Appeal Nos. 13-17430, 14-15108

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

VIETNAM VETERANS OF AMERICA, et al.,

Plaintiffs-Appellants,

v.

CENTRAL INTELLIGENCE AGENCY, et al.,

Defendants-Appellees.

Appeal from the United States District Court
Northern District of California
The Honorable Claudia Wilken
District Court Case No. 4:09-cv-00037-CW

THIRD BRIEF ON CROSS-APPEAL: APPELLANTS'/CROSS-APPELLEES' REPLY BRIEF AND OPPOSITION TO CROSS-APPEAL

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REPLY IN SUPPORT OF OPENING BRIEF ON APPEAL

I. THE DISTRICT COURT DID NOT HAVE DISCRETION TO REFUSE TO COMPEL THE ARMY TO PROVIDE MEDICAL CARE.

A. The District Court Determined that AR 70-25 Created a Non-Discretionary Duty To Provide Medical Treatment.

In the Opening Brief, the Test Subject Veterans showed that the district court erred when it refused to compel the Army to provide them medical treatment despite explicitly finding that AR 70-25 entitles them to such treatment. The Army responds by insisting that the district court never made an "affirmative finding" or a "proper determination" that AR 70-25 imposes a mandatory duty on the Army to provide medical care to Test Subject Veterans. (Opening Brief for Defendants-Appellees/Cross-Appellants ("Army Br.") 28, 35, 36.) But the Army's suggestion that the APA requires some talismanic "proper" determination is unfounded. The district court indeed determined that AR 70-25 imposes a legal obligation on the Army enforceable under the APA.

In its painstaking analysis, the district court described AR 70-25 as a "regulation promising to provide volunteers with medical treatment associated with injuries or illnesses that result from participation in testing." (E.R. 38.)[1] As the Army itself acknowledges (Army Br. 28), the district court specifically found that

[1] As in the Opening Brief, "E.R." refers to Appellants' Excerpts of Record, and "C.R." refers to the district court record. "S.E.R." refers to the Supplemental Record Excerpts for Defendants-Appellees/Cross-Appellants.

"AR 70-25 entitles [the Test Subject Veterans] to medical care for disabilities, injuries or illnesses caused by their participation in government experiments."[2] (E.R. 58.) And it held that AR 70-25 was promulgated under "statutory grants of authority sufficient to create enforceable rights," thereby "creat[ing] duties that are enforceable against the Army under the APA." (E.R. 38.) Thus, the district court properly determined that AR 70-25 imposes an enforceable non-discretionary duty on the Army to provide medical treatment to the Test Subject Veterans.

B. The Use of the Imperative "Shall" in Section 706(1) Is Mandatory and Leaves No Room for Judicial Discretion.

The Opening Brief showed that Congress's directive to courts in section 706(1) of the APA—"the reviewing court shall . . . compel agency action unlawfully withheld"—is mandatory and not permissive. (Opening Brief of Appellants ("Open. Br.") 14.) The plain meaning of the imperative "shall" indicates no discretion is left to the subject of the command. *See, e.g.*, *Bennett v. Spear*, 520 U.S. 154, 175 (1997) (Contending that a statute is "discretionary would fly in the face of its text, which uses the imperative 'shall.'"). Thus, once a court determines that the agency has not done what the regulation requires—has

[2] The Army misinterprets the district court's unambiguous finding as a restatement of a "previous" finding in a January 2010 order. (Army Br. 28 (citing S.E.R. 81-82).) Nothing in the court's summary judgment order supports the Army's interpretation.

"unlawfully withheld" action—the court must issue an order compelling that action. That is where the district court erred.

1. The Imperative Form of "Shall" Does Not Mean "May."

The Army responds that "shall" as used in section 706(1) actually means "may." Its argument begins not with textual analysis, but with a quotation from a treatise cited in a footnote in *Gutierrez de Martinez v. Lamagno*, 515 U.S. 417 (1995). (Army Br. 34.) That case does not help the Army.

In *Lamagno*, the Supreme Court construed a provision of the Westfall Act that used "shall" but not in the imperative form: "Upon certification by the Attorney General . . . any civil action or proceeding . . . shall be deemed an action against the United States . . . , and the United States shall be substituted as a party defendant." 515 U.S. at 432 (citation and emphasis omitted). Unsurprisingly, in the absence of a specific command to an actor, the Court viewed that language as rendering the statute "reasonably susceptible to divergent interpretation." *Id.* at 434. That contrasts starkly with the unambiguous imperative "shall" in section 706(1) now before this Court. The specific footnote the Army cites is no more helpful to its argument. That footnote begins: "Though 'shall' generally means 'must,' legal writers sometimes use, *or misuse*, 'shall' to mean 'should,' 'will,' or even 'may.'" *Id.* at 433 n.9 (emphasis added). As discussed below, the Army

offers no analysis to show Congress's "misuse" of "shall" to mean "may" in section 706(1).

None of the other three (non-APA) cases the Army uses for its "'shall' means 'may'" argument is persuasive or even pertinent. (Army Br. 34.) For instance, the court in *Dubois v. Thomas*, 820 F.2d 943, 946-47 (8th Cir. 1987), refused (without careful textual analysis) to read the imperative "shall" as mandatory as used in a provision of the Federal Water Pollution Control Act because of the clearly established enforcement exception. That exception recognizes that Congress cannot dictate against whom an enforcement action will be brought, removing the executive's enforcement discretion by using the word "shall." *City of Seabrook v. Costle* is a Clean Air Act case that falls along the same lines. 659 F.2d 1371, 1375 (5th Cir. 1981) ("[W]hen duties within the traditional realm of prosecutorial discretion are involved, the courts have not found" controlling the "maxim that the word 'shall' is normally interpreted to impose a mandatory duty.").[3]

As our Opening Brief showed, *Forest Guardians v. Babbitt*, 174 F.3d 1178, 1187-88 (10th Cir. 1999), is most directly on point. (Open. Br. 16-17.) The court there explained how in section 706(1), "Congress has imposed a mandatory duty

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[3] The third case, *Bartholomew v. United States*, 740 F.2d 526, 530-31 (7th Cir. 1984), involved a Postal Service regulation that used "must," not "shall." The court refused to treat the word "must" as mandatory because doing so "would yield absurd results." *Id.* There is no such danger in section 706(1).

upon the subject of the command" by using the word "shall." *Id.* at 1187. The Army responds that *Forest Guardians* "does not compel reversal" simply because it is "from a different circuit." (Army Br. 35.) But it is the plain language of section 706(1) that "compel[s] reversal." And in any event, the Army offers no detailed analysis of why *Forest Guardians* is wrong or, again, why the imperative use of "shall" in section 706(1) is not mandatory. *Forest Guardians* has a thorough and convincing analysis that is consistent with the statute's plain language, and the case has been cited favorably in this circuit; the Court should adopt its analysis. (*See* Open. Br. 17.)

2. Clear Statutory Language Removes the Court's Equitable Discretion.

As we argued in the Opening Brief, because the district court found that the Test Subject Veterans are entitled to medical treatment and the Army admitted that it is not providing it, the mandatory nature of section 706(1) required the court to compel the Army to act. This aligns with the general rule that the "term 'shall' is usually regarded as making a provision mandatory, and the rules of statutory construction presume that the term is used in its ordinary sense unless there is clear evidence to the contrary." *Firebaugh Canal Co. v. United States*, 203 F.3d 568, 573-74 (9th Cir. 2000) (citing *Bennett*, 520 U.S. at 172). Without pointing to such "clear evidence," the Army merely argues in opposition that Congress's use of the word "shall" in section 706(1) did not "divest[] courts of discretion for claims under

Section 706(1)." (Army Br. 33.) The Army relies on *Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166 (9th Cir. 2002), to argue that a "statutory violation does not always lead to the automatic issuance of an injunction." (*Id.*) But that quotation from *Biodiversity* actually follows the enunciation of what is clearly the standard from section 706(2), and not 706(1), as the Army suggests. *See Biodiversity*, 309 F.3d at 1177 (quoting *Envtl. Prot. Info. Ctr. v. Simpson Timber Co.*, 255 F.3d 1073, 1078 (9th Cir. 2001)). In any event, *Biodiversity* does not support the assertion that "shall" was used in a permissive rather than mandatory sense in section 706(1).

The Army also looks to *Hecht Co. v. Bowles*, 321 U.S. 321 (1944), to support its argument that Congress did not curtail courts' powers to exercise equitable discretion. (Army Br. 33.) Though the Court in that case held that an injunction was not mandatory, the Army fails to mention that "on the face of" the statute at issue there was "some room for the exercise of discretion on the part of the court." *Id.* at 328 (The statute required the court to grant a "permanent or temporary injunction, restraining order, or *other order*." (emphasis added)). Of course, section 706(1) offers no such discretion on its face. Indeed, the Army simply ignores the discussion from *Forest Guardians* that the Supreme Court "has made clear Congress' power to curb the courts' discretion by clear expression." *Forest Guardians*, 174 F.3d at 1187 (citing *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982)). Plaintiffs' simple argument is, and has been, that Congress's use of

the imperative "shall" is just the sort of "clear expression" contemplated in *Weinberger*.

II. THE ARMY'S OBLIGATION TO PROVIDE MEDICAL TREATMENT, PURSUANT TO AR 70-25, IS ONGOING.

As discussed further in the Opposition to Cross-Appeal below, the legal obligations imposed by AR 70-25 are forward-looking, requiring the Army to provide notice and medical treatment on an ongoing basis. The district court correctly, and consistent with the regulation's plain meaning, "found that AR 70-25 entitles [the Test Subject Veterans] to medical care for disabilities, injuries or illnesses caused by their participation in government experiments." (E.R. 58.) The Army nevertheless argues that the medical care provisions show the regulation is "plainly limited to medical care during the pendency of a testing program," "like the provisions in earlier versions of AR 70-25." (Army Br. 26.) But AR 70-25's text does not support the Army's argument; the regulation does not contain the limitations the Army claims. *See* AR 70-25 ¶ 3-1(k) (1990) ("Volunteers are authorized all necessary medical care for injury or disease that is a proximate result of their participation in research.").

Indeed, the Army's reading of AR 70-25 would render the medical care provision superfluous. Active military service members are already entitled to medical care while in service. (*See* Army Br. 27 (citing 10 U.S.C. § 1074 (a)(2)(A)).) Were a service member injured during active duty service, including

being injured while a test subject, the service member would receive medical treatment. If AR 70-25 were read as covering only medical treatment during a test, the medical care provision would serve no purpose: it would provide for medical care that a service member test subject receives anyway. Regulations should not be read in a way that renders them purposeless.[4] *See*, *e.g.*, *Khatib v. Cnty. of Orange*, 639 F.3d 898, 904 (9th Cir. 2011) ("it is an 'elementary canon of construction that a statute should be interpreted so as not to render one part inoperative'" (quoting *Mountain States Tel. & Tel. Co. v. Pueblo of Santa Ana*, 472 U.S. 237, 249 (1985))).

III. THE ARMY'S OBLIGATION TO PROVIDE MEDICAL TREATMENT UNDER AR 70-25 IS NOT INCONSISTENT WITH ITS STATUTORY AUTHORITY.

The Army admits that AR 70-25 "contemplate[s]" medical treatment for test subjects, just not "beyond the period that an individual is participating in a specific experiment." (Army Br. 26.) It argues that construing AR 70-25 as authorizing

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[4] The Army also claims the district court conceded that "it was not clear whether AR 70-25 applies 'to individuals who participated in experiments before 1988.'" (Army Br. 28 (citing E.R. 44).) As discussed below, the district court made no such concession and, in fact, carefully rejected Defendants' argument that the regulation applies only to tests after AR 70-25 was reissued in 1988. For example, "the regulation applied to research involving 'deliberate exposure of human subjects to nuclear weapons effect, to chemical warfare agents, or to biological warfare agents.'" (E.R. 50 (quoting AR 70-25 ¶ 1-4.d.(4) (1990)).) Because the Army represents that the military stopped such live agent testing in 1976 (Army Br. 4), AR 70-25 would be rendered nugatory were the regulation read, as the Army asserts, to exclude such test subjects.

medical treatment "beyond the pendency of a testing program" would be "inconsistent" with its "limited statutory authority to provide health care" under 10 U.S.C. § 1074. (Army Br. 27.) That argument is unpersuasive for several reasons.

First, 10 U.S.C. § 1074 is not the only statute authorizing military healthcare, as the Army argues. On the contrary, as the district court correctly found, 10 U.S.C. § 4503 and 10 U.S.C. § 3013—the authorizing statutes for AR 70-25 (1990)—separately authorize the provision of such care.[5] (E.R. 32-38.) In relevant part, section 4503 authorized the Army to "conduct and participate in research and development programs relating to the Army" and "procure or contract for the use of facilities, supplies, and services that are needed for those programs." 10 U.S.C. § 4503 (1992).[6] Section 3013 sets forth the responsibilities and authority of the Secretary of the Army, including to "assign, detail, and prescribe the duties of members of the Army and civilian personnel," and to "prescribe regulations to carry

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[5] The authority for the 1962 and 1974 versions of AR 70-25 was 10 U.S.C. § 4503 and 10 U.S.C. § 3012. *See* AR 70-25 Appendix. Section 3012 was redesignated as section 3013 in 1986. *See* Goldwater-Nichols Department of Defense Reorganization Act of 1986, Pub. L. No. 99-433, § 501(a), 100 Stat. 992, 1034 (1986). The two statutes are identical in all relevant respects.

[6] Congress repealed 10 U.S.C. § 4503 in 1993. (E.R. 35.) A concurrent amendment to 10 U.S.C. § 2358 rendered section 4503 "redundant and obsolete authority." National Defense Authorization Act for Fiscal Year 1994, Pub. L. No. 103-160, § 827(c), 107 Stat. 1547, 1713 (1993).

out his functions, powers, and duties under this title," which includes section 4503. 10 U.S.C. § 3013(g). These statutes evince Congress's intent to authorize the Army "to contract for services needed to carry out research and to implement regulations to do so." (E.R. 38.) There is "no reason" why such authority would exclude adopting a regulation, such as AR 70-25, which promises test subjects "medical treatment associated with injuries or illnesses that result from participation in testing." (*Id.*) Accordingly, as the district court held, sections 3013 and 4503 authorize the Army to provide medical treatment pursuant to AR 70-25.

Even under 10 U.S.C. § 1074, moreover, the Army is authorized to provide medical care to the Test Subject Veterans because they are "persons entitled to such care by law *or regulations*," namely AR 70-25. 10 U.S.C. § 1074(c)(1) (emphasis added). The Army does not dispute that AR 70-25 has the force of law. And AR 70-25 mandates that "medical treatment and hospitalization will be provided," AR 70-25 ¶ 5(c) (1962), and that "[v]olunteers are authorized all necessary medical care for injury or disease that is a proximate result of their participation in research," AR 70-25 ¶ 3-1(k) (1990).

The Army suggests that the DOD's Secretarial Designee regulation is the sole means by which a military department can authorize medical care, but that is at odds with the language of section 1074(c)(1) and AR 70-25. (Army Br. 27-28 (citing 32 C.F.R. § 108.4 (Dec. 27, 2010)).) Indeed, the Army concedes that section

1074(c)(1) authorizes it to "promulgate regulations establishing eligibility for health care," such as AR 70-25. (Army Br. 27.) Not to mention that DOD Instruction 3216.02, concerning the "Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research," states that DOD components, such as the Army, "may *supplement* [the] Secretarial Designee procedure with *additional procedures* consistent with applicable authority" in order to "protect human subjects from medical expenses." DOD Instruction 3216.02(10)(b) (Nov. 8, 2011) (emphasis added). AR 70-25, a legally binding and valid regulation that entitles test subjects to medical care, "supplements" the Secretarial Designee regulation.

The Secretarial Designee regulation—promulgated 26 years after the enactment of section 1074(c)(1), 20 years after the promulgation of AR 70-25 (1990), and almost two years after Plaintiffs commenced their lawsuit—simply does not apply here.[7]

[7] The timing of the Secretarial Designee regulation further emphasizes the weakness of the Army's argument. In the Army's view, in the 20 years between the promulgation of AR 70-25 (1990) and the Secretarial Designee regulation in 2010, the medical care provision in AR 70-25 was meaningless and without effect. The more logical scenario is that this provision was a valid exercise of the Army's authority to provide medical care under sections 4503 and 3013, and section 1074(c)(1).

IV. NEITHER SOVEREIGN IMMUNITY NOR THE EXISTENCE OF DVA BENEFITS BARS REVIEW OF THE ARMY'S INACTION.

The Army argues that sovereign immunity was not waived under the APA and thus courts cannot hear this suit to compel the Army to perform its duties. (Army Br. 29-32.) The reason, it says, is that section 704 of the APA limits the sovereign immunity waiver "to circumstances where there is no other adequate remedy" and that "the availability of medical care from the VA was an adequate remedy" for Plaintiffs. (*Id.* at 31.) The Army also looks to the fact that the Department of Veterans Affairs ("DVA") provides medical care to certain veterans as another reason "apart from Section 704" that the district court declined to compel the Army to act. Each of these arguments is addressed in turn.

A. Sovereign Immunity Was Waived.

The Army argues that "Section 704 limits the APA's waiver of sovereign immunity" contained in APA section 702. (Army Br. 31.) It insists the district court was correct in the July 24, 2013 summary judgment ruling—even though the same district court rejected its initial discussion of sovereign immunity when it reissued its ruling after Plaintiffs' proposed Motion for Reconsideration (C.R. 538-1). (Army Br. 30-31.) The Army also asserts that, even if section 702 is unaffected by section 704, it bars this action because Plaintiffs seek relief that is "expressly or impliedly forbidden by another statute." (*Id.* at 31.)

1. Section 704 Does Not Affect Section 702's Sovereign Immunity Waiver.

The pertinent language of the APA's sovereign immunity provision states that an action "seeking relief other than money damages . . . shall not be dismissed nor relief therein be denied . . . on the ground that it is against the United States. . . ." 5 U.S.C. § 702. Actions such as this one, seeking specific relief rather than monetary damages, are permitted. *See Bowen v. Massachusetts*, 487 U.S. 879, 891-92 (1988); *see also Presbyterian Church (U.S.A.) v. United States*, 870 F.2d 518, 524 (9th Cir. 1989) ("The clear objective of the 1976 amendment was to waive sovereign immunity as a defense in actions seeking relief other than money damages."). The district court explained this well in an earlier order: "Under 5 U.S.C. § 702 . . . sovereign immunity is waived 'in all actions seeking relief from official misconduct except for money damages.'" (S.E.R. 71-72 (quoting *Presbyterian Church*, 870 F.2d at 525; *see also Rosemere Neighborhood Ass'n v. U.S. EPA*, 581 F.3d 1169, 1172 n.2 (9th Cir. 2009) ("Section 702 waives the government's sovereign immunity for actions, such as this one, that seek injunctive relief.")).)

