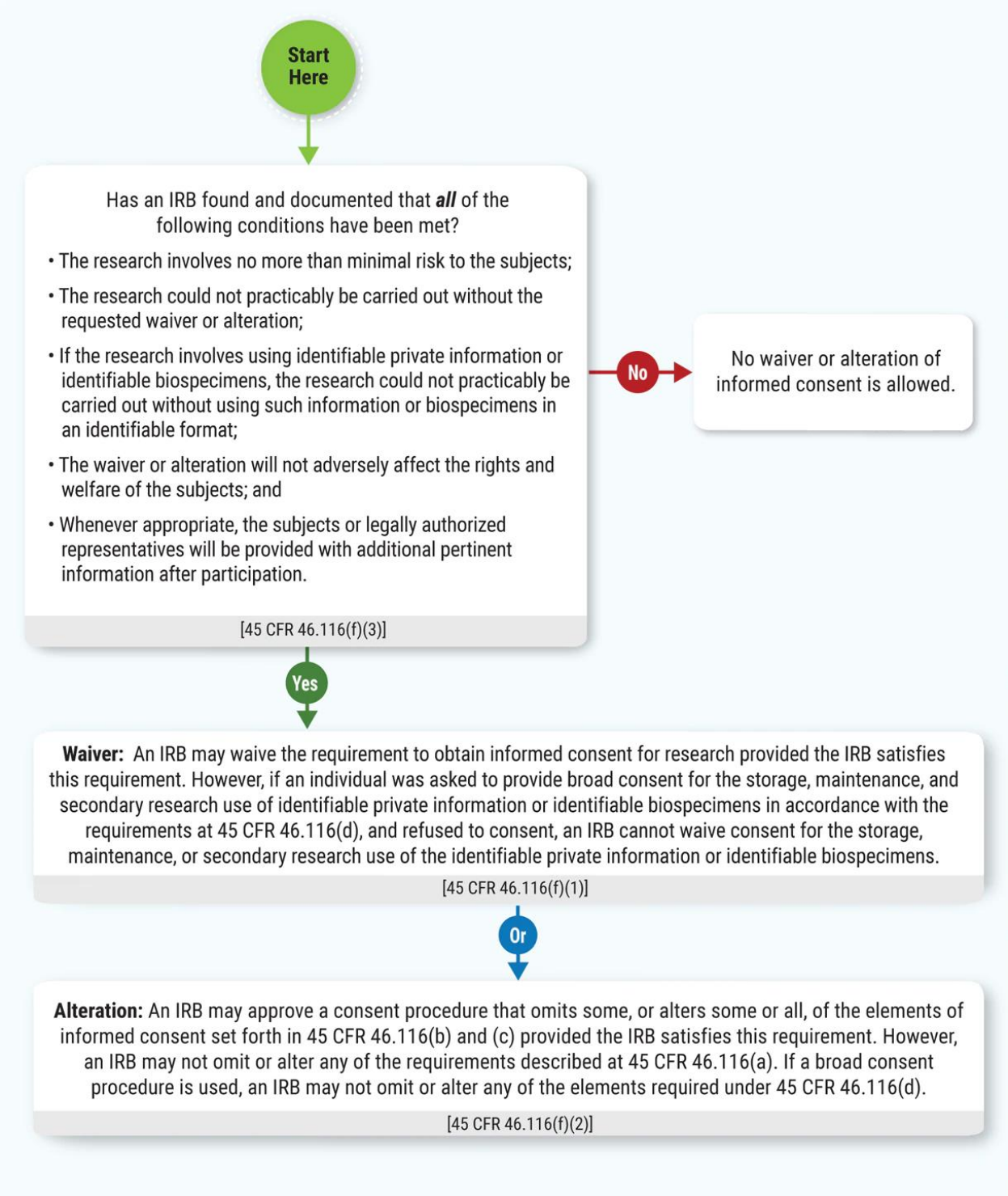

Figure 12: When Can Informed Consent Be Waived or Altered Under 45 CFR §46.116(f)? (From the Human Subject Regulations Decision Charts website [64])

