	Peregrine Eye and Laser Institute Institutional Review Board
	Glossary

Glossary

1	Active Files	Are documents pertaining to protocols which are currently being assessed, managed or monitored by the REC
2	Active Study	An ongoing study, implementation of which is within the period covered by ethics clearance
3	Ad hoc SOP committee	Group formed for the special purpose of writing or revising SOPs.
4	Adjournment	Formal closure of the meeting.
5	Administrative Documents	Documents pertaining to the operations of the IRB and are not directly related to any protocol
6	Agenda	The list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a “Call to Order
7	Alternate Members	Individuals who possess qualifications of specified regular members. They are called to attend a meeting and substitute for regular members to comply with the quorum requirement when the latter cannot attend the meeting
8	Amendments	Changes or revisions of the protocol made after it has been approved

9	Appeal	A request of a researcher/ investigator for a reconsideration of the REC recommendation
10	Archiving	A systematic keeping of protocol files in storage after the studies have been completed with final reports accepted or terminated or declared inactive
11	Assessment form	Evaluation tool accomplished by the reviewers when appraising the Protocol and the Informed Consent.
12	Business Arising from the Minutes	Are matters generated from the discussions in the previous meeting that need continuing attention and require reporting.
13	CAPA	Corrective and Preventive Action
14	CIOMS	Council for International Organizations of Medical Sciences (CIOMS), which prepares international ethical guidelines for health-related research involving humans
15	Clarificatory Interview/meeting	Is a meeting or consultation of the IRB with the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the IRB
16	Coding	A unique number assigned to a protocol indicating the year and series it was received

17	Collegial Decision	A course of action arrived at after a group deliberation where members were considered of equal authority such that the course of action is considered a group action and is not ascribed to any one member
18	Competent Authority	Designated officer or member of the IRB with the authority to respond to queries and complaints regarding studies approved by the IRB
19	Complaint	The act of expressing discontent or unease about certain events or arrangements in connection with a study
20	Confidentiality	Is the duty to not freely disclose private/research information entrusted to an individual or organization
21	Confidentiality of document	Pertains to the document that has been entrusted or submitted to the IRB that must not be freely shared or disclosed such that it is appropriately tagged and its distribution carefully tracked, monitored and appropriately recorded.
22	Conflict of Interest	A situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties.

23	Consensus	The process of arriving at a decision without voting but by generating the over all sentiment of a group such that deliberations continue until no more strong objection is registered
24	Continuing Review	Is the decision of the REC to extend the ethical clearance of a study based on an assessment that the research is proceeding according to the approved protocol and there is reasonable expectation of its completion
25	Database	A collection of information that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually an electronic platform used for tracking and monitoring the implementation of a study.
26	Date of Effectivity	Date when the guidelines shall be enforced
27	Decision	The result of the deliberations of the REC in the review of a protocol or other submissions
28	Declaration of Helsinki	A statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data
29	Document template	A document type which creates a copy of itself when opened; it has a pre-determined structure and layout.
30	Draft Agenda	A list of possible topics for discussion in the upcoming meeting

		prepared by the Staff Secretary under the supervision of the Member-Secretary and submitted to the Chair for review and approval
31	Early Termination	Ending the implementation of a study before its completion which is decided by the sponsor or regulatory authority or the researcher in considering the safety of participants, funding issues, protocol violations and data integrity issues
32	Exemption from review	Human subject research that is classified as "exempt" means that the research qualifies as no risk or minimal risk to subjects and is exempt from most of the requirements of the Federal Policy for the Protection of Human Subjects, but is still considered research requiring an IRB review for an exemption determination.
33	Expedited Review	Is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committ
34	Final Report	Is a summary of the outputs and outcomes (including documented risks and benefits) of the study upon its completion, as well as the status of all participants. The IRB requires the accomplishment of the Final Report form within a reasonable period after the end of the study.
35	Final agenda	Approved provisional agenda by the IRB members and the Chair during the scheduled meeting

36	Format	General style or layout of the document
37	Full Review	Is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.
38	Greater than Minimal Risk to subjects-	The probability and magnitude of harm or discomfort anticipated in the research risks are more than minimal risk, but not significantly greater
39	High Risk Studies	Research where harm or danger resulting from the study intervention is very likely for participants
40	Honorarium	Monetary payment for specific professional services of IRB members
41	Identifier	Unique number assigned to a particular SOP that reflects its serial position among the SOPs and version number to indicate the number of times it has been revised
42	Inactive Study	A study whose proponent has not communicated with the IRB with regard to issues pertaining to the approval or implementation of the study within a period of time required by the IRB
43	Incoming communications	Documents directed to the IRB