The Army incorrectly argues that section 704 curtails the clear sovereign immunity waiver in section 702. (Army Br. 31-32.) There is no question that section 704 must be satisfied for APA causes of action, but it is not a sovereign

immunity hurdle.[8] Rather, as the Supreme Court noted, "the primary thrust of § 704 was to codify the exhaustion requirement." *Bowen*, 487 U.S. at 903. This Court has rejected the argument that the exhaustion requirement limits section 702's sovereign immunity waiver. In *Presbyterian Church*, this Court reversed the district court's ruling that sovereign immunity barred the church's suit for declaratory and injunctive relief. 870 F.2d at 524-26. The Court distinguished exhaustion from sovereign immunity in ruling that the suit could go forward under section 702 and explained that the APA embodied Congress's conclusion that "[t]he need to channel and restrict judicial control over administrative agencies . . . could be better achieved through doctrines such as . . . exhaustion . . . rather than through 'the confusing doctrine of sovereign immunity.'" *Id.* at 524 (citation omitted).[9]

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[8] Section 704 reads: "Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority." 5 U.S.C. § 704.

[9] The Army mentions *Gallo Cattle Co. v. U.S. Dep't of Agriculture*, 159 F.3d 1194, 1198 (9th Cir. 1998), to note the seeming tension in this Court's cases as to whether section 704's exhaustion requirement is simply an element of an APA claim or should somehow be engrafted onto the sovereign immunity test in section 702 (i.e., that there must be exhaustion before a sovereign immunity waiver will be

Section 704, then, is an exhaustion requirement. And that demonstrates why the Army's argument that *the DVA system* is an "adequate remedy" is so misguided. Clearly, it is the remedies internal to, or related to, *the Army* that must be exhausted, not those of another agency such as the DVA. *See Glisson v. U.S. Forest Serv.*, 55 F.3d 1325, 1326 (7th Cir. 1995) (Posner, J.) ("Exhaustion of administrative remedies is a doctrine . . . now codified in cases governed by the Administrative Procedure Act . . . , 5 U.S.C. § 704 - - under which a court asked to invalidate an administrative order will stay its hand until the plaintiff has exhausted whatever *internal remedies* the agency provides." (internal citations omitted; emphasis added)).

The Army cites no legal authority requiring a plaintiff to exhaust administrative remedies against one agency by proceeding against *another*. The "other adequate remedy" under section 704 must be against the wrongdoing agency that issued the "agency action" (or engaged in the challenged inaction). The fact that the DVA—an altogether different agency—has its own internal procedures by which veterans can seek review of DVA compensation decisions is not relevant to

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found). (Army Br. 32 n.6.) Plaintiffs' view is that there is no basis for reading section 704 as relating to sovereign immunity. But the Court need not resolve this fine point of jurisprudence here because Plaintiffs satisfy the exhaustion requirement and thus win the point either way.

the question of whether the Army's failures are properly subject to judicial review.[10]

That simple principle readily distinguishes another case the Army relies on, *Vietnam Veterans of America v. Shinseki*, 599 F.3d 654 (D.C. Cir. 2010). (Army Br. 32.) In that case, plaintiffs sued under the APA to challenge the average time it took DVA to process benefits claims. The court grappled with the argument that individual plaintiffs could have brought their claims in the Court of Appeals for Veterans Claims, which it noted "possesses the exact same authority to deal with excessive delay . . . that district courts have under the APA." *Id.* at 659. As the Army admits, that discussion was "tentative," and ultimately dicta, because of confusion in that circuit's own precedents about whether section 704 is jurisdictional. *Id*. at 660-61; (*see* Army Br. 32). But it is worth noting in any event that the potentially adequate alternative remedy in that case was one against the DVA in the DVA system (and before a court established to handle DVA claims). There is no suggestion in that case, or in any other the Army relies on, that a

[10] There is no issue of failure to exhaust here because there is nothing for Plaintiffs to exhaust. It is undisputed that there is no internal Army procedure available by which Plaintiffs can challenge the Army's failure to provide medical treatment pursuant to AR 70-25. The Army admits it has not provided such treatment under the regulation and has no intention of doing so (E.R. 318; C.R. 495 at 39 n.39); thus, there is no dispute that the APA's final agency action requirement is satisfied. *See* 5 U.S.C. § 704.

remedy against some agency *other than the one against whom the claim arose* must be exhausted before a challenge can be heard.

The injury Plaintiffs seek to remedy is the Army's unlawful failure to abide by its own regulation's requirement that it provide medical treatment. That injury can be remedied only by requiring the Army to act and to follow its own regulation. That the DVA—assuming a class member is honorably discharged and can successfully navigate the DVA's delay-ridden service-connection process and medical care system—may also be obligated to provide that class member with medical care is irrelevant to the injury that Plaintiffs seek to remedy. As the Supreme Court has reasoned, "[t]he remedy for denial of action that might be sought from one agency does not ordinarily provide an 'adequate remedy' for action already taken by another agency. The Government, to its credit, does not seriously contend that other available remedies alone foreclose review under § 704." *Sackett v. EPA*, 566 U.S. __, 132 S. Ct. 1367, 1372 (2012).

2. This Action Is Not Expressly or Impliedly Forbidden by Another Statute.

The Army asserts that "Plaintiffs' claim for medical care fails" because the claim "seeks relief both expressly and impliedly forbidden under the scheme Congress created to provide benefits to veterans." (Army Br. 31.) The Army did not raise this argument below, but it appears to be invoking section 702 of the APA, which does not "confer[] authority to grant relief if any other statute that grants

consent to suit expressly or impliedly forbids the relief which is sought." 5 U.S.C. § 702(2).

The Army offers up two statutory provisions as candidates to show that Congress expressly or impliedly forbade this action to compel the Army to perform its obligations under AR 70-25. (Army Br. 30.) But neither one works. First, section 7301 of Title 38 simply describes the "primary function" of the Veterans Health Administration as providing "complete medical and hospital service for the medical care and treatment of veterans." 38 U.S.C. § 7301(b). It certainly does not expressly forbid the Army from providing medical treatment to injured subjects of its ghastly experiments. Nor does it impliedly do so; nothing in section 7301 leads one to conclude that the VHA's responsibility to provide medical and hospital service for veterans entails that *it and it alone* can provide such service. After all, the Army admits that *the Army* provides such care.[11] (*See* Army Br. 27 (citing 10 U.S.C. § 1074(b)(1)).) Second, section 511 of Title 38 merely shields from judicial review certain benefits decisions that are made *within* the DVA system. 38 U.S.C. § 511(a). Nothing in that provision speaks expressly or impliedly about the

[11] Veterans also receive benefits and care regularly from other government agencies, such as Medicare and Social Security.

obligation of another agency—the Army—to provide medical treatment under a regulation that is not part of the DVA statutory scheme.[12]

In the cases the Army relies on, the Court was presented with statutory provisions that forbade suits outside a certain forum. (Army Br. 31.) In *United States v. Park Place Assocs.*, 563 F.3d 907 (9th Cir. 2009), the Court held that a specific provision of the Tucker Act, 28 U.S.C. § 1491(a)(1) (grant of exclusive jurisdiction to Court of Claims for claims against the United States over $10,000), forbade suit to confirm a contract-based arbitration award and thus, Section 702's sovereign immunity waiver did not operate. *Id.* at 931. Similarly, in *Tucson Airport Authority v. General Dynamics Corp.*, 136 F.3d 641 (9th Cir. 1998), the Court held that the same specific Tucker Act provision impliedly forbade General Dynamics' contract-based claim. *Id.* at 646-47. By contrast, the statutory provisions the Army relies on here do not forbid the relief that the Test Subject Veterans seek—medical treatment for injuries arising from the military's experiments, pursuant to an Army regulation.

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[12] The Army relies on *Veterans for Common Sense v. Shinseki*, 678 F.3d 1013, 1023 (9th Cir. 2012) (en banc), but that case is irrelevant to the Court's APA analysis. (Army Br. 30.) Plaintiffs do not challenge any DVA benefits decision; they seek medical treatment from the Army.

B. Whether the DVA System of Medical Care Is Adequate or Inadequate Is Irrelevant to This Lawsuit.

The Army next contends the district court simply engaged in "an independent exercise of equitable discretion" when it refused to compel the Army under section 706(1) to provide medical treatment to injured test subjects because of the existence of the DVA scheme.[13] (Army Br. 30.) It characterizes a claim by test subjects—seeking medical treatment from the Army for injuries caused by the Army, pursuant to a regulation repeatedly reissued by the Army—as an "end run" around the DVA scheme. And then the Army incorrectly claims the district court in its discretion "properly recognized" this. (*Id.*)

First, as shown above, the use of the word "shall" in section 706(1) is mandatory and consequently removes the district court's equitable discretion to deny relief. Second, as explained in the Opening Brief, the district court did not offer any legal authority or articulated reasoning for its denial of relief. (Open. Br.

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[13] In the Opening Brief, Plaintiffs noted that, while they had no burden to show a systemic denial of DVA claims, there was substantial evidence on that issue, including DVA's own internal contemporaneous reports. (Open. Br. 24 n.4 ("only 2 out of 86 decisions related to the testing programs included a grant of service-connection").) The Army responds that this report "does not reflect an accurate statistical analysis of grant rates." (Army Br. 39 n.9 (claiming "test participants were granted service connection for at least one claimed disability approximately 85% of the time").) The DVA admitted, however, that these "85%" statistics—generated for purposes of this litigation—do not differentiate *testing-related* decisions. (C.R. 495 at 62 (admitting "it is not apparent from these statistics alone whether the test participants were granted service connection related to their participation in the test program").)

18-19.) Third, there is in any event no reason to conclude that the test subjects injured by the Army are seeking any "end run" around the DVA system. The existence of that system simply has nothing to do with the obligation of the Army to provide medical treatment under its own regulation. And the Army points to no case that allows it to shirk its own duties simply because another government agency provides a benefit that is similar to one it is obligated to provide.

V. THERE ARE NO OTHER IMPEDIMENTS TO AN ORDER COMPELLING THE ARMY TO ACT.

Nor is there merit to the supposed other "numerous impediments" that the Army asserts prevent enforcement of Plaintiffs' entitlement to medical treatment from the Army. (Army Br. 29.)

A. The District Court Did Not Find that Plaintiffs' Entitlement to Medical Treatment Was "Not Clear."

The Army contends "the district court expressly found that [the medical treatment] entitlement was not clear." (Army Br. 29.) But the district court "expressly" found no such thing. The Army cites to the discussion in the district court's order about the duty to *provide notice*; the district court was *not* discussing medical treatment there. (*Compare* E.R. 44 *to* Army Br. 29.) Indeed, nowhere in the district court's order is there an express finding that Plaintiffs' entitlement to medical treatment is "not clear." On the contrary, the district court plainly "found

that AR 70-25 entitles Plaintiffs to medical care for disabilities, injuries or illnesses caused by their participation in government experiments." (E.R. 58.)

B. The Action Plaintiffs Seek to Compel from the Army Is Sufficiently Discrete for Purposes of Section 706(1).

The Army argues that providing medical treatment to veterans injured in its experiments is "not a discrete undertaking" but rather "would require a broad restructuring of Army programs and operations." (Army Br. 29.) But the Army does not show what that supposed "broad restructuring" would be, and it never submitted evidence to the district court of any Army program that would have to be so restructured.[14]

In fact, the act that would be compelled—giving medical treatment to the injured—is discrete and quite within the Army's expertise. Under *Norton v. S. Utah Wilderness Alliance* ("*SUWA*"), 542 U.S. 55, 62-63 (2004), a "failure to act" is "properly understood as a failure . . . to take one of the agency actions (including their equivalents) earlier defined in § 551(13)." *See* 5 U.S.C. § 551(13) ("agency action" includes "the whole or a part of an agency rule, order, license, sanction, relief"). The Army's failure to comply with its legal obligation to provide medical treatment is a failure to provide "relief." 5 U.S.C. § 551(11) (defining

[14] It is hard to imagine that any "restructuring" would be necessary, in light of the DOD Tricare system already in place to provide medical care to veterans. *See* 10 U.S.C. § 1074; (Open. Br. 23).

"relief" in part as "recognition of a claim, right, immunity, privilege, exemption, or exception"). The Army has failed to recognize specific rights to medical treatment owed to a defined group of people under its own regulation, thereby failing to take discrete agency action.

Furthermore, the case the Army relies on is instructive on the issue of discreteness and actually helpful to Plaintiffs. (Army Br. 29 (citing *Hells Canyon Preservation Council v. U.S. Forest Service*, 593 F.3d 923 (9th Cir. 2010)).) In *Hells Canyon*, the Court made clear that "a court can compel [an] agency to act"—there it was to establish the wilderness area boundary required by statute—but cannot "specify what the action must be." *Id.* at 933 (quotations omitted) (The agency could not be ordered "to use any particular topographical feature as the boundary."). Similarly here, Plaintiffs seek to have the Army compelled to provide medical treatment to a definite class of people, as specified in its regulation. Plaintiffs do not ask the Court to tell the Army *how* to go about providing that treatment.

The Army's misunderstanding of the discreteness issue is apparent when it argues that "AR 70-25 leaves ample discretion to the Army Surgeon General" in directing medical follow-up on test subjects. (Army Br. 29.) Right. But that is as it should be; Plaintiffs are not asking the Court to tell the Army when medical

follow-up is appropriate.[15] Plaintiffs seek "to compel the agency to act"—give medical treatment to the injured under its own regulation—but do not ask the Court to "specify what the action must be" in providing that medical treatment.

[15] The separate provision of AR 70-25 referring to the Army Surgeon General is irrelevant to the Court's analysis here. The Army's legal obligation to provide medical treatment to injured test subjects is not contingent on any actions by the Army Surgeon General.

OPPOSITION TO CROSS-APPEAL

VI. THE DISTRICT COURT CORRECTLY FOLLOWED THE PLAIN TEXT OF THE REGULATION CONCERNING NOTICE.

After thorough analysis, the district court concluded that, under AR 70-25, "Defendants have an ongoing duty to warn about newly acquired information that may affect the well-being of test subjects after they completed their participation in research" and ordered the Army "to provide test subjects with newly acquired information that may affect their well-being that it has learned since its original notification, now and in the future as it becomes available." (E.R. 51, 55.) This holding was based on the plain meaning of AR 70-25, including: "Commanders have an obligation to ensure that research volunteers are adequately informed concerning the risks involved with their participation in research, and to provide them with any newly acquired information that may affect their well-being when that information becomes available." AR 70-25 ¶ 3-2.h. (1990) ("The duty to warn exists *even after* the individual volunteer *has completed his or her participation* in research." (emphasis added)).

A. The District Court's Interpretation of the Duty To Warn Was Correct and Its Premise Sound.

The Army argues that this "provision was only meant to apply prospectively" and "[t]here is no evidence that the Army ever intended for AR 70-25 to impose a broad duty to collect and provide information to persons who participated in tests

that took place decades before that regulation was issued." (Army Br. 40.) The plain text of the regulation demonstrates otherwise.

The district court found that "the duty to warn" in the 1988 and 1990 versions of the regulation "is manifestly and unambiguously forward-looking in nature." (E.R. 43.) The district court continued that applying this duty to warn on an

> on-going basis, not just as part of the pre-experiment consent process, and [as] owed to service members who became test subjects before 1988 . . . is consistent with the text itself, including the statement that this duty is owed to individuals who have "participated" in research, not just to those who will participate in such research.

(E.R. 50.) Indeed, the provision contemplates a system that will provide for the "identification of volunteers *who have participated* in research." AR 70-25 ¶ 3-2.h. (1990) (emphasis added). The regulation thus obviously contemplates providing notice to former test subjects after their testing participation has ended. There are no temporal limitations in AR 70-25, contrary to the Army's argument.

The district court's reading of the regulation is further "supported by the addition to the 1990 version of AR 70-25, which made clear that the regulation applied to research involving 'deliberate exposure of human subjects to nuclear weapons effect, to chemical warfare agents, or to biological warfare agents.'" (E.R. 50 (quoting AR 70-25 ¶ 1-4.d.(4) (1990)).) Even now, "the DOD, including the Army, represents that it does not 'still conduct human experimentation with chemical and biological warfare agents' and that its research programs 'involving

human subjects do not involve the exposure of these subjects to chemical or biological warfare agents' any longer." (E.R. 50 (quoting C.R. 513-2, 495 at 2).) Accordingly, the district court concluded that, "[b]ecause the Army did not--and does not--engage in such ongoing testing, there would have been no reason to add this language to AR 70-25 in 1990 if the regulation did not encompass those who had already become such test subjects." (E.R. 51.)

The Army continues to represent that the "military stopped testing live agents on human subjects in 1976" (Army Br. 4), and the regulation expressly applies to testing involving "deliberate exposure of human subjects" to chemical and biological agents (*id.* at 42). Yet it argues that "the premise of the court's reasoning is mistaken" because the Army "continues to administer chemical and biological testing programs that involve the use of human subjects in controlled clinical trials to evaluate the safety and effectiveness of medical products designed to *protect* against chemical agents (that is defensive measures such as the anthrax vaccine)." (*Id.*)

The very document the Army cites to support this argument—a DOD webpage (S.E.R. 54)—contradicts its position and supports the district court's conclusion. The webpage states that "[c]urrent medical chemical & biological defense programs involving human subjects *do not involve the exposure of these subjects* to chemical or biological warfare agents." (S.E.R. 54 (emphasis added).)

There is a separate provision for vaccines and medical devices in the regulation (AR 70-25 ¶ 1-4(d)(2)) and on the DOD's website. (S.E.R. 54 ("There are medical chemical & biological defense programs that involve the use of human subjects in controlled clinical trials to test and evaluate the safety and effectiveness, of medical products (drugs, therapies, etc.) to protect against chemical agents.").) Because the Army "does not engage in such ongoing testing" (E.R. 51) involving "deliberate exposure of human subjects" (E.R. 50), the provision of AR 70-25 would be rendered superfluous if the regulation were read to exclude pre-1988 test subjects. *See Khatib*, 639 F.3d at 904.

