

## SUMMARY OF AMENDMENTS AND CORRECTIONS

*NIH Guidelines, April 2002*

Page 1	Federal Register Notices: New -- (66 FR 57970, 64051, 64052)
Page 1	Issue Date Updated: April 2002
Pages 1-8	Updated Table of Contents and New -- List of Tables
Page 10	Section I-E: Additions to General Definitions. New sections -- I-E-8, I-E-9, I-E-10
Page 11	Section II-A-3 [¶ 4, L 2]: Reference to OSHA added and deletion of the reference to 56 FR
Page 12	Section II-B [Line 3]: “V-A” changed to “V-B”
Page 16	Section III-D-1-d [Line 3]: “V-L” changed to “V-M”
Page 18	Sections III-D-5-a, -5-b, -5-c: “V-W” changed to V-M”
Page 19	Section III-E-1 [Line 2]: “V-K” changed to “V-J”
Page 19	Sections III-E-2-b-(2), -b(3), -b-(4), -b-(5): “V-W” changed to “V-M”
Page 19	Sections III-E-2-b-(4) [Line 2]: Added omitted terms “...serious <i>detrimental impact on managed or natural ecosystems...</i> ”
Pages 21-22	Section IV-B-1-f. [Line 6]: Added language consistent with Appendix. M-I-B-1 -- approval requirements from IBC, IRB and other regulatory authorizations.
Page 22	Section IV-B-1-g [Line 2]: “IV-B-4” changed to “IV-B-7”
Page 23	Section IV-B-2-a-(1) [¶ 2, Line 2 –“Note”]: “IV-E” changed to “IV-D”
Page 24	Section IV-B-2-b-(1) [Line 9]: Added language consistent with Appendix. M-I-B-1 -- approval requirements from IBC, IRB and other regulatory authorizations.
Page 28	Section IV-B-7-e-(5) [Line 2]: Reference “Appendix M-VII” changed to “Appendix M-I-C”
Page 30	Section IV-C-2: New paragraphs (1 and 2) -- Changes to the RAC Charter and RAC composition
Page 31	Section IV-C-3-c [Line 2]: Reference “Appendix M-VII” changed to “Appendix M-I-C”
Page 31	Section IV-C-3-e [Line 2]: Changed “Office for Protection from Research Risks” to “Office for Human Research Protections”
Page 31	Section IV-C-3-e [Lines 4-5]: Corrected the title of Appendix M-I
Page 33	Section IV-D-5-b [¶ 3; Lines 1 & 4]: Clarified the role of the NIH (--not <i>DHHS</i> ) FOIA Officer in the pre-submission review process.
Page 33	Section V-B: [Line 4] “(see Section IV-B-4-c-(1), <i>Principal Investigator</i> ).” was changed to “(see Section IV-B-7-c-(1)).”
Page 33	Section V-C: Reference updated
Page 34	Section V-E: Reference updated
Page 34	Section V-H: Reference updated
Page 34	Section V-I: Reference updated
Page 34	Section V-J: Reference updated
Page 36	Appendix B-1 [Lines 5-8]: New – General definition of an <i>E. coli</i> strain as a RG1 agent
Page 42	Appendix C-I [¶ 1, Line 2]: “(see Appendix C-VI-D...” changed to “(see Appendix C-VII-E...””; section rewritten to read: “Recombinant DNA molecules containing less than one-half of any eukaryotic viral genome (all viruses from a single family being considered identical -- see Appendix C-VII-E, <i>Footnotes and References of Appendix C</i> ), that are propagated and maintained in cells in tissue culture are exempt from these <i>NIH Guidelines</i> with the exceptions listed in Appendix C-I-A.
Page 43	Appendix C-II [¶ 1, Lines 4 & 6]: “Appendix C-VI-B” and “Appendix C-VI-C” changed to “Appendix C-VII-B” and “Appendix C-VII-C”
Page 45	Appendix C-VII-A [Line 2]: The sentence “The list of organisms in each Risk Group is located in Appendix B.” was changed to “The revised list of organisms in each Risk Group is located in Appendix B.”
Page 45	Appendix C-VII-A-1 is deleted.
Page 67	Appendix F-III. [¶ 1, Line 4-5]: “IV-C-b-(2)-(c), <i>Major Actions</i> .” changed to “IV-C-b-(2)-(c), <i>Minor Actions</i> .”
Page 68	Appendix G-I. [¶ 1, Line 3]: Reference to Section IV-B-1-e corrected to “IV-B-1-h”; [¶1, Line 4]: “IV-B-4-d, <i>Principal Investigator</i> .” changed to “IV-B-7-d, <i>Responsibilities of the Principal</i>

Investigator Prior to Initiating Research).”

