

COMMAND NAMING CONVENTION FOR Research Protocol Submissions & IRB Minutes DON HRPP File and Information System

RESEARCH PROTOCOL SUBMISSIONS:

There are five (5) sections to the file name:

“Command Name”•“Research Protocol Number”•“Submission Type”–“Review Process”–“IRB action”

Command names: All caps using the acronym format in the DON HRPP directory/library. (See page 4)

Protocol number:

Number includes the full FY then four digit consecutive numbers starting with 0001.

Numbering restarts each FY (1 October) and with the first research protocol submitted for review. Use periods for separation.

Example: NMCP.2013.0001

Submission type

IR – Initial Review (all new protocols)

CR – Continuing Review

*Number each CR consecutively. Example: The first is CR01, then CR02, CR03, etc.

AM – Amendment and later modifications or changes

*Number each AM consecutively. Example: The first amendment is AM01, then AM02, AM03.

*Include all amendments after the research protocol is approved; for example: PI changes, medical monitor changes, or anything that is changed in the protocol or informed consent document, etc.

UP/AE/SAE – Unanticipated Problem/Adverse Event/Serious Adverse Event

*Number each UP/AE/SAE consecutively. The first UP/AE/SAE is UP01, then UP02, UP03; or AE01, then AE02, AE03; or SAE01, then SAE02, SAE03.

PD – Protocol Deviation

*Number each PD consecutively. The first PD is PD01, then PD02, PD03, etc.

FR – Final Report

Review Process

Use the three available review processes: convened review; expedited review; and review for exemption.

EM – Review for exemption criteria

*MUST add the EM category number(s) after the letters – EM1,...EM6.

*Review for exemption only.

*There are only 6 categories that pertain to IR submissions.

EP – Expedited review procedures

*MUST add the EP category number(s) after the letters - EP4,...EP9

*Review under expedited procedures may apply to IR, CR, AM, UP/AE, RI, & FR.

*There are 9 categories that are only used for IR and CR.

CONV – Review by the convened IRB

*May apply to IR, CR, AM, UP/AE, RI, and FR.

IRB Action or Recommendation

One-two letter for the IRB recommendation

A – Approved

M – Minor modifications required to secure approval; modifications can be reviewed by IRB chair

D – Deferred; major modification required; revised protocol must be re-reviewed by the convened IRB

TB – Tabled; not sufficient time for the IRB to review during the meeting or PI request to postpone and reschedule the review

R – Referred, research protocols that were initially reviewed for exemption or by expedited review procedures that do not meet criteria and must be reviewed by the convened IRB; research protocols that must be reviewed by higher authority than CO/IO

X – Disapproved

S – Suspended

T – Terminated

Examples: Navy IRB providing IRB review and recommendations for its own command:

1. From NAMRU-D: New protocol reviewed under expedited procedures, category 4, approved
Then File Name = NAMRUD.2013.0034-IR-EP4-A.pdf
2. From NMCS D: Second continuing review of research protocol that convened IRB reviewed and recommended approval
Then File Name = NMCS D.2011.0235-CR02-CONV-A
3. From NEDU: First amendment on research protocol that the convened IRB reviewed and recommended approval
Then File Name = NEDU.2012.0017-AM01-CONV-A
4. From NRL: Second amendment to research protocol that was reviewed under expedited procedures but referred to convened IRB
Then File Name = NRL.2010.0037-AM02-EP-R

Examples: Navy IRB providing IRB review and recommendations to another Navy command. Use the other Navy command's name for the file naming and start the consecutive number at 0001 for each external command separately. Do NOT use the IRB's command name or consecutive number.

1. From NH Camp Lejeune: NMC Portsmouth convened IRB reviews the first new research protocol for NH Camp Lejeune and recommends approval
Then File Name = NHCL.2012.0001-IR-CONV-A
2. From NH Naples: NMC Portsmouth reviews the first continuing review on a previously expedited IR review procedures and recommends approval.
Then File Name = NHNA.2011.0001-CR01-EP2-A
3. From NH Bremerton, NMCS D reviews the third new protocol under expedited review procedures and recommends approval under category 4
Then File Name = NHBR.2012.0003-IR-EP4-A

Examples: Navy IRB providing IRB review and recommendations to a non-DoD institution such as a university or company. These ‘extramural’ cases are identified by starting the file name with EXT following the reviewing IRB name and consecutively numbered – regardless of the name of the extramural performer.

1. From NPRST: NPRST’s convened IRB reviews the first new research protocol for City University and recommended approval
Then File Name = NPRST.EXT.2012.0001-IR-CONV-A
2. From NEDU: NEDUs convened IRB reviews a third new research protocol for an extramural performer, this one for State Company Inc., and recommended approval
Then File Name = NEDU.EXT.2012.0003-IR-CONV-A
3. From NPRST: NPRST’s IRB reviews the second continuing review of the seventh extramural performer, this one from Local University, under expedited review procedures and recommended approval
Then File Name = NPRST.EXT.2010.0007-CR02-EP1-A

Examples: Navy medical IRB making review and recommendations on an Emergency One-Time-Use

1. From NMCP’s convened IRB: NMCP.OTU.2012.0003-IR-A

Examples: Navy medical IRB making review and recommendations on a Humanitarian Use Device (HUD).