10.1.13. Chart 14: Can Documentation of Informed Consent Be Waived Under 45 CFR §46.117(c)?

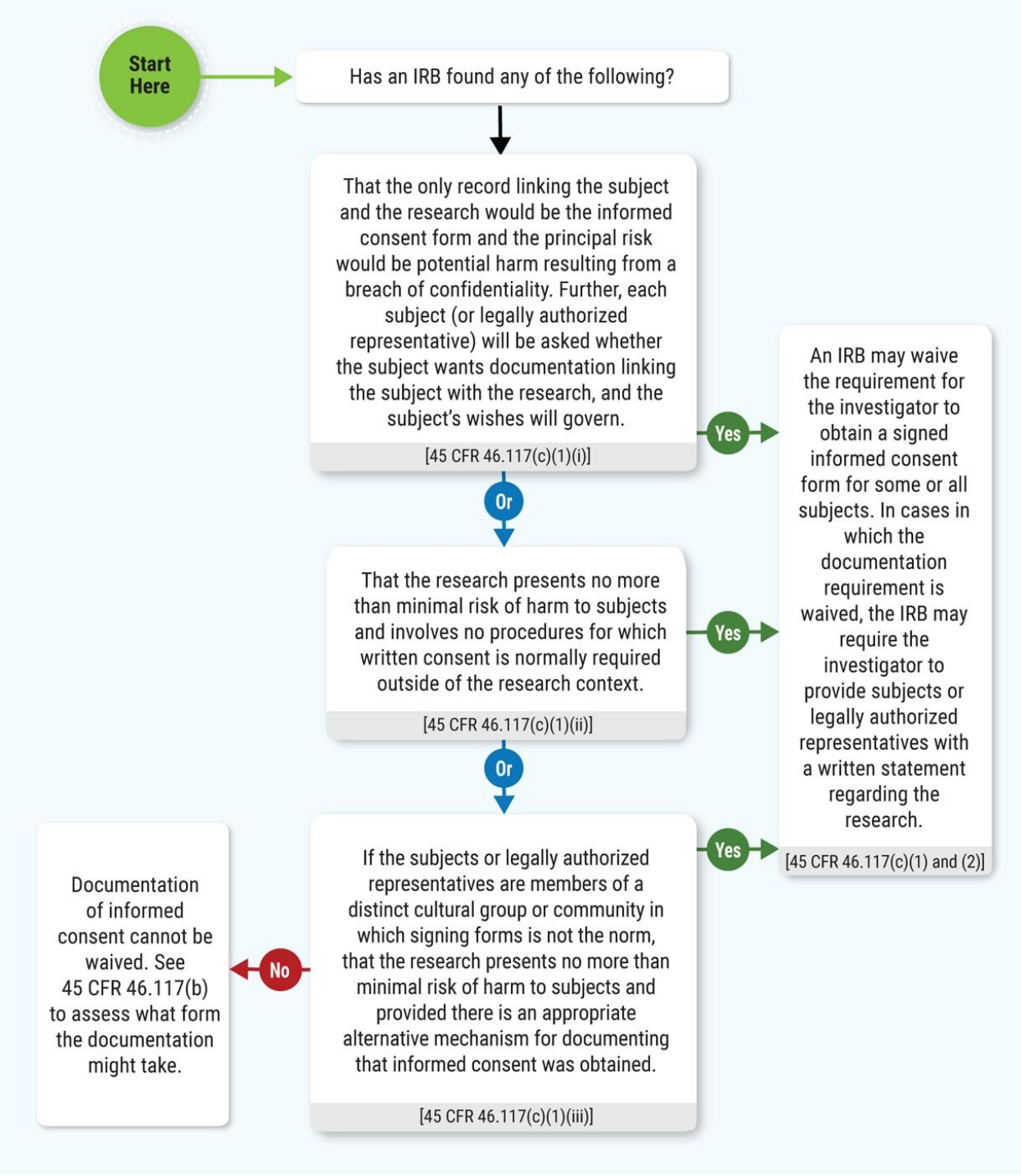

Figure 13: Can Documentation of Informed Consent Be Waived Under 45 CFR §46.117(c)? (From the Human Subject Regulations Decision Charts website [64])

10.2. U.S Department of Justice (DOJ) Office of Justice Programs (OJP) Decision Tree

The following decision tree was developed by OJP for determining whether an activity constitutes research involving human subjects. The chart here is included verbatim from their website [66].

