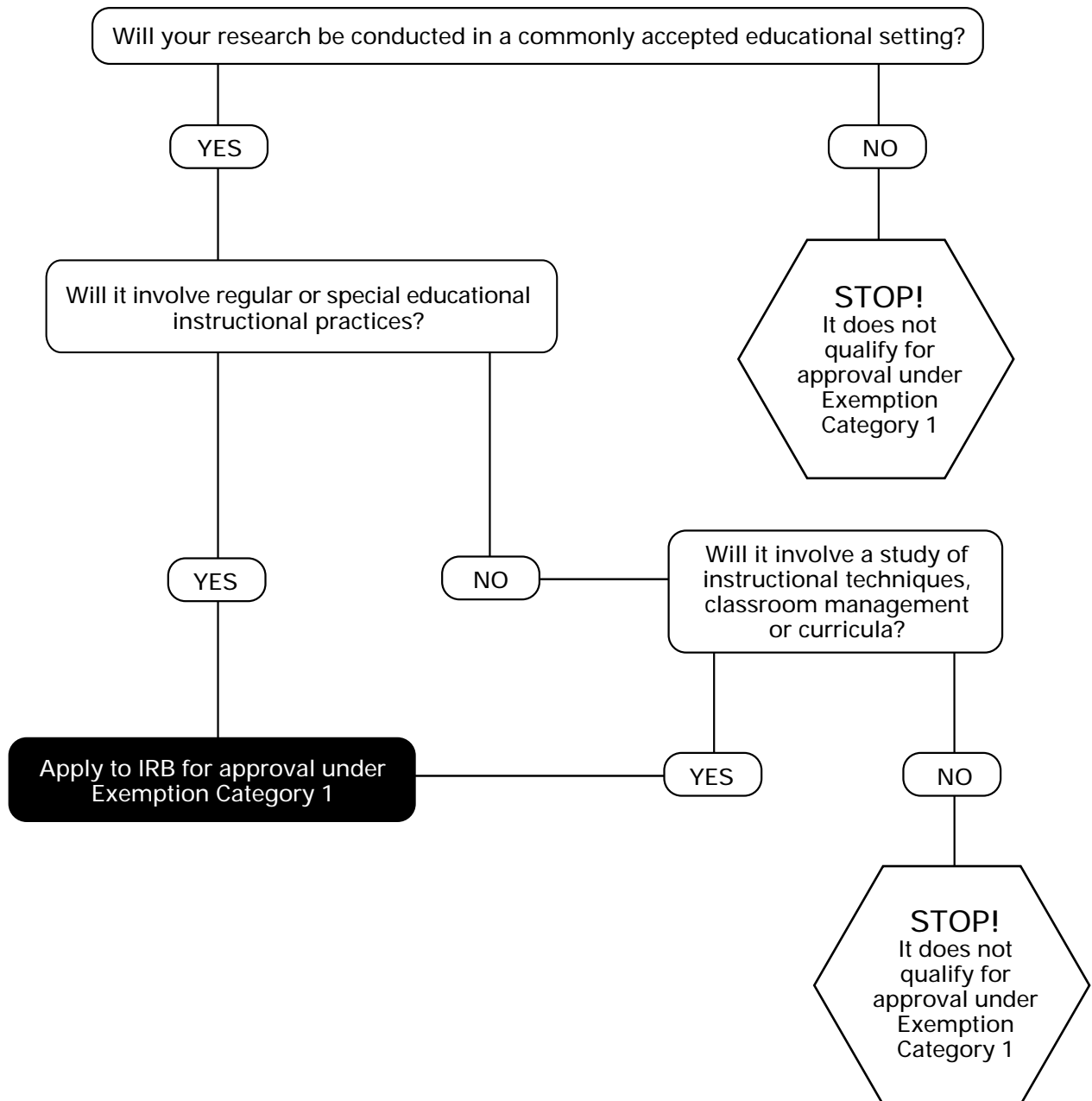


DESCRIPTION OF CATEGORY 1:

