Avera McKennan
Institutional Review Board
Standard Operating Procedures

- 100 – Authority and Purpose
- 101 – Activities Requiring IRB Review and Approval
- 102 – SOP Maintenance
- 103 – IRB Member and Staff Training and Education
- 104 – Management of IRB Personnel
- 105 – Conflict of Interest
- 106 – Signature Authority
- 200 – Composition of the Board
- 201 – Management of the Board
- 202 – Duties of IRB Members
- 300 – Submission Requirements for IRB Review
- 301 – IRB Meeting Administration
- 302 – Administrative Review and Distribution of IRB Materials
- 303 – Document Management, Retention and Archiving
- 304 – Guests at IRB Meetings
- 400 – Exempt Review
- 401 – Expedited Review
- 402 – Initial Review – Criteria for IRB Approval
- 403 – Amendments
- 404 – Continuing Review
- 405 – Research Study Completion
- 406 – IRB Meeting Determinations
- 407 – Protocol Deviations and Noncompliance
- 409 – Suspension and Termination
- 410 – Reportable New Information AE SAE UPs
- 411 – Investigational Drug or Device
- 412 – Review of Non Reportable Events
- 413 – Emergency Use of a Test Article
- 414 – International Research
- 500 – Pregnant Women, Unborn Babies and Neonates
- 501 – Categories of Research
- 502 – Research Involving Persons with Impaired Decision-making Capacity
- 503 – Research with Children
- 504 – Research with Prisoners
- 505 – Humanitarian Use Device HUD)
- 506 – Expanded Access (Single Patient, Compassionate Use)
- 600 – Communications
- 601 – Reliance Agreements (IAAs), Single IRB (sIRB) and Cooperative Research
- 700 – Informed Consent
- 701 – Waiver of Informed Consent
- 702 – Documentation of Informed Consent
- 703 – Assent and Waiver of Assent
- 800 – IRB Required PI Actions
- 801 – Conflict of Interest (PI)
- 900 – Quality Assurance / Quality Improvement Program