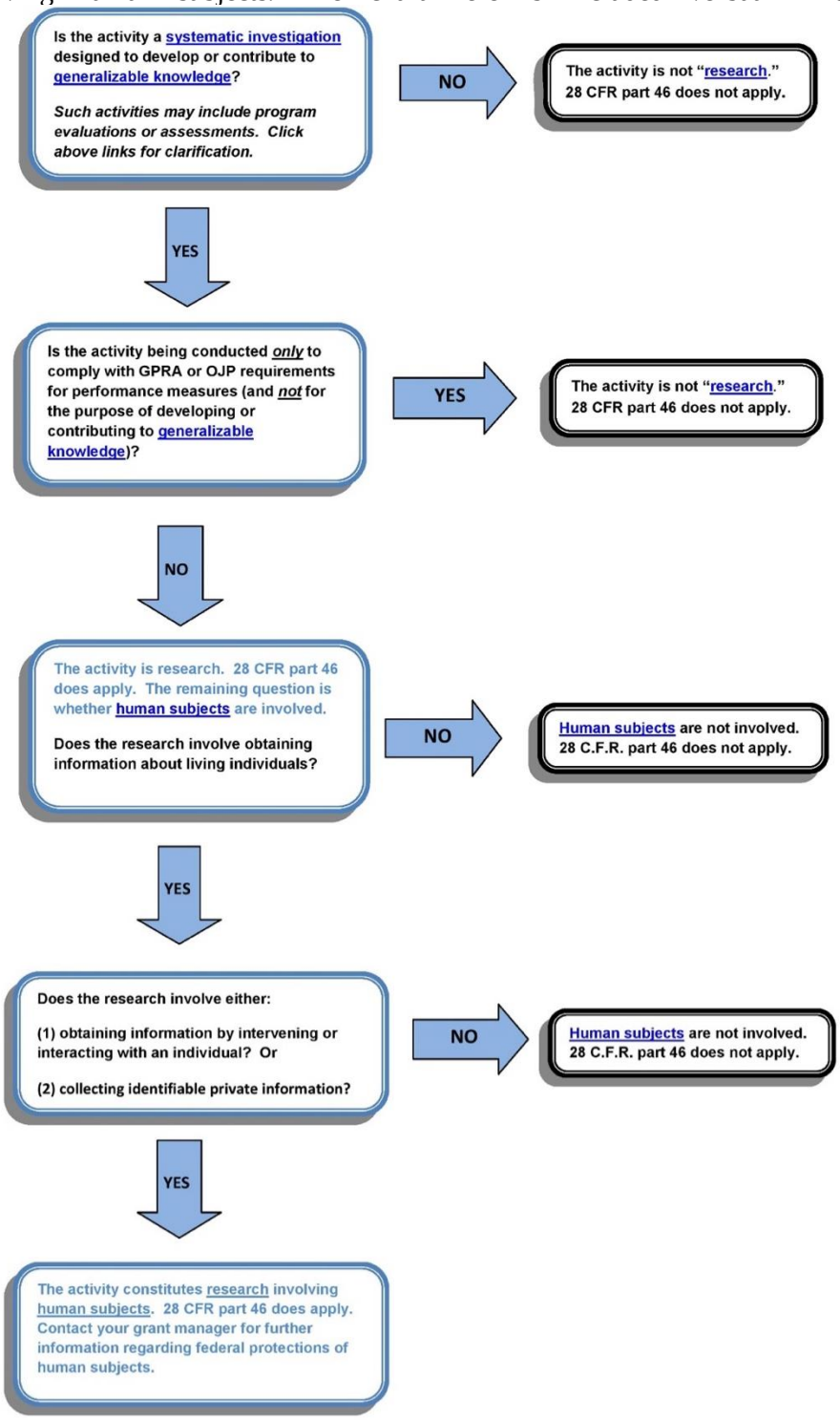

Figure 14: DOJ OJP Decision Tree (From the OJP website [66])

