

TRAINING CHECKLIST AND DOCUMENTATION -- IRB MEMBER

PURPOSE: ___ NEW MEMBER ___ CONTINUING EDUCATION ___ OTHER

NAME: _____

TRAINING/EDUCATION SOURCE (*=REQUIRED)	COMPLETED	VERIFIED BY
University of Pennsylvania IRB Standard Operating Policies		
Applicable State and Federal Laws		
DHHS 45 CFR 46		
FDA 21 CFR 50 and 21 CFR 56		
Committee Member Responsibilities		
Types of Review: Exempt, Expedited, Convened Committee, Prime		
Primary & Secondary Reviewer Assignments and Responsibilities		
Distribution of Materials for Review		
Pre-Review Process by the IRB Administrator (Completeness Check)		
Process for Contacting Investigators & Study Personnel		
Assessment of Risks		
Process of Informed Consent: Documentation, Required Elements, Waiver, Etc.		
Confidentiality and HIPAA		
Vulnerable Populations and Supplemental Review Forms		
Study Monitoring Requirements		
Voting Process: Motions, Recusals, Abstentions, Etc.		
Conflict of Interest		
Determination of Review Intervals (yearly, bi-annual, etc.)		
Attendance Requirements		

DOCUMENTATION RECEIVED DURING TRAINING	RECEIVED	INITIAL
IRB Staff Contact List		
Primary Reviewer Checklist		
Vulnerable Populations Checklists (Subparts B, C, and D)		
Completeness Checklist & Appendices		
Social/Behavioral Checklists (If Applicable)		
Continuing Review Checklist		
Guidelines for Submission - Levels of Risk		
IRB Member Handbook (Amder & Bankhart)		

CERTIFICATIONS AND ONGOING EDUCATIONS	RECEIVED	INITIAL
POR certification		
OHRP Training Modules for Assurances		
Observing Attendance of IRB being joined		