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (1) research on regular and special education instructional strategies; or (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

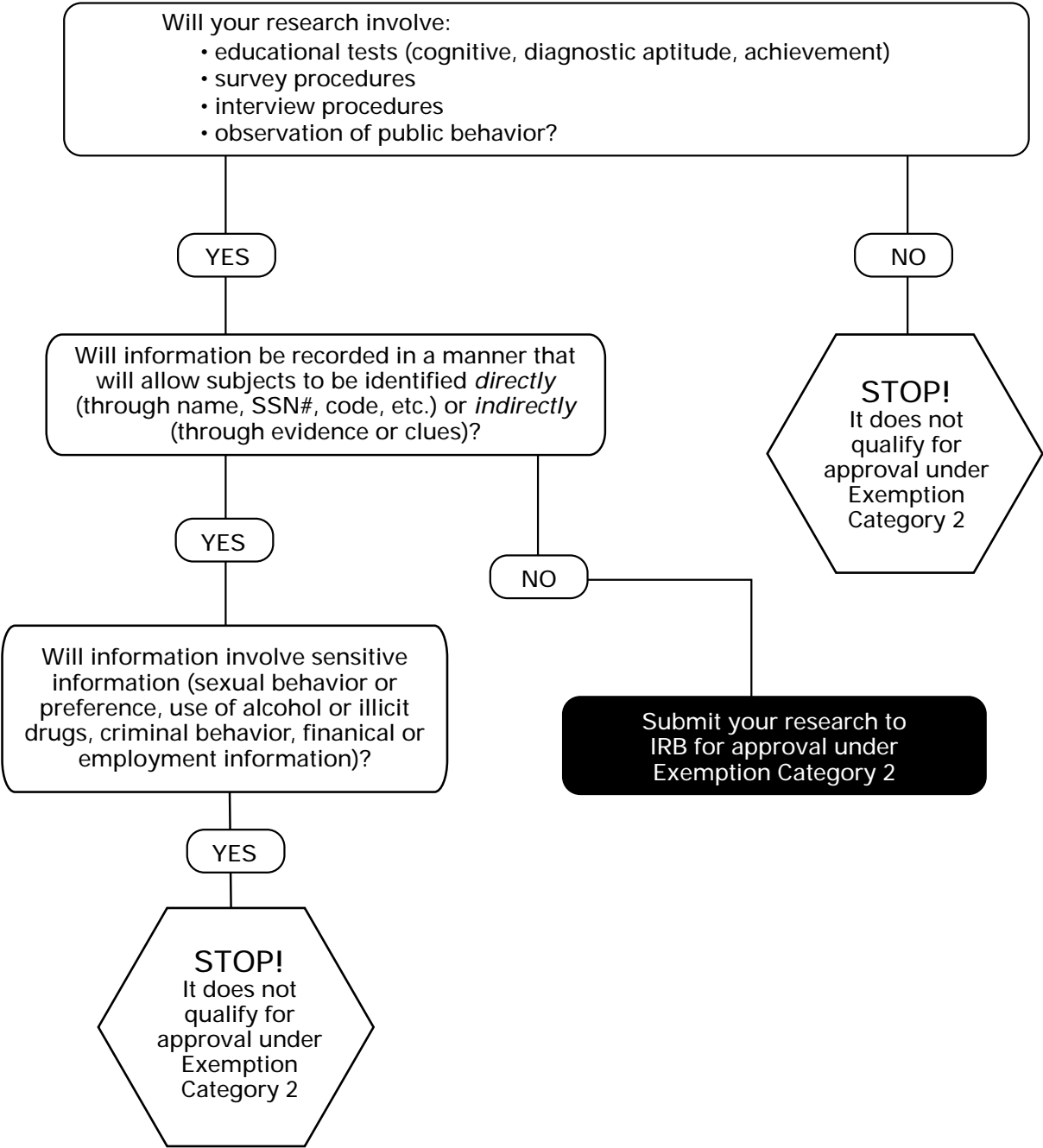
EXEMPTION CATEGORY ONE



DESCRIPTION OF CATEGORY 2:

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, observation of public behavior, **unless** the information is obtained and recorded in such a manner that human subjects can be identified, directly or through identifiers linked to subjects; **and** any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. Research involving children cannot be approved under Category 2.