11. Frequently Asked Questions (FAQs)

The following section presents a list of frequently asked questions and potential responses to those questions. It is always important to abide by the guidance provided by your IRB and funding/managing organization, however, these FAQs may help resolve some early questions or provide additional material for resolving questions with your managing organizations.

Note: All activities must be performed in accordance with your organization, state and local laws, funding agency requirements, and federal regulations. The guidance presented in these FAQs does not take precedence over those rules and regulations.

1. **In determining whether something is human subjects research, does it matter if I never intend to publish?**

   No. The intent to publish does not change what is considered "research" or "human subjects."

2. **I plan to use my biometric data (i.e., my own fingerprints) in my research. Am I required to complete informed consent documentation?**

   Whether a consent form is needed when using your own biometrics is dependent on the sponsoring organization. Some organizations require consent forms to be signed by all individuals providing personal data, including biometrics. In other organizations, there could be concerns of potential bias, and the use of a researcher's biometric data may be discouraged or even prohibited. In some cases, your organization may have already collected your biometric data (e.g., for employee enrolment purposes) at which time you may have signed a form stating your biometrics could be used for research.

   In all cases, it is important to first check with your organization's policy. If no policy exists, it is recommended that a consent form be filed both for record-keeping in case audits occur and the general scientific integrity of your research.

3. **What is the difference in the rules and regulations that apply if the work being done is considered training, validation for publication, internal validation, or proficiency testing – instead of research per se?**

   The rules and regulations that will apply are dependent on the purpose of the activity. If the purpose of the activity you are performing will have processes or outcomes that could be considered research, your activity could be bound by IRB review and oversight. As a best practice, it is important to have your IRB, or human subjects protection official, review the proposed activity. While they may not find the definition of "research" applies, they may find other regulations like the Paperwork Reduction Act or privacy laws apply and can inform you of those regulations.

4. **I am conducting internal validation testing on a new computer program/system with an in-house collection of past and current employees' fingerprints. Do I need to pursue IRB approval and informed consent to use employee data in this manner?**

   This is dependent on the purpose of the activity and how the data being used was collected. If the data being used was collected for previous research efforts or as part of employee enrolment, you would need to refer to the data use agreements to ensure such data could be used for purposes other than originally intended. You also need to consider the purpose of your validation testing and assess whether the purpose meets the definition of "research" or whether the testing requires individuals meeting the definition of "human subjects" to complete.

   If you have any reason to question whether IRB approval is needed, speak with your IRB or human subjects protection official.

5. **We have been asked to publish results from extensive validation tests for biometrics systems that we have conducted. The validation tests were conducted using operational data collected from agency casework over the years (including, but not limited to, criminal arrest data). What are our options for publishing?**

   What can and cannot be published depends on multiple factors. The aggregate results of the validation tests can be published. The sensitive nature of the images however could not be published. Publishing may also depend on existing data use agreements (if any). The agency publishing the research must also be authorized to give permission to use the data, otherwise, permission would need to be sought by the owner of the data used. In all cases, coordinate with your IRB office to ensure there are no human subjects concerns.

6. **We have been asked to share results from extensive in-house validation with other companies. What rules and regulations apply to this?**

   The rules and regulations that would apply to this situation are dependent on your organization's regulations surrounding the data used and the results. If your organization does not have an official stance, talk to your IRB or human subjects protection official to determine whether the shared information meets the definition of research, human subject, or neither.