44	Independent Consultant	Resource person who is not a member of the Research Ethics Committee, whose expertise is needed in the review of a research protocol/proposal and who may be invited to attend a committee meeting but is non-voting during the deliberations.
45	Informed Consent	A process by which a subject voluntarily confirms his/her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form
46	Initial Review	The ethical assessment of the first complete set of study documents submitted to the REC so that review can be conducted
47	Initial Submission	Refers to the first (initial) package of study documents forwarded to the REC for review
48	Intellectual property right	The exclusive right given to persons over the use of his/her work over a period of time
49	IRB Operations	The over all activities of the IRB that reflect performance of its Functions and responsibilities
50	Logbook	A real-time, chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name and Signature of the Submitting Entity, Name and Signature of the Receiver and Action done.

51	Major Modification	Is a recommended revision of significant aspects/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data statistical analysis, mitigation of risks, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research.
52	Medical device	Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose
53	Medical Members	Are individuals with academic degrees in the medical profession and a master's in the nursing profession
54	Memorandum of Agreement (MOA)	Is a document written between parties to cooperatively work together on an agreed upon project or meet an agreed upon objective. The purpose of an MOA is to have a written formal understanding of the agreement between parties
55	Minimal Risk	The probability and magnitude of physical or psychological harm anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life, or in routine medical, dental, or psychological examination

56	Minor Modification	Is a recommended revision of particular aspect/s of the study or related documents that do not impact on potential risks/harms to participants and on the integrity of the research, e.g. incomplete documentation, incomplete IC elements, unsatisfactory IC format)
57	Minor Protocol Violation	Is repeated or frequent major protocol deviation that may still not be categorized
58	Minutes of the meeting	The official narration and record of the proceedings of the assembly of IRB Members, based on the agenda.
59	More than Minimal Risk	Term used when the probability and magnitude of harm or discomfort anticipated in a research are greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests
60	Non-affiliated member	A member of the board not under direct employment by the institution where IRB is established. This is to make sure the unbiased preservation of the IRB's main roles in assuring patient safety and upholding the main ethical principles it follows
61	Non-Medical or Non-Scientific or Lay Member	A member who represents the interest and concerns of the community. This member's main responsibility is to evaluate the content of informed consent form and make sure that the said form is comprehensible, complete, and in of best interest for the subject.

62	Non-scientific member-	A member whose primary activity is not related to the social sciences, medicine, dentistry,nursing, pharmacy, other biomedical health professions or medical or dental resear
63	Non-significant risk (NSR)-	An NSR device investigation is one that does not meet the definition for a significant risk study. NSR device studies, however, should not be confused with the concept of "minimal risk," a term utilized in the Institutional Review Board (IRB) regulations [21 CFR part 56] to identify certain studies that may be approved through an "expedited review" procedure
64	Notification or Approval letter	A letter sent to the investigator informing him of the decision of the IRB regarding his protocol
65	Operations-related Matters	Are items included in the agenda that are not directly related to any protocol under review.
66	On-site Serious Adverse Events (SAEs)	Are SAE's that occur in study participants enrolled in study site that has ethical clearance from Peregrine Eye and Laser Institute-Institutional Review Board
67	Outgoing communications	Documents from the IRB directed to individuals or offices related to the operations of the IRB
68	Primary Reviewer	Are members of the IRB (usually a scientist and a non-scientist) assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the committee
69	Principal Investigator	The lead person selected by the sponsor to be primarily responsible for the implementation of a sponsor-initiated clinical drug trial

70	Progress report	A description of how the study is progressing submitted to the IRB using the Progress Report Form
71	Protocol	Documentation of the study proposal that includes a presentation of the rationale and significance of the study, background and review of literature, study objectives, study design and methodology, data collection, dummy tables, plan for analysis of data, ethical consideration, and dissemination plan
72	Protocol Database	A collection of information about protocols that is structured and organized for easy access, management, intepretation, analysis and updating. It is usually in an electronic platform used for tracking and monitoring the implementation of a study
73	Protocol Deviation	Non-compliance with the approved protocol that does not increase risk nor decrease benefit to participants and does not significantly affect their rights, safety and welfare or the integrity of the data
74	Protocol File Folder	Is an organized compilation of all documents received from the site (physical or electronic) related to a study
75	Protocol File	Is an organized physical or electronic compilation of all documents related to a Protocol
76	Protocol Index	A chronological record in table form of the documents in the protocol file which includes the date of filing, the nature of the document filed, the name and signature of the person who filed and

		an extra column to record any movement of the document. The index is pasted inside the cover page of the protocol file folder
77	Protocol-related Documents	Consists of all other documents aside from the proposal/protocol itself that required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of proponent, advertisements, In-depth Interview Guide Questions,
78	Protocol Violation	Non-compliance with the approved protocol that may result in an increased risk or decreased benefit to participants or significantly affects their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria
79	Provisional agenda	Approved draft agenda by the Chair which is to be included in the Notice of Meeting; this provisional agenda is to be approved by the members during the upcoming meeting
80	Query	The act of asking for information or clarification about a study
81	Quorum	the minimum number (i.e., majority of the members) and type of members of the IRB that are required to be present in any meeting for the proceedings to be considered valid. International and national guidelines require the presence of at least 5 regular members including the non-affiliated and the non-scientist members
82	Regular Meeting	A periodically scheduled assembly of the REC