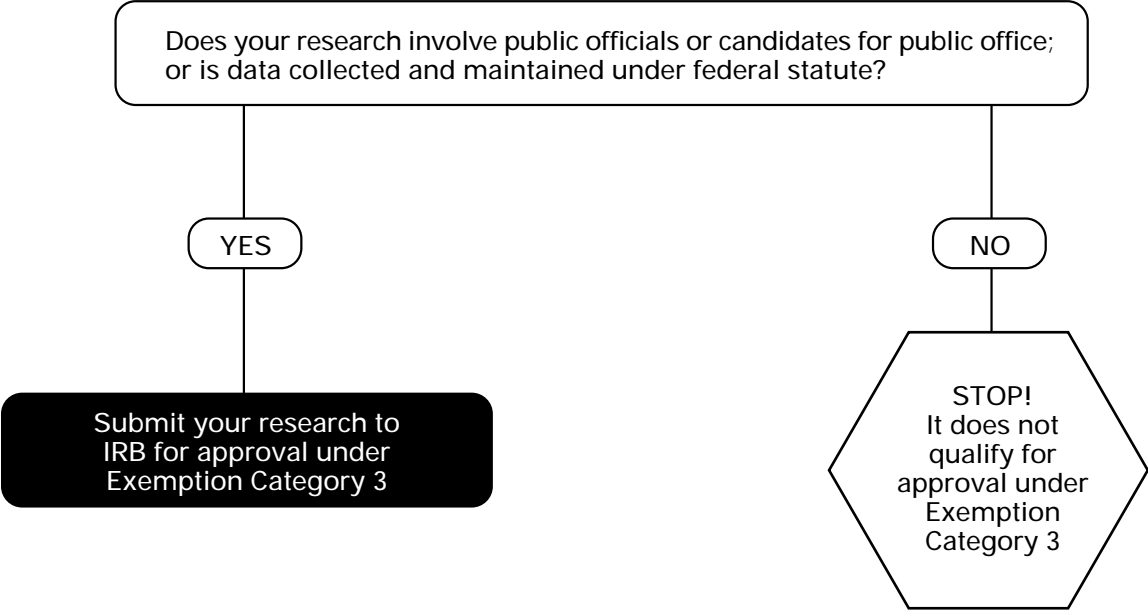
EXEMPTION CATEGORY TWO



DESCRIPTION OF CATEGORY 3:

