ISCEV extended protocols: process for proposal, review and approval

ISCEV publishes standards for clinical electrophysiologic tests of the visual system that define the minimum protocols for clinical diagnostic testing. These are developed and updated by ISCEV standardization committees and published following consultation and approval by a vote of the ISCEV membership. For information on the most recent standards see www.ISCEV.org/standards/

ISCEV standards encourage more extensive testing for specific clinical indications and for clinical trials, but do not contain recommendations for such extended protocols. Examples include protocols to record S-cone ERG and multichannel recording of the VEP.

ISCEV Approved Extended Protocols are intended to provide rigorous specifications for specialized procedures that are sufficiently well established and that have broad acceptance by experts in the field. These will be useful for applications such as non-standard diagnostic testing and clinical trials. They will also encourage better inter-laboratory comparison. This document explains the process for development, review and approval of extended protocols. The intention is encourage the development of protocols that meet criteria for well-established clinical needs, and for techniques that can be endorsed broadly by leading authorities. This designation is not intended for newly developed tests, or for protocols specific to one laboratory or investigator.

The process of establishing an approved extended protocol has THREE parts:

I. Approval of a concept (proposal): This will acknowledge the need for a specialized procedure and approve a process of preparing a formal protocol.

II. Preparation of the protocol

III. Approval of protocol: Submitted protocols will be reviewed by the Director of Standards and the full ISCEV Board to consider acceptance as an ISCEV-Approved Extended Protocol

I. SUBMISSION OF CONCEPT (PROPOSAL):

A concept or proposal can be submitted to the ISCEV Director of Standards at any time with the support of a minimum of three ISCEV members, who can contribute independent perspectives and are not all linked to one lab or group[1]. The proposal document should be concise and not exceed 700 words on 2 pages (excluding final bibliography). It should include the following:

1. Title of the extended protocol and date of the outline proposal.
2. Name of the authors with contact details for a corresponding author
3. Description of clinical need and applications for the proposed protocol
4. Brief summary of the protocol (or of the main variations to be considered).

[1] Members eligible to propose extended protocols must be voting members of ISCEV (regular, honorary, family or emeritus type 1). Junior and emeritus type 2 are non-voting memberships)

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5. Evidence that the procedure is sufficiently established in the peer-reviewed literature, and across a diversity of laboratories.
6. Outline of consultative process. This section should briefly define the likely users and principal manufacturers who will be consulted, and specify the expected opportunities for discussion. It should document how the major schools of thought relevant to the procedure will be incorporated and reconciled. It should indicate how committees will gather evidence and seek membership input.
7. Bibliography. A bibliography of no more than 10 citations should document the clinical need, and breadth of usage, of the protocol.

The Director of Standards will consider concept proposals, and inform the ISCEV Board of Directors which may approve, provide feedback or request expert opinion at this stage. The proposal stage can be waived by the Director of Standards under special circumstances, such as for proposals that are modifications to existing approved protocols or that have been reviewed extensively prior to the establishment of these application procedures.

II. PREPARATION OF PROTOCOL

Once a concept has been approved, the submitters may formally begin the process of committee review, drafting, etc. It is a minimum requirement that proposals for extended protocols must be announced to ISCEV members and posted on the web for at least two months to allow discussion. Discussion must also be advertised and open to all members during at least one ISCEV Symposium. Only approved concepts (proposals) will be eligible for publicity through ISCEV media (website, Wiki, Symposia), and for scheduling of discussion time at Symposia.

III. SUBMISSION OF AN EXTENDED PROTOCOL

Following consultation, drafting and membership review, the protocol may be submitted for ISCEV approval. This application has two parts: Part A is the proposed protocol itself. Part B is a summary of the consultation process including any major modifications or considerations made to facilitate acceptance relative to alternative procedures or schools of thought. The submitted protocol should be concise and should not exceed 3000 words in total (excluding figures, tables and bibliography).

Part A. Proposed Extended Protocol for Clinical Electrophysiology of Vision.

1. **Title:** concise and specific name for the extended protocol
2. **Scope and applications:** Short description and/or list of likely applications for the protocol
3. **Identification**: Protocol number, version, date, corresponding author, other authors and, if relevant, names involved in a larger consultation group
4. **Patient population** for whom the protocol is targeted.
5. **Technical issues** such as specialist equipment, facilities, expertise and/or responsibilities. If the protocol is technically similar to one of the ISCEV Standards, simply cite the relevant standard.
6. **Calibration:** Specify the nature and frequency of calibration required to reliably carry out the proposed extended protocol or cite the relevant ISCEV Standard.

7. **Protocol Specifications:** Clearly describe the patient preparation, procedures and the sequence of the protocol. This section should include complete electrode specifications, amplification and recording parameters, stimulus specifications and should be tabulated when appropriate.
8. **Response evaluation:** Specify the expected results of testing with illustrations and indicate how they will be measured. Atypical (abnormal) results should also be defined. Normative ranges are helpful.
9. **Reporting:** Specify how results of the extended protocol will be reported including details which should be included in all reports.
10. **Relevant References:** Bibliography

Part B: Justification for the protocol details and description of the consultation process

This section must document that the major international "players" for the given protocol have been brought into the consultative process. Protocols must be developed in a collaborative fashion, with evidence that diverse opinions are included, and that diverse groups agree to the proposal. The applicants should indicate how the minimum consultation time (two months), and the requirement for a discussion with the ISCEV membership at a Symposium, have been met.

Any substantial alternative protocols or opposition should be discussed in this section along with a description of modifications made and of reasons that the current proposal should be widely acceptable.

ISCEV APPROVAL

Final applications are submitted to the Director of Standards who will present the material to the ISCEV Board of Directors for consideration. Acceptance as an 'ISCEV Approved Extended Protocol' will proceed by vote of the elected ISCEV Board of Directors. The Board may submit the application for independent expert review.

Criteria for approval include:

1 The protocol characterizes a useful physiologic process or processes.

2 The procedures are well-established and not currently in the early stages of development. The test is in use in several different laboratories, whose experience has contributed to the protocol under submission.

3 The protocol is clearly defined and can be satisfactorily replicated in diverse laboratories resulting in comparable results.

4 While it is recognized that some protocols were developed using specific equipment, they must be specified in such a way that they are reasonably accessible to those using instruments made by different manufacturers.

Accepted protocols will be posted in a special category within the ISCEV website, and publicized to the Society. Publication is optional, but if the authors wish to publish an extended protocol, Documenta Ophthalmologica must be given first option.