7. **Is there a human subjects protection concern if human data is necessary for validating a newly acquired or an updated system? Such acceptance testing is sometimes time critical, and delays may have cost implications.**

   When using human data in acceptance testing, there could be a human subjects protection concern if the acceptance testing activities fall into the definition of "research" or "human subject research." The final decision of whether your acceptance testing activities fall within these categories must be made by an authorized representative (IRB or human subjects protections officer) within your organization. Also note that time criticality or cost are not factors when reviewing a study, so it is important to plan accordingly.

8. **How are internal employee evaluations related to research restrictions?**

   Unless the employee evaluation data is being used for research purposes, there are no research restrictions placed on that data. In some cases, you may be using this data to gauge how work could be triaged or whether there is a need for training, but this would be considered operational management rather than research. However, there are cases where the employee evaluation data is used in ways that could be research related. If you are using the data to develop new procedures or systems, you may be approaching research. You are always encouraged to discuss your plans with your IRB representative to know whether human subjects research or other regulations could apply to your activities.

9. **I have conducted training for years and have the aggregate information for many classes. I work for a small, private company that has no federal contracts:**
   - **If I report the ongoing, aggregate information in future classes, is this considered human subjects research?**

     If the retained data does not include potentially identifiable information, there is human data involved but human subjects research regulations would not apply. In some cases, your aggregate data may be considered "retrospective research" that meets exemption criteria as determined by an IRB or human subjects protection official.

   - **Is publishing this in a journal permissible?**

     Speak with your IRB or human subjects protection official. Depending on the nature of the content being published, it could qualify as research (e.g., retrospective research) and be subject to review.

   - **Does publishing in aggregate affect what is permissible?**

     Aggregate results could be generalizable to a larger audience and therefore could be considered research that would require review.

10. **I have an unusual case (e.g., a particularly unusual fingerprint) that I want to share with the forensic science community via a publication. What rules and regulations apply in this situation?**

    In this situation, it would depend on how the print was obtained and whether you received permission to share it. The print may not qualify as "research" or "human subjects research" but there may be a variety of privacy issues that need to be observed before publication which may vary from organization to organization. Speak with your IRB or human subjects protection official to learn more about your situation.

11. **Can I use an independent IRB, even if my institution has an in-house IRB?**

    This depends on your institutional policies and the requirements of the funding agency. If you have an IRB at your organization, your institutional policy may require that you use that IRB. A separate IRB may be necessary for situations where your organization's IRB

specializes in a specific type of research (e.g., medical research), but your research focuses on a different type (e.g., social behavior). The IRB may not be familiar with the specific research being performed and may require an appropriate IRB. However, researchers should be working directly with their organization to resolve these types of situations, should they arise.

In all cases, the selected IRB must know which federal agency (where appropriate) is the funding agency as specific regulations may apply. For example, if DOJ is the funding agency, the IRB must use 28 CFR §46 [9]*, pre-2018 Common Rule, and if OJP-funded, the IRB must also consider the privacy certificate.*

12. What if my institution has no IRB? How can I locate an IRB that will review outside research?

If your organization does not have its own IRB, you may consider establishing one. If that is not an option, you may consider partnering with another institution that could provide IRB review and oversight or seek out commercial IRB solutions.

13. What if my research involves multi-agency collaboration? Who is ultimately responsible for obtaining IRB approval?

Ultimately, the appointed Principal Investigator (PI) is responsible for obtaining IRB approval.

If internal funding is involved or multiple agencies are supplying funding, the IRB representatives from each funding agency may wish to collaborate to decide who the reviewing IRB is and establish an IRB Authorization Agreement. To the extent possible, only one IRB should oversee the review.

For research funded by organizations observing the new Common Rule, single IRB (sIRB) requirements must be observed. See the HHS' Single IRB Exception Determinations page for more on sIRB requirements [49].

14. Once IRB approval is granted, is it possible for the IRB to subsequently revoke the approval (before, during, or after research has been performed)?