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

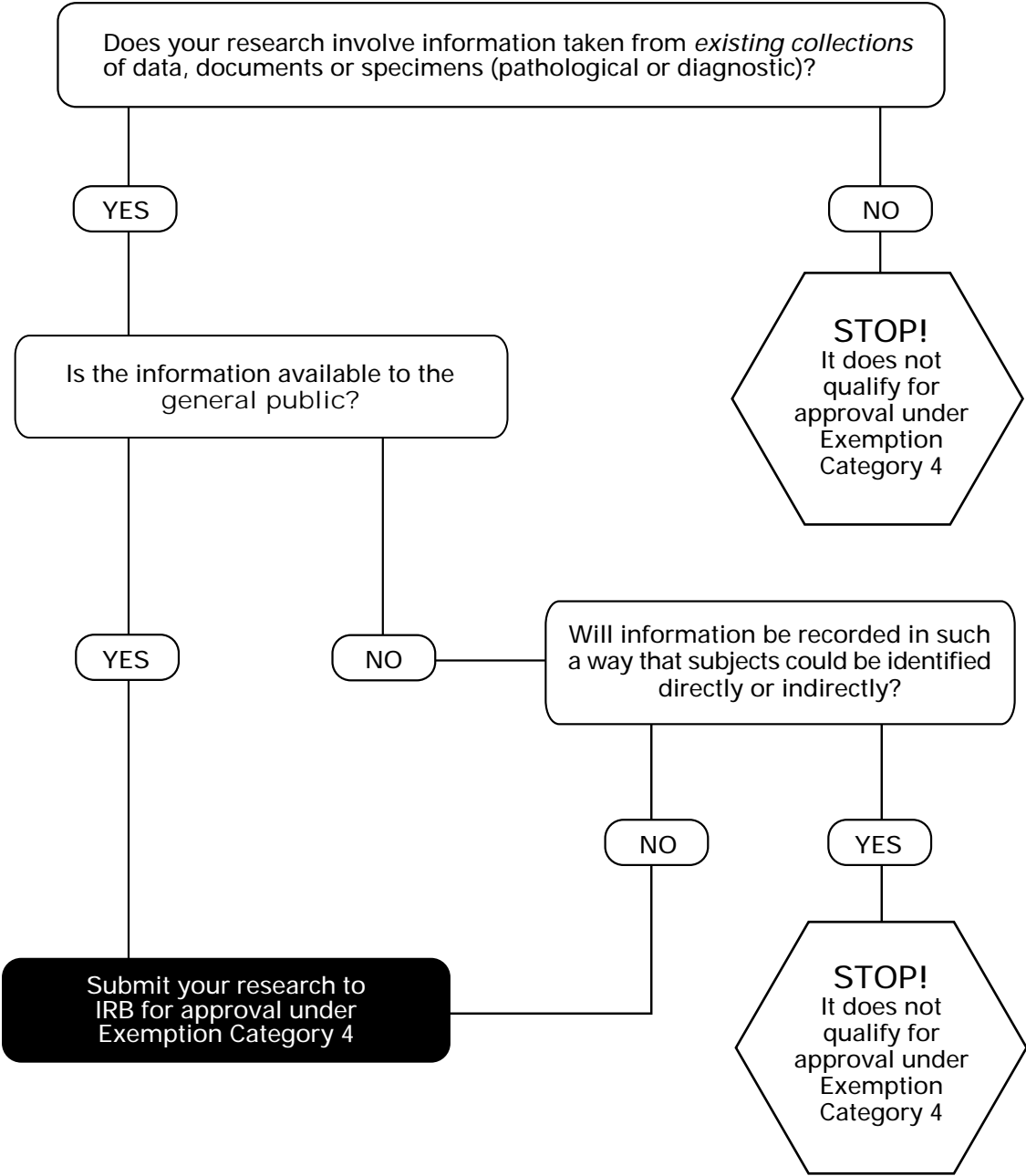
EXEMPTION CATEGORY THREE



DESCRIPTION OF CATEGORY 4:

