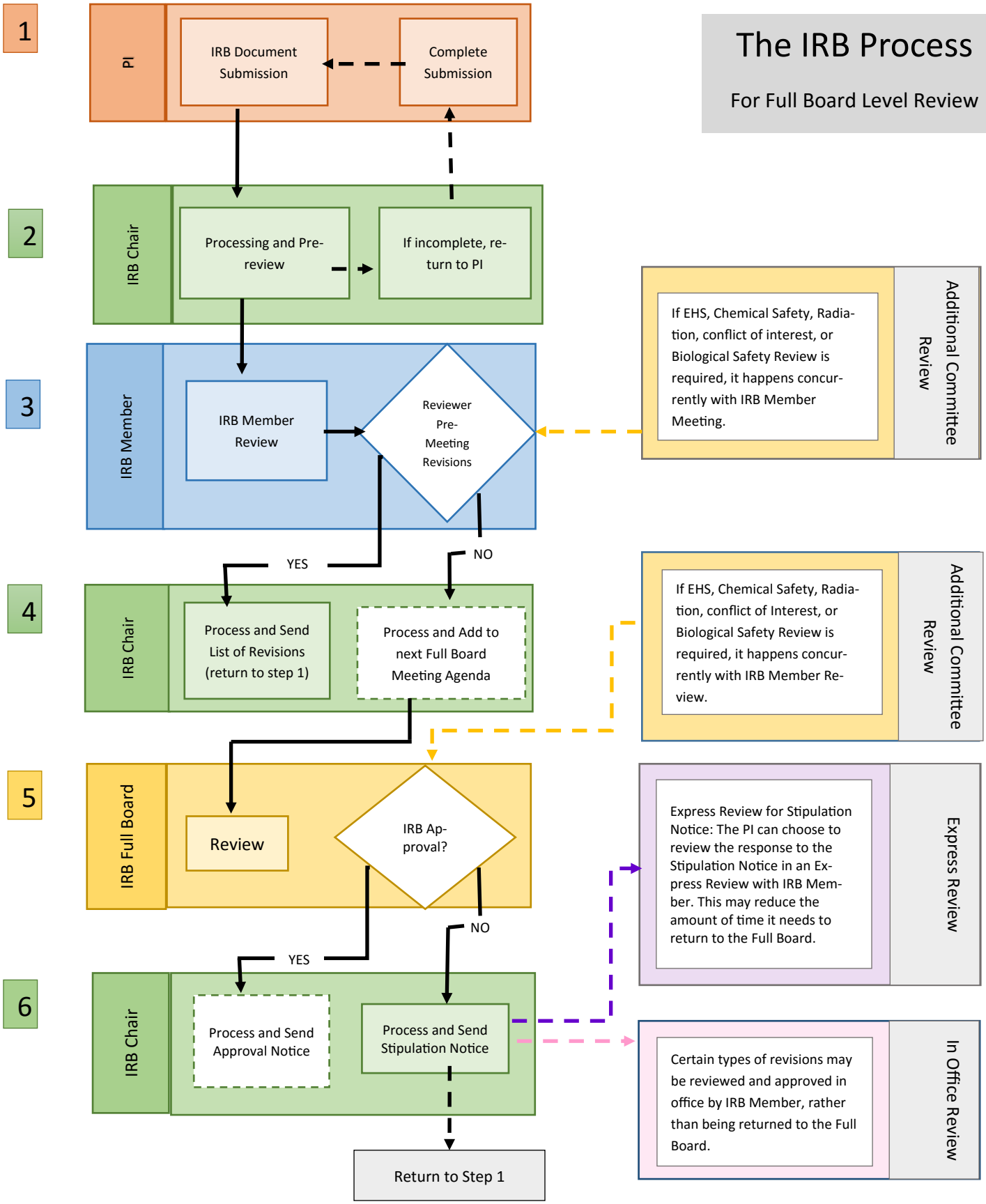
The IRB Process

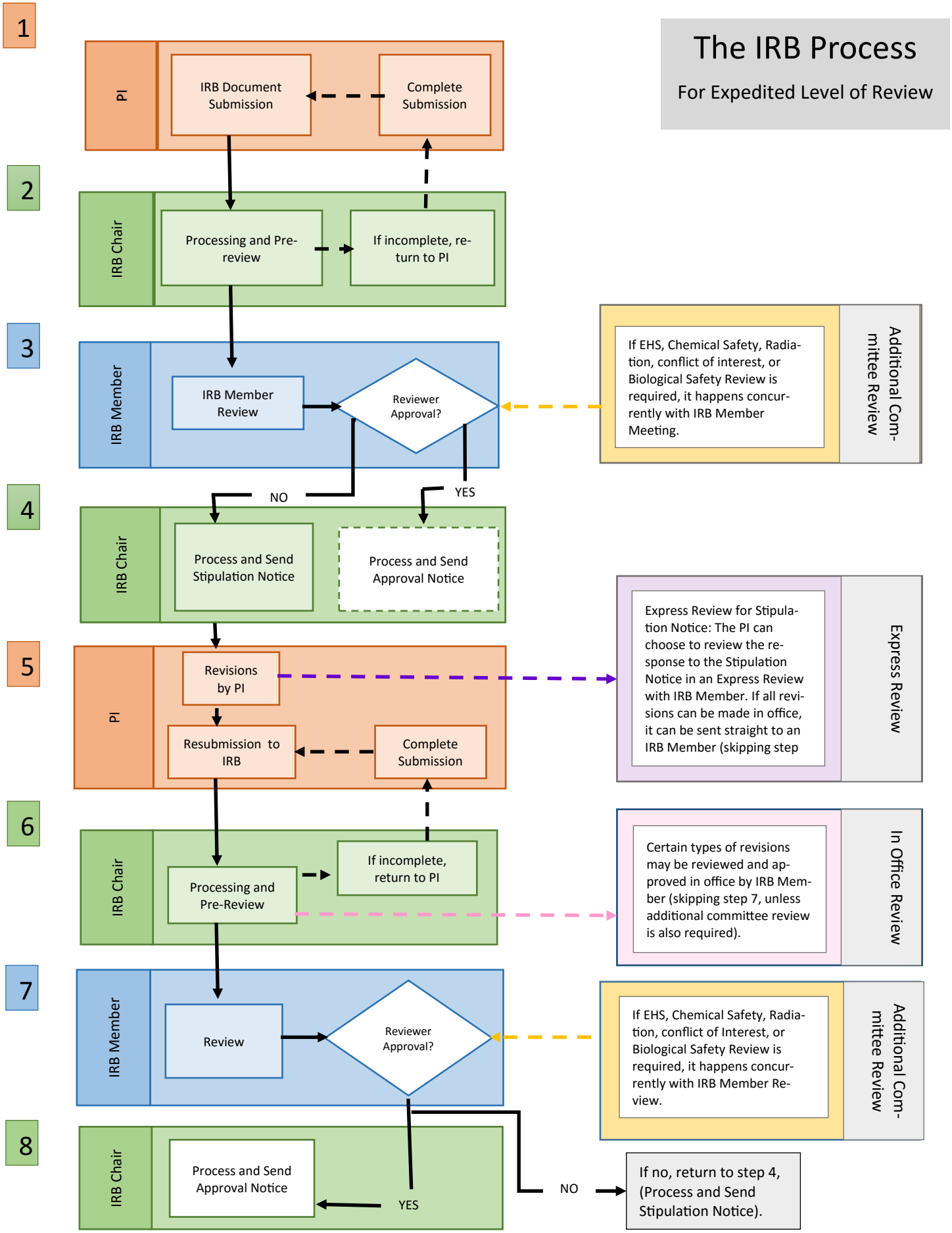
For Full Board Level Review



If you have any questions about this process, please contact IRB Chair, Dr. Shane Kendell: skendell@alamo.edu.

The IRB Process

For Expedited Level of Review



If you have any questions about this process, please contact IRB Chair, Dr. Shane Kendell: skendell@alamo.edu.

St. Philip's College
IRB Submission Cover Sheet
Checklist

If this box is checked, check page 2 to see in which category.

