

LIST OF ATTACHMENTS

100 GA GENERAL ADMINISTRATION

GA 101 Policies and Procedures Maintenance

- GA 101-A SOP Template
- GA 101-B Notification of SOP Change

GA 102 Training and Education

- GA 102-A Training Checklist and Documentation – IRB Member
- GA 102-B Training Checklist and Documentation – IRB Staff

GA 103 Management of IRB Personnel

GA 104 Conflict of Interest

- GA 104-A IRB Member Recusal Agreement

GA 105 Signatory Authority

- GA 105-A Definitions Relating to Signatory Authority

GA 106 IRB Review Fee

- GA 106-A IRB Review Fee Invoice/Receipt

GA 107 IRB Administrative Recordkeeping

200 OR IRB ORGANIZATION

OR 201 Composition of the IRB

- OR 201-A IRB Roster Fields

OR 202 Management of the IRB

- OR 202-A New IRB Member Orientation Checklist
- OR 202-B IRB Welcome Letter
- OR 202-C IRB Appointment Agreement
- OR 202-D IRB Member Confidentiality Agreement
- OR 202-E IRB Reappointment Letter
- OR 202-F IRB Member Contact Information Questionnaire
- OR 202-G Member Documentation Checklist

OR 203 Duties of IRB Members

OR 203-A	Member Responsibilities – Regular Member
OR 203-B	Member Responsibilities – Chairperson
OR 203-C	Member Responsibilities – Alternate Member
OR 203-D	Member Responsibilities – Reviewer Duties

300 FO FUNCTIONS AND OPERATIONS

FO 301 Research Submission Requirements

FO 301-A	IRB Application for Initial Review
FO 301-B	IRB Application for Renewed Approval
FO 301-C	Application for Revision and/or Amendment
FO 301-D	Data Security Guidelines
FO 301-E	Investigator Delegation of Responsibility

FO 302 Research Exempt from IRB Review

FO 302-A	Exemption Screening Questions
FO 302-B	Claim of Exemption
FO 302-C	Claim of Exemption Checklist for Staff

FO 303 IRB Meeting Administration

FO 303-A	IRB Agenda/Minutes Template
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FO 304 Administrative Review and Distribution of Materials

FO 305 Documentation and Document Management

FO 306 IRB Reliance and Central IRB Submitted Protocols

FO 306-A	IRB Reliance Review Process (SHS/MSU Agreement)
FO 306-B	Application for IRB Reliance Project Review
FO 306-C	IRB Member Review Form

400 RR REVIEW OF RESEARCH

RR 401 Expedited Review

RR 401-A	Determination of Qualifications for Expedited Review
RR 401-B	Guidance – Expedited Review
RR 401-C	Expedited Review Determination

RR 402 Initial Review – Criteria for IRB Approval

RR 402-A	Protocol Review Worksheet – Primary Reviewer(s)
RR 402-B	Risk Assessment Checklist for Research Studies

RR 402-C Significant and Non-Significant Risk Checklist (Medical Devices)

RR 403 Continuing Review - Ongoing (Site Visits and Third Party Verification; Serious and/or Unexpected Adverse Events; Amendments)

RR 403-A IRB Reporting of Unanticipated Internal Problems and/or Adverse Events
FO 301-C Application for Revision and/or Amendment
RR 403-C Site Visit Confirmation
RR 403-D Site Visit Worksheet
RR 403-E Site Visit Report

RR 404 Continuing Review – Criteria for Renewal

FO 301-B Application for Renewed Approval

RR 405 Humanitarian Use Device (HUD / HDE)

RR 405-A HDE Product Use Report
RR 405-B HDE Follow-Up Report

RR 406 Study Completion

RR 406-A Application for Closure

RR 407 Categories of Action

500 SC SPECIAL CONSIDERATIONS

SC 501 Vulnerable Populations

SC 501-A Checklist – Requirements for Research Involving Children
SC 501-B Checklist – Requires for Research Involving Pregnant Women & Fetuses
SC 501-C Checklist – Requirements for Research Involving Cognitively Impaired Adults

SC 502 Categories of Research

SC 502-A Reporting Emergency Use of a Test Article
SC 502-B Notice of IRB Approval/Acceptance of Emergency Use
SC 502-C Reporting of Emergency Use – Investigator Template
SC 502-D Checklist – Emergency Research Conducted Under 21 CFR 50.24

600 CO IRB COMMUNICATION AND NOTIFICATION

CO 601 Investigative Staff

CO 601-A	Notice of IRB Approval (Initial Review, Continuing Review, Amendment)
CO 601-B	Approval Withheld Pending (Conditional Approval)
CO 601-C	Notice of Disapproved Study
CO 601-D	HIPAA Waiver
CO 601-E	Determination of Not Research
CO 601-F	Acknowledgement (Internal/External SAE, HDE Reporting, or other miscellaneous documents from sponsor and/or PI)
CO 601-G	Completion (Closure) Acknowledgement
CO 601-H	Notice of Study Termination by IRB
CO 601-I	SHS/MSU IRB Reliance Acceptance Letter (New study) - BIRB/SIRB/CRIRB
CO 601-J	OCIRB Reliance Acceptance Letter (New study)
CO 601-K	IRB Compliance Assurance
CO 601-L	Exemption Disqualification Notice
CO 601-M	Exempt Determination Letter

700 IC INFORMED CONSENT

IC 701 General Requirements and Documentation

IC 701-A	Informed Consent Checklist – Primary Reviewer(s)
IC 701-B	Informed Consent – Guidelines and Basic Elements
IC 701-C	Informed Consent Template
IC 701-D	Glossary of Medical to Lay Terms

IC 702 Exceptions from General Consent Requirements

IC 702-A	Waiver or Alteration of Informed Consent Under 45 CFR 46.116(d) Decision Chart
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IC 703 Assent

IC 703-A	Requirements Checklist for Consent/Assent of Minors
IC 703-B	Informed Consent Document Template: Assent

800 RI RESPONSIBILITIES OF INVESTIGATORS

RI 801 IRB-Required Investigator Actions

RI 801-A	Investigator Responsibilities – IRB Requirements
RI 801-B	Essential Documents

QA 901 QA/QC Program for the IRB

QA 902-A Self-Evaluation Checklist for IRBs (FDA)