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

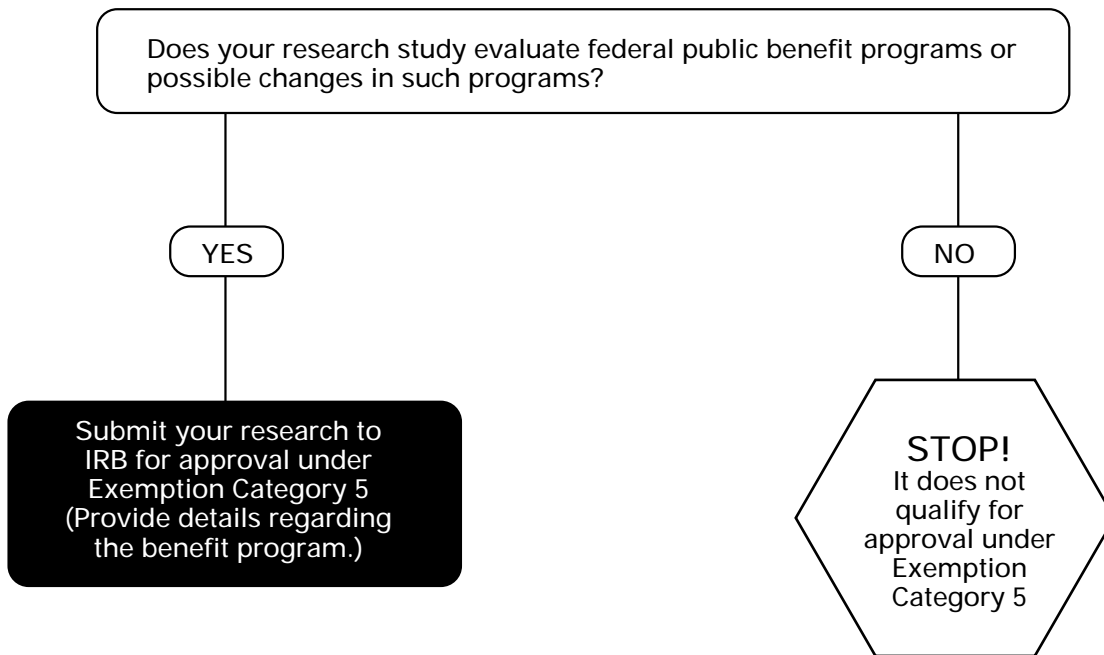
EXEMPTION CATEGORY FOUR



DESCRIPTION OF CATEGORY 5:

Research and demonstration projects which are conducted by or subject to the approval of [federal] department or Agency heads and which are designed to study, evaluate, or otherwise examine methods and procedures of public benefit or service programs.

