Office of Human Research Ethics Training Tips
Revised OHRE SOPs, effective June 2, 2017: June 2017

SOP #	Abbrev. Title	New or Changed	Text	Additional Information
1201	Vulnerable subjects	**New**	**New:** Information reviewed as part of the continuing review process includes the number of participants considered to be members of specific vulnerable populations. At Continuing Review the investigator should identify the number and categories of vulnerable subjects enrolled and any problems that arose relevant to their rights and welfare.	Pending implementation: Additional question added to IRBIS annual progress report to collect the number of subjects enrolled in each group (children, pregnant women, non-viable neonates, neonates of uncertain viability, prisoners and cognitively impaired individuals).
201	Quality Assurance	**New**	Investigator Compliance Reviews for directed audits and "not for cause" reviews of the consent process.	The IRB is responsible for the conduct of directed (i.e., for cause) audits.
901	Multicenter Research and Reliance Process (AKA Off site policies)	Change	Expands on previous SOP, Version 4/2014 (Agreements to provide IRB review of research conducted by collaborating external investigators) AND 3.4 (Agreements for reliance on IRBs between collaborating institutions) AND SOP 3.5 (Reliance on Independent IRBs) Adds information about NCI CIRB Appendix M. Guidance, Flowchart and documents for external agreements deleted.	Expands on previous SOP, Version 4/2014
1901	Information Security	**New**	No significant policy changes	
1301	FDA regulated research	**New**	New text but information is not new.	Expands on FDA regulatory requirements, including dietary supplements, expanded access treatments, and off label use of HUDs.
701	IRB review process	**New**	Scientific or scholarly review is documented and provided to the IRB by the Scientific Review Committee for all biomedical research conducted at the University of North Carolina at Chapel Hill involving procedures that pose greater than minimal risk that have not received external independent scientific/scholarly review.	New to SOPs but process is not new
701	IRB Review process	Change	4. Data and Safety Monitoring plans should specify: • The entity or person(s) who will perform the monitoring, and the independence or affiliation that the entity or person(s) has with the sponsor or investigator • The safety information that will be collected and monitored, including serious adverse events and unanticipated problems	Expands on data and safety monitor plans.

			• The frequency or periodicity of review of safety data • The procedures for analysis and interpretation of the data • The procedures for review of scientific literature and data from other sources that may inform the safety or conduct of the study • The conditions that trigger a suspension or termination of the research (i.e., stopping rules), if applicable • The procedures for reporting to the IRB, including a summary description of what information, or the types of information, that will be provided	
701	IRB Review Process	**New**	**Requesting a Single Subject Protocol Exception** The Investigator will submit a modification requesting a Protocol Exception. Protocol Exceptions should be submitted separately from other modification requests. A Protocol Exception Request Form must be completed and submitted along with any additional required documentation. The investigator must explain the underlying reasons for which the protocol exception is requested and where an over-riding safety concern or ethical issue indicates that it is in the best interest of the individual to continue participating.	Pending implementation: New form and process
701	IRB Review Process	**New**	**Requesting a Protocol Exception to Conduct Research during Approval Lapse** Interventions are allowed to continue only when it is in the best interest of the subjects and when approved by the IRB. To request the continuation of certain aspects of the research, the investigator must submit a Protocol Exception Request Form describing the activities.	Pending implementation: New form and process.
301	Education and Training	**New**	Continuing education requirements in the Protection of Human Research must be completed at least every 3 years. All IRB members must complete eROC training	Pending implementation: New training modules and retraining requirements.
2101 and 2102	Conflict of Interest policies	Change	Replaces Individual and IRB member COI policies	Expands on previous SOP, Version 4/2014
601	Exempt Research	**New**	Separate SOP created	Expands on previous SOP, Version 4/2014
801	Institution, Investigator or Sponsor-Initiated Holds	**New**	An institutional, investigator or sponsor hold should be reported to the IRB as new safety information in accordance with SOP 1401, Reporting New Safety Information if the hold is a result of safety concerns. All other institutional, investigator or sponsor	Changes from previous SOP, Version 4/2014

			holds should be submitted as modifications to previously approved research.	
1401 1402 1403	Reporting New Safety Information Management of New Safety Information Questions, Concerns or Complaints from Research Participants or Third Parties	Revised	Replaces SOPs 19, 22, 23 and 36 Key Points: <u>SOP 1401: Reporting New Safety Information</u> 1. What type of information is promptly reportable to the IRB: TABLE 1, New Safety Information 2. Promptly reportable = 7 calendar days 3. Assessment of Risk 4. Root Cause Analysis 5. Corrective and Preventative Action (CAPA) Plans 6. Detailed examples of New Safety Information: SUPPLEMENT 1. <u>SOP 1402: IRB Management of New Safety Information:</u> 1. Pre-review by the Safety and Welfare Analysis Group (SWAG) 2. Safety Committee Review 3. Types of Determinations 7. Review of Corrective and Preventative Action (CAPA) Plans 4. Reporting to federal agencies <u>SOP 1403: Questions, Concerns, or Complaints from Research Participants or Third Parties</u> 1. Requirement to include the contact information of the investigator (or designee) and the IRB in the UNC consent document. 2. Procedures for managing complaints from participants or third parties. 3. Procedures for IRB review and resolution of complaints from participants or third parties.	See Upcoming Events on the OHRE/IRB Homepage for new Safety Reporting training schedule.