1. From NMCS D’s convened IRB: NMCS D.HUD.2012.0004-IR-A

Examples: Navy medical IRB making review and recommendations on a Humanitarian Device Exemption (HDE).

1. From NMCP’s convened IRB: NMCP.HDE.2012.0012-IR-A

IRB MEETING MINUTES

Label the complete IRB meeting minutes document with three (3) sections:

“Command name” ■ “IRBMIN” ■ “date” (4-digit year- 2-digit month-2-digit date)

File Name Example: NSMRL-IRBMIN-2013-01-25

COMMAND NAMES AND ABBREVIATIONS AS USED IN DON HRPP RECORDS

Manpower and Reserve Affairs, Headquarters, USMC	M&RA Quantico	MRAMC
Marine Corps Combat Development Command	MCCDC Quantico	MCCDC
Marine Corps Operational Test and Evaluation Activity	MCOTEA Quantico	MCOTEA
Marine Corps Systems Command	MCSC Quantico	MCSC
Naval Air Warfare Center, Aircraft Division	NAWCAD Patuxent	NAWCAD
Naval Air Warfare Center, Training Systems Division	NAWCTSD Orlando	NAWCTSD
Naval Experimental Diving Unit	NEDU Panama City	NEDU
Naval Health Clinic Annapolis	NHC Annapolis	NHCA
Naval Health Clinic Hawaii	NHC Hawaii	NHCH
Naval Health Clinic New England	NHC New England	NHCNE
Naval Health Clinic Quantico	NHC Quantico	NHCQ
Naval Health Research Center	NHRC San Diego	NHRC
Naval Hospital Beaufort	NH Beaufort	NHBU
Naval Hospital Bremerton	NH Bremerton	NHBR
Naval Hospital Camp Lejeune	NH Camp Lejeune	NHCL
Naval Hospital Camp Pendleton	NH Camp Pendleton	NHCP
Naval Hospital Jacksonville	NH Jacksonville	NHJX
Naval Hospital Lemoore	NH Lemoore	NHLM
Naval Hospital Oak Harbor	NH Oak Harbor	NHOH
Naval Hospital Pensacola	NH Pensacola	NHPC
Naval Hospital Twenty-Nine Palms	NH Twenty-Nine Palms	NH29
Naval Medical Center Portsmouth	NMC Portsmouth	NMCP
Naval Medical Center San Diego	NMC San Diego	NMCSD
Naval Medical Research Center Silver Spring	NMRC Silver Spring	NMRC
Naval Medical Research Unit No. 2	NAMRU-2 Hawaii	NAMRU2
Naval Medical Research Unit No. 3	NAMRU-3 Cairo	NAMRU3
Naval Medical Research Unit No. 6	NAMRU-6 Lima	NAMRU6
Naval Medical Research Unit Dayton	NAMRU-Dayton	NAMRUD
Naval Medical Research Unit San Antonio	NAMRU-San Antonio	NAMRUSA
Naval Personnel Research Studies & Technology Department	NPRST Memphis	NPRST
Naval Postgraduate School	NPS Monterey	NPS
Naval Research Laboratory	NRL Washington	NRL
Naval Special Warfare Group Four Virginia Beach	NSWG-4 Virginia Beach	NSWG4
Naval Submarine Medical Research Laboratory	NSMRL Groton	NSMRL
Naval Surface Warfare Center Carderock Division	NSWC Carderock	NSWCC
Naval Surface Warfare Center Dahlgren Division	NSWC Dahlgren	NSWCD
Naval Surface Warfare Center Fallbrook Detachment	NSWC Fallbrook	NSWCF
Naval Surface Warfare Center Panama City Division	NSWC Panama City	NSWCPC
Naval Undersea Warfare Center Newport	NUWC Newport	NUWC
Navy and Marine Corps Public Health Center (Portsmouth)	NMCPHC Portsmouth	NMCPHC
Navy Medicine Operational Training Center	NMOTC Pensacola	NMOTC
Navy Medicine Professional Development Center	NMPDC Bethesda	NMPDC
Space and Naval Warfare Systems Center Atlantic (Charleston)	SSC Atlantic	SSCA
Space and Naval Warfare Systems Center Pacific (San Diego)	SSC Pacific	SSCP
Survival Evasion Resistance Escape East (Brunswick)	SERE East	SERE
United States Naval Academy	USNA Annapolis	USNA
United States Naval Hospital Naples	NH Naples	NHNA
United States Naval Hospital Okinawa	NH Okinawa	NHOK
United States Naval Hospital Sigonella	NH Sigonella	NHSG
United States Naval Hospital Yokosuka	NH Yokosuka	NHYO
United States Naval War College	NWC Newport	NWC