Yes. If new details are presented, such as overlooked or misunderstood information, the approval could be suspended or terminated if the new information is deemed unacceptable. Alternatively, if you make changes to the project and the IRB decides those changes are unacceptable, or if you fail to inform the IRB of those changes, your approval could be suspended or terminated. The principal investigator must keep the IRB informed of all protocol changes and seek IRB approval of a modification to avoid the risk of approval suspension or termination.

15. What are the implications to my research if my subjects' personal information is compromised?

The implications to your research, if subjects' personal information is compromised, vary. Some studies may not be impacted at all. Others may need to make payments to individuals to account for damages but could otherwise continue. In other cases, your research may need to be altered or shut down entirely. ***Regardless of the potential impact, breaches of personal information must be reported to your IRB.***[h]

16. What if the subjects whose data I am collecting are not in the US?

If your research depends on subjects outside of the US, you may need to observe both local and US regulations. For example, if your subjects reside in the EU, you will need to observe US regulations as well as EU regulations such as the General Data Protection Regulation (EU GDPR).

For more information on international regulations, please see the OHRP Directory of International Human Subjects Protections Regulations [67].

17. How do handle consent forms for non-English speakers?

If you are working with individuals who are non-English speakers, or who natively speak a language other than the one your consent form is written in, you will need to ensure your consent form is properly translated to the target language. You will also need to ensure a professional translator is available to aid in responding to questions if potential subjects need clarification.

18. Is practicability (e.g., time constraints, costs) a sufficient argument for exemption from IRB review?

No. Exempt research has very specific criteria and practicability is not one of them. The nature of your research will determine whether your research may be exempt from further review and will be determined by your IRB or human subjects protection official.

19. Are there additional requirements (i.e., other than standard IRB processes) for publishing research in journals?

Publishing requirements are dependent on the target journal. Your organization may also have administrative requirements for publishing. Some journals may require approval letters or agreements showing research complies with the appropriate federal, state, and local laws. When seeking journal publication, contact the individual journal to see if additional paperwork is necessary. Some journals require a statement from the institution saying the research was assessed and determined to be exempt, for example.

[h] Certain organizations may have their own procedures for handling data breaches. For example, if OJP-funded research and privacy are compromised, there are penalties outlined in 28 CFR §22 [8].

20. Are there any circumstances in which some or all the required elements of informed consent can be waived or altered?

A request for Waiver of Informed Consent can be filed by your principal investigator within the IRB application. If approved, your IRB will grant the waiver. The requirements for a waiver of consent are described in the Common Rule. Note that even if your research qualifies for a waiver of consent, you are still obligated to abide by other regulations set forth by your organization, such as privacy regulations, applicable state and local laws, or your funding agency's regulations.

*Your IRB may require certain items in your consent form to be updated before it is accepted. If you wish to change a section of a consent form that was previously accepted, you **must** inform your IRB of your intent to do so and have your consent form re-approved. Failure to work with your IRB when altering your consent form could harm your research and even your organization.*

21. I have collected a great deal of research data over the years with appropriate consent but in some cases detailed restrictions on use. I am leaving my agency and I am concerned that there is not a specific responsible party to pass this to. What are my responsibilities other than documenting the data on a server and crossing my fingers that no one misuses it?

Part of the IRB process requires researchers to state what will be done with the data after the study is completed. You will want to ensure whatever path was decided on (retaining data in a secured manner, destroying the data after the research is completed, etc.) is carried out to the maximum degree possible. For example, if your study is closed and you stated the data would be destroyed upon project completion, make sure the data is destroyed.

Record retention is extremely important for cases such as this. Records describing what can and cannot be done with the data, along with what will be done with the data throughout the course of the research, is vital.