- Page 68 Appendix G-I. [¶ 2, Line 4]: Reference to Section IV-B-4-d corrected to “IV-B-7-d, *Responsibilities of the Principal Investigator Prior to Initiating Research*” and reference to “IV-B-4-e, *Principal Investigator*.” corrected to “IV-B-7-e, *Responsibilities of the Principal Investigator During the Conduct of the Research*.”
- Page 69 Appendix G-II. [¶ 3, Line 7]: “Consideration will be given by the NIH Director, with the advice of the RAC, to other combinations which achieve an equivalent level of containment (see Section IV-C-1-b-(2)-(a), *Minor Action*).” changed to “Consideration will be given to other combinations which achieve an equivalent level of containment (see Sections IV-C-1-b-(1), *Major Actions* and IV-C-1-b-(2), *Minor Actions*).”
- Page 78 Appendix G-III-A. Reference changed to the 4<sup>th</sup> Edition, BMBL
- Page 86 Appendix K-III-F. [Line 4]: “Section K-III-C” changed to “Appendix K-III-C
- Page 87 Appendix K-IV-F. [Line 4]: “Section K-IV-C” changed to “Appendix K-IV-C
- Page 88 Appendix K-V-F. [Line 4]: “Section K-V-C” changed to “Appendix K-V-C
- Page 93 Appendix L. [Line 11]: “OPRR” changed to “OHRP”
- Page 93 Appendix M. [¶ 2, Lines 1, 8 and 10]: “therapy” changed to “transfer”; [Line 9]: “of therapy” deleted
- Page 94 Appendix M. [¶ 3, Line 2]: “therapy” changed to “transfer”
- Page 94 Appendix M. [¶ 5, Line 5]: “Appendix M-I, *Submission Requirements – Human Gene Transfer Experiments*” changed to “Appendix M-I-A, *Requirements for Protocol Submission*.”
- Page 94 Appendix M. [¶ 7, Lines 5-7]: Clarification of the NIH and OBA Directors’ roles in the review process
- Page 94 Appendix M. [¶ 7, Lines 9-10]: “If the Director, NIH determines ...” changed to “If it is determined...”
- Page 94 Appendix M. [¶ 7, Lines 15-16]: “...*Protection of Proprietary Data*”)” changed to “...*Protection of Proprietary Data – Voluntary Compliance*)
- Page 95 Appendix M. [¶ 9, Line 4]: “therapy” changed to “transfer”
- Page 97 Appendix M-I-B-2. [¶ 2, Line 5]: “...”that summarizes” changed to “summarizing”
- Page 97 Appendix M-I-C-1. [Line 2]: “...”participant on a gene transfer experiment,...” changed to “...”participant in a gene transfer experiment,...”
- Page 97-98 Appendix M-I-C-3.: Annual Reports. New – (harmonized submission requirements)
- Page 97 Appendix M-I-C-3., as published in the Federal Register on November 19, 2001 (66 FR 57970, specifically, 57975), is corrected to state that annual safety reports are to be filed with OBA within 60 days of the anniversary of the date the IND went into effect, consistent with Food and Drug Administration (FDA) reporting requirements.
- Page 98 [¶ 1, Line 2]: “...patient accrual...” changed to “...accrual of subjects...”
- Page 98 Appendix M-I-C-4.: Safety Reporting; new appendix – (harmonized reporting requirements)
- Page 98 Appendix M-I-C-4-a.: Safety Reporting; new appendix
- Page 99 Appendix M-I-C-4-b.: Safety Reporting; new appendix
- Page 99 Appendix M-I-C-5.: Confidentiality; new appendix
- Page 99 Appendix M-I-C-5.: Confidentiality; [¶ 2, Line 4]: “patients” changed to “human subjects” (*cf 66 FR 57976 – M-I-C-5*)
- Page 99 Appendix M-I-C-5.: Confidentiality; [¶ 3, Line 2]: “...must not contain individually identifiable patient information.” changed to “...must not contain any information that would identify human research participants.” (*cf 66 FR 57976 – M-I-C-5*)
- Page 99 Appendix M-I-D.: Safety Assessment; new appendix
- Page 100 Appendix M-II-A-1-a. [Line 1]: “treatment” changed to “experimental treatment”; “therapy” changed to “transfer”
- Page 100 Appendix M-II-A-1-b. [Line 2]: “treatment” changed to “experimental treatment”; [Line 4]: “therapy” changed to “transfer”
- Page 100 Appendix M-II-A-1-d. [Line 1]: “patients” changed to “subjects”; [Line 3]: “therapy” changed to “transfer”
- Page 101 Appendix M-II-B-1-b. [Line 1]: “patient” changed to “research participant”
- Page 101 Appendix M-II-B-1-b-(1). [Line 2]: “patient” changed to “human research subject”; “patient’s” changed to “subject’s”; [Line 12]: “patient” changed to “subject”
- Page 101 Appendix M-II-B-1-b-(2). [Line 2]: “patient” changed to “human research subject”

