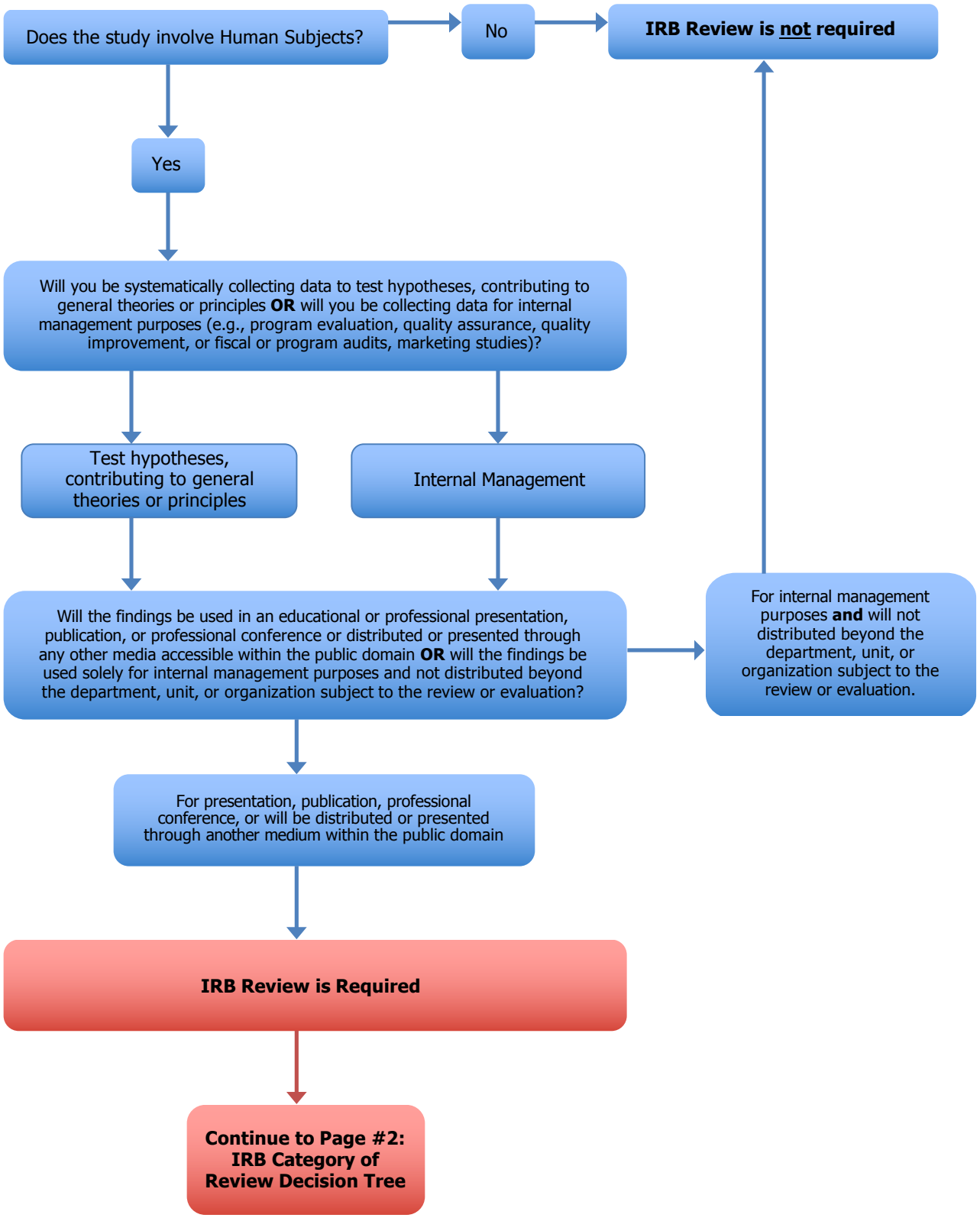
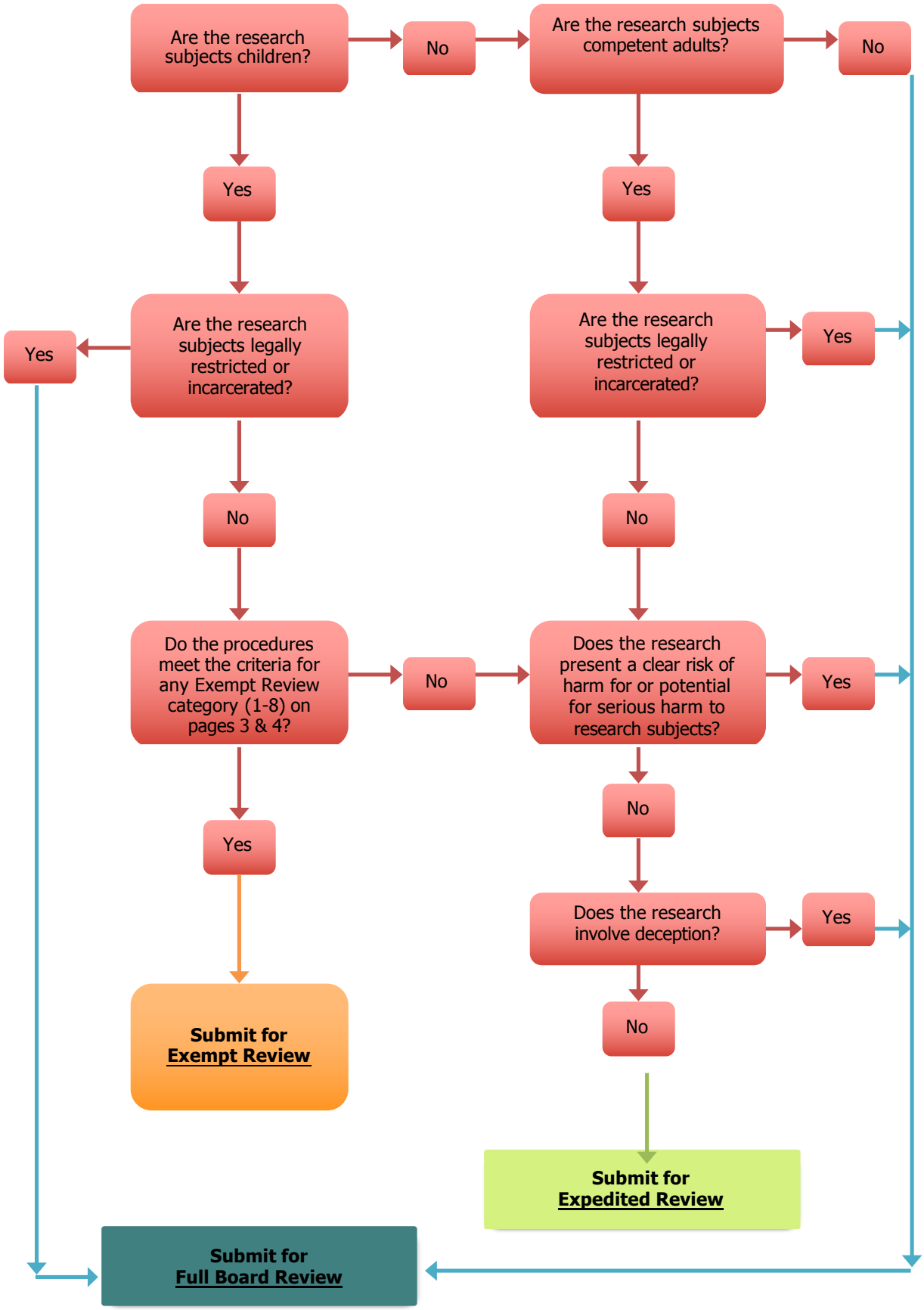
Research/IRB Review Decision Trees
For the Protection of Human Subjects

