

## Index

- A**
- Access to HIV/AIDS Pharmaceuticals and Medical Technologies.  
*See* Executive Order 13155
- Acquired immune deficiency syndrome. *See* Human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS)
- Active treatment concurrent control
- equivalence (noninferiority) trial, 26
  - explanation of, iv, 26
  - Latin America proposed study use, ethical concerns, 25
  - placebo control vs., ethical concerns, 25
  - superiority trial, 26
- See also* Clinical trials; Control groups; Health care
- Africa
- Eastern/Southern, AIDS vaccine development efforts, 105
  - established effective treatment, example of, 10
  - health care services, 12
  - HIV perinatal transmission, placebo-controlled trials in, controversy, 1, 2
  - informed consent in biomedical research in, 36
  - informed consent involvement of community leaders, issues for, 43
  - post-trial benefits in international research, prior agreements on, criticisms of, 71
  - review of clinical trials, 83
  - sub-Saharan, HIV/AIDS drugs for, Executive Order on, 73
  - vaccine initiatives for, 73
- Agency for International