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Subject: ALARACT 031/2008
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To: AL ALARACT(UC), ALARACT

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THIS MESSAGE HAS BEEN SENT BY THE PENTAGON TELECOMMUNICATIONS CENTER ON BEHALF OF DA WASHINGTON DC//DASG//

THIS ALARACT MESSAGE IS BEING SENT ON BEHALF OF THE SURGEON GENERAL

SUBJECT: ARMY HUMAN RESEARCH SUBJECT PROTECTION REQUIREMENTS

REF/A/(U) 32 CFR 219/FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS//
REF/B/(U) DODD 3216.02/PROTECTION OF HUMAN SUBJECTS AND ADHERENCE TO ETHICAL STANDARDS IN DOD-SUPPORTED RESEARCH//
REF/C/(U) SECRETARY OF THE ARMY MEMO FOR THE SURGEON GENERAL OF THE ARMY/US ARMY HUMAN RESEARCH SUBJECTS PROTECTION PROGRAM, DTD 14APR05//
REF/D/(U) DDR&E MEMO FOR THE SECRETARY OF THE ARMY/DELEGATION OF AUTHORITY TO APPROVE AND ACCEPT ASSURANCES, DTD 28APR05//

1. (U) THE SURGEON GENERAL (TSG) HAS BEEN DESIGNATED AS THE AUTHORITY WITHIN THE ARMY FOR APPROVING ASSURANCES TO ENSURE COMPLIANCE WITH FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS (REF/A-C). THIS AUTHORITY APPLIES TO ALL RESEARCH CONDUCTED, SPONSORED, FUNDED, OR OTHERWISE SUPPORTED BY THE ARMY THAT INVOLVES HUMAN SUBJECTS REGARDLESS OF THE SOURCE OF FUNDING OR THE COMMAND, STAFF, OR AGENCY OVERSEEING THE RESEARCH. THE DIRECTOR, ARMY HUMAN RESEARCH PROTECTIONS OFFICE (AHRPO), IS RESPONSIBLE FOR MANAGING THE ARMY HUMAN RESEARCH PROTECTION PROGRAM (HRPP), WHICH INCLUDES NEGOTIATING NEW ASSURANCES AND HRPPS AND ASSURANCE AND HRPP RENEWALS FOR APPROVAL BY THE ASSISTANT SURGEON GENERAL FOR FORCE PROJECTION (ASG-FP) AND PROVIDING OVERSIGHT FOR ACTIVE ASSURANCES AND HRPPS.
2. (U) ALL ARMY INSTITUTIONS CONDUCTING, SPONSORING, FUNDING OR OTHERWISE SUPPORTING HUMAN SUBJECTS RESEARCH WILL OPERATE UNDER AN APPROVED ASSURANCE FOR THE PROTECTION OF HUMAN RESEARCH SUBJECTS (HEREAFTER REFERRED TO AS "ASSURANCE") AND/OR APPROVED HRPP AS REQUIRED NLT 01 AUG 08.
3. (U) THE PURPOSE OF THIS MESSAGE IS TO ANNOUNCE IMPLEMENTING INSTRUCTIONS FOR ARMY ASSURANCES AND HRPPS. POLICY CONTAINED IN THIS MESSAGE IS EFFECTIVE IMMEDIATELY. THIS POLICY IS APPLICABLE TO ALL HQDA STAFF, ARMY FIELD OPERATING AGENCIES, ARMY COMMANDS, ARMY SERVICE COMPONENT COMMANDS, AND ARMY DIRECT REPORTING UNITS (HEREAFTER REFERRED TO AS "INSTITUTIONS") THAT CONDUCT, SPONSOR, FUND, OR OTHERWISE SUPPORT HUMAN SUBJECTS RESEARCH. THE KEY TASKS ARE SUBMITTING APPLICATIONS FOR INITIAL APPROVAL OR RENEWAL OF AN ASSURANCE AND/OR HRPP, SUBMITTING ANNUAL HRPP REPORTS, AND SUBMITTING OTHER HRPP INFORMATION AS NEEDED TO THE DIRECTOR, AHRPO FOR MANAGEMENT OF THE ARMY HRPP. ENDSTATE IS ACHIEVED WHEN ALL ARMY INSTITUTIONS OPERATE UNDER AN APPROVED ASSURANCE OR HRPP.
4. (U) THERE ARE THREE CATEGORIES OF INSTITUTIONS THAT ARE BEING TASKED BY THIS MESSAGE: (A) ARMY INSTITUTIONS THAT CURRENTLY DO NOT HAVE AN ASSURANCE OR HRPP, (B) ARMY INSTITUTIONS THAT HAVE AN ASSURANCE AND/OR HRPP WHICH WILL EXPIRE WITHIN 90 DAYS, AND (C) ARMY INSTITUTIONS THAT HAVE AN ACTIVE ASSURANCE AND/OR HRPP AND HEADQUARTERS HRPP OFFICES. EACH CATEGORY OF INSTITUTION HAS SPECIFIC APPLICATION AND REPORTING REQUIREMENTS THAT MUST BE MET FOR THE INSTITUTION TO CONTINUE CONDUCTING, SPONSORING, FUNDING AND/OR OTHERWISE SUPPORTING HUMAN SUBJECTS RESEARCH.

