



IRB Manual Major Changes Summary:

Critical Compliance Changes:

1. **5-Day Reporting Requirements** - Major protocol deviations, unanticipated problems, and serious noncompliance must now be reported within 5 calendar days
2. **Mandatory ORDES Training** - Effective January 12, 2026, all researchers must complete additional training
3. **AI/ML Research** - New requirements for any research using artificial intelligence or machine learning
4. **Protocol Deviation Logging** - Comprehensive new system for tracking and reporting deviations

Significant Process Changes:

1. **Student PI Eligibility** - Clearly limited to doctoral students only
2. **Application Quality Standards** - Applications with writing deficiencies will not be reviewed
3. **Funded Research** - Enhanced requirements for contract-based and funded projects
4. **Summer Review Policy** - Detailed criteria for extraordinary circumstances

New Sections Added:

- **Section 1.2.4:** Summer Research Fellowship Program
- **Section 1.3:** General Process and Timeline
- **Section 4.3:** Additional Training Requirements (effective January 12, 2026)
- **Section 7.2:** Expanded Noncompliance Procedures (Protocol Deviations)
- **Section 7.10:** Research Using AI or ML
- **Section 7.11:** Externally Supported Research



The table provides page-by-page comparisons and color-coded indicators for new content, modified content, and critical changes, helping users quickly identify what requires their attention.

Detailed Changes by Section

| Section | 2024 Page | 2025 Page | Change Summary | Details |
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| Cover Page | 1 | 1 | Date Updated | Approval date changed from September 15, 2024 to August 15, 2025 |
| 1.2 Definition of Terms | 5 | 5-6 | Expanded Definitions | <ul style="list-style-type: none">• "Systematic investigation" definition expanded with more specific guidance• Added clarification about subscription data being public• Added note about AI/ML requiring IRB approval regardless of human subject consideration |
| 1.2.3 Marymount Student Research Conference | 7 | 9 | Terminology Change | Changed "faculty mentor" to "faculty member" in responsibility description |

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| 1.2.4 | N/A | 9 | NEW SECTION | Added Summer Research Fellowship Program - states research in DISCOVER Research Program is subject to IRB review |
| 1.3 | N/A | 9-10 | NEW SECTION | <p>General Process and Timeline - Comprehensive new section including:</p> <ul style="list-style-type: none"> • Getting Started procedures • Application preparation requirements • Review timelines (15 days initial review) • Post-approval responsibilities • Note about writing deficiencies preventing review |
| 2.2 IRB Duties | 8 | 11 | Language Update | Changed "assure" to "ensure" for University compliance |
| 2.3.4 IRB Coordinator and Chair | 10 | 14 | Expanded Roles | <p>Added detailed IRB Coordinator responsibilities as separate subsection, including:</p> <ul style="list-style-type: none"> • Leading IRB and facilitating review process • Providing guidance and education • Federal agency communication • Pre-review analyses and protocol assignment |

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| 3.1 Principal Investigators | 10-11 | 15-16 | Major Additions | <ul style="list-style-type: none"> • Added requirement for funded research contract provision to IRB • Clarified doctoral students can serve as PI • Added detailed PI responsibilities for funded/contract projects • Added requirement for Faculty Oversight Agreement for student-led studies • Clarified alumni cannot continue as PI after graduation |
| 3.2.2 Record Retention | 12 | 17 | Added Reference | Added reference to Office of Sponsored Programs Policy 5 for federally funded research |
| 3.3 Student Researchers | 12 | 17-18 | Clarification | Clarified "faculty advisor" terminology to "faculty advisor/mentor" throughout |
| 4.3 Additional Training | 14 | 19-20 | NEW REQUIREMENT | Effective January 12, 2026: <ul style="list-style-type: none"> • All undergraduates, student PIs, faculty mentors, and researchers must complete ORDES training • Proof of training required for new protocols • Contact: ORDES@marymount.edu |

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| 5.2 Preparing Application | 14 | 20 | Quality Standards | <p>Added: "Applications with significant writing deficiencies...will not be reviewed until these issues have been addressed"</p> <p>Includes: unclear purpose, poor alignment, grammatical errors, incomplete sections</p> |
| 5.5.2 Expedited Review | 22-23 | 29-30 | Added Categories | <p>Added specific categories for expedited review:</p> <ul style="list-style-type: none"> • Clinical studies of drugs/medical devices • Note about continuing review for research closed to enrollment • Clarified medical device requirements |
| 5.5.3 Full Review | 23 | 31 | Summer Review Policy | <p>Added detailed extraordinary circumstances for summer Full reviews:</p> <ul style="list-style-type: none"> • Serious unanticipated adverse events • New information indicating higher risk • Vulnerable population circumstances • Immediate threats to participant safety |
| 6.2 Review Process | 24 | 33 | Process Updates | <ul style="list-style-type: none"> • Changed "all members" to "quorum of members" for Full review • Added provision for expedited approvals list at monthly meetings • Added limited review determinations for exemptions |

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| <p>7.1 Unanticipated Problems</p> | <p>29</p> | <p>40-41</p> | <p>Expanded Procedures</p> | <ul style="list-style-type: none"> • Added detailed flowchart reference • Clarified internal vs. external adverse events • 5-day reporting requirement via email • Added Chair review and recommendation process • Added appeals process |
| <p>7.2 Noncompliance</p> | <p>29-30</p> | <p>42-47</p> | <p>MAJOR EXPANSION</p> | <p>New Subsections Added:</p> <p>7.2.1 Protocol Deviations</p> <ul style="list-style-type: none"> • Major vs. minor deviations defined • Immediate reporting for major deviations (5 days) • Logging requirements in Sitero Mentor <p>7.2.2 Noncompliance Categories</p> <ul style="list-style-type: none"> • Serious noncompliance definition • Continuing noncompliance definition <p>7.2.3 Unapproved Research</p> <ul style="list-style-type: none"> • Department staff retention recommendations • Supervisor concurrence requirements <p>7.2.4 Reporting & Remedial Actions</p> <ul style="list-style-type: none"> • 5-day reporting requirement • Investigation procedures • Detailed flowchart for reporting |

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| 7.4.1 Prisoners | 32-33 | 50-52 | Enhanced Requirements | <p>Added definition of "association" with prison:</p> <ul style="list-style-type: none"> • Close family member incarcerated • Pecuniary interest in prison • Requirement for prisoner/representative on approving IRB |
| 7.4.2 Children | 33-35 | 52-54 | Clarification | <p>Added requirement for IRB to appoint advocate for wards (45 CFR 46.409(b))</p> |
| 7.10 | N/A | 63-64 | NEW SECTION | <p>Research Using AI or ML</p> <ul style="list-style-type: none"> • IRB review required for AI/ML training and secondary data use • Most projects qualify for exemption • Considerations for de-identification and group harms • Reference to HHS guidance document |
| 7.11 | N/A | 64-65 | NEW SECTION | <p>Externally Supported Research</p> <p>7.11.1 Federally Sponsored</p> <ul style="list-style-type: none"> • DOD, NSF, NIH, Dept of Education requirements <p>7.11.2 State/Local Sponsored</p> <p>7.11.3 Privately Sponsored</p> <ul style="list-style-type: none"> • Additional sponsor requirements • Documentation requirements in Sitero Mentor |

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| Acknowledgment Form | N/A | 66 | NEW ADDITION | Added IRB Policy Manual Acknowledgment form requiring: <ul style="list-style-type: none">• Employee/student signature• Supervisor signature (for students)• Upload requirement in Sitero/Mentor |
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