Please check off or provide details on the following (enter N/A if not applicable)

_____ Exemption Requested
See Page 2 - 3

_____ Expedited Review Requested
See Page 4 - 5

Principal Investigator Name: _____ (Must be full name)

Affiliation: Faculty ____ Student ____ (must include signature of committee chair on protocol) ACCD Professional ____ Other____

College /Dept / Organization _____

Contact: Home Phone _____ **Work Phone** _____ **Email** _____

Project Title: _____ (Complete title of the project must be included in order to follow up on research at the institution)

Subjective Estimate of Risk to Subject: Low ____ Moderate ____ High ____ None ____

Gender of subjects: Male____ Female ____ Both ____

Age(s) of subjects: _____

Total Participants (est.) _____

If any category other than "None" is checked indicates a need for review. If the "Exempt" category is checked and any other category than "None" is also checked there is a conflict that must be reviewed.

If subjects are under 18, a parental consent signature line must be included in the consent form.

Source of Subjects:

____ Classroom
____ Early College High School/Dual Credit
____ Campus (General)
____ Posted notices (attach)
____ Online Course
____ Other _____

Subject Recruitment:

____ Direct, person to person contact
____ Telephone solicitation
____ Newspaper advertisement (attach)
____ Letter (attach)
____ Other _____

Will subjects be compensated? Yes ____ (If yes, attach compensation conditions and schedule of payment) No

Will any means of deception be utilized? Yes ____ (if yes, attach debriefing form) No ____

Location of Experiment (Digital/Physical Location): _____

Specify digital location (webpage, etc.) or the physical location/address.

Will invasive or sensitive procedures be utilized? Yes ____ (if yes, indicate type below) No ____

If "yes" is check, this is an automatic referral to the IRB for full review.

____ Blood Samples ____ Urine Samples ___ Stress Exercise ____ Physical Measurements

____ Psychological Inventory ____ Review of Medical Records ____ rDNA ____ Other (Specify) _____

Will research involve sensitive subject matter? Yes ____ (if yes, indicate type below) No ____

If yes, automatic review by IRB

____ Alcohol, Drugs, Sex ____ Depression/Suicide ____ Learning Disability

____ Other (Specify)_____

Use of Video or Audio tapes (indicate type)_____

Retained? Yes ____ No ____ Length of time retained _____ Destroy/ Erase? Yes ____ No ____

Other (Explain) _____

Is use specified in consent form? Yes ____ No ____

Use/Access to tapes:_____

Provisions for Confidentiality/Anonymity

Replies Coded? Yes ____ No ____ Secure Storage? Yes ____ No ____

Anonymous Response? Yes ____ No ____ Confidential Response? Yes ____ No ____

Exact location where consent forms will be filed: _____
(Must be kept on file for 3 years after completion of the project)

Please enclose an abstract of the Research Proposal with Statement of Consent and Debriefing Form

St. Philip's College
IRB Submission Cover Sheet
Protocol for Human Subjects in Research

Please check off or provide details on the following (enter N/A if not applicable)

_____ Exemption Requested
See Pages 2 - 3

_____ Expedited Review Requested
See Pages 4 - 5

Principal Investigator Name: _____

Affiliation: Faculty ____ Student ____ (must include signature of committee chair on protocol) ACCD Professional ____ Other____

College /Dept / Organization _____

Contact: Home Phone _____ Work Phone _____ Email_____

Project Title: _____

Subjective Estimate of Risk to Subject: Low ____ Moderate ____ High ____ None ____

Gender of subjects: Male____ Female ____ Both ____

Age(s) of subjects: _____

Total Participants (est.) _____

Source of Subjects:

____ Classroom
____ Early College High School/Dual Credit
____ Campus (General)
____ Posted notices (attach)
____ Online Course
____ Other _____

Subject Recruitment:

____ Direct, person to person contact
____ Telephone solicitation
____ Newspaper advertisement (attach)
____ Letter (attach)
____ Other _____

Will subjects be compensated? Yes ____ (If yes, attach compensation conditions and schedule of payment) No ____

Will any means of deception be utilized? Yes ____ (if yes, attach debriefing form) No ____

Location of Experiment (Digital/Physical Location): _____

Will invasive or sensitive procedures be utilized? Yes ____ (if yes, indicate type below) No ____

____ Blood Samples ____ Urine Samples ___ Stress Exercise ____ Physical Measurements

____ Psychological Inventory ____ Review of Medical Records ____ rDNA ____ Other (Specify) _____

Will research involve sensitive subject matter? Yes ____ (if yes, indicate type below) No ____

____ Alcohol, Drugs, Sex ____ Depression/Suicide ____ Learning Disability

____ Other (Specify)_____

Use of Video or Audio tapes (indicate type)_____

Retained? Yes ____ No ____ Length of time retained _____ Destroy/ Erase? Yes ____ No ____

