

 NIAID Bethesda, MD USA	GUIDANCE FOR TEMPLATE USE	Version No: 2.0 Date: July 16, 2008
		Page 1 of 4
	Effective Date: <i>June 1, 2006</i> Release Date: <i>June 1, 2006</i>	
Title: NIAID PROTOCOL TEMPLATE GUIDANCE		

APPROVAL

Approval Mechanism

NIAID Executive Committee (EXCOM)

April 13, 2006

1.0 PURPOSE

- 1.1 To provide a standardized template to assist NIAID investigators in writing and developing clinical research protocols that are in compliance with regulatory and other requirements.

2.0 BACKGROUND

- 2.1 This template was developed by a group of NIAID staff from all Divisions in an effort to facilitate protocol development for investigators. This trans-NIAID working group proposed that the use of a standard protocol template would result in greater efficiencies in protocol writing and review processes.

3.0 SCOPE

- 3.1 These templates will not supersede current templates already in use in existing Networks. However, new initiatives and new Networks will use these templates as a basis for developing protocol templates.

4.0 RESPONSIBILITIES

- 4.1 DCR personnel are responsible for ongoing evaluation of the template to assure that it meets current requirements for protocol submission.
- 4.2 Investigators are responsible for accessing relevant reference links and specific guidance for protocol submissions from individual Divisions.

5.0 PROTOCOL TEMPLATES WITH INSTRUCTIONS FOR USE BY EXTRAMURAL AND INTRAMURAL INVESTIGATORS ARE ATTACHED

6.0 REFERENCES/LINKS

- 6.1 Supersedes: None
- 6.2 The below online information is current as of the Effective Date of this policy:

Guidance for Industry E 6 Good Clinical Practice: Consolidated Guidance
www.cc.nih.gov/ccc/clinicalresearch/guidance.pdf

- 6.3 NIAID Protocol Template Guidance
<http://www3.niaid.nih.gov/research/resources/toolkit/guidance/>
- 6.4 Protocol Template and Instructions for Extramural Investigators
<http://www3.niaid.nih.gov/research/resources/toolkit/protocol>
- 6.5 Protocol Template and Instructions for Intramural Investigators
<http://www3.niaid.nih.gov/research/resources/toolkit/protocol>

7.0 INQUIRIES/CONTACT INFORMATION

- 7.1 For questions or comments please contact NCRSexecsec@niaid.nih.gov.

8.0 AVAILABILITY

- 8.1 This guidance and the sample protocol templates are available on the DCR website. Hard copy documents are filed in the DCR office.

9.0 ATTACHMENTS

- 9.1 Attachment A. List of Protocol Development Committee members, ad hoc members and Adverse Event Working Group members

10.0 REVIEW SCHEDULE/CHANGE SUMMARY

- 10.1 The change summary table below will be updated when this guidance is reviewed or revised.

Title: NIAID Protocol Template and Guidance

Version No: 2.0

Page 4 of 6

PROTOCOL GUIDANCE DOCUMENT Version #	Date	Replaces	Date of Review/Revision	Rationale for Review/Revision/Retirement
V2.0	01 June 06	V1.0	16 July 2008	Review dates for Extramural template have been changed from every 6 months to every 2 years.
V2.1	01 September 08	V2.0	29 June 2009	Review dates for Intramural CT templates have been changed from every 6 months to every 2 years.
V1.0	01 January 08	N/A	29 June 2009	Review dates for Intramural NH templates have been changed from every 6 months to every 2 years.

- 10.2 The protocol templates will be evaluated in an ongoing manner based on feedback from investigators and other users, and in conjunction with direction from regulatory and review staff.
- 10.3 The extramural protocol template will have a focused annual regulatory review and a comprehensive review every two years in order to assure the template meets current regulatory requirements.
- 10.4 The intramural protocol template will be reviewed and evaluated annually in order to assure that the template meets current regulatory and intramural requirements.

Title: NIAID Protocol Template and Guidance

Version No: 2.0

Page 5 of 6

EXTRAMURAL TEMPLATE				
Version #	Date	Replaces	Date of Review/Revision	Rationale for Review/Revision/Retirement
V2.0	01June06	V1.0	16July08	Multiple revisions from most recent 2 year review
INTRAMURAL TEMPLATE				
Version #	Date	Replaces	Date of Review/Revision	Rationale for Review/Revision/Retirement
V1.0	01Aug06	New	Initial Posting	New Clinical Trial (CT)Template and Guidance documents posted
V1.0	01Sep06	V 1.0	14July06	CT Guidance document updated
V2.0	31Jan08	V 1.0	1Oct07	Multiple revisions based on change to NIH/NIAID policies, 508 compliant versions posted
V2.1	1 Sep08	V 2.0	1Sep08	CT Guidance document updated, harmonization with Extramural changes
V1.0	31Jan08	New	Initial Posting	New Natural History (NH) Template and Guidance documents posted- 508 compliant

Attachment A:

List of Protocol Development Committee members

Peter Bianchine (Chair) DAIT

Susan Brobst (DAIDS)

Mary Enama (VRC)

Karin Klingman (DAIDS)

Peter Mannon (DIR)

Katherine Muth (DMID)

Michael Polis (DCR)

Shy Shorer (DMID)

With additional ad hoc contributions by:

Doreen Chaitt (DCR)

April Powers (DCR)

Cynthia Kleppinger (RCHSPP)

Mary Smolskis (DAIT)

Obianuju Anya (DAIT)

Adverse Event Working Group (intramural template):

Heather Bridge (DCR)

Kelly Cahill (DCR)

Doreen Chaitt (DCR)

Betsey Herpin (DCR)

Cynthia Kleppinger (RCHSPP)

Peter Mannon (LCI)

Patricia Price-Abbott (RCHSPP)

Mary Smolskis (DAIT)

Jorge Tavel (DCR)

Susan Vogel (DCR)