Page 101 Appendix M-II-B-2-a-(1). [Line 2]: “patient” changed to “human subject”

Page 102 Appendix M-II-B-2-c-(2). [Line 3]: “patient’s” changed to “human subject’s”

Page 102 Appendix M-II-B-3. [Title]: The term “Patient” in the heading is changed to “Research Participant”

Page 102 Appendix M-II-B-3. [Lines 1 and 2]: “treatment” changed to “experimental treatment”; “patients” changed to “human subjects”

Page 102 Appendix M-II-B-3-a. [Line 1]: “patients” changed to “human subjects”

Page 102 Appendix M-II-B-3-b. [Line 1]: “patients” changed to “human subjects”

Page 102 Appendix M-II-B-3-c. [Line 1]: “patients” changed to “human subjects”; [Line 3]: “treatments” changed to “experimental treatments”

Page 103 Appendix M-II-B-3-d. [Line 1]: “patient’s” changed to “subject’s”

Page 103 Appendix M-II-B-3-f. [Line 2]: “patient” changed to “human subject”; [Line 3]: “patients” changed to “subjects”; [Line 4]: “patient” deleted

Page 103 Appendix M-II-B-3-g. [Line 1]: “treatment” changed to “experimental treatment”

Page 103 Appendix M-II-B-3-h. [Line 1]: “patient” changed to “human subject”

Page 103 Appendix M-II-B-4. [Line 1]: “therapy” changed to “gene transfer”; Line 2]: “...patients being treated.” Changed to “...human subjects receiving the experimental treatment”

Page 103 Appendix M-II-B-4-b. [Line 1]: “patient” changed to “subject”

Page 103 Appendix M-II-B-4-c. [Line 1]: “patients” changed to “subjects”

Page 103 Appendix M-II-B-4-e. [Line 2]: “patients” changed to “subjects”

Page 103 Appendix M-II-B-5-a. [Lines 3 and 4]: “(see Appendix M-I, *Submission Requirements—Human Gene Transfer Proposals*).” changed to “(see Appendix M-I-A, *Requirements for Protocol Submission*).”

Page 103 Appendix M-II-B-5-b. [Line 1]: “treatment” changed to “experimental treatment”; [Lines 2 and 3]: “patients” changed to “subjects”; [Lines 4 and 6]: “patient(s)” changed to “research participant(s)”

Page 103 Appendix M-II-C. [Heading]: “Selection of Patients” changed to “Selection of the Human Subjects”

Page 103 Appendix M-II-C. [¶ 1, Line 1]: “patients” changed to “human subjects”; [Line 2]: “patient” deleted

Page 104 Appendix M-II-C-1. [Line 1]: “patients” changed to “subjects”

Page 104 Appendix M-II-C-2. [Line 1]: “patients” changed to “subjects”

Page 104 Appendix M-II-C-5. [Line 1]: “patients” changed to “subjects”

Page 106 Appendix M-IV: Privacy; deleted “...and Confidentiality” from heading; clarification of protection measures.

Page 106 Appendix M-IV. [¶ 1, Line 1]: “patients” changed to “subjects”

Page 106 Appendix M-IV-A. [Line 1]: “patients” changed to “human subjects”; [Line 2]: “handicapped patients” changed to “handicapped subjects” [Line 3]: “patients” changed to “a subject”

Page 106 Appendix M-IV-B. [Line 2]: “patients” changed to “human subjects”

Page 106 Appendix M-V-A. [Line 1]: “Appendix M-IV, *Privacy and Confidentiality*” changed to “Appendix M-IV, *Privacy*”

Page 107 Appendix M-VI-A. [Line 4]: “*Submission Requirements, and Appendix-M-I-C, Reporting Requirements-Human Gene Transfer Experiments*” changed to “*Requirements for Protocol Submission, Review and Reporting – Human Gene Transfer Experiments.*”