Other (Explain) _____

Is use specified in consent form? Yes ____ No ____

Use/Access to tapes:_____

Provisions for Confidentiality/Anonymity

Replies Coded? Yes ____ No ____ Secure Storage? Yes ____ No ____

Anonymous Response? Yes ____ No ____ Confidential Response? Yes ____ No ____

Exact location where consent forms will be filed: _____
(Must be kept on file for 3 years after completion of the project)

Please enclose an abstract of the Research Proposal with Statement of Consent and Debriefing Form

REQUEST FOR EXEMPTION FROM IRB REVIEW

Some research projects involving human subjects are exempt from a review by the IRB. See the attached sheet on research categories exempt from full IRB review.

Basis for Exemption [Refer to attach "Categories Exempt From Full IRB Review"]

____ Established educational settings/normal educational practice (a letter of approval from a school official must be obtained before the study can be conducted; send copy to the IRB).

____ Use of educational anonymous test (cognitive, diagnostic, aptitude, advancement; attach copy).

____ Survey or interview procedures, [unless subjects might be identified, put at legal or personal risk, and unless survey or procedures deal with sensitive matters of personal behavior]

____ Observations of public behavior [unless subjects might be identified, put at legal or personal risk, and unless observations deal with sensitive matters of personal behavior]

____ Anonymous collection or study of existing documents, records, pathological or diagnostic specimens.

____ Taste and food quality evaluation and consumer acceptance studies.

The U.S. population is becoming increasingly culturally, linguistically, economically, and ethnically diverse. The research needs to make a concerted effort to ensure that research subjects reflect the population demographically, including these groups who have been traditionally underrepresented. However, it is recognized that the available pool of subjects may preclude having a balanced population. If you cannot use a diverse population in your research, you must justify why not.

_____
Principal Investigator Signature and Date

_____
Student's Committee Chair Signature and Date

_____
Department Head Signature and Date

_____
Institutional Review Board Chair or Designee Signature and Date

Categories Exempt From Full IRB Review

Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from full review by the IRB:

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

- **Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:** information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the 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 the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the second bullet of this section, if:** the human subjects are elected or appointed public officials or candidates for public office; or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- **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 subjects cannot be identified, directly or through identifiers linked to the subjects.**

- **Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine:** public benefit or service programs; procedures for obtaining benefits or services under these 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.

- **Taste and food quality evaluation and consumer acceptance studies:** if wholesome foods without additives are consumed; or 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.

Source: Federal Register, Vol. 56, No. 117 (June 18, 1991), §46.101 (b) (1)- (6).

REQUEST FOR EXPEDITED IRB REVIEW

Some research projects involving human subjects may be reviewed by the IRB through an Expedited Review Procedure. See the attached sheet on applicable research categories.

Basis for Expedited Review [Refer to attached "OHRP Expedited Review Categories "]

____ Clinical studies of drugs and medical devices only when (a) an investigational new drug application is not required OR (b) an investigational device exemption application is not needed/the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

____ Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture

____ Prospective collection of biological specimens for research purposes by noninvasive means.

____ Collection of data through noninvasive procedures.

____ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes.

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

____ 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.

____ Continuing review of research previously approved by the convened IRB.

____ Other continuing review of research about which the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

The U.S. population is becoming increasingly culturally, linguistically, economically, and ethnically diverse. The research needs to make a concerted effort to ensure that research subjects reflect the population demographically, including these groups who have been traditionally underrepresented. However, it is recognized that the available pool of subjects may preclude having a balanced population. If you cannot use a diverse population in your research, you must justify why not.

_____
Principal Investigator Signature and Date

_____
Student's Committee Chair Signature and Date

_____
Department Head Signature and Date

_____
Institutional Review Board Chair or Designee Signature and Date

OHRP Expedited Review Categories (1998)

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure[1]

Applicability

A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

B. The categories in this list apply regardless of the age of subjects, except as noted.

C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

D. The expedited review procedure may not be used for classified research involving human subjects.

E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

    a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

    a. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

    b. from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.
Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

    b. where no subjects have been enrolled and no additional risks have been identified; or

    c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

[2] Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

Source: 63 FR 60364-60367, November 9, 1998.