B. Defendants' Litigation Position Is Not Entitled to Deference.

The Army's attack on the district court's careful analysis of the regulation should be rejected. The Army's primary argument is that the court should have deferred to the Army's interpretation of AR 70-25—that it applies only to testing taking place after the 1988 version. (Army Br. 41 ("The court refused to apply the established rule . . . because it believed the Army's construction of AR 70-25 was a 'post hoc rationalization' advanced for the first time in litigation.").) But the Army misstates the district court's order and misconstrues the standard for giving deference to agency interpretations. That the Army's interpretation of the regulation offered for the first time in this litigation was a "post hoc rationalization"

was only one reason why the district court rejected it. And agency deference comes into play only if the regulation is ambiguous, which AR 70-25 is not.[16]

In any event, even agency interpretations of an ambiguous regulation are not entitled to deference if there is "reason to suspect that the interpretation does not reflect the agency's fair and considered judgment on the matter in question." *Auer v. Robbins*, 519 U.S. 452, 461 (1997). The district court's rejection of the Army's purported "interpretation" of AR 70-25 followed this well-established legal standard. (E.R. 45-50); *see, e.g., Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 213 (1988) ("Deference to what appears to be nothing more than an agency's convenient litigating position would be entirely inappropriate.").[17]

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[16] The regulation provisions concerning notice and medical treatment are not ambiguous; AR 70-25 contains specifically prescribed requirements. Where a regulation is not ambiguous, courts apply its terms as written. *See, e.g.*, *Christopher v. SmithKline Beecham Corp.*, 635 F.3d 383, 392 (9th Cir. 2011), *aff'd*, 132 S. Ct. 2156 (2012); *see also Safe Air for Everyone v. U.S. EPA*, 488 F.3d 1088, 1097 (9th Cir. 2007) (An agency's interpretation of a regulation "should not be considered when the regulation has a plain meaning.") (internal citation omitted).

[17] The Army argues that: "The court's recognition that AR 70-25 does not impose a clear duty should have ended the inquiry. Whatever 'duty to warn' the regulation might be thought to impose is not sufficiently clear to be enforceable under section 706(1)." (Army Br. 40.) The Army overstates the district court's order, which did not find that the duty was unclear. Rather, as compared to the "duty to warn [which is] manifestly and unambiguously forward looking in nature," the district court stated that "[i]t is less clear whether this ongoing duty is owed to individuals who participated in experiments before 1988." (E.R. 44.) The district court then conducted a thorough analysis of the issue, and found in Plaintiffs' favor, holding that the legal obligation was enforceable under the APA. (*See* E.R. 51, 55.)

There is no dispute that the Army's interpretation of AR 70-25 was offered for the first time in this litigation. The district court explained that such "an 'interpretation advanced for the first time in a litigation brief'" may be entitled to "near indifference." (E.R. 46-47 (quoting *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001)).) The court's skepticism was well-founded: "a position established only in litigation may have been developed hastily, or under special pressure, or without an adequate opportunity for presentation of conflicting views." *Fed. Labor Relations Auth. v. U.S. Dep't of Treasury*, 884 F.2d 1446, 1455 (D.C. Cir. 1989).

The Army argues that the "provision was only meant to apply prospectively" and "its implementation requires that systems be in place at the time that research is conducted in order to comprehensively collect and maintain the necessary information to warn test participants." (Army Br. 40 (citing E.R. 45 (referring to "testimony of Army's Rule 30(b)(6) witness")).) The district court correctly rejected this position, concluding that the witness's testimony was not accurate: "the explanation put forward by the DOD and Army's Rule 30(b)(6) witness is simply not accurate. . . . [A]lthough it may be easier to make such a database at the outset, it is also possible to create one after the fact, using whatever information is available. . . ." (E.R. 48.)

The Army continues that "this Court has long recognized that this ['post hoc rationalization'] rule does not apply with the same force in cases under Section 706(1)." (Army Br. 41.) It cites three cases: *Independence Mining Co. v. Babbitt*, 105 F.3d 502, 511-12 (9th Cir. 1997); *Chase Bank USA, N.A. v. McCoy*, 131 S. Ct. 871, 880-81 (2011); and *Talk America, Inc. v. Michigan Bell Tel. Co.*, 131 S. Ct. 2254, 2263-64 (2011). None of them supports reversal. Neither *Chase Bank* nor *Talk America* is an APA case. And both involved deference to *non-party* agencies *invited by the Court* to offer their interpretation. *See Chase Bank*, 131 S. Ct. at 881 (finding interpretation controlling because "[t]he Board is not a party to this case," but submitted an amicus brief at the Court's request, and "there is no reason to believe [its] interpretation . . . is a 'post hoc rationalization' taken as a litigation position"); *Talk Am.*, 131 S. Ct. at 2263 (deferring to interpretation in invited amicus brief because "[w]e are not faced with a *post-hoc* rationalization . . . of agency action that is under judicial review").

The Court in *Independence Mining*, which pre-dates *Chase Bank* and *Talk America*, did not hold that courts must defer to an agency's litigation position in APA section 706(1) cases. Rather, the Court merely explained that "the district court was not prohibited from considering [supplemental evidence such as an agency declaration], especially where the court permitted both sides to submit supplemental evidence." *Independence Mining*, 105 F.3d at 511-12. The district

court there was not required to defer to the agency's litigation position, but was not prohibited from considering it. And that is what the district court did here. (*See* E.R. 45-50.)

As the district court noted, the fact that the Army has "not previously interpreted the regulation does not mean that whatever interpretation they put forward now must be adopted." (E.R. 47 ("Instead, this simply means that there is no prior interpretation against which their current understanding can be compared to determine whether they have maintained a consistent position or not.").) The district court then concluded that "there is substantial reason to suspect that Defendants' current interpretation of AR 70-25 does not reflect the Army's fair and considered judgment on the matter." (E.R. 47-48 (noting the context "suggests that they were under special pressure to take this position to further" their defense and it "was developed quickly and without a careful consideration of AR 70-25 (1988) and the context in which it was issued and developed").) The court's conclusion was bolstered, in part, by its finding that "the agency representative upon whose interpretation Defendants rely was mistaken about the date on which the operative parts of the regulation were amended, suggesting that he did not have a clear understanding of the context in which these changes were made."[18] (E.R. 48.)

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[18] The Army did not produce nor identify the 1988 and 1989 versions of AR 70-25 until over four years after the complaint was filed, during summary

VII. THE DISTRICT COURT PROPERLY COMPELLED THE ARMY TO COMPLY WITH ITS NON-DISCRETIONARY AND DISCRETE DUTY TO PROVIDE NOTICE.

A. The Army Has No Discretion over Whether To Provide Notice.

The district court held that AR 70-25 obligates the Army to provide the Test Subject Veterans with any "newly acquired information that may affect their well-being that it has learned since its original notification" and properly enforced that obligation under APA section 706(1). (E.R. 50-55.) The Army argues this was error because the scope of its obligations under the duty to warn provision is "necessarily uncertain" and turns on "discretionary scientific and medical judgments." (Army Br. 42-43.) The Army misapplies the APA standard.

As the district court correctly articulated, "the government can be held liable for the breach of its duty to warn, so long as the decision on *whether to warn* is not considered a discretionary act." (S.E.R. 80-81 (emphasis added) (citing *In re Consol. U.S. Atmospheric Testing Litig.*, 820 F.2d 982, 996-99 (9th Cir. 1987); 28 U.S.C. § 2680(a)).) AR 70-25 affords the Army no discretion over "whether to warn," and its duty to warn provision is not "necessarily uncertain." It is unambiguously mandatory: "Commanders have an *obligation* to ensure that

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judgment briefing. (*See* E.R. 20 n.2.) Regarding the duty to warn language, the "Rule 30(b)(6) witness for the Department of Defense and the Army testified that 'this change in AR 70-25 has an effective date of 1990.'" (E.R. 45 (quoting C.R. 496-4 at 140).) Yet "the operative parts of the regulation were amended" in 1988. (E.R. 48.)

research volunteers are adequately informed concerning the risks involved with their participation in research, and to provide them with any newly acquired information that may affect their well-being when that information becomes available." AR 70-25 ¶ 3-2.h. (1990) (emphasis added).

The Army focuses on the "may affect" language and makes various arguments about the "discretionary judgments" involved in discharging its duty. (Army Br. 42-43.) But those arguments miss the point. Agencies will always have some inherent discretion over *how* to do something they are required to do. But that does not negate the underlying duty to act. *See Bennett v. Spear*, 520 U.S. 154, 172 (1997) ("It is rudimentary administrative law that discretion as to the substance of the ultimate decision does not confer discretion to ignore the required procedures of decisionmaking."); *Firebaugh Canal*, 203 F.3d at 578 (compelling agency under section 706(1) to provide drainage service as mandated by statute, without "eliminat[ing] agency discretion as to how it satisfies the drainage requirement"); *Legal Aid Soc'y of Alameda Cnty. v. Brennan*, 608 F.2d 1319, 1330-31 (9th Cir. 1979) (affirming summary judgment for plaintiff on section 706(1) claim where, although regulations placed "heavy reliance upon administrative expertise and discretion," the agency had a "non-discretionary duty" to comply with mandatory terms of regulation).

The district court properly applied this standard in crafting its order and entering its injunction—compelling the Army to comply with its duty to warn without directing how it must do so. *See SUWA*, 542 U.S. at 64 (Under section 706(1), a court is empowered to compel an agency to "'take action upon a matter, without directing *how* it shall act.'" (quoting Attorney General's Manual on the Administrative Procedure Act 108 (1947))).

B. The Army's Duty to Warn Is Discrete.

The Army also seems to argue that its duty to warn is not "discrete," and therefore, its failure to comply is not remediable under section 706(1). (Army Br. 42-43, 45-46.) But the Army again misapplies the APA standard. As explained above, under *SUWA*, a "failure to act" is "properly understood as a failure . . . to take one of the agency actions (including their equivalents) earlier defined in § 551(13)." 542 U.S. at 62-63. The Army's failure to comply with its duty to warn is a failure to provide "relief." *See* 5 U.S.C. § 551(11) (defining "relief" in part as "recognition of a claim, right, immunity, privilege, exemption, or exception"). By failing to recognize the specific rights to notice owed to a defined group of people (i.e., the Test Subject Veterans) under its own regulation, the Army has failed to take discrete agency action.

Further, Plaintiffs' challenge to the Army's failure to act is not the kind of "broad programmatic attack" that *SUWA* cautioned against. Unlike the plaintiffs in

SUWA, Plaintiffs here do not seek to enforce a "broad statutory mandate" that lacks specificity and discreteness. *SUWA*, 542 U.S. at 66-67. Rather, as the district court held and as discussed above, the duty to warn in AR 70-25 prescribes specific actions that the Army must perform for a defined group of people. (E.R. 9-10, 42.) There is thus no danger of "undue judicial interference" with the Army's discretion or "judicial entanglement in abstract policy disagreements." *See SUWA*, 542 U.S. at 66. The district court is not interfering with the Army's discretion; the court is simply compelling the Army to do what it is already legally obligated to do. (*See* E.R. 9-11.)

C. The District Court's Carefully Crafted Injunction Is Proper.

The Army next argues that the district court's injunction must be vacated, claiming it imposes "wide-ranging, prospective obligations and continuous judicial oversight" that will embroil the court in the "day-to-day minutiae" of Army programs, including determining the medical journals the Army must search and deciding when information of "questionable relevance" must be provided to test participants. (Army Br. 43, 45.) But this characterization of the court's injunction bears little resemblance to its actual terms.

The injunction simply requires the Army to create a plan to collect and transmit newly acquired information to test subjects, as its own regulation requires. (E.R. 9-11.) The injunction does not remove the Army's discretion in carrying out

its terms; in fact, it *expressly* preserves the Army's discretion. (*See* E.R. 11 (requiring the Army to provide report explaining the plans it has "in its discretion" developed for collecting and disseminating Newly Acquired Information).) The injunction merely ensures that the Army can no longer ignore its regulation and fail to exercise its discretion altogether. (*See* E.R. 54 (noting that Defendants "do not acknowledge any intent or duty" to comply with their duty to warn).)[19]

The Army's complaints about "continuous judicial oversight" appear to be directed at the district court's retention of jurisdiction to enforce its injunction. (E.R. 11 ("The Court retains jurisdiction to enforce the terms of this Injunction and Order.").) But this is standard and uncontroversial language for any injunction. *See, e.g.*, *Sierra Club v. Penfold*, 857 F.2d 1307, 1321-22 (9th Cir. 1988) (finding court did not abuse discretion in retaining jurisdiction to review environmental

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[19] The Army also objects to the district court's use of the Volunteer Agreement Affidavit, but the injunction does not go "well beyond" the scope of the duty to warn in AR 70-25. (Army Br. 46 n.11.) The provision requires disclosure of two interrelated types of information: (1) information "concerning the risks involved with [test subjects'] participation in research" (i.e., as part of the informed consent process) and (2) "newly acquired information that may affect [test subjects'] well-being." AR 70-25 ¶ 3-2.h. (1990). The injunction concerns the second category, but it is logically linked to the first category—information can be "new" only if it was not previously disclosed to test subjects during their "participation in research," i.e., through the Volunteer Agreement Affidavit (AR 70-25, Appendix E). The court reasonably interpreted the duty to provide "newly acquired information" as a duty to update that previously disclosed information. (E.R. 10, 42.) The Army has not shown this was an abuse of discretion. *See Momot v. Mastro*, 652 F.3d 982, 986 (9th Cir. 2011) (scope of injunctive relief reviewed for abuse of discretion).

studies as part of injunctive relief under APA); *United States v. Fisher*, 864 F.2d 434, 436 (7th Cir. 1988) ("[W]hen a court issues an injunction, it automatically retains jurisdiction to enforce it."). Otherwise, even flagrant violations of the injunction could not be addressed without filing a new, separate lawsuit.

VIII. THE COURT'S ORDER DOES NOT ADDRESS THE SUFFICIENCY OF AGENCY ACTION, BUT RATHER THE ARMY'S FAILURE TO PROVIDE ONGOING NOTICE.

After holding that the Army has "an ongoing duty to warn about newly acquired information that may affect the well-being of test subjects after they completed their participation in research" (E.R. 51), the district court found "[t]here is no material dispute of fact that the Army is not doing this on an ongoing basis." (E.R. 54.) The district court continued that the Army "ha[s] not provided evidence that they have sent any updated information to test subjects since the DVA sent the notice letters and do not acknowledge any intent or duty to do so." (E.R. 54.) The Army fails to show that this factual finding was clearly erroneous. *See Walters v. Reno*, 145 F.3d 1032, 1047 (9th Cir. 1998) (Factual findings are reviewed for clear error.).

The Army argues that, in light of the efforts "the Army has undertaken to determine what adverse health effects exposure to particular substances might cause and to make all relevant information available to former test participants, plaintiffs' claim for additional notice is necessarily a challenge to the sufficiency of the

Army's notification efforts." (Army Br. 43-44.) The Army repeatedly, and incorrectly, uses the term "additional notice" to characterize Plaintiffs' claim and the district court's order. Plaintiffs' notice claim is not for "additional notice." As the district court stated, "Plaintiffs do not challenge the sufficiency of agency action and properly attack the Army's failure to act." (E.R. 54.) Nor did the district court order "additional notice." The district court never stated that the Army's purported efforts were "insufficient" or "inadequate" (Army Br. 43-44). Rather, it is undisputed that the Army "do[es] not acknowledge any intent or duty" to provide notice pursuant to AR 70-25 (E.R. 54), and the district court found that "the Army is not doing [so] on an ongoing basis." (E.R. 54.) Accordingly, the district court properly compelled the Army to act.

A. The Army Continues To Deny Any Duty; Any Purported "Ongoing" Outreach Efforts Are Irrelevant.

The Army attempts to frame Plaintiffs' claim as challenging (and the district court's order as going to) "the *sufficiency* of the Army's actions." It asserts that "[i]t is undisputed that both DoD and the VA *continue* to maintain public websites and telephone hotlines to provide information to World War II and Cold War-era test participants and respond as needed to requests from individual veterans seeking their test files." (Army Br. 44 (emphasis original).) These assertions do not satisfy the Army's burden to show that the district court's pertinent factual findings are clearly erroneous.

The clear error standard gives deference to the district court's findings of fact, requiring for reversal "'a definite and firm conviction that a mistake has been made.' Thus, if the district court's findings are plausible in light of the record viewed in its entirety, the appellate court cannot reverse even if it is convinced it would have found differently." *Husain v. Olympic Airways*, 316 F.3d 829, 835 (9th Cir. 2002) (quoting *Easley v. Cromartie*, 532 U.S. 234, 242 (2001)). The district court found "no material dispute of fact that the Army is not [providing notice] on an ongoing basis." (E.R. 54.) The Army's reliance on these passive "efforts" (the website, 1-800 number, and test record requests) does not satisfy its heavy burden to demonstrate clear error in the court's factual findings. *See Houseton v. Nimmo*, 670 F.2d 1375, 1378 (9th Cir. 1982) (affirming district court's order in section 706(1) case because its findings were not clearly erroneous).

In addition, these passive activities are not the notice required by the regulation. As the district court held, AR 70-25 requires the Army "to provide test subjects with newly acquired information that may affect their well-being that it has learned since its original notification, now and in the future as it becomes available." (E.R. 55); AR 70-25 ¶ 3-2.h. (1990) ("Commanders have an obligation . . . to provide [research volunteers] with any newly acquired information that may affect their well-being when that information becomes available."). As the Army's cross-appeal makes clear, however, these passive activities are merely remnants of

the 2005/2006 DVA outreach efforts, which the court specifically excluded from the scope of the injunction.[20] (Army Br. 7-8; E.R. 10.)

And in light of the Army's continued denial of any duty under AR 70-25, these activities are irrelevant to the Court's analysis. Note that the Army does not say that it is actively providing newly acquired information to test subjects or updating the website with such information. In fact, the Army's arguments, including those in its Emergency Motion to Stay the district court's injunction, suggest otherwise. (*See* Docket No. 7-1 (denying any ongoing legal obligation and continuing to strenuously resist the district court's injunction).)