4.A. (U) ARMY INSTITUTIONS THAT CURRENTLY DO NOT HAVE AN ASSURANCE OR HRPP MUST SUBMIT A REPORT NLT 01 APR 08, DESCRIBING THEIR RESEARCH ACTIVITIES THAT USE HUMAN VOLUNTEERS. THIS INCLUDES ALL ACTIVITIES THAT INVOLVE CONDUCTING, SPONSORING, FUNDING OR OTHERWISE SUPPORTING RESEARCH INVOLVING HUMANS. THE REPORT MUST BE SUBMITTED TO THE DIRECTOR, AHRPO, WHO WILL WORK WITH EACH ORGANIZATION'S APPOINTED STAFF MEMBER TO NEGOTIATE AN INITIAL ASSURANCE AND/OR WRITTEN HRPP PLAN FOR APPROVAL NO LATER THAN 01 AUG 08.

4.B. (U) ARMY INSTITUTIONS THAT HAVE AN ASSURANCE AND/OR HRPP WHICH WILL EXPIRE WITHIN 90 DAYS MUST CONTACT THE DIRECTOR, AHRPO TO OBTAIN SPECIFIC REQUIREMENTS FOR THEIR ASSURANCE AND/OR HRPP RENEWAL. AN INSTITUTION'S ASSURANCE AND/OR HRPP MUST BE RENEWED BEFORE ITS STATED EXPIRATION DATE AND WHEN THERE IS A CHANGE IN THE INSTITUTIONAL OFFICIAL. GENERAL SUBMISSION REQUIREMENTS FOR OBTAINING AND RENEWING AN ASSURANCE AND/OR HRPP INCLUDE THE FOLLOWING AS APPLICABLE:

4.B.(1) (U) COMPLETED ARMY ASSURANCE AGREEMENT WITH INSTITUTIONAL REVIEW BOARD (IRB) ROSTER(S).

4.B.(2) (U) WRITTEN PLAN FOR THE INSTITUTION'S HRPP.

4.B.(3) (U) HRPP POLICIES AND PROCEDURES.

4.B.(4) (U) DESCRIPTION OF INSTITUTION'S HUMAN SUBJECTS PROTECTION CONTINUING EDUCATION AND TRAINING PROGRAM AND SUMMARY OF ASSURANCE AND HUMAN SUBJECTS PROTECTION EDUCATION AND TRAINING FOR KEY HRPP STAFF.

4.B.(5) (U) SUMMARY OF PREVIOUS AND PROJECTED HRPP WORKLOAD, TO INCLUDE: CURRENT ACTIVE RESEARCH PROTOCOLS, TYPE AND VOLUME OF RESEARCH PROTOCOLS THAT HAVE BEEN OR WILL BE FUNDED OR CONDUCTED IN THE PREVIOUS AND UPCOMING YEARS, CURRENT HRPP MEMOS OF UNDERSTANDING OR AGREEMENT, AND INSTITUTIONAL AGREEMENTS FOR IRB REVIEW.

4.B.(6) (U) COMPLETION OF A RECENT HUMAN SUBJECTS PROTECTION SITE VISIT, WITH FINDINGS ADEQUATELY ADDRESSED.

