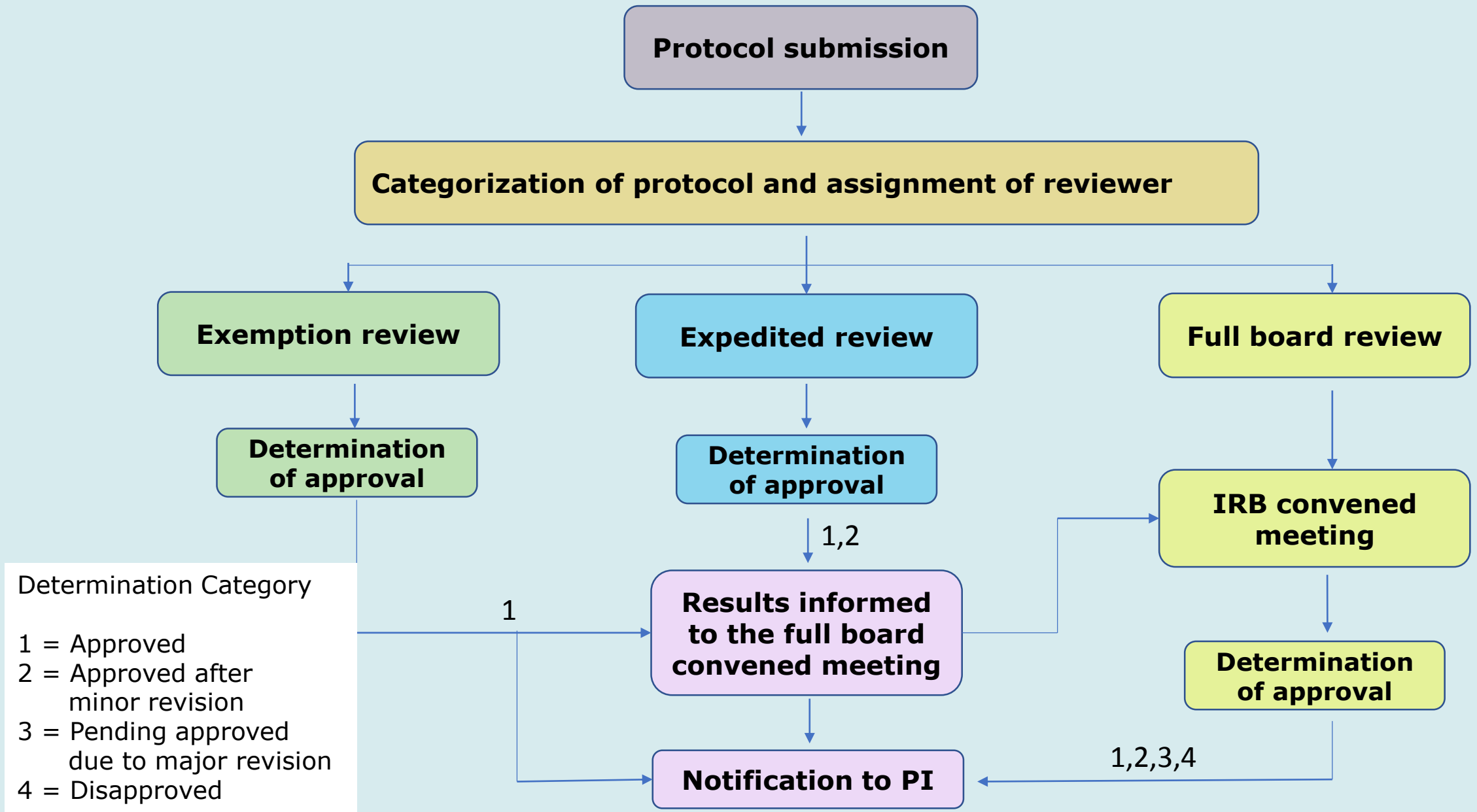
Operating procedures for initial IRB review



Initial Review Categorizations

All proposed activities that involve human subjects and satisfy the definition of research must be reviewed and approved prior to the beginning of a study. The levels of initial review are categorized as Exempt, Expedited and Full Board.

Exempt Research Activities

Research can be approved as exempt if it is no greater than "minimal risk" and meets one or more of the following characteristics:

1. Research conducted in established educational settings involving normal educational practice such as research on regular and special education instructional strategies, the effectiveness of comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests: cognitive, diagnostic, aptitude and achievement, the information obtained cannot identify or link to an individual subject and the results report as whole information.
3. Research involving the use of survey procedures, interview procedures, or observation of public behavior and the information obtained is recorded in such a manner that human subjects cannot be identified individually and the research shall not be damaging to the subjects, reputation, employability, financial standing, or reasonably place the subjects at risk of civil liability.

Exempt Research Activities

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens and these sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
5. Customer satisfaction for quality development of the division’s operation.
6. Research involving the quality assessment or inspection which cannot identify or link to individual subject.
7. Research involving the taste and food quality evaluation and consumer acceptance
   7.1 Foods without consumption of additives.
   7.2 Food consumed containing a food ingredient at or below the safety level or agricultural chemical or environmental contamination at or below the safety level by the Food and Drug Administration.

Expedited Research Activities

The activities listed in an application for expedited review should meet the following

1. The research must not be the cause of legal risks such as drug addiction, or damage, or discredit the financial reputation, social status of the participants or making them lose their jobs or invasion of privacy and breach of confidentiality.

2. The research must be the minimal risk with the following characteristics:

   2.1 Research on individual or group behavior observation or interview excluding the research studies in the vulnerable subjects or sensitive issues.

   2.2 The collection of biological specimens for research purposes by noninvasive means.

   2.3 Data collection through noninvasive procedures (excluding procedures involving x-ray or microwaves) that do not involve general anesthesia or sedation is routinely employed in clinical practice. If medical devices are employed, they must be approved for marketing.

Expedited Research Activities

2.4 If the research needs the participant's blood sample, the blood will be collected from the fingertip or heel or earlobe of the infant or venipuncture. The amount of blood drawn and times for collection should be as follows:

- Blood collection in adult participants: must be the healthy and non-pregnant adults who weigh at least 50 kg. The amounts drawn may not exceed 550 ml in 8 weeks' period and collection must not occur more frequently than 2 times per week.
- Blood collection in children or adults who weigh less than 50 kg. The amount of blood drawn must not exceed 50 ml or 3 ml per kg in 8 weeks' period and collection must not occur more frequently than 2 times per week.

2.5 Research involving data, documents, records, or specimens that have been collected for diagnosis or medical treatment not for research purposes.

2.6 Data collection from voice, video, digital or image recordings.

2.7 Sending specimens for examination must not be the genetic examination which can be reached to the data or specimen owner.

Research Activities that Require Full Board Initial Review

Categories of research activities that require Full Board Review at the convened meeting includes:

1. Initial applications that appear to involve more than minimal risk or research using vulnerable human research participants that do not specifically fit an exempt or expedited review category.

2. All other protocols determined by the IRB Chair or an Expedited Reviewer to require Full Board Review.

3. Revisions to initial protocols that contain non-minor changes.