22. Is PII inherently shielded from Freedom of Information Act (FOIA) requests?

PII is not inherently shielded from FOIA requests but there are additional regulations in place that may prevent that information from being released. Under FOIA, there are nine exemptions for which information cannot be released. If the PII in question is determined to be covered by one of those nine exemptions, the information cannot be released. Certain organizations may also have their own rules and regulations that protect PII from FOIA requests.[i]

One of the best ways to protect the PII you collect during your research is to destroy it as soon as it is no longer needed. Even if your research is ongoing, if you no longer need the PII you collected, dispose of it appropriately. The longer you hold onto PII, the more opportunity there is for a breach to occur. Eliminate identifiers as soon as possible.

[i] Under 34 USC 10231(a), identifiable data collected in OJP-funded research can only be used for research and statistical purposes and no other purpose without subject consent. It cannot be released under subpoena or used in any other type of judicial, administrative, or other proceedings.

12. Key Takeaways

The information presented in this document provides a starting point for biometric and forensic science researchers interested in performing research involving human subjects. While the content of this document provides resources and best practice solutions for navigating the IRB process, all researchers must work closely with their managing organizations, funding organizations, and IRB representatives. All activities must be performed in accordance with your organization, state and local laws, funding agency requirements, and federal regulations. Failure to perform research activities in accordance with these regulations can result in fines, suspension, and/or removal of human subjects research permissions. If there is ever any doubt about how to proceed, contact the organization in charge of your research effort and/or your IRB representative for answers that apply to your specific case.

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[2] Code of Federal Regulations, 21 CFR §56: Food and Drugs, Institutional Review Boards, 2017. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56.

[3] U.S. Department of Health and Human Services Office for Human Research Protections, Attachment B: Recommendation on IRB Membership and Definition of Non-scientist under 45 CFR 46 and 21 CFR 56, (2011). https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2011-january-24-letter-attachment-b/index.html (accessed August 4, 2022).

[4] Code of Federal Regulations, 45 CFR §46.107: IRB membership, 2018. https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.107.

[5] Code of Federal Regulations, 45 CFR §46.102: Definitions, 2018. https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.102.

[6] Code of Federal Regulations, 45 CFR §46.102 (2009): Definitions, 2009. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/regulatory-text/index.html#46.102.

[7] Code of Federal Regulations, 45 CFR §46.104: Exempt research, United States of America, 2018. https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104.

[8] Code of Federal Regulations, 28 CFR §22: Confidentiality of Identifiable Research and Statistical Information, United States of America, 2017. https://www.ecfr.gov/current/title-28/chapter-I/part-22.

[9] Code of Federal Regulations, 28 CFR §46: Judicial Administration, Protection of Human Subjects, 2020. https://www.ecfr.gov/current/title-28/chapter-I/part-46.

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Appendix A. HUMAN SUBJECTS RESEARCH CONSENT FORM TEMPLATE

The template below is an example of the format that may be used when developing your initial consent form. Your final consent form, including all language, formatting, and topics covered, should be completed in accordance with your managing organization(s) and IRB representatives.

INFORMED CONSENT FORM

Sponsor / Study Title: *[Name of Organization Conducting Research] [Name of Study]*

Principal Investigator: *[Name of Principal Investigator]*

Telephone: *[Contact number of PI]*

Additional Contact(s): *[Contact information for additional study staff, if applicable]*

(Study Staff)

Address: *[Address of study site]*

Key Information

[Key information should contain a high-level description of the purpose, benefits, risks and discomforts, and alternatives. This is to provide prospective participants an opportunity to consider whether they are interested in participating in the research effort without having to read the full consent form. Note that if the information included here satisfies the elements of informed consent under 45 CFR §46.116(b) and (c), these elements do not need to be repeated in the body of the consent form]

Purpose

[The purpose of the study should be highlighted here including the expected impact, expected number of participants, and information specific to your funding source as required by the funding organization (e.g., grant number)]

Participation

[Describe who can participate in the study and any pre-requisites that may be required of a potential participant]

Procedures

[Describe the specific procedures of the test including how participants access the test, what will be expected of them, and how results will be disseminated]