83	Regular Members	Are members constituting the research ethics committee, who receive official appointments from the institutional authority with specific terms and responsibilities including review of research proposals and attendance of meetings
84	Regulatory Authorities	Agencies or institutions that have oversight or control over the conduct of research
85	Researcher	Is the individual primarily responsible for the conceptualization, planning and implementation of a study.
86	Researcher-Initiated Studies	Are research activities whose conceptualization, protocol development and implementation are done by a researcher or group of individuals who may request for external funding support.
87	Resubmission	The revised study proposal that is re-forwarded to the REC following the recommendations from the initial review
88	Reviewer	A regular member of the Research Ethics Committee who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee
89	Room-use restriction	The rule that limits the use of a document within the designated premises

90	SAE (Serious Adverse Events)	Is an event observed during the implementation of a study where the outcome is any of the following o Death o Life threatening o Hospitalization (initial or prolonged) o Disability or permanent damage o Congenital anomaly/ birth defect o Required intervention to prevent permanent impairment or damage (devices) o Other serious (important medical) events whether or not it is related to the study intervention.
91	SAE Reviewer	Is a scientific reviewer that assesses serious adverse event reports and make sure that necessary actions were done to ensure patient safety
92	Scientific Member	Are technically qualified experts in their field, such as clinical medicine, engineering, biological sciences, physical sciences, biostatistics and many others. (US-FDA)
93	Significant risk (SR)	An SR device study is defined [21 CFR 812.3(m)] as a study of a device that presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

94	Site Visit	Is an activity of the REC where an assigned team goes to the research site or office for specific monitoring purposes.
95	Site Visiting Team	Members/staff of the IRB (2-4 members) assigned by the IRB Chair to formally go to the research site, meet with the research team and evaluate compliance with the approved protocol and Informed Consent Form and Process, including other related research procedures to ensure promotion of the rights, dignity and well-being of participants and protection of integrity of data
96	SOP	Abbreviation of Standard Operating Procedures, they are the step-by-step description of the different procedures done to accomplish the objective of an activity. They consist of clear, unambiguous instructions for ethical review to ensure quality and consistency.
97	Special Meeting	An assembly of the Committee outside of the regular schedule of meetings for a specific purpose
98	Sponsor	An individual, company, institution or organization, which takes responsibility for the initiation, management, and financing of a clinical trial.
99	Sponsored-Clinical Trials	Are a systematic study on pharmaceutical products in human subjects (including research participants and other volunteers), whose conceptualization, protocol development and support for their conduct are the responsibilities of sponsors who manufactured the products, in compliance with the requirements of regulatory authorities.

100	Staff Secretary	A full-time staff employed by the institution responsible for administrative groundwork support under the supervision of the board
101	Study Documents	Include all materials (protocol, forms, certificates, research tools) pertinent to a research proposal that have to be submitted to the REC for review
102	Support Staff	Institutional personnel assigned by administration to assist in the operations of the IRB
103	SUSAR (Suspected Unexpected Serious Adverse Reaction)	A serious event the nature and severity of which is not consistent with the applicable product information. In the case of an unapproved investigational product, the event is not consistent with the investigator's brochure (IB). In the case of a licensed product, the event is not consistent with the approved package insert or summary of product characteristics
104	Technical Reviewer	Has the authority to review the technical aspect of the study and has the responsibility to ensure that proposed research for review is scientifically sound before proceeding with PELI-IRB's ethical review
105	Termination package	Refers to the entitlements of study participants in the event of discontinuance of the study, which can come in the form of access

		to the study intervention, treatment, or information, for purposes of adherence to the principle of fairness for all concerned
106	Terms of reference (TOR)	Instructions given to someone when they are asked to consider or investigate a particular subject, telling them what they must deal with and what they can ignore.
107	Venue	Unit or room within the institution that is used for office events like meetings
108	Voting	Act of formally manifesting a choice in a meeting
109	Vulnerable participants	Persons who may be relatively or absolutely incapable of protecting their own interests due to limitations in decision-making capacity, power relationships, education, or resources, and therefore require additional protections when participating in research.