Research Decision Tree:



For additional assistance, please contact the IRB Coordinator, OSPRS@coastal.edu or 843.349.2978.

IRB Category of Review Decision Tree:



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OFFICE OF SPONSORED PROGRAMS AND RESEARCH SERVICES
COASTAL CAROLINA UNIVERSITY

As of **January 21, 2019** under the revised Common Rule (45 CFR 46.104), research can be approved as ***EXEMPT*** only if activities involving human subjects involve **no more than minimal risk** and will be in one or more of the following federally designated exempt categories. Studies that may qualify for ***EXEMPT*** must still be submitted to the IRB for review.

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

Examples: Researching regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if *at least one* of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts at least a *limited review*.

Examples: Surveying teachers, nurses or doctors about a technique or an outcome; interviewing managers about a management style or best practice; or conducting a focus group about an experience or an opinion of a community program.

(3) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts at least a *limited review* to make the determination.

Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

Examples: Having participants play an online game; having them solve puzzles under various noise conditions; or having them view a video and then answer questions based on what they've seen or heard.

(4) Secondary research for which consent is not required. Secondary research uses of identifiable private information or identifiable bio-specimens, if at least one of the following criteria is met:

i. The identifiable private information or identifiable bio-specimens are publicly available;

ii. Information, which may include information about bio-specimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA (i.e., 45 CFR parts 160 and 164, subparts A and

E), for the purposes of ''*health care operations*'' or ''*research*'' as those terms are defined at 45 CFR 164.501 or for ''*public health activities and purposes*'' as described under 45 CFR 164.512(b); or

iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, and conducted in compliance with 45 CFR 46.104(d)(4)(iv).

Example: Analyzing existing tissue samples or data set which are recorded by the investigator without identifiers.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads, or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine:

- public benefit or service programs;
- procedures for obtaining benefits or services under those programs;
- possible changes in or alternatives to those programs or procedures; or
- possible changes in methods or levels of payment for benefits or services under those programs.

Example: Evaluating the feasibility of using state financial assistance records to determine families eligible for free or reduced school lunch programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or 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 Food Safety and Inspection Service of the U.S. Department of Agriculture.

Example: A study to determine the preference of green apples to red apples.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts at least a *limited review* and makes the determinations.

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with
   a. § .116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained;

(iii) An IRB conducts at least a *limited review* and makes the determination that the research to be conducted is within the scope of the broad consent; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from any legal requirements to return individual research results.

Research activities are never exempt if the targeted participant population includes: prisoners, fetuses or pregnant women; participants will be exposed to more than minimal risk; or if the research involves deception of participants.

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Research can be reviewed as ***EXPEDITED*** only if activities involving human subjects do not involve more than "minimal risk" and are in one of the following nine federally designated ***EXPEDITED*** categories. Minimal risk means that "*the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests*."

(1) Clinical studies on drugs or medical devices for which an investigational new drug (IND) application or investigational device exemption (IDE) is not required.

Example: A study that uses a cleared medical device in accordance with its approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick or venipuncture.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Example: Hair and nail clippings in a non-disfiguring manner.

(4) Collection of data through noninvasive procedures routinely employed in clinical practice provided where:
- The procedure does not involve general anesthesia or sedation routinely employed in clinical practice or procedures involving x-rays or microwaves; or
- The medical devices employed are cleared/approved for marketing.

Example: Moderate exercise, muscular strength testing, body composition assessment and flexibility testing where appropriate given the age, weight, and health of the individual(s).

(5) Research involving data, documents, records or specimens that have been collected or will be collected solely for non-research purposes.

Example: Medical treatment or diagnosis information.

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies.

Example: Performing historical research of an event by bringing together people who were involved or have knowledge of the event to ask questions and record their responses for use.

For continuing research projects only:

(8) Review of research previously approved by the full/convened IRB where the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions and the research remains active only for long-term follow-up of subjects; no subjects have been enrolled and no additional risks have been identified; or the remaining research activities are limited to data analysis.

(9) Review of research not conducted under an IND application or IDE, and where categories two through eight do not apply, but the IRB has determined and documented that the research involves no greater than minimal risk and no additional risks have been identified.

Research that will require ***FULL BOARD*** review involves "possible risk" to human subjects.

Example: Drug or medical device trials, surgical or other invasive procedures, surveys or questionnaires that involve children or impaired populations, and any population of subject not covered under either *Exempt* or *Expedited* categories.