The Army would apparently require that a Test Subject Veteran know that he must affirmatively contact the Army, and continuously check the website or repeatedly call the 1-800 number in hopes of obtaining any new information. Having access to historic information—if one knows to ask for it—is not the same as receiving notice; responding as needed to requests is not "provid[ing] [research volunteers] with any newly acquired information that may affect their well-being when that information becomes available." AR 70-25 ¶ 3-2.h. (1990). The Army

[20] With respect to "requests from individual veterans seeking their test files" (Army Br. 44), such historic test files that date from the time of the testing programs are by definition not "newly acquired information."

does not argue that it is and does not even purport to be acting in compliance with the regulation.[21]

Even assuming the Army has undertaken some efforts pursuant to the regulation, the Ninth Circuit has held that such circumstances do not foreclose review under section 706(1). *See Brower v. Evans*, 257 F.3d 1058, 1070 (9th Cir. 2001) (finding unreasonable delay despite Secretary's emphasis on work completed because "[c]ompletion of other studies does not relieve the Secretary from progressing with clearly mandated studies"). Because of the ongoing nature of the Army's legal obligation, the Army's continued denial of any obligation to provide notice as required by AR 70-25 demonstrates the agency's unlawful failure to act.

B. The District Court Correctly Found that the Army Has Unlawfully Failed To Act.

The Army argues that "the court did not make the requisite finding that the Army failed to take any 'discrete agency action' that it was required to take." (Army Br. 44-45 ("Specifically, the court did not find that the Army has acquired any significant new information regarding possible effects on the health and well-being of test participants that it has not disclosed.").) This argument misses

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[21] Even setting aside these facts, it seems unlikely that a previously contacted Test Subject Veteran would repeatedly reach out on his own accord. The 2006 DVA outreach letter assured these veterans that "VA continues to study the possibility of long-term health effects. . . . If the medical community identifies such health effects, I assure you that we will share this information with you and other veterans as it becomes available to us." (S.E.R. 40.)

the point. The Army admits that "[t]he court next held that the Army had failed to carry out its obligations under AR 70-25 and that this failure could be remedied under Section 706(1)." (*Id.* at 15.) Nothing else was required of the district court.

Nevertheless, the Army continues that "[i]n the absence of any record evidence that the Army has acquired any new information regarding adverse health effects from any testing programs since 2006, there is simply no factual predicate for concluding that the Army failed to do something it had a 'discrete and mandatory' duty to do." (Army Br. 45.) But the Army did not raise this argument below, and even if it had, Plaintiffs had no obligation to prove there was information currently in the Army's possession that had not been provided. The Army offers no authority to support this contention.

In any event, the ongoing nature of the obligation to provide notice renders this issue irrelevant. Even if hypothetically no newly acquired information were currently available, it is still the case that "when that information becomes available," "Commanders have an obligation" to provide it. AR 70-25 ¶ 3-2.h. (1990). This "duty to warn exists even after the individual volunteer has completed his or her participation in research." *Id.* The Army continues to deny any duty, and as the district court found, does "not acknowledge any intent or duty to" send "any updated information to test subjects." (E.R. 54.)

The Army goes on that "[n]or is there any reason to believe any such information exists, given the comprehensive studies conducted *long ago* on all the substances used in these testing programs." (Army Br. 45 (emphasis added).) But that is precisely the problem; the Army is pointing to "studies" from "long ago." It is not providing, nor even purporting to provide, "newly acquired information" on an ongoing basis "when that information becomes available." AR 70-25 ¶ 3-2.h. (1990). And absent court intervention, the Army has made clear it has no intention of doing so.

CONCLUSION

For the foregoing reasons, the district court's judgment on the medical care APA claim should be vacated and the case remanded with instructions to enter an appropriate injunction. The district court's order and injunction compelling the Army to provide notice should be affirmed.

Dated: April 7, 2014

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CERTIFICATE OF WORD COUNT

Pursuant to Ninth Circuit Rule 32-1, counsel hereby certifies that the foregoing THIRD BRIEF ON CROSS-APPEAL: APPELLANTS'/CROSS-APPELLEES' REPLY BRIEF AND OPPOSITION TO CROSS-APPEAL has been produced using 14-point Times New Roman font and contains approximately 10,808 words, including footnotes. Counsel relies on the word count of the computer program used to prepare this brief.

Dated: April 7, 2014

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Statutory Addendum
Pursuant to Circuit Rule 28-2.7

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5 U.S.C. § 551

TITLE 5. GOVERNMENT ORGANIZATION AND EMPLOYEES
PART I. THE AGENCIES GENERALLY
CHAPTER 5. ADMINISTRATIVE PROCEDURE
SUBCHAPTER II. ADMINISTRATIVE PROCEDURE

§ 551. Definitions

For the purpose of this subchapter [*5 USCS §§ 551* et seq.]--

(1) "agency" means each authority of the Government of the United States, whether or not it is within or subject to review by another agency, but does not include--

(A) the Congress;

(B) the courts of the United States;

(C) the governments of the territories or possessions of the United States;

(D) the government of the District of Columbia;

or except as to the requirements of section 552 of this *title [5 USCS § 552*]--

(E) agencies composed of representatives of the parties or of representatives of organizations of the parties to the disputes determined by them;

(F) courts martial and military commissions;

(G) military authority exercised in the field in time of war or in occupied territory; or

(H) functions conferred by sections 1738, 1739, 1743, and 1744 of title 12; subchapter II of chapter 471 of title 49 [*49 USCS §§ 47151* et seq.]; or sections 1884, 1891-1902, and former section 1641(b)(2), of title 50, appendix;

(2) "person" includes an individual, partnership, corporation, association, or public or private organization other than an agency;

(3) "party" includes a person or agency named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party, in an agency proceeding, and a person or agency admitted by an agency as a party for limited purposes;

(4) "rule" means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing;

(5) “rule making” means agency process for formulating, amending, or repealing a rule;

(6) “order” means the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing;

(7) “adjudication” means agency process for the formulation of an order;

(8) “license” includes the whole or a part of an agency permit, certificate, approval, registration, charter, membership, statutory exemption or other form of permission;

(9) “licensing” includes agency process respecting the grant, renewal, denial, revocation, suspension, annulment, withdrawal, limitation, amendment, modification, or conditioning of a license;

(10) “sanction” includes the whole or a part of an agency--

(A) prohibition, requirement, limitation, or other condition affecting the freedom of a person;

(B) withholding of relief;

(C) imposition of penalty or fine;

(D) destruction, taking, seizure, or withholding of property;

(E) assessment of damages, reimbursement, restitution, compensation, costs, charges, or fees;

(F) requirement, revocation, or suspension of a license; or

(G) taking other compulsory or restrictive action;

(11) “relief” includes the whole or a part of an agency--

(A) grant of money, assistance, license, authority, exemption, exception, privilege, or remedy;

(B) recognition of a claim, right, immunity, privilege, exemption, or exception; or

(C) taking of other action on the application or petition of, and beneficial to, a person;

(12) “agency proceeding” means an agency process as defined by paragraphs (5), (7), and (9) of this section;

(13) “agency action” includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act; and

(14) “ex parte communication” means an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports on any matter or proceeding covered by this subchapter [*5 USCS §§ 551* etc.].

Statutory Addendum
Pursuant to Circuit Rule 28-2.7

5 U.S.C. § 704

TITLE 5. GOVERNMENT ORGANIZATION AND EMPLOYEES
PART I. THE AGENCIES GENERALLY
CHAPTER 7. JUDICIAL REVIEW

§ 704. Actions reviewable

Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.

Statutory Addendum
Pursuant to Circuit Rule 28-2.7

10 U.S.C. § 3012 (1982)

TITLE 10. ARMED FORCES
SUBTITLE B. ARMY
PART I. ORGANIZATION
CHAPTER 303. DEPARTMENT OF THE ARMY

§ 3012. Secretary of the Army: powers and duties; delegation by

(a) There is a Secretary of the Army, who is the head of the Department of the Army.
(b) The Secretary is responsible for and has the authority necessary to conduct all affairs of the Department of the Army, including–
(1) functions necessary or appropriate for the training, operations, administration, logistical support and maintenance, welfare, preparedness, and effectiveness of the Army, including research and development; and
(2) direction of the construction, maintenance, and repair of buildings, structures, and utilities for the Army;
(3) acquisition of all real estate and the issue of licenses in connection with Government reservations;
(4) operation of water, gas, electric, and sewer utilities; and
(5) such other activities as may be prescribed by the President or the Secretary of Defense as authorized by law.

He shall perform such other duties relating to Army affairs, and conduct the business of the Department in such manner, as the President or the Secretary of Defense may prescribe. The Secretary is responsible to the Secretary of Defense for the operation and efficiency of the Department. After first informing the Secretary of Defense, the Secretary may make such recommendations to Congress relating to the Department of Defense as he may consider appropriate.

(c) The Secretary may assign such of his duties as he considers appropriate to the Under Secretary of the Army and to the Assistant Secretaries of the Army. Officers of the Army shall, as directed by the Secretary, report on any matter to the Secretary, the Under Secretary, or any Assistant Secretary.

(d) The Secretary or, as he may prescribe, the Under Secretary or an Assistant Secretary shall supervise all matters relating to–

(1) the procurement activities of the Department of the Army; and

(2) planning for the mobilization of materials and industrial organizations essential to the wartime needs of the Army.

(e) The Secretary, as he considers appropriate, may assign, detail, and prescribe the duties of members of the Army and civilian personnel of the Department of the Army.

(f) The Secretary may change the title of any other officer, or of any activity, of the Department of the Army.

(g) The Secretary may prescribe regulations to carry out his functions, powers, and duties under this title.

(Aug. 10, 1956, ch. 1041, 70A Stat. 157; Sept. 2, 1958, Pub. L. 85-861, § 1(57), 72 Stat. 1462; Sept. 7, 1962, Pub. L. 87-651, title II, § 211, 76 Stat. 524; Aug. 14, 1964, Pub. L. 88-426, title III, §§ 305(2), 306(j)(1), 78 Stat. 422, 431; Nov. 2, 1966, Pub. L. 89-718, § 22, 80 Stat. 1118.)

Statutory Addendum
Pursuant to Circuit Rule 28-2.7

10 U.S.C. § 3013

TITLE 10. ARMED FORCES
SUBTITLE B. ARMY
PART I. ORGANIZATION
CHAPTER 303. DEPARTMENT OF THE ARMY

§ 3013. Secretary of the Army

(a)
(1) There is a Secretary of the Army, appointed from civilian life by the President, by and with the advice and consent of the Senate. The Secretary is the head of the Department of the Army.
(2) A person may not be appointed as Secretary of the Army within five years after relief from active duty as a commissioned officer of a regular component of an armed force.

(b) Subject to the authority, direction, and control of the Secretary of Defense and subject to the provisions of chapter 6 of this *title [10 USCS §§ 161* et seq.], the Secretary of the Army is responsible for, and has the authority necessary to conduct, all affairs of the Department of the Army, including the following functions:
(1) Recruiting.
(2) Organizing.
(3) Supplying.
(4) Equipping (including research and development).
(5) Training.
(6) Servicing.
(7) Mobilizing.
(8) Demobilizing.
(9) Administering (including the morale and welfare of personnel).
(10) Maintaining.
(11) The construction, outfitting, and repair of military equipment.
(12) The construction, maintenance, and repair of buildings, structures, and utilities and the acquisition of real property and interests in real property necessary to carry out the responsibilities specified in this section.

(c) Subject to the authority, direction, and control of the Secretary of Defense, the Secretary of the Army is also responsible to the Secretary of Defense for--

(1) the functioning and efficiency of the Department of the Army;
(2) the formulation of policies and programs by the Department of the Army that are fully consistent with national security objectives and policies established by the President or the Secretary of Defense;
(3) the effective and timely implementation of policy, program, and budget decisions and instructions of the President or the Secretary of Defense relating to the functions of the Department of the Army;
(4) carrying out the functions of the Department of the Army so as to fulfill the current and future operational requirements of the unified and specified combatant commands;
(5) effective cooperation and coordination between the Department of the Army and the other military departments and agencies of the Department of Defense to provide for more effective, efficient, and economical administration and to eliminate duplication;
(6) the presentation and justification of the positions of the Department of the Army on the plans, programs, and policies of the Department of Defense; and
(7) the effective supervision and control of the intelligence activities of the Department of the Army.

(d) The Secretary of the Army is also responsible for such other activities as may be prescribed by law or by the President or Secretary of Defense.

(e) After first informing the Secretary of Defense, the Secretary of the Army may make such recommendations to Congress relating to the Department of Defense as he considers appropriate.

(f) The Secretary of the Army may assign such of his functions, powers, and duties as he considers appropriate to the Under Secretary of the Army and to the Assistant Secretaries of the Army. Officers of the Army shall, as directed by the Secretary, report on any matter to the Secretary, the Under Secretary, or any Assistant Secretary.

(g) The Secretary of the Army may--
(1) assign, detail, and prescribe the duties of members of the Army and civilian personnel of the Department of the Army;
(2) change the title of any officer or activity of the Department of the Army not prescribed by law; and
(3) prescribe regulations to carry out his functions, powers, and duties under this *title [10 USCS §§ 101* et seq.].

Statutory Addendum
Pursuant to Circuit Rule 28-2.7

10 U.S.C. § 4503 (1988)

TITLE 10 — ARMED FORCES

§ 4503. Research and development programs

The Secretary of the Army may conduct and participate in research and development programs relating to the Army, and may procure or contract for the use of facilities, supplies, and services that are needed for those programs.
This section does not authorize the design or development of any prototype aircraft intended primarily for commercial use.

(Aug. 10, 1956, ch. 1041, 70A Stat. 252.)

Statutory Addendum
Pursuant to Circuit Rule 28-2.7

38 U.S.C. § 511

TITLE 38. VETERANS' BENEFITS
PART I. GENERAL PROVISIONS
CHAPTER 5. AUTHORITY AND DUTIES OF THE SECRETARY
SUBCHAPTER I. GENERAL AUTHORITIES

§ 511. Decisions of the Secretary; finality

(a) The Secretary shall decide all questions of law and fact necessary to a decision by the Secretary under a law that affects the provision of benefits by the Secretary to veterans or the dependents or survivors of veterans. Subject to subsection (b), the decision of the Secretary as to any such question shall be final and conclusive and may not be reviewed by any other official or by any court, whether by an action in the nature of mandamus or otherwise.

(b) The second sentence of subsection (a) does not apply to--
(1) matters subject to section 502 of this *title [38 USCS § 502*];
(2) matters covered by sections 1975 and 1984 of this *title [38 USCS §§ 1975* and *1984*];
(3) matters arising under chapter 37 of this *title [38 USCS §§ 3701* et seq.]; and
(4) matters covered by chapter 72 of this *title [38 USCS §§ 7251* et seq.].

Statutory Addendum
Pursuant to Circuit Rule 28-2.7

38 U.S.C. § 7301

TITLE 38. VETERANS' BENEFITS
PART V. BOARDS, ADMINISTRATIONS, AND SERVICES
CHAPTER 73. VETERANS HEALTH ADMINISTRATION-ORGANIZATION AND FUNCTIONS
SUBCHAPTER I. ORGANIZATION

§ 7301. Functions of Veterans Health Administration: in general

(a) There is in the Department of Veterans Affairs a Veterans Health Administration. The Under Secretary for Health is the head of the Administration. The Under Secretary for Health may be referred to as the Chief Medical Director.

(b) The primary function of the Administration is to provide a complete medical and hospital service for the medical care and treatment of veterans, as provided in this title and in regulations prescribed by the Secretary pursuant to this title.

Public Law 99-433
99th Congress

An Act

To reorganize the Department of Defense and strengthen civilian authority in the Department of Defense, to improve the military advice provided to the President, the National Security Council, and the Secretary of Defense, to place clear responsibility on the commanders of the unified and specified combatant commands for the accomplishment of missions assigned to those commands and ensure that the authority of those commanders is fully commensurate with that responsibility, to increase attention to the formulation of strategy and to contingency planning, to provide for more efficient use of defense resources, to improve joint officer management policies, otherwise to enhance the effectiveness of military operations and improve the management and administration of the Department of Defense, and for other purposes.

Oct. 1, 1986
[H.R. 3622]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Goldwater-Nichols Department of Defense Reorganization Act of 1986.
Armed Forces.
Defense and national security.
10 USC 111 note.

SECTION 1. SHORT TITLE; TABLE OF CONTENTS

(a) SHORT TITLE.—This Act may be cited as the "Goldwater-Nichols Department of Defense Reorganization Act of 1986".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. References to title 10, United States Code.
Sec. 3. Policy.

TITLE I—DEPARTMENT OF DEFENSE GENERALLY

Sec. 101. Organization of the Department of Defense.
Sec. 102. Powers and duties of the Secretary of Defense.
Sec. 103. Modification of authority of Secretary of Defense to reorganize the Department of Defense.
Sec. 104. Office of the Secretary of Defense.
Sec. 105. Under Secretary for Policy and Director of Defense Research and Engineering.
Sec. 106. Assistant Secretaries of Defense.
Sec. 107. Comptroller of the Department of Defense.
Sec. 108. Inspector General of the Department of Defense.
Sec. 109. Management studies of Office of the Secretary of Defense.
Sec. 110. Technical and conforming amendments.

TITLE II—MILITARY ADVICE AND COMMAND FUNCTIONS

PART A—JOINT CHIEFS OF STAFF

Sec. 201. Revised functions of Chairman; establishment of Vice Chairman.
Sec. 202. Provisions relating to Vice Chairman.
Sec. 203. Participation in National Security Council meetings.
Sec. 204. Transition.

PART B—COMBATANT COMMANDS

Sec. 211. Establishment of combatant commands and authority of commanders.
Sec. 212. Initial review of combatant commands.
Sec. 213. Repeal of certain limitations on command structure.
Sec. 214. Transition.

(1) CAPSTONE COURSE.—Subsection (a) of section 663 of such title (as added by section 401) shall apply with respect to officers selected in reports of officer selection boards submitted to the Secretary concerned after the end of the 120-day period beginning on the date of the enactment of this Act.

(2) REVIEW OF MILITARY EDUCATION SCHOOLS.—(A) The first review under subsections (b) and (c) of such section shall be completed not later than 120 days after the date of the enactment of this Act. The Secretary of Defense shall submit to Congress a report on the results of the review at each Department of Defense school not later than 60 days thereafter.

Reports.