Benefits

[If the study provides any benefits to the participants, describe those benefits here. The study may not provide benefits to the participant themselves but instead to a greater community or scientific discipline. If that is the case, describe those benefits here as well]

Risks and Discomforts

[If your study includes potential risks or discomforts, describe those here. If the study does present potential risks or discomforts that may be experienced during normal operation (e.g., eye strain, fatigue), those risks should also be described here]

New Findings

[If any new information is discovered during the study that is pertinent to continued participation, describe how that information will be provided]

Alternatives

[If there are other ways of participating outside of the intended described, describe those alternatives here. This section should also include a note stating individuals have the option of not participating, if they wish not to, with no negative consequences]

Costs and Compensation for Participation

[If there are any charges or opportunities for monetary compensation, describe those here. If there are no costs or opportunities for compensation, state that here]

Confidentiality

[Describe how the confidentiality of the participants will be maintained here and resources for questions or concerns should participants have questions specific to the confidentiality of the information being collected]

Whom to Contact

If you have questions about the study, please contact the study staff listed on page one of this document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

[Insert contact information for your IRB including mailing address, phone number, and/or email. Your IRB should be able to provide the necessary and preferred contact information to include here]

Refusal or Withdrawal of Participation

[Include a statement that participation in this study is voluntary. Participants may withdraw from the study for any reason without penalty or loss of benefits. Also include a statement noting how data will be handled if early withdraw is requested (e.g., data will be destroyed, data will be used unless otherwise requested by the participant, etc.)]

Injury Statement

[Include a statement on what procedures will be followed if injury occurs as a result of participation in the study. Also include a statement on procedures to be followed if illness occurs during the study but is not related to the study itself (e.g., if the participant has a cold or injury that prevents them from being able to participate). This should also include a statement about the preservation of legal rights for all involved in the study (e.g., "You will not lose any of your legal rights or release the sponsor, the Investigator, the study staff, or study site from liability for mistakes by signing this consent document")]

Consent Signature

[Your consent form signature block may be required to contain specific wording from your IRB or managing organization. If no specific requirements are necessary, the text below is a general outline that may be used]

I confirm that the purpose of the research, the study procedures and the possible risks and discomforts as well as potential benefits that I may experience have been explained to me. Alternatives to my participation in the study also have been discussed. All my questions have been answered. I have read this consent form. My dated signature below indicates my willingness to participate in this study and my consent to the participation aspects described herein.

My signature below indicates my willingness to participate in this study described herein.

_____

Subject's Printed Name

_____

Subject's Signature & Date

_____

Principal Investigator's Printed Name

_____

Principal Investigator's Signature & Date

Appendix B. DATA USE AGREEMENT EXAMPLES

This appendix includes resources for finding examples of data use agreement templates and guides for developing Data Use Agreements. The resources contained within this appendix are for informational purposes only. All Data Use Agreements developed should be done so in accordance with your managing organization(s) and IRB representatives.

- The National Institute of Health (NIH) Data Use Code of Conduct for Genotypes and Phenotypes (dbGaP) repositories
  - https://osp.od.nih.gov/wp-content/uploads/Genomic_Data_User_Code_of_Conduct.pdf
- NIH Data Use Certification Agreement for the request of their datasets
  - https://osp.od.nih.gov/wp-content/uploads/Model_DUC.pdf)
- ContractStandards.com
  - https://www.contractstandards.com/public/contracts/data-sharing-agreement
- The University of Texas Health Science Center at San Antonio
  - https://uthscsa.edu/hipaa/Forms/datause.pdf
- Harvard Catalyst (Harvard Clinical and Translational Science Center)
  - https://catalyst.harvard.edu/publications-documents/data-use-agreement/
- Health Care Systems Research Network
  - http://www.hcsrn.org/en/Tools%20&%20Materials/GrantsContracting/HCSRN_DUAToolkit.pdf
- Stanford University Privacy Office Data Use Agreement FAQs
  - https://privacy.stanford.edu/other-resources/data-use-agreement-dua-faqs