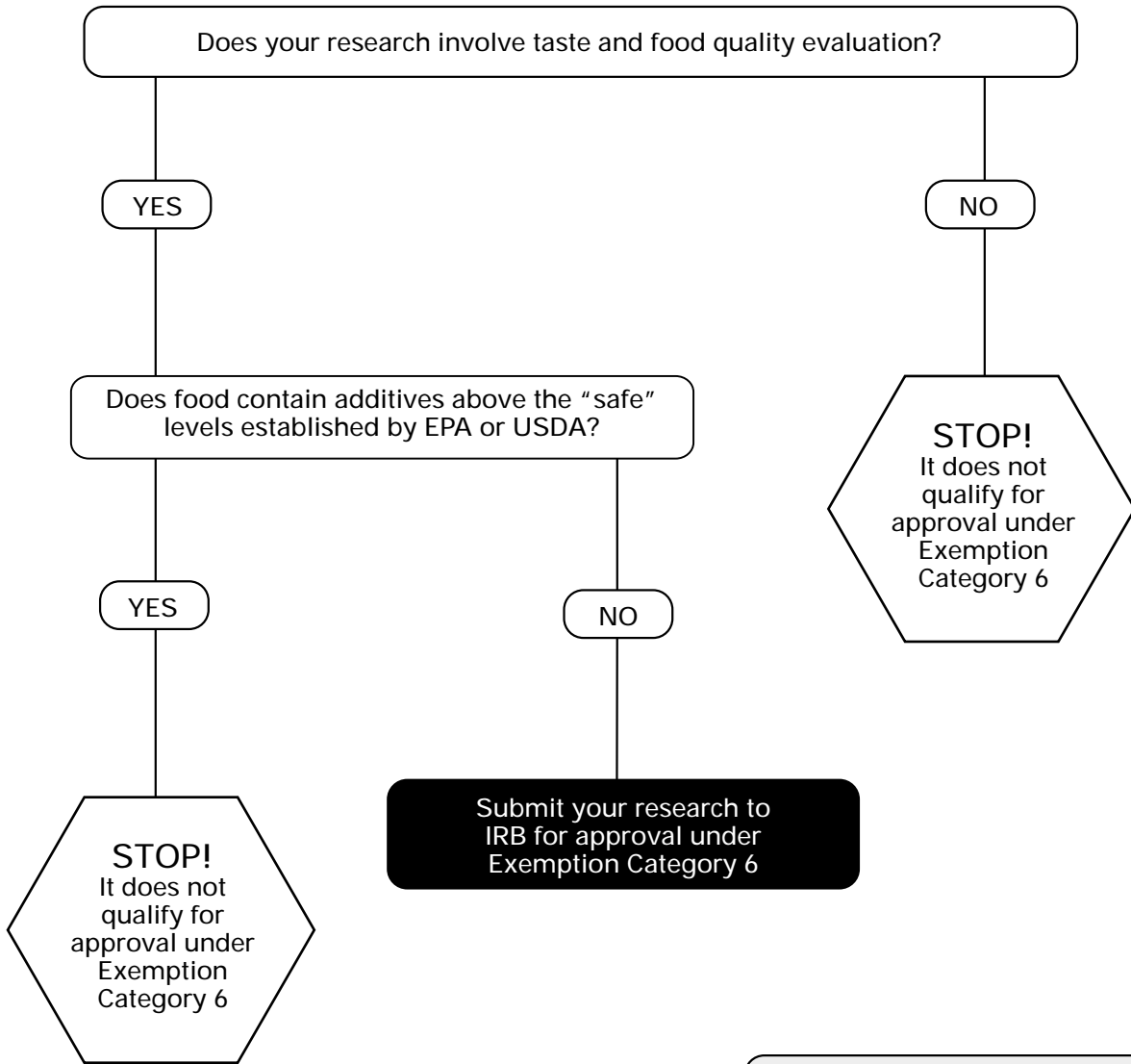
EXEMPTION CATEGORY FIVE



DESCRIPTION OF CATEGORY 6:

Taste and food quality evaluation and consumer acceptance studies, **if** wholesome foods without additives are consumed, **or** a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or an agricultural, chemical, or environmental contaminant at or below the level found to be safe by the Food and Drug Administration, or approved by the Environmental Protection Agency or the U.S. Department of Agriculture.

EXEMPTION CATEGORY SIX



NOTE:
If your research **DOES NOT QUALIFY** for exemption under **ANY CATEGORY** identified in these diagrams then it **MUST BE SUBMITTED TO IRB** for approval.

RESEARCH is defined as a systematic investigation designed to develop or contribute to generalizable knowledge (45 CFR 46.102.(d)).

Example: Professor X is teaching a course on research techniques. She asks each student in her class to interview five persons about their attitudes on abortion. Students are to keep no identifiers that could link answers to the subjects who are interviewed. A summary of answers is to be provided by each student to Professor X for evaluation. Because this information is gathered for a class assignment and is not intended to contribute to generalizable knowledge, the class activity does not meet the definition of research, and therefore need not be submitted to the IRB. However, if Professor X decides to aggregate all of the data received from student assignments, and to publish the results, then Professor X is planning research designed to contribute to generalizable knowledge. Her study must be submitted to the IRB. The IRB may find that the study qualifies for exemption because it contains no identifiers, but Professor X may not proceed with the study until the IRB has approved it.

HUMAN SUBJECT is defined as a living individual about whom a PI (whether a professional or a student) obtains data through intervention or interaction with the individual, or identifiable private information.

Example 1: Professor Y is doing research comparing leading causes of death in the inner city with leading causes of death in the suburbs. He searches the death certificates of all persons who died in the last five years in the City of White Plains and surrounding counties. This study does not meet the definition of research involving human subjects because the research subjects are all deceased. The study need not be submitted to the IRB. However, Professor Y may choose to submit the research to the IRB because the research (though not subject to federal regulations) may affect survivors of the deceased persons in the study.