4.C. (U) ARMY INSTITUTIONS THAT HAVE AN ACTIVE ASSURANCE AND/OR HRPP AND HEADQUARTERS HRPP OFFICES MUST COMPLY WITH THE FOLLOWING REQUIREMENTS FOR MAINTAINING THEIR ASSURANCE AND/OR HRPP:

4.C.(1) (U) INITIAL REPORTS OF SERIOUS AND CONTINUING NONCOMPLIANCE MUST BE SUBMITTED TO AHRPO WHEN REPORTED TO THE INSTITUTION'S INSTITUTIONAL REVIEW BOARD (IRB) OR HUMAN PROTECTIONS ADMINISTRATOR (HPA). A FINAL REPORT MUST BE SUBMITTED AS SOON AS THE INVESTIGATION HAS BEEN COMPLETED. ADDITIONAL REPORTS WILL BE REQUESTED AS NEEDED.

4.C.(2) (U) A SITE VISIT IS REQUIRED FOR RENEWAL OF AN INSTITUTION'S ASSURANCE AND/OR HRPP. ADDITIONAL SITE VISITS WILL BE CONDUCTED WHEN NEEDED AS DETERMINED BY THE DIRECTOR, AHRPO. SITE VISITS WILL BE CONDUCTED IN COORDINATION WITH AN INSTITUTION'S HEADQUARTERS HRPP OFFICE, WHEN SUCH AN OFFICE EXISTS.

4.C.(3) (U) AHRPO WILL PERFORM HEADQUARTERS LEVEL ADMINISTRATIVE REVIEW (HLAR) OF HUMAN SUBJECTS RESEARCH THAT IS CONDUCTED BY AN ASSURED INSTITUTION FOR ALL INSTITUTIONS THAT DO NOT HAVE AN APPROVED AGREEMENT FOR A HEADQUARTERS HRPP OFFICE TO CONDUCT THE HLAR.

4.C.(4) (U) ALL INSTITUTIONS HOLDING AN ARMY ASSURANCE AND/OR AN ARMY HRPP AND ALL ARMY HEADQUARTERS HRPP OFFICES WILL SUBMIT AN ANNUAL REPORT ON THE MANAGEMENT OF THEIR HRPP TO AHRPO. THE ANNUAL HRPP REPORT IS DUE ON THE ANNIVERSARY DATE OF THE ASSURANCE OR HRPP APPROVAL AND WILL INCLUDE, BUT IS NOT LIMITED TO, THE FOLLOWING: UPDATES TO THE ASSURANCE AND HRPP APPROVAL REQUIREMENTS; UPDATED HRPP PLAN; CHANGES IN KEY HRPP STAFF OR THEIR RESPONSIBILITIES; ADEQUACY OF RESOURCES TO MEET THE CURRENT WORKLOAD; BRIEF SUMMARY OF REPORTS OF NONCOMPLIANCE OVER THE LAST YEAR, TO INCLUDE A GENERAL DESCRIPTION OF THE INCIDENT, SPECIFIC ALLEGATIONS, SUMMARY OF THE INVESTIGATION COMPLETED, DESCRIPTION OF THE FINDINGS AND OUTCOME, AND CHANGES IMPLEMENTED; DESCRIPTION OF QUALITY IMPROVEMENT AND COMPLIANCE ACTIVITIES CONDUCTED OVER THE PAST YEAR; AND INFORMATION ON HUMAN SUBJECTS RESEARCH PROCESSING TIME.

4.C.(5) (U) AHRPO WILL REVIEW AN INSTITUTION'S ASSURANCE AND/OR HRPP AT OTHER TIMES IN ADDITION TO THE TIME OF THEIR EXPIRATION AND WILL COLLECT ASSURANCE AND HRPP DATA FOR MANAGEMENT PURPOSES WHEN NEEDED AS DETERMINED BY THE DIRECTOR, AHRPO.

5. (U) POC: FOR HUMAN RESEARCH SUBJECTS PROTECTION POLICY GUIDANCE, TO INCLUDE

REQUIREMENTS FOR OBTAINING, RENEWING, AND MAINTAINING AN ASSURANCE AND/OR HRPP AND
REQUIRMENTS FOR ANNUAL HRPP REPORTS, COL JULIE ZADINSKY, COM: 703-601-4720, DSN:
329-4720, EMAIL: JULIE.ZADINSKY@US.ARMY.MIL.

6. (U) EXPIRATION DATE CANNOT BE DETERMINED.