ABC's OF IRBs

1. **AAHRPP** ('a – harp') – Association for the Accreditation of Human Research Protection Programs. An independent, non-profit accrediting body that uses a voluntary, peer-driven, educational model to ensure that HRPPs meet rigorous standards for quality and protection.

2. **AE** – Adverse Event. Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product, and which does not necessarily have a causal relationship with that treatment.

3. **CFR**- Code of Federal Regulations. The codification of the general and permanent rules published in the Federal Register by the departments and agencies of the Federal Government. It is divided into 50 titles that represent broad areas subject to Federal regulation. IRBs are mainly concerned with titles 21 and 45.

4. **CRF** – Case Report Form. Data collection tool used during a research subjects participation in research.

5. **DHHS** – US Department of Health and Human Services. The United States government's principal agency for protecting the health of all Americans and providing essential human services.

6. **DSMB** – Data Safety and Monitoring Board. An independent group of experts that advises the sponsor and study investigators.

7. **FDA** – Food and Drug Administration. Responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health.

8. **FWA** – Federalwide Assurance. Through the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46. The Federalwide Assurance (FWA) is the only type of assurance currently accepted and approved by OHRP.

9. **HDE** – Humanitarian Device Exemption. Application filed to obtain approval for an HUD (see Humanitarian Use Device below).

10. **HIPAA** – Health Insurance Portability and Accountability Act. Also known as the Kennedy-Kassebaun Action. Title I of HIPAA protects health insurance workers and their families when they change or lose their jobs. Title II of HIPAA, known as the Administrative Simplification (AS) provisions, requires the establishment of national standards for electronic health care and national identifiers for providers, health insurance plans, and employers.

11. **HUD** – Humanitarian Use Device. A device that is intended to benefit patients by treating or diagnosing a disease that affects fewer than 4,000 individuals in the United States per year.

12. **IB** – Investigator's Brochure. A compilation of the clinical and nonclinical data on an investigational product that is relevant to the study of the product in human subjects.

13. **IC** – Informed Consent. A process for getting permission before conducting a healthcare intervention on a person/potential participant. The **ICF** – Informed Consent Form is a written document used as part of the informed consent process to obtain participant permission.

14. **ICP** – Informed Consent Process. A continual two-way dialogue (throughout participation in research) that includes discussion and education as needed.

15. **IDE** – Investigational Device Exemption. FDA designation that allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval.

16. **IND** – Investigation New Drug. Application to the FDA for drug approval.

17. **IO** – Institutional Official. The individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance.

18. **IRB** – Institutional Review Board. Also known as an independent ethics committee or ethical review board, that is formally designated to approve, monitor, and review biomedical and behavioral research involving humans.

19. **LAR** – Legally Authorized Representative. An individual or entity that makes decisions for a person who cannot represent her/himself.

20. **NCI** – National Cancer Institute. Part of the National Institutes of Health (NIH), and is the Federal Government's principal agency for cancer research and training.

21. **NIH** – National Institutes of Health. The nation's medical research agency.

22. **OHRP** ('o-harp') – Office for Human Research Protections. Provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS).

23. **PHI** – Protected Health Information. Individually identifiable health information.

24. **QA** – Quality Assessment. Activities that are designed to determine whether aspects of medical practice are being performed in line with established standards.

25. **QI** – Quality Improvement. Activities initiated with a goal of improving the performance of institutional practice in relationship to an established standard.

26. **SAE** – Serious Adverse Event. Any undesirable experience associated with the use of a medical product in a patient. The event is serious and should be reported when the patient outcome is: death, life-threatening, hospitalization (initial or prolongation of), disability or permanent damage, congenital anomaly/birth defect.