Example 2: Professor Z wishes to gather data on blood units donated, but not used for transfusion by the New York State Blood Donor system. The New York State Blood Donor system removes all identifiers from the blood units prior to turning them over to Professor Z for research. Because Professor Z cannot link the blood samples to identifiable living individuals, he is not conducting research involving human subjects. Professor Z need not submit his research to the IRB. See Exemption (4) below.

CATEGORIES THAT MAY QUALIFY FOR IRB ADMINISTRATIVE (EXEMPT) REVIEW

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (1) research on regular and special education instructional strategies; or (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, observation of public behavior, **unless** the information is obtained and recorded in such a manner that human subjects can be identified, directly or through identifiers linked to subjects; **and** any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, or observation of public behavior that is not exempt under category 2 (above) **if** the human subjects are elected or appointed public officials or candidates for public office; **or** federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, **if** these sources are publicly available, **or** if the information is recorded by the investigator in such a manner that the subjects cannot be identified directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of [federal] department or Agency heads and which are designed to study, evaluate, or otherwise examine methods and procedures of public benefit or service programs.
6. Taste and food quality evaluation and consumer acceptance studies, **if** wholesome foods without additives are consumed, **or** a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or an agricultural, chemical, or environmental contaminant at or below the level found to be safe by the Food and Drug Administration, or approved by the Environmental Protection Agency or the U.S. Department of Agriculture.

INSTITUTIONAL REVIEW BOARD (IRB):

Each institution that conducts research subject to Federal Regulations for the Protection of Human Subjects is required to establish a Board to review and approve research prior to its initiation and at appropriate intervals thereafter. A research study must be reviewed no less than once per year. The IRB's primary obligation is to exercise oversight of research to protect the rights and the well-being of research subjects. The IRB is charged to: protect the autonomy of subjects; to minimize risks to subjects and maximize benefits to the subjects and/or to society as a whole; and to assure that the risks and benefits of research are equitably distributed across all segments of society. The IRB has additional responsibilities to protect vulnerable populations including human fetuses, prisoners, children, and the cognitively impaired. The IRB has responsibility to minimize physical, psychological or social risks to subjects, and to maximize benefits to the subjects and to society.

INTERVENTION OR INTERACTION WITH SUBJECTS:

Interaction includes interpersonal communication between investigators and subjects through surveys, interviews, administration of educational tests etc. Interventions include physical procedures (e.g. taking blood samples, spinal taps, or x-rays). Interventions also include manipulation of the environment in order to stimulate certain types of response behaviors.

PUBLICLY AVAILABLE:

Information is publicly available if it can legally be accessed by any adult member of society. For example: if the information can be found in a newspaper or magazine, in a public library, in publicly accessible data banks, in city directories or telephone books, on the internet (unless access is restricted), or in information published by federal agencies such as the Bureau of the Census or the National Center for Health Statistics. Information is not publicly available if access to it is restricted to certain individuals. Examples of information that is not public include: college registration records, education transcripts, medical records, personal files, individuals' credit card debts, private correspondence, personnel files, etc. Please note that if information like credit card debt is not very secure, it is nevertheless not intended to be available to any member of the public.

LINKED TO A SUBJECT:

This phrase refers to any information that can identify a subject who participates in research. Information that can be directly linked to a subject includes: a person's name, address, social security number, medical record number, or e-mail address. An indirect link is information that can be combined with other sources of information such as file codes, birth dates, zip codes, height, weight, and physical characteristics. These items of information can provide clues as to the identity of subjects. Indirect links might include: date of surgery, residence in a small town, (e.g. the subject is identified as a student at Columbia who comes in Manville, WY.) Birth, graduation, and marriage dates, can often be combined with other data to identify a person. For example, if information is filed in a database that includes 30 persons, and 5 of 30 are African Americans, one of the five African Americans is a woman. Any reference to an African American woman in the study could be easily linked to the single African American woman in the study.