(B) Such subsections shall be implemented so that the revised curricula take effect with respect to courses beginning after July 1987.

Effective date.

(3) POST-EDUCATION DUTY ASSIGNMENTS.—Subsection (d) of such section shall take effect with respect to classes graduating from joint professional military education schools after January 1987.

Effective date.

10 USC 664 note.

(e) LENGTH OF JOINT DUTY ASSIGNMENTS.—Subsection (a) of section 664 of title 10, United States Code (as added by section 401), shall apply to officers assigned to joint duty assignments after the end of the 90-day period beginning on the date of the enactment of this Act. In computing an average under subsection (b) of such section, only joint duty assignments to which such subsection applies shall be considered.

Effective date.
10 USC 612 note.

(f) PROMOTION POLICY.—The amendments made by section 402 shall take effect with respect to selection boards convened under section 611(a) of title 10, United States Code, after the end of the 120-day period beginning on the date of the enactment of this Act.

10 USC 113 note.

(g) INITIAL REPORT.—The first report submitted by the Secretary of Defense after the date of the enactment of this Act under section 113(c) of title 10, United States Code (as redesignated by section 101), shall contain as much of the information required by section 667 of such title (as added by section 401) as is available to the Secretary at the time of the preparation of the report.

TITLE V—MILITARY DEPARTMENTS

PART A—DEPARTMENT OF THE ARMY

SEC. 501. THE ARMY SECRETARIAT

10 USC 3010 *et seq.*
10 USC 3031 *et seq.*

(a) AMENDMENTS TO CHAPTER 303.—(1) Section 3015 is transferred to the end of chapter 305 and redesignated as section 3040.

(2) Sections 3010, 3011, 3012, 3013, and 3014 are redesignated as sections 3011, 3012, 3013, 3014, and 3015, respectively.

(3) Section 3016 is transferred within chapter 303 to appear after section 3017 and is redesignated as section 3018.

(4) Section 3019 is transferred to chapter 305, inserted after section 3037, and redesignated as section 3038.

(5) Chapter 303 is amended by striking out sections 3013, 3014, and 3015 (as redesignated by paragraph (2)) and inserting in lieu thereof the following:

Public Law 103-160
103d Congress

An Act

To authorize appropriations for fiscal year 1994 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe personnel strengths for such fiscal year for the Armed Forces, and for other purposes.

Nov. 30, 1993
[H.R. 2401]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

National Defense Authorization Act for Fiscal Year 1994.

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Defense Authorization Act for Fiscal Year 1994".

SEC. 2. ORGANIZATION OF ACT INTO DIVISIONS; TABLE OF CONTENTS.

(a) DIVISIONS.—This Act is organized into three divisions as follows:

(1) Division A—Department of Defense Authorizations.

(2) Division B—Military Construction Authorizations.

(3) Division C—Department of Energy National Security Authorizations and Other Authorizations.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title.
Sec. 2. Organization of Act into divisions; table of contents.
Sec. 3. Congressional defense committees defined.

DIVISION A—DEPARTMENT OF DEFENSE AUTHORIZATIONS

TITLE I—PROCUREMENT

Subtitle A—Authorization of Appropriations

Sec. 101. Army.
Sec. 102. Navy and Marine Corps.
Sec. 103. Air Force.
Sec. 104. Defense-wide activities.
Sec. 105. Defense Inspector General.
Sec. 106. Reserve components.
Sec. 107. Chemical demilitarization program.
Sec. 108. National Shipbuilding Initiative.
Sec. 109. Denial of multiyear procurement authorization.

Subtitle B—Army Programs

Sec. 111. Procurement of helicopters.
Sec. 112. Light utility helicopter modernization.
Sec. 113. Nuclear, biological, and chemical protective masks.
Sec. 114. Chemical agent monitoring program.
Sec. 115. Close Combat Tactical Trainer Quickstart program.

Subtitle C—Navy Programs

Sec. 121. Seawolf attack submarine program.
Sec. 122. Trident II (D-5) missile procurement.

(A) by striking out subsection (a);

(B) by redesignating subsections (b), (c), (d), (e), (f), and (g) as subsections (a), (b), (c), (d), (e), and (f), respectively;

(C) in subsection (a), as redesignated by subparagraph (B)—

(i) in paragraph (1), by striking out "subsection (a)" and inserting in lieu thereof "section 2358 of this title"; and

(ii) in paragraph (2), by striking out "subsection (e)" and inserting in lieu thereof "subsection (d)";

(D) in subsection (d), as redesignated by subparagraph (B), by striking out "subsection (a)" and inserting in lieu thereof "section 2358 of this title"; and

(E) in subsection (e), as redesignated by subparagraph (B)—

(i) in paragraph (4), by striking out "subsection (b)" and inserting in lieu thereof "subsection (a)"; and

(ii) in paragraph (5), by striking out "subsection (e)" and inserting in lieu thereof "subsection (d)".

(2) CONSISTENCY OF TERMINOLOGY.—Such section, as amended by paragraph (1), is further amended—

(A) in subsection (c)(1), by inserting "and development" after "research" both places it appears;

(B) in subsections (d) and (e)(3), by striking out "advanced research" and inserting in lieu thereof "research and development"; and

(C) in subsection (e)(1), by striking out "advanced research is" and inserting in lieu thereof "research and development are".

(c) REDUNDANT AND OBSOLETE AUTHORITY FOR THE ARMY AND THE AIR FORCE.—Sections 4503 and 9503 of title 10, United States Code, are repealed.

SEC. 828. TECHNICAL AND CLERICAL AMENDMENTS RELATING TO ACQUISITION LAWS.

(a) AMENDMENTS TO TABLES OF SECTIONS.—The table of sections at the beginning of each chapter of title 10, United States Code, listed in the following paragraphs is amended by striking out the items relating to the sections listed in such paragraphs:

(1) Chapter 137: section 2317.

(2) Chapter 139: section 2362.

(3) Chapter 141: section 2389.

(4) Chapter 144: sections 2436 and 2437.

(5) Chapter 433: sections 4531, 4533, 4534, 4535, 4537, 4538, and 4541.

(6) Chapter 631: sections 7201, 7210, 7213, and 7230.

(7) Chapter 633: sections 7296, 7298, and 7301.

(8) Chapter 637: section 7366.

(9) Chapter 933: sections 9531, 9534, 9535, 9537, 9538, and 9541.

(b) AMENDMENTS TO TABLES OF CHAPTERS.—

(1) The tables of chapters at the beginning of subtitle A, and part IV of subtitle A, of title 10, United States Code, are amended by striking out the item relating to chapter 135.

Department of Defense

INSTRUCTION

NUMBER 3216.02
November 8, 2011

USD(AT&L)

SUBJECT: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research

References: See Enclosure 1

1. PURPOSE. This Instruction reissues DoD Directive (DoDD) 3216.02 (Reference (a)) as a DoD Instruction in accordance with the authority in DoDD 5134.01 (Reference (b)) to establish policy and assign responsibilities for the protection of human subjects in DoD-supported programs to implement part 219 of title 32, Code of Federal Regulations (CFR) (also known and hereinafter referred to as "the Common Rule" (Reference (c)).

2. APPLICABILITY

a. This Instruction applies to:

(1) OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the Department of Defense (hereinafter referred to collectively as the "DoD Components").

(2) All DoD-conducted or -supported research involving human subjects as defined in the Glossary. All such activities must include both systematic investigation designed to develop or contribute to generalizable knowledge AND involve a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or about whom identifiable private information is obtained. All activities meeting both of these conditions will hereinafter be referred to as "research involving human subjects" in this Instruction.

(3) Activities such as research, development, testing, and evaluation (RDT&E) that meet the definition of research involving human subjects (as defined in the Glossary), as well as clinical investigations or medical activities regulated by the Food and Drug Administration (FDA) in parts 50, 56, 312, 600, and 812 of title 21, CFR (Reference (d)).

b. Applicability is not dependent upon the budget activities funding the research, the mission of the DoD organization conducting or supporting the research, the security classification of the research, the location of the research in the United States or a foreign country, or whether the research is conducted or supported under a program that is not considered research for other purposes.

3. DEFINITIONS. See Glossary.

4. POLICY. It is DoD policy that:

a. All research involving human subjects that is conducted or supported by the Department of Defense shall comply with part 219 of Reference (c), which incorporates the ethical principles of respect for persons, beneficence, and justice, as codified in page 23192 of the Federal Register (also known as "The Belmont Report" (Reference (e)).

b. Certain categories of human subjects in research are recognized as vulnerable populations, groups, or individuals and are afforded additional protections as specified in section 7 of Enclosure 3 of this Instruction.

c. Research involving human subjects for testing of chemical or biological warfare agents is generally prohibited by section 1520a of title 50, United States Code (U.S.C.) (Reference (f)), subject to possible exceptions for research for prophylactic, protective, or other peaceful purposes.

d. DoD-appropriated funds shall not be used to support research involving a human being as an experimental subject, as defined in this Instruction, without the prior informed consent of the experimental subject or in accordance with section 980 of title 10, U.S.C. (Reference (g)) and this Instruction (see section 9 of Enclosure 3 of this Instruction for details). The definitions of research involving a human being as an experimental subject and research involving human subjects are different; see the Glossary for an explanation.

e. Research involving human subjects covered under this Instruction shall also comply with applicable Federal and State laws and regulations. When the research is conducted outside of the United States, it must also comply with applicable requirements of the foreign country and its national laws and requirements. In the event of an unresolved conflict between this Instruction, including its references, and other applicable laws and requirements such that compliance with both is impossible, the requirements most protective of the human subjects shall be followed. When there is an unresolved conflict, DoD Components shall consult with legal counsel and seek guidance from the Assistant Secretary of Defense for Research and Engineering (ASD(R&E)).

5. RESPONSIBILITIES. See Enclosure 2.

6. PROCEDURES. See Enclosure 3.

7. RELEASABILITY. UNLIMITED. This Instruction is approved for public release and is available on the Internet from the DoD Issuances Website at http://www.dtic.mil/whs/directives.

8. EFFECTIVE DATE. This Instruction is effective upon its publication to the DoD Issuances Website.

Frank Kendall
Acting Under Secretary of Defense
for Acquisition, Technology, and Logistics

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ENCLOSURE 1

REFERENCES

(a) DoD Directive 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," March 25, 2002 (hereby cancelled)
(b) DoD Directive 5134.01, "Under Secretary of Defense for Acquisition, Technology and Logistics (USD(AT&L))," December 9, 2005
(c) Parts 22 (Appendix B), 37 (Appendix D), 108 and 219[1] of title 32, Code of Federal Regulations
(d) Parts 50, 56, 312, 600, and 812 of title 21, Code of Federal Regulations
(e) Page 23192 of Volume 44, Federal Register, April 18, 1979 (also known as "The Belmont Report") [2]
(f) Section 1520a of title 50, United States Code
(g) Sections 139(a)(2)(A), 980, 1074f , and 1102 of title 10, United States Code
(h) Part 46, subparts A-D of title 45, Code of Federal Regulations
(i) Memorandum of Understanding between the Food and Drug Administration and the Department of Defense, "Concerning Investigational Use of Drugs, Antibiotics, Biologics, and Medical Devices by the Department of Defense," May 21, 1987
(j) Sections 241(d) and 289g–289g-2 of title 42, United States Code
(k) Public Law 107-347, "Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA)," December 17, 2002
(l) Pages 33362-33377 of Volume 72, Federal Register, June 15, 2007
(m) Sections 2105, 3109, 3371-3376,[3] and 5536 of title 5, United States Code
(n) Sections 2.101 and 252.235-7004 of title 48, Code of Federal Regulations
(o) Section 252 of Public Law 103-160, "National Defense Authorization Act for Fiscal Year 1994," November 30, 1993
(p) DoD Directive 2310.01E, "The Department of Defense Detainee Program," September 5, 2006
(q) Section 30 of title 24, United States Code
(r) Executive Order 13526, "Classified National Security Information," December 29, 2009
(s) DoD 6025.18-R, "DoD Health Information Privacy," January 24, 2003
(t) Executive Order 12333, "United States Intelligence Activities," as amended, August 18, 2010
(u) DoD 5400.11-R, "Department of Defense Privacy Program," May 14, 2007
(v) DoDI 6000.08, "Funding and Administration of Clinical Investigation Programs," December 3, 2007
(w) DoD Instruction 5025.01, "DoD Directives Program," October 28, 2007
(x) DoD Instruction 6200.02, "Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Program," February 27, 2008

[1] Also known as "the Common Rule"
[2] Available on the Internet at http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm. The Belmont Report's 2-volume appendix is available from the Government Printing Office as DHEW Publication Nos. (OS) 78-0013 and (OS) 78-0014
[3] Also known as "The Intergovernmental Personnel Act of 1970, as amended"

(y) DoD Instruction 6025.13, "Medical Quality Assurance (MQA) and Clinical Quality Management in the Military Health System (MHS)," February 17, 2011
(z) DoD Directive 5240.01, "DoD Intelligence Activities," August 27, 2007

ENCLOSURE 2

RESPONSIBILITIES

1. ASD(R&E). The ASD(R&E), under the authority, direction, and control of the Under Secretary of Defense for Acquisition, Technology, and Logistics, shall:

a. Be the single DoD point of contact for all matters related to DoD compliance with this Instruction and shall act as the principal DoD liaison with organizations outside the Department of Defense on matters pertaining to research involving human subjects.

b. Provide guidance and procedures necessary to implement this Instruction. The ASD(R&E) will consult with the Assistant Secretary of Defense for Health Affairs (ASD(HA)) for matters affecting medical research involving human subjects.

c. Exercise the authorities of the Head of the Department identified in part 219 of Reference (c), the Secretary as identified in subparts B-D of part 46 of title 45, CFR (Reference (h)) for research described in section 7 of Enclosure 3 of this Instruction, and the Secretary of Defense identified in section 980 of Reference (g).

d. Grant exceptions to any procedures or requirements in this Instruction based upon an appropriate justification from the Head of an OSD or DoD Component and consistent with law.

e. Establish a process to oversee the DoD Components' implementation of their respective Component human research protection program (HRPP) management plan and compliance with this Instruction.

f. Establish a framework for educational training requirements for DoD personnel in key HRPP roles commensurate with their duties and responsibilities.

g. Work with the DoD Components supporting international research involving human subjects to resolve conflicts between this Instruction, including its references, and other applicable foreign laws and requirements.

h. Maintain a list of foreign country and international standards that are at least equivalent to those in part 219 of Reference (c).

i. Designate DoD representatives to Federal committees, such as the Human Subject Research Subcommittee of the National Science and Technology Council's Committee on Science or other committees established by the White House.

j. Designate a DoD representative to the Secretary's Advisory Committee on Human Research Protection established by the Secretary of Health and Human Services (HHS) and successor entities established by the Secretary of HHS.

k. Establish the DoD Coordinating Committee for Human Research Protection Programs (CCHRPP) to act as the central advisory committee to the ASD(R&E) on all matters regarding the ethical involvement of human subjects in research. Membership shall be appointed as described in section 18 of Enclosure 3 of this Instruction.

2. ASD(HA). The ASD(HA), under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness (USD(P&R)), shall:

a. Advise the ASD(R&E) on matters related to the participation of human subjects in research, especially regarding medical safety, bioethics, and standards of professional health care and conduct.

b. Represent the Department of Defense on matters relating to implementation of FDA regulatory requirements in Reference (d) and the Memorandum of Understanding between the FDA and the Department of Defense (Reference (i)).

3. HEADS OF THE OSD AND DoD COMPONENTS. The Heads of the OSD and DoD Components that conduct or support research involving human subjects covered by this Instruction shall:

a. Develop, issue, and monitor a Component HRPP management plan (see section 1 of Enclosure 3 of this Instruction for details).

b. Establish and oversee DoD Component policies and procedures that ensure compliance with this Instruction and any other supplementing or implementing issuances (see section 1 of Enclosure 3 for details).

c. Exercise the authority as outlined in this Instruction.

d. Oversee each institutional official's (IO) (see Glossary) implementation of their organization's HRPP.

e. Provide members to intra- and interagency committees and to the CCHRPP when requested by the ASD(R&E) consistent with section 18 of Enclosure 3.

f. Provide in a timely manner to the ASD(R&E) the following:

(1) A copy of all reports provided to the appropriate Congressional Committees in accordance with Reference (f) for any research involving human subjects for testing of chemical or biological warfare agents. DoD Components shall also send a copy to the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs.

(2) Copies of any waivers from requirements that have been granted in accordance with this Instruction.

(3) Copies of any approved fetal research covered under sections 289g–289g-2 of title 42, U.S.C. (Reference (j)).

(4) Copies of any research involving human subjects conducted consistent with section 512 of Public Law 107-347 (Reference (k)). DoD Components shall also send a copy to the Office of Management and Budget (OMB), as required by Reference (k) and pages 33362-33377 of Volume 72, Federal Register (Reference (l)).

(5) Any allegation of serious or continuing noncompliance related to research involving human subjects that has been substantiated by inquiry or investigation and any subsequent actions taken based on the findings consistent with section 16 of Enclosure 3. The DoD Component may send an initial notification of potential serious or continuing noncompliance to ASD(R&E) based on the gravity or magnitude of the initial allegation.

(6) Any notifications to a DoD Component by another Federal agency or by an appropriate State agency or foreign government that an institution of the Component is under investigation for cause or for noncompliance with the applicable laws and regulations, including the Common Rule.

(7) Any substantiated unanticipated problems involving risks to human subjects or others (UPIRTSO).

g. Maintain all records identified in this Instruction or required by a reference in this Instruction as described in section 15 of Enclosure 3.

4. IOs OF DoD INSTITUTIONS. Each IO, under the authority, direction, and control of the Heads of the OSD and DoD Components shall:

a. Establish and maintain an HRPP to ensure the institution's compliance with this Instruction.

b. Provide the resources needed to ensure compliance with this Instruction.

c. Establish and maintain a DoD assurance and other appropriate Federal assurances, if the institution is engaged in non-exempt research involving human subjects (see Glossary).

d. Evaluate and improve the institution's HRPP.

ENCLOSURE 3

PROCEDURES

1. DoD COMPONENT HRPP MANAGEMENT PLAN

a. The DoD Component HRPP management plan shall include, by reference, DoD Component policies to implement the procedures set forth in this enclosure and identify the responsible DoD Component office(s) for actions identified in this Instruction. DoD Component policies may be more restrictive than the requirements in this Instruction, but they may not be less restrictive. They may also impose additional requirements needed to implement this Instruction.

b. The plan shall identify a single, senior official having the authority and responsibility for implementing the DoD Component HRPP management plan. This authority shall not be delegated lower than the general or flag officer (GO/FO), Senior Executive Service (SES), or equivalent level. All authorities delegated by the Head of the OSD or DoD Component must be identified in the management plan.

c. The plan shall reference DoD Component policies and procedures that:

(1) Direct each institution within the DoD Component conducting or supporting research involving human subjects to establish an HRPP that is compliant with this Instruction and the DoD Component's HRPP management plan.

(2) Describe DoD Component oversight of each institution's HRPP.

(3) Describe DoD Component administrative review of DoD-conducted and -supported research involving human subjects (see sections 3 and 4 of this enclosure for details).

(4) Delineate institutional responsibilities when performing research involving human subjects in collaboration with another DoD Component. These responsibilities shall include establishing written agreements for tasks such as minimizing the number of institutional review boards (IRBs) and DoD Components that review and approve the research (see sections 3 and 4 of this enclosure for details). DoD Component policies and procedures shall include a requirement to justify the duplication of reviews of protocols (for example, IRB and Component Headquarters reviews).

(5) Outline education and training for implementation, management, and oversight of this Instruction (see paragraph 1.f. of Enclosure 2 and section 5 of this enclosure for details).

(6) Address the management of allegations and findings of noncompliance concerning DoD-conducted and -supported research involving human subjects (see section 16 of this enclosure for details).

(7) Identify and manage conflicts of interest, not limited to financial, for DoD personnel involved in the HRPP.

(8) Require a process to evaluate and improve the DoD Component's implementation of its HRPP management plan down to the level of the institutional HRPP.

d. A DoD Component may rely on another DoD Component for implementation of elements of the management plan except for designation of the single, senior official responsible for the management plan identified in paragraph 1.b. of this enclosure. Any such reliance must be reflected in the DoD Component's HRPP management plan.

2. REQUIREMENTS FOR A FEDERAL ASSURANCE

a. Activities for Which an Institution is Required to Have a Federal Assurance. Any institution engaged in non-exempt research involving human subjects that is conducted or supported by the Department of Defense shall have a Federal assurance consistent with section 219.103 of Reference (c) and acceptable to the funding agency.

(1) A DoD institution engaged in non-exempt research involving human subjects shall have a DoD assurance of compliance. Additionally, a DoD institution shall have an HHS assurance when engaged in non-exempt research involving human subjects funded by HHS (unless HHS will accept a DoD assurance). When conducting HHS-funded research involving human subjects, the DoD institution must follow this Instruction and any additional HHS requirements.

(2) In complying with the requirements of section 219.103 of Reference (c), a non-DoD institution that is engaged in DoD-supported non-exempt research involving human subjects:

(a) Need not have a DoD assurance if it has an existing Federal assurance appropriate for the research being conducted. If the institution does not have a Federal assurance, the institution must provide either a DoD assurance to the DoD Component supporting the research or a Federal wide assurance to HHS, Office for Human Research Protections. Alternatively, if the institution does not have a Federal assurance, the researcher may use an Individual Investigator Agreement to associate with an institution having a Federal assurance and thus fulfill the requirement of conducting non-exempt research involving human subjects under an approved Federal assurance. In summary, all researchers conducting non-exempt research involving human subjects must be covered either directly under their institution's Federal assurance or indirectly using an Individual Investigator Agreement.

(b) Shall comply with the terms of its Federal assurance, applicable sections of this Instruction, and relevant policies of the supporting DoD Component.

(3) All institutions providing a DoD assurance to a designated DoD Component office shall include the items identified in section 219.103(b) of Reference (c).

(a) All institutions shall identify at least one IRB on their DoD assurance. DoD institutions shall identify all IRBs that are internal to the institution on their DoD assurance.

(b) When any institution relies upon another institution's IRB, there must be a written agreement defining the responsibilities and authorities of each organization in complying with the terms of each institution's Federal assurance and this Instruction (e.g., an Institutional Agreement for IRB Review). The existence of a DoD Institutional Agreement for IRB Review or a similar agreement will satisfy the Federal assurance requirements at sections 219.103(b)(2)-(5) of Reference (c).

b. Activities for Which an Institution is not Required to Have a Federal Assurance

(1) An institution is not required to have a Federal assurance if its personnel only conduct research that does not involve human subjects or the research involving human subjects meets at least one of the exemption criteria in section 219.101(b) of Reference (c).

(2) An institution that is only providing resources to support research involving human subjects (see Glossary definition of DoD-supported research involving human subjects) is not required to have a Federal assurance unless its involvement also meets the definition of being engaged in non-exempt research involving human subjects. When a DoD institution passes resources to another institution that will not be engaged in research, but will only transfer the resources to a third institution that will engage in research involving human subjects, the pass through institution is not required to have a Federal assurance. The institution engaged in non-exempt research involving human subjects must have a Federal assurance.

(3) An institution is not required to have a Federal assurance if it is collaborating in a research protocol that is non-exempt research involving human subjects and the institution's role in the collaborative research is limited to any of the following:

(a) Specific tasks that do not involve research involving human subjects; or

(b) Specific tasks that do not include the collection or handling of identifiable data or specimens. Research in which the human subjects' data or specimens are coded and the institution is prevented from having access to the code are considered non-identifiable for the purpose of this subparagraph.

(4) A DoD institution that does not meet the criteria for requiring a Federal assurance but conducts only exempt research involving human subjects or supports research involving human subjects must have an HRPP approved by its DoD Component that includes relevant policies and procedures to ensure compliance with this Instruction.

3. DoD-CONDUCTED RESEARCH INVOLVING HUMAN SUBJECTS

a. DoD Institutional Approval and Oversight

(1) DoD institutions conducting intramural research as defined in the Glossary involving human subjects shall have procedures to ensure appropriate regulatory determinations for activities that constitute research, activities that constitute research involving human subjects, or activities that are research involving human subjects but that meet the exemption criteria in section 219.101(b) of Reference (c). Such procedures shall include the designation, oversight, and appropriate training of DoD personnel.

(2) The DoD institution shall have policies and procedures to require scientific review of non-exempt research involving human subjects and to ensure this review is considered during the IRB review process.

(3) IRBs may use expedited review procedures under section 219.110(a) of Reference (c) to review minimal risk, non-exempt research involving human subjects using materials (e.g., data, documents, records, or specimens) that have previously been collected for any purpose, provided the materials were not collected for the currently proposed research.

(4) When the research is being conducted in a foreign country whose laws and regulations are applicable to that research, the DoD institution shall confirm that all applicable national laws and requirements of the foreign country have been met in addition to the requirements in this Instruction. The IRB shall also consider the cultural sensitivities in the setting where the research will take place.

(5) The DoD institution shall have policies and procedures to ensure the research involving human subjects has been approved by all required organizations before human subjects are recruited or any other research activities with human subjects begin. The IRB may approve a research protocol contingent upon its approval by other organizations (e.g., required reviews can be conducted in parallel).

(6) An IRB, in accordance with part 219 of Reference (c), shall approve all non-exempt research involving human subjects before any activities that involve human subjects can begin. An official cannot approve research that has been disapproved by the IRB in accordance with part 219 of Reference (c) (i.e., an IRB disapproval of a protocol cannot be overturned). The IRB must provide oversight of the ongoing research and review such research at intervals appropriate to the degree of risk, but not less than once per year.

(7) DoD institutions shall rely on an IRB whose membership meets the requirements in subparagraphs 3.a.(7)(a) through (d). In special circumstances, DoD institutions may rely on a non-Federal IRB if the conditions in subparagraph 3.a.(8) of this section are met.

(a) DoD IRBs shall consist of members who are Federal employees; Service members; individuals covered by sections 3371-3376 of title 5, U.S.C. (also known as "The Intergovernmental Personnel Act of 1970, as amended") (Reference (m)); or individuals appointed as experts or consultants in accordance with section 3109 of Reference (m).

(b) For DoD IRBs, the requirement to have a non-affiliated IRB member (section 219.107(d) of Reference (c)) can be fulfilled by a person who meets the criteria in subparagraph

3.a.(7)(a) of this section and is from an organization that is not part of the institution as defined on the institution's Federal assurance. DoD IRBs shall designate at least one alternate for the non-affiliated member. Although the presence of a non-affiliated member is not a requirement to have a quorum, the designation of one or more alternates will increase the likelihood that a non-affiliated member is present at the meetings.

(c) The IRB shall also have a scientist and a non-scientist to meet the requirements in section 219.107(c) of Reference (c). A member whose primary concerns are in a non-scientific area (i.e., the non-scientist) must be present to have a quorum at convened meetings. The non-affiliated position and the non-scientist position may be filled by the same person, or the non-affiliated position and the scientist position may be filled by the same person.

(d) The DoD institution shall consider including one or more community members on the IRB who are familiar with the perspectives of the human subjects (i.e., the community being recruited) commonly recruited and vulnerable subjects recruited by the institution. Community members may or may not be affiliated with the institution or have a scientific background. The appointment of the community members must comply with subparagraph 3.a.(7)(a) of this section.

(e) DoD IRBs may consult with subject matter experts (e.g., in science, in statistics, in ethics, for the subject population) who are not Federal employees or board members, but these consultants may not vote.

(8) DoD institutions engaged in non-exempt research involving human subjects and collaborating with a non-DoD institution may rely on a collaborating non-DoD institution's IRB if these minimum conditions are met:

(a) The DoD Component determines the collaborating non-DoD institution has an appropriate Federal assurance.

(b) The involvement of DoD personnel in the conduct of the research involving human subjects is secondary to that of the non-DoD institution.

(c) The DoD institution, the non-DoD institution, and the non-DoD institution's IRB have a written agreement defining the responsibilities and authorities of each organization in complying with the terms of the Federal assurances and this Instruction (i.e., have an Institutional Agreement for IRB Review or similar agreement). The DoD Component shall approve the terms of the agreement prior to the DoD institution's engagement in the research involving human subjects.

(d) The DoD Component must conduct an appropriate administrative review of the research involving human subjects to ensure it is in compliance with DoD policies and procedures prior to the DoD institution's engagement in the research.

b. DoD Component Review and Oversight

(1) At a minimum, the DoD Components must conduct an administrative review and approve all research involving non-exempt human subjects approved by a DoD institution when any of these conditions occur:

(a) The research will be conducted in a foreign country unless one of the following conditions apply:

1. The research will be conducted by an established DoD overseas research institution and the research will be conducted in the host country, or

2. The research will be conducted by a DoD overseas institution and will include only DoD personnel or U.S. citizens as human subjects.

(b) The research involves a collaboration with a non-DoD institution and the DoD institution is relying on the non-DoD institution's IRB, which is not composed of Federal employees (i.e., the research is approved by the IRB using the criteria described in subparagraph 3.a.(8)) of this section.

(c) The research permits a waiver of informed consent under paragraph (b) of section 980 of Reference (g).

(d) The research involves any fetal research covered under sections 289g–289g-2 of Reference (j).

(e) The research is required to be approved by either the ASD(R&E) or the Head of the OSD or DoD Component as delegated by the ASD(R&E) (e.g., the requirements in sections 7, 9, or 13 of this enclosure apply).

(2) The DoD Component administrative review must be conducted before the research involving human subjects can begin to ensure compliance with all applicable regulations and policies, including any applicable laws and requirements and cultural sensitivities of a foreign country if conducted in a foreign country. This Component review is not intended to be an additional IRB review.

4. RESEARCH INVOLVING HUMAN SUBJECTS CONDUCTED BY A NON-DoD INSTITUTION

a. Clause in Contracts and Agreements. The DoD Component must ensure the institution conducting the research involving human subjects is aware of its obligation to comply with the requirements of this Instruction and part 219 of Reference (c).

(1) Contracts for DoD-supported research involving human subjects must contain the Defense Federal Acquisition Regulation Supplement (DFARS) clause in accordance with section 252.235-7004 of title 48, CFR (Reference (n)). In addition to identifying contractor requirements and responsibilities, this clause also describes the role of the DoD Human Research

Protection Official (HRPO). Comparable agreements not subject to section 252.235-7004 of Reference (n) (e.g., grants, assistance agreements, and cooperative research and development agreements) must contain language affirming the responsibilities of the non-DoD institution as required by Parts 22 (Appendix B), 37 (Appendix D), and 219 of Reference (c).

(2) The DFARS clause (or similar language) is not required to be included in an agreement with another Federal department or agency that has adopted the Common Rule. Approval by the HRPO is not required. The Federal department or agency may apply its own HRPP requirements in lieu of this Instruction. However, the Federal department or agency must comply with the requirements in sections 7, 9, 13, and 17 of this enclosure and the requirements of Reference (f).

b. Non-DoD Institutional Responsibilities

(1) The non-DoD institution shall comply with the terms of the DFARS clause or comparable language used in the agreement with the DoD Component supporting the research involving human subjects, as provided in subparagraph 4.a.(1) of this section.

(2) When a non-DoD institution is conducting non-exempt research involving human subjects, the IRB review must consider the scientific merit of the research, as required by section 219.111 of Reference (c). The IRB may rely on outside experts to provide an evaluation of the scientific merit.

(3) IRBs may use expedited review procedures under section 219.110(a) of Reference (c) to review minimal risk, non-exempt research involving human subjects using materials (e.g., data, documents, records, or specimens) that have previously been collected for any purpose, provided the materials were not collected for the currently proposed research.

(4) To the extent provided in section 219.103 of Reference (c), the non DoD-institution shall promptly notify the HRPO of the following: when significant changes to the research protocol are approved by the IRB, the results of the IRB continuing review, if the IRB used to review and approve the research changes to a different IRB, when the institution is notified by any Federal department or agency or national organization that any part of its HRPP is under investigation for cause involving a DoD-supported research protocol, and all UPIRTSOs, suspensions, terminations, and serious or continuing noncompliance regarding DoD-supported research involving human subjects.

(5) Non-DoD institutions shall comply with requirements of this Instruction applicable to them. They are not required to comply with provisions of this Instruction either solely directed to actions of the DoD Components or specifically limited to DoD-conducted research involving human subjects.

c. DoD Component Review, Approval, and Oversight

(1) When the contract or other agreement may include research involving human subjects and if the non-DoD institution determines either the activity is not research involving

human subjects or is exempt research involving human subjects, the HRPO must concur with the performing institution's determination before activity can begin.

(2) If the non-DoD institution determines the activity is non-exempt research involving human subjects, the HRPO must perform an administrative review of the research before the activities that involve human subjects can begin (e.g., human subject recruitment and data collection). Such review and approval shall be based on confirmation that the research and non-DoD institution are in compliance with applicable requirements of this Instruction and Parts 22 (Appendix B), 37 (Appendix D), and 219 of Reference (c). At a minimum, the HRPO must:

(a) Confirm the non-DoD institution has a Federal assurance appropriate for the research in question (see paragraph 2.a. of this enclosure).

(b) Review the research protocol and accept the IRB determination of level of risk and approval of the study for compliance with this Instruction.

(c) Review and accept IRB-approved substantive changes to an approved research protocol before they are implemented.

(d) Ensure the IRB conducts an appropriate continuing review at least annually.

(e) When the research involving human subjects is being conducted in a foreign country, confirm all applicable national laws and requirements of the foreign country have been met and confirm the IRB considered the cultural sensitivities in the setting where the research will take place.

(3) Upon receipt of notifications directed in subparagraph 4.b.(4) of this section, the supporting DoD Component shall promptly review the report and determine if further review of any or all the institution's research involving human subjects that is supported by the DoD Component is warranted. When appropriate, the DoD Component may defer its investigation to an ongoing Federal investigation. The DoD Component shall notify the ASD(R&E) in accordance with paragraph 3.f. of Enclosure 2 and section 16 of this enclosure.

(4) DoD Components conducting a for-cause review of research conducted by a non-DoD institution shall evaluate and ensure the adequacy of human protection in DoD-supported programs and provide recommendations to the DoD Component about allowing continued DoD support of research involving human subjects, suspending the research until necessary changes have been made, or terminating the research.

5. EDUCATION AND TRAINING. The DoD Components shall ensure that all DoD personnel involved in the conduct, review, or approval of research involving human subjects, including the non-affiliated and prisoner representative members on the DoD IRB, receive initial and continuing education and training in compliance with the standards set forth by ASD(R&E) (see paragraph 1.f. of Enclosure 2 for details).

a. Initial and continuing education and training shall be commensurate with the duties and responsibilities of the DoD personnel.

b. All training and education of DoD personnel shall be documented.

c. Professional certification in the field of human research protection is encouraged for all DoD personnel involved in review and oversight of research involving human subjects.

d. When assessing whether to support or collaborate with a non-DoD institution for research involving human subjects, the DoD Components should evaluate the non-DoD institution's education and training policies to ensure the personnel are qualified to perform the research. The rigor of the evaluation should be appropriate for the complexity and risk of the research.

6. SELECTION OF HUMAN SUBJECTS AND EVALUATING RISK

a. Selection of Human Subjects. The selection of human subjects reflecting gender and minority participation in DoD-conducted or -supported clinical research involving human subjects shall comply with section 252 of Public Law 103-160 (Reference (o)). The Head of the OSD or DoD Component may exercise the waiver authority under this law. This waiver authority may be delegated, as described in the Component's HRPP management plan, but not to an individual at the level of the institutional HRPP.

b. Evaluating Risk. The phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests" in the definition of minimal risk (section 219.102(i) of Reference (c)) shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

7. ADDITIONAL PROTECTIONS FOR HUMAN SUBJECTS. In addition to the requirements of part 219 of Reference (c), additional safeguards described in this section shall be provided for human subjects in all DoD-conducted research involving human subjects who may be considered vulnerable due to their association with groups or populations specifically defined by Federal regulations in subparts B-D of Reference (h) and this Instruction. Similarly, as provided in Reference (n) or Parts 22 (Appendix B) and 37 (Appendix D) of Reference (c), such additional safeguards shall also be provided in comparable DoD-supported research involving human subjects. For purposes of this Instruction, actions authorizing or requiring any action by an official of HHS about any requirements of subparts B-D of Reference (h) shall be under the authority of the ASD(R&E). Investigators, IRBs, IOs, and DoD Component personnel reviewing research protocols shall consider the need for appropriate similar safeguards for other vulnerable populations, such as: research involving human subjects and investigators in supervisor-subordinate relationships, human subjects with decisional or mental impairments, human

subjects with a physical disability, or any other kind of human subjects in circumstances that may warrant provision of additional protections. As appropriate, qualified individuals (e.g., research monitors, ombudsmen, advocates) may be appointed to perform oversight functions or assist the human subjects.

a. Pregnant Women, Fetuses, and Neonates as Subjects

(1) Non-exempt research involving pregnant women, fetuses, or neonates as human subjects must meet the additional relevant protections of subpart B of Reference (h), unless modified by this Instruction. Research involving pregnant women as subjects may be exempt from the requirements of part 219 of Reference (c) and subpart B of Reference (h) if the research meets the exemption criteria at section 219.101(b) of Reference (c). If the pregnant woman is a prisoner, then paragraph 7.b. of this section also applies. If the pregnant woman is a minor, paragraph 7.d. of this section also applies. For purposes of applying paragraph 7.a., the phrase "biomedical knowledge" in subpart B of Reference (h) shall be replaced with "generalizable knowledge" throughout the subpart.

(2) The applicability of subpart B of Reference (h) is limited to research involving:

(a) Pregnant women as human subjects involved in research that is more than minimal risk and includes interventions or invasive procedures to the woman or the fetus; or

(b) Fetus or neonate (see Glossary) as human subjects.

(3) Research involving human subjects using fetal tissue shall comply with sections 289g–289g-2 of Reference (j).

b. Prisoners as Subjects

(1) Research Intending to Include Prisoners as Subjects

(a) Research involving human subjects that includes prisoners must meet the additional relevant protections of subpart C of Reference (h), unless modified by this Instruction. If the prisoner is a pregnant woman, then paragraph 7.a. of this section also applies. If the prisoner is a minor, then paragraph 7.d. of this section also applies.

(b) Research intending to include prisoners as subjects cannot be reviewed by the IRB through an expedited review procedure.

(c) The IRB reviewing research intending to include prisoners as subjects shall be composed of at least one prisoner representative (see Glossary). The prisoner representative may be a prisoner, an employee of the prison, or an individual not affiliated with the prison. The prisoner representative shall have knowledge of the culture(s) of the prisoners and knowledge of the prison operations. At least one prisoner representative must be present for a quorum.

(d) Research involving prisoners at prisons or other types of institutions may be subject to additional review by institution authorities (e.g., Bureau of Prisons).

(2) Categories of Allowable Research Involving a Prisoner. In addition to the four categories of permissible research involving human subjects identified in subpart C of Reference (h), two additional categories are allowable.

(a) Epidemiological research that meets the following criteria can also be approved in accordance with the requirements of subpart C of Reference (h) and the requirements of this Instruction:

1. The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor associations for a disease.

2. The research presents no more than minimal risk.

3. The research presents no more than an inconvenience to the human subject.

4. Prisoners are not a particular focus of the research.

(b) Research involving human subjects that would meet the criteria described at section 219.101(b) of Reference (c) can be conducted, but must be approved by a convened IRB and meet the requirements of subpart C of Reference (h), this Instruction, and other applicable requirements.

(3) When a Subject Becomes a Prisoner

(a) When a previously enrolled human subject becomes a prisoner and the relevant research protocol was not reviewed and approved by the IRB in accordance with the requirements of subparagraphs 7.b.(1) and (2) of this section, the principal investigator shall promptly notify the IRB.

(b) If the principal investigator asserts to the IRB that it is in the best interest of the prisoner-subject to continue to participate in the research while a prisoner, the IRB Chair may determine that the prisoner-subject may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the IO and DoD Component office review the IRB's approval to change the research protocol. Otherwise, the IRB Chair shall require that all research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) cease until the convened IRB can review this request to approve a change in the research protocol.

(c) The convened IRB, upon receipt of notification that a previously enrolled human subject has become a prisoner, shall promptly re-review the research protocol to ensure that the rights and wellbeing of the human subject, now a prisoner, are not in jeopardy. The IRB should consult with a subject matter expert having the expertise of a prisoner representative if the IRB reviewing the research protocol does not have a prisoner representative. If the prisoner-subject

can continue to consent to participate and is capable of meeting the research protocol requirements, the terms of the prisoner-subject's confinement does not inhibit the ethical conduct of the research, and there are no other significant issues preventing the research involving human subjects from continuing as approved, the convened IRB may approve a change in the study to allow this prisoner-subject to continue to participate in the research. This approval is limited to the individual prisoner-subject and does not allow recruitment of prisoners as subjects.

(d) This type of request for change in the research protocol cannot be reviewed and approved by the IRB using expedited review procedures. The research involving human subjects does not have to meet one of the six allowable categories of research as described in subparagraph 7.b.(2) of this enclosure.

(e) If the research involving human subjects is conducted by a non-DoD institution, the non-DoD institution shall promptly report all decisions in this matter to the HRPO. If the research is conducted by a DoD institution, the IRB shall promptly report all decisions in this matter to the IO and to the DoD Component office conducting the reviews identified in paragraph 3.b. of this enclosure. For all DoD-conducted or -supported research involving human subjects, the applicable DoD Component office conducting the reviews identified in paragraphs 3.b. or 4.c. of this enclosure must concur with the IRB before the human subject can continue to participate while a prisoner. This approved change to a research protocol does not require ASD(R&E) approval.

c. Treatment of Detainees

(1) Research involving a detainee, as defined in DoD Directive 2310.01E (Reference (p)), as a human subject is prohibited.

(2) The prohibition in paragraph c.(1) of this section does not apply to activities covered by investigational new drug or investigational device provisions of Reference (d) when for the purpose of diagnosis or treatment of a medical condition in a patient. Such treatment (e.g., an investigational new drug) may be offered to detainees with the detainees' informed consent when the medical products are subject to Reference (d) as investigational new drugs or investigational medical devices, and only when the same product would be offered to members of the U.S. Military Services in the same location for the same medical condition and only when consistent with established medical practice involving investigational drugs and devices. Such permitted treatment involving detainees as subjects shall comply with all sections of this Instruction, including paragraphs 6.a., b., and d. of this section, as applicable.

d. Children as Subjects

(1) Research involving human subjects conducted or supported by the Department of Defense that recruits children to be subjects must meet the additional relevant protections of subpart D of Reference (h), unless modified by this Instruction. If the minor is a pregnant woman, then paragraph 7.a. of this section also applies. If the minor is a prisoner, paragraph 7.b. of this section also applies.

(2) The footnote in section 219.101(i) of Reference (c), prohibiting specific exemptions described in section 219.101(b) from applying to children, is also applicable to DoD-conducted or -supported research involving human subjects unless otherwise clarified in this Instruction.

e. DoD Personnel as Subjects

(1) Military Personnel as Subjects

(a) Service members shall follow their command policies regarding the requirement to obtain command permission to participate in research involving human subjects while on-duty. Additionally a Service member's ability to perform his or her military duties may be affected by participating during off-duty time (i.e., on leave or during non-duty hours). Therefore, Service members shall follow their Component and command's policies for approving off-duty employment or activities. The IRBs of DoD institutions or HRPOs may require Principal Investigators to confirm that a Service member's commander supports the member's participation in DoD-supported research involving human subjects.

(b) Superiors (e.g., military and civilian supervisors, unit officers, and noncommissioned officers (NCOs)) are prohibited from influencing the decisions of their subordinates (e.g., junior enlisted personnel and equivalent civilians) regarding participation as subjects in research involving human subjects covered by this Instruction.

(c) Superiors of Service members (e.g., unit officers, senior NCOs, and equivalent civilians) in the chain of command shall not be present at any human subject recruitment sessions or during the consent process in which members of units under their command are afforded the opportunity to participate as human subjects. When applicable, the superiors so excluded shall be afforded the opportunity to participate as human subjects in a separate recruitment session.

(d) For research involving Service members as human subjects that has been determined to be greater than minimal risk and when recruitment occurs in a group setting, the IRB shall appoint an ombudsman. The ombudsman shall not be associated in any way to the research and shall be present during the recruitment in order to monitor that the voluntary involvement or recruitment of the Service members is clearly and adequately stressed and that the information provided about the research is clear, adequate, and accurate. The ombudsman may also be the research monitor (see section 8 of this enclosure). For research involving Service members as human subjects, that has been determined to be NO greater than minimal risk and when recruitment occurs in a group setting, the IRB shall determine when it is appropriate to appoint an ombudsman for the purposes described in this paragraph. The decision to require the appointment of an ombudsman should be based in part on the human subject population, the consent process, and the recruitment strategy.

(2) DoD Civilians as Subjects

(a) DoD Civilians shall follow their organization's policies regarding the requirement to obtain permission to participate in research involving human subjects.

(b) Supervisors (e.g., military and civilian supervisors or anyone in the supervisory structure) are prohibited from influencing the decisions of their subordinates regarding participation as subjects in research involving human subjects covered by this Instruction.

(c) Supervisors (e.g., military and civilian supervisors or anyone in the supervisory structure) shall not be present at any human subject recruitment sessions or during the consent process in which DoD civilians under their supervision are afforded the opportunity to participate as human subjects. When applicable, supervisors so excluded shall be afforded the opportunity to participate as human subjects in a separate recruitment session.

(d) For research involving civilians as human subjects and when recruitment occurs in a group setting, the IRB shall discuss appointing an ombudsman for the purposes described in subparagraph e.(1)(d) of this section. The decision to require the appointment of an ombudsman should be based in part on the human subject population, the consent process, and the recruitment strategy.

8. RESEARCH MONITOR

a. For DoD-conducted research involving human subjects determined by the IRB to involve more than minimal risk to human subjects (as defined in section 219.102(i) of Reference (c)), and, to the extent provided pursuant to Parts 22 (Appendix B), 37 (Appendix D), and 219 of Reference (c) and Reference (n), comparable DoD-supported research, the IRB shall approve an independent research monitor by name. Additionally, the research monitor may be identified by an investigator or appointed by an IRB or IO for research involving human subjects determined to involve minimal risk. There may be more than one research monitor (e.g., if different skills or experiences are necessary). The monitor may be an ombudsman or a member of the data safety monitoring board.

(1) The duties of the research monitor shall be determined on the basis of specific risks or concerns about the research. The research monitor may perform oversight functions (e.g., observe recruitment, enrollment procedures, and the consent process for individuals, groups or units; oversee study interventions and interactions; review monitoring plans and UPIRTSO reports; and oversee data matching, data collection, and analysis) and report their observations and findings to the IRB or a designated official.

(2) The research monitor may discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research. The research monitor shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report. Research monitors shall have the responsibility to promptly report their observations and findings to the IRB or other designated official.

(3) The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities. The IRB or HRPP official shall communicate with research monitors to confirm their duties, authorities, and responsibilities.

(4) The research monitors shall have expertise consonant with the nature of risk(s) identified within the research protocol, and they shall be independent of the team conducting the research involving human subjects.

b. The Heads of the OSD and DoD Components may waive the requirement to have a research monitor on a case-by-case basis when the inclusion of a research monitor is not necessary to provide additional protections for human subjects. This waiver authority may be delegated to a DoD official, as described in the Component's HRPP management plan, but not at or below the position of the institution's DoD IO.

9. UNIQUE DoD LIMITATIONS ON WAIVER OF INFORMED CONSENT

a. Sections 219.116(c) and (d) of Reference (c) identify conditions where an IRB may waive informed consent for DoD-conducted and DoD-supported research involving human subjects. Section 980 of Reference (g) imposes limitations on waiving informed consent when using DoD appropriated funds. Section 980 of Reference (g) is applicable ONLY to DoD funded research involving a human being as an experimental subject as defined in the Glossary. The definition of research involving a human subject as an experimental subject is not the same as the definition of research involving human subjects. Section 980 of Reference (g) is not applicable to exempt research involving human subjects.

b. When the research meets the Glossary definition of research involving a human being as an experimental subject, informed consent must be obtained in advance from the experimental subject or the subject's legal representative consistent with part 219 of Reference (c) if the subject cannot consent. If consent is to be obtained from the experimental subject's legal representative, the research must intend to benefit the individual subject. The determination that research is intended to be beneficial to the individual experimental subject must be made by an IRB consistent with part 219 of Reference (c).

c. The requirement of paragraph 9.b. of this section may be waived by the ASD(R&E) if all the following conditions are met:

(1) The research is necessary to advance the development of a medical product for the Military Services.

(2) The research may directly benefit the individual experimental subject.

(3) The research is conducted in compliance with all other applicable laws and regulations.

d. The ASD(R&E) may delegate the waiver authority described in paragraph 9.c. to the Heads of the OSD and DoD Components if they have appropriate policies and procedures in their management plans. This authority is further delegable only to a DoD Component official who is a Presidential Appointee with Senate Confirmation.

10. PROTECTING HUMAN SUBJECTS FROM MEDICAL EXPENSES IF INJURED

a. DoD-Supported Research Involving Human Subjects. All non-exempt research involving human subjects shall, at a minimum, meet the requirement of section 219.116(a)(6) of Reference (c). The Common Rule does not require payment or reimbursement of medical expenses, provision of medical care, or compensation for research-related injuries.

b. DoD-Conducted Research Involving Human Subjects. The DoD Components shall establish procedures to protect human subjects from medical expenses (not otherwise provided or reimbursed) that are the direct result of participation in DoD-conducted non-exempt research involving human subjects that involves more than minimal risk. Such procedures may consist of utilizing the Secretarial Designee program as described by section 108.4(i) of Reference (c) during the period of the human subject's involvement in the research, which may be extended further upon the approval of the USD(P&R). DoD Components may supplement this Secretarial Designee procedure with additional procedures consistent with applicable authority. This requirement does not apply when the Department of Defense is supporting the research but is not engaged in the non-exempt research involving human subjects (i.e., when the non-exempt research involving human subjects is performed solely by non-DoD institutions).

c. DoD Collaborative Research Involving Human Subjects

(1) When collaborating with a non-DoD institution, the DoD Components shall establish procedures comparable to those required by paragraph 10.b. of this section to protect human subjects from medical expenses (not otherwise provided or reimbursed) that are the direct result of participation in non-exempt research involving human subjects and that are a direct result of research activities performed by DoD personnel. This does not apply to expenses resulting from the injury due to actions performed by the non-DoD institution(s).

(2) When DoD personnel are conducting the research involving human subjects at the collaborating institution and the Department of Defense does not have the primary involvement, the DoD Components are not required to have procedures to protect human subjects from medical expenses. For this purpose the determination of primary involvement shall be based on consideration of the type and portion of the DoD involvement in the collaborative research (e.g., research staff, human subjects, facilities, equipment, IRB, and all other assets).

(3) When the collaboration is such that it is difficult to separate DoD involvement from that of the non-DoD institution, the Head of the OSD or DoD Component may waive this requirement to have procedures to protect human subjects from medical expenses. This waiver authority may be delegated, as described in the Component's HRPP management plan, but not at or below the position of the institution's DoD IO.

11. COMPENSATION TO HUMAN SUBJECTS FOR PARTICIPATION IN RESEARCH

a. DoD-Conducted Research Involving Human Subjects

(1) When the Human Subjects Are On-Duty Federal Personnel

(a) Federal personnel (civil servants or Service members) participating as human subjects in DoD-conducted research while on duty (i.e., not on leave and participating during their duty hours) may be compensated up to $50 for each blood draw if the research meets the purpose of section 30 of title 24, U.S.C. (Reference (q)). Payment for blood draws may come directly from a Federal or non-Federal source. By permitting compensation for blood draws, Reference (q) provides an exception to section 5536 of Reference (m), which prohibits Federal personnel from being paid by any source other than their regular Federal salaries while they are on duty.

(b) Federal personnel participating as human subjects in DoD-conducted research while on duty may only be compensated for blood draws as described in this paragraph and may not be otherwise compensated for general research participation.

(2) When the Human Subjects Are Off-Duty Federal Personnel

(a) Federal personnel (civil servants or Service members) participating as human subjects in DoD-conducted research while off duty may be compensated up to $50 for each blood draw if the research meets the purpose of Reference (q). Payment for blood draws may come from a Federal or non-Federal source.

(b) Additionally Federal personnel while off duty may be compensated for research participation other than blood draws in the same way as human subjects who are not Federal personnel (i.e., compensated for participation in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research). However, payment to off-duty Federal personnel for research participation other than blood draws must not be directly from a Federal source (payment from a Federal contractor or other non-Federal source is permissible).

(3) When the Human Subjects Are Not Federal Personnel

(a) Non-Federal personnel participating as human subjects in DoD-conducted research may be compensated up to $50 for each blood draw if the research meets the purpose of Reference (q). Payment for blood draws may come directly from a Federal or non-Federal source.

(b) Additionally non-Federal personnel may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research. Payment for general research participation may come directly from a Federal or non-Federal source.

b. Non DoD-Conducted Research Involving Human Subjects

(1) When the Human Subjects Are On-Duty Federal Personnel

(a) Federal personnel (civil servants or Service members) participating as human subjects in research conducted by a non-DoD institution (whether or not the research is Federally funded) may be compensated up to $50 for each blood draw if the research meets the purpose of Reference (q). By permitting compensation for blood draws, Reference (q) provides an exception to section 5536 of Reference (m), which prohibits Federal personnel from being paid by any source other than their regular Federal salaries while they are on duty.

(b) Federal personnel participating as human subjects in non-DoD-conducted research while on duty may only be compensated for blood draws as described in this paragraph and may not be otherwise compensated for general research participation, even if the research is not Federally funded or conducted.

(2) When the Human Subjects Are Off-Duty Federal Personnel

(a) Federal personnel (civil servants or Service members) participating as human subjects in Federally-funded human subject research conducted by a non-DoD institution may be compensated up to $50 for each blood draw if the research meets the purpose of Reference (q). However, if the research is not Federally funded, the human subjects may be compensated for blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the blood draw unless it is prohibited by this Instruction or another policy (i.e., the $50 limitation per blood draw does not apply).

(b) Additionally Federal personnel while off duty may be compensated for research participation other than blood draws in the same way as human subjects who are not Federal personnel (i.e., compensated for participation in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research). However, payment to off-duty Federal personnel for general research participation must not be directly from a Federal source (payment from a Federal contractor or other non-Federal source is permissible).

(3) When the Human Subjects Are Not Federal Personnel

(a) Non-Federal personnel participating as human subjects in DoD-funded research may be compensated up to $50 for each blood draw if the research meets the purpose of Reference (q).

(b) Additionally non-Federal personnel may be compensated for participation in DoD-supported research for other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research. Payment for general research participation may come directly from a Federal or non-Federal source.

12. SERVICE MEMBERS AND THEIR STATUS AS ADULTS. For purposes of legal capacity to participate in DoD-conducted or -supported research involving human subjects, all active duty Service members and all Reserve Component members in a Federal duty status are considered for purposes of this Instruction to be adults. The participation of such members is not subject to requirements of paragraph 7.d. of this enclosure or subpart D of Reference (h) regarding research involving children or minors. When Service members are under 18 years of age, students at Service Academies, or trainees, the IRB shall carefully consider the recruitment process and the necessity to include such members as human subjects.

13. CLASSIFIED RESEARCH INVOLVING HUMAN SUBJECTS. For all DoD-conducted non-exempt research involving human subjects that involves classified information as defined in Executive Order 13526 (Reference (r)), and, to the extent provided pursuant to Parts 22, 37, and 219 of Reference (c) and Reference (n), comparable DoD-supported research, the additional requirements in this section apply. The involvement of classified information may be limited to information needed for IRB approval and oversight of the research; information needed to inform the human subjects during the consent process; and information provided by the human subjects during the course of the research. If this activity is part of a classified program, this section does not apply if the information required to be contained in the research protocol or needed by either the IRB or the human subjects is not classified.

a. Secretary of Defense approval is required for all classified non-exempt research involving human subjects. Submission for approval shall be from the Head of the OSD or DoD Component conducting or supporting the non-exempt research involving human subjects. The request shall be coordinated with the ASD(R&E) and General Counsel of the Department of Defense after the IRB has approved the research.

b. Waivers of informed consent are prohibited.

c. Informed consent procedures shall include:

(1) Identification of the Department of Defense as the supporting institution of the research, unless the research involves no more than minimal risk. The Secretary of Defense may grant an exception to this requirement on the grounds that providing this information could compromise intelligence sources or methods.

(2) A statement that the research involving human subjects is classified and an explanation of the impact of the classification.

d. IRB approval process shall meet the following requirements:

(1) IRB review shall be conducted using a full board review. Use of an expedited review procedure is prohibited.

(2) At least one non-affiliated member shall be a non-Federal employee (other than as an individual appointed as an expert or consultant in accordance with section 3109 of Reference (m) for purposes of service on the IRB).

(3) Any IRB member who disagrees with a majority decision approving a project may appeal the decision to the Secretary of Defense. The appeal shall be included in the DoD Component's submission to the Secretary of Defense.

(4) The IRB shall determine whether potential human subjects need access to classified information to make a valid, informed consent decision.

e. Disclosure or use of classified information must comply with the requirements of Reference (r) for access to and protection of classified information.

14. ADDITIONAL PROTECTIONS FOR CONFIDENTIALITY. This section outlines certain authorities that the DoD Components may consider using, subject to applicable requirements, for particular sensitive research activities when additional protections for confidentiality would improve participation and results.

a. Confidential Information Protection and Statistical Efficiency Act (CIPSEA) for Non-Statistical Agencies. Any DoD Component may use the authority pursuant to sections 501-513 of Reference (k) to assure that data or information acquired by the DoD Component under a pledge of confidentiality for exclusively statistical purposes shall be used exclusively for statistical purposes and may not be disclosed in identifiable form for any other purpose, except with the informed consent of the respondent. Use of this authority is subject to the requirements of sections 512 and 523-525 of Reference (k) and of Reference (l), including that the research involving human subjects is conducted by a DoD Component or other Federal agency and not by a contractor, grantee, or other non-Federal entity, and that use of the authority is reported annually to OMB by the DoD Component.

b. CIPSEA for Statistical Agencies. Any DoD Component or unit thereof designated a statistical agency by the OMB pursuant to section 522 of Reference (k) and Reference (l) may designate agents (e.g., contractor, grantee, or other non-Federal entity under a qualifying agreement) that may assure that data or information acquired for the Component under a pledge of confidentiality for exclusively statistical purposes shall be used exclusively for statistical purposes, and may not be disclosed in identifiable form for any other purpose, except with the informed consent of the respondent. Use of this authority is subject to the requirements of sections 512 and 523-525 of Reference (k) and of Reference (l).

c. Certificate of Confidentiality. A DoD Component or a contractor, grantee, or other non-Federal entity conducting DoD-supported research involving human subjects may request from the National Institutes of Health (NIH) of the Department of HHS a Certificate of Confidentiality pursuant to section 241(d) of Reference (j). Such a Certificate of Confidentiality authorizes persons engaged in biomedical, behavioral, clinical, or other research related to mission areas of the NIH to protect the privacy of human subjects of sensitive research against compulsory disclosure in any Federal, State, or local judicial, administrative, or legislative proceeding to

identify human subjects. Issuance of any Certificate of Confidentiality is at NIH's discretion and is subject to the requirement of section 241(d) of Reference (j) and any other NIH guidelines.

15. RECORD KEEPING

a. Part 219 of Reference (c) requires all institutions engaged in DoD-conducted or -supported research involving human subjects to retain records for at least 3 years after the completion of the research. Research involving human subjects may be covered by other Federal regulations that impose longer record keeping requirements. The DoD Components may rely on the non-DoD institutions to keep the required records that were generated by the institution, or the DoD Components may make arrangements to transfer the records.

b. The DoD Components shall also retain records regarding the oversight of DoD Component-supported research involving human subjects for at least 3 years after the completion of the research, HRPP education or training program, or other action relevant to the HRPP. Additionally, the DoD Components shall keep all records regarding DoD Component waivers, exemptions, and extensions, and all DoD Component requests for exceptions, waivers, exemptions, and extensions submitted to the ASD(R&E) for action for at least 3 years after the completion of the research.

c. The DoD Components may be required to retain records for longer than specified in paragraphs 15.a. and 15.b. of this section. For example, some Health Insurance Portability and Accountability Act documentation is required to be retained for 6 years (in accordance with DoD 6025.18-R (Reference (s))). For complete recordkeeping guidance and instruction, the DoD Components shall consult their respective records disposition schedules.

d. Records maintained by non-DoD institutions that document compliance or noncompliance with this Instruction shall be made accessible for inspection and copying by authorized representatives of the Department of Defense at reasonable times and in a reasonable manner as determined by the supporting DoD Component.

16. NONCOMPLIANCE WITH THIS INSTRUCTION. The DoD Components shall respond to allegations of noncompliance with this Instruction. For allegations that involve more than one DoD Component or a non-DoD institution, the involved institutions should jointly determine and assign executive responsibility for responding to the allegation(s). For allegations involving a non-DoD institution, the DoD Component supporting the research involving human subjects shall ensure the allegation is properly investigated and reported to the DoD Component. All findings of serious or continuing noncompliance with this Instruction that have been substantiated by inquiry or investigation shall be reported to the ASD(R&E) in a timely manner.

17. APPLICABILITY TO OTHER REQUIREMENTS. Compliance with this Instruction does not imply that all other applicable requirements have been met for DoD-conducted and -supported research involving human subjects. No DoD agency within the Intelligence

Community shall sponsor, contract for, or conduct non-exempt research involving human subjects except in accordance with paragraph 2.10 of Executive Order 12333 (Reference (t)). Additionally, research involving human subjects using surveys, materials under the purview of the FDA, or individually identifiable health information may be subject to additional Federal or DoD requirements, such as those identified in Reference (s), DoD 5400.11-R (Reference (u)), and DoDI 6000.08 (Reference (v)). States may have differing definitions and protections for vulnerable populations. Research involving human subjects conducted in foreign countries may be subject to additional national and local requirements.

18. CCHRPP MEMBERSHIP. The CCHRPP shall be composed of senior officials at the GO/FO, SES, or equivalent level. The Heads of the OSD and DoD Components with a DoD Component HRPP management plan shall each identify one member to represent their Component to the ASD(R&E). The Chair shall be designated by the ASD(R&E). The CCHRPP shall be supported by an Executive Secretariat (O-6 or equivalent level) composed of representatives from the DoD Components' human research protection oversight offices.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

ASD(HA)	Assistant Secretary of Defense for Health Affairs
ASD(R&E)	Assistant Secretary of Defense for Research and Engineering
CCHRPP	Coordinating Committee for Human Research Protection Programs
CFR	Code of Federal Regulations
CIPSEA	Confidential Information Protection and Statistical Efficiency Act of 2002
DFARS	Defense Federal Acquisition Regulation Supplement
DoDD	Department of Defense Directive
FDA	Food and Drug Administration
GO/FO	general or flag officer
HHS	Health and Human Services
HRPO	human research protection official
HRPP	Human Research Protection Program
IO	institutional official
IRB	institutional review board
NCOs	noncommissioned officers
NIH	National Institutes of Health
OMB	Office of Management and Budget
OT&E	operational test and evaluation
RDT&E	research, development, test and evaluation
SES	Senior Executive Service
UPIRTSO	unanticipated problems involving risks to subjects or others
U.S.C.	United States Code
USD(P&R)	Under Secretary of Defense for Personnel and Readiness

PART II. DEFINITIONS

Unless otherwise noted, these terms and their definitions are for the purpose of this Instruction.

administrative review. A review of a research protocol and supporting documents (e.g., safety review, scientific review, IRB minutes) related to DoD-supported research involving human subjects which ensures the institution engaged in the research involving human subjects has met the requirements of all applicable regulations and policies. This review is NOT an IRB review.

classified research involving human subjects. Research involving human subjects where the protocol or other information required by the IRB for review and oversight or required or provided by the research subjects includes classified information, as defined in Reference (q).

clinical investigations. Any research or experiments that involve a test article, one or more human subjects, and are performed under the requirements of Reference (d). Clinical investigations are a subcategory of research involving human subjects.

continuing noncompliance. A pattern of noncompliance (see definition of noncompliance) that suggests the likelihood that, without intervention, instances of noncompliance will recur. A repeated unwillingness to comply with this Instruction or a persistent lack of knowledge of how to comply with this Instruction.

Common Rule. The regulation adopted by multiple Federal departments and agencies for the protection of human subjects in research. The Department of Defense's implementation of the Common Rule is part 219 of Reference (c); the Department of HHS's implementation of the Common Rule is subpart A of Reference (h).

detainee. Defined in Reference (p).

DoD-conducted research involving human subjects. Research involving human subjects that is performed by DoD personnel. Intramural research is one type of DoD-conducted research involving human subjects. See "engaged in research involving human subjects."

DoD personnel. DoD civilian employees and members of the military services.

DoD civilian employee. An individual meeting the definition of "employee" consistent with section 2105 of Reference (m). It includes employees of DoD Non-Appropriated Fund Instrumentalities; DoD civilian employees filling full-time, part-time, intermittent, or on-call positions; and individuals serving under personal services contracts consistent with section 2.101 of Reference (n). It excludes employees of contractors (other than personal services contractors) and foreign nationals of host countries.

Service members. Individuals appointed, enlisted, or inducted for military service under the authority of the Department of Defense. The Military Services are the Army, the Navy, the Air Force, the Marine Corps, the Coast Guard, and the Reserve Components, which includes the Army and the Air National Guards of the United States. Members of the Reserve Components are included when in a duty status.

DoD-supported research involving human subjects. Research involving human subjects for which the Department of Defense is providing at least some of the resources (see "research involving human subjects"). Resources may include but are not limited to funding, facilities, equipment, personnel (investigators or other personnel performing tasks identified in the research protocol), access to or information about DoD personnel for recruitment, or identifiable data or specimens from living individuals. It includes both DoD-conducted research involving human subjects (intramural research) and research conducted by a non-DoD institution.

engaged in research involving human subjects. An institution is engaged in research involving human subjects when its personnel are conducting activities covered by section 219.101(a) of Reference (c) and this Instruction. An institution that is funding, providing equipment, providing access to or information about potential human subjects (but not recruiting human subjects), providing data or specimens (either identifiable or not), or overseeing the research from a regulatory or compliance standpoint is not engaged in the research involving human subjects (but is supporting the research (see "DoD-supported research involving human subjects")).

exempt research involving human subjects. Research involving human subjects where the only involvement of the human subjects in the research will be in one or more of the categories identified in section 219.101(b) of Reference (c).

experimental subject. See "research involving a human being as an experimental subject."

Federal assurance. A written document in which an institution (not an IRB) commits to a Federal department or agency their compliance with the requirements set forth in the Common Rule. Institutions engaged in non-exempt research involving human subjects conducted or supported by the Department of Defense or other Federal departments and agencies that have adopted the Common Rule must have a Federal assurance approved or accepted by the Federal agency supporting the research. The elements of a Federal assurance are outlined in section 219.103(b) of Reference (c).

fetus. The product of conception from implantation until delivery as defined in subpart B of Reference (h).

HRPO. An individual who is delegated the responsibilities as defined in paragraph (a)(2) of section 252.235-7004 of Reference (n). There may be more than one HRPO in a DoD Component. Some DoD Components may use a different title for the person(s) with the defined responsibilities.

HRPP. An institution's system of interdependent elements that implement policies and practices to protect human subjects involved in research. An HRPP may or may not include a Federal assurance. If the HRPP includes a Federal assurance, it may contain policies and procedures for an IRB belonging to the institution or for a relationship with an IRB external to the institution.

human subject. A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information as defined in section 219.102(f) of Reference (c). (FDA regulations include a different definition

of human subject. With respect to research subject to FDA regulations, the FDA definition in section 50.3(g) of Reference (d) also applies.)

identifiable private information. Defined in section 219.102(f) of Reference (c).

intervention and interaction. An intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. See section 219.102(f) of Reference (c) for more information. Examples include, but are not limited to, a physical procedure, a drug, a manipulation of the human subject or subject's environment, the withholding of an intervention that would have been undertaken if not for the research purpose, or communication such as a survey or interview.

intramural research. Research (see "research involving human subjects") that is conducted by an entity that is part of the Department of Defense.

institution. An organization or entity defined in a Federal assurance or HRPP.

IO. The senior person authorized to establish and responsible to maintain the HRPP for the institution. Responsible for a Federal assurance and the IRBs internal to the institution, if these elements are part of the HRPP.

neonate. Newborns as defined in subpart B of Reference (h).

non-affiliated IRB member. Defined in section 219.107(d) of Reference (c). This member is not connected with the institution(s), as defined in the institution's Federal assurance that is creating or relying on the IRB, or a member of the immediate family of a person who is associated with the institution creating or relying on the IRB.

noncompliance. Failure of a person, group, or institution to act in accordance with this Instruction, its references, or applicable requirements.

non-DoD institution. An entity that is not part of the Department of Defense.

non-exempt research involving human subjects. An activity that meets the definitions of research and human subject but does not meet the criteria where the only involvement of the human subjects in the research are in one or more of the categories identified in section 219.101(b) of Reference (c).

ombudsman. A person who acts as an impartial and objective advocate for human subjects participating in research.

OSD Component. Defined in DoD Instruction 5025.01 (Reference (w)).

OT&E. Defined in section 139(a)(2)(A) of Reference (g).

prisoner. Defined in subpart C of Reference (h). Includes military personnel in either civilian or military custody or detainment.

prisoner representative. An individual member on the IRB who shall have working knowledge of the human subject population to be recruited, a reasonable familiarity with the operations of the prison or confinement facility, and any other legally imposed restrictive conditions involved in the research, and appropriate background and expertise to serve in this capacity.

private information. Defined in section 219.102(f) of Reference (c).

research. Any activity that is a systematic investigation, including RDT&E, designed to develop or contribute to generalizable knowledge as defined in section 219.102(d) of Reference (c).

research involving human subjects. Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge AND involve a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information. Activities covered by section 219.101(a) of Reference (c) (including exempt research involving human subjects) and this Instruction.

The following activities conducted or supported by the Department of Defense are NOT research involving human subjects:

Activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel under force health protection programs of the Department of Defense, including health surveillance pursuant to section 1074f of Reference (g) and the use of medical products consistent with DoD Instruction 6200.02 (Reference (x)).

Authorized health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of patient treatment.

Activities performed for the sole purpose of medical quality assurance consistent with section 1102 of Reference (g) and DoDD 6025.13 (Reference (y)).

Activities performed solely for an OT&E project where the activities and project meet the definition of OT&E as defined in section 139(a)(2)(A) of Reference (g).

Activities performed solely for assessing compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units, including such activities as occupational drug testing, occupational health and safety reviews, network monitoring, and monitoring for compliance with requirements for protection of classified information.

Activities, including program evaluation, customer satisfaction surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results of the evaluation are only for the use of Government officials

responsible for the operation or oversight of the program being evaluated and are not intended for generalized use beyond such program.

Survey, interview, or surveillance activities and related analyses performed solely for authorized foreign intelligence collection purposes, as authorized by DoDD 5240.01 (Reference (z)).

research involving a human being as an experimental subject. An activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving a human being as an experimental subject is a subset of research involving human subjects. This definition relates only to the application of section 980 of Reference (g); it does not affect the application of part 219 of Reference (c). This definition does not include activities that are not considered research involving human subjects, activities that meet the exemption criteria at section 219.101(b) of Reference (c), and research involving the collection or study of existing data, documents, records, or specimens from living individuals.

research monitor. Individuals with expertise consonant with the nature of risk(s) identified within the research protocol, whose role is to protect the safety and well-being of human subjects.

secretarial designee program. Defined in section 108.3 of Reference (c).

serious noncompliance. Failure of a person, group, or institution to act in accordance with this Instruction and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.

UPIRTSO. Any incident, experience, or outcome that meets ALL three of the following conditions:

Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied.

Is related or possibly related to participation in the research (in this Instruction, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).

Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

CERTIFICATE OF SERVICE

I hereby certify that on April 7, 2014, I electronically filed the foregoing THIRD BRIEF ON CROSS-APPEAL: APPELLANTS'/CROSS-APPELLEES' REPLY BRIEF AND OPPOSITION TO CROSS-APPEAL with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. All participants in the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

Pursuant to Ninth Circuit Rule 31-1, paper copies of the foregoing THIRD BRIEF ON CROSS-APPEAL: APPELLANTS'/CROSS-APPELLEES' REPLY BRIEF AND OPPOSITION TO CROSS-APPEAL will be submitted to the Court at the direction of the Clerk of the Court.

Dated: April 7, 2014 /s/ Eugene Illovsky

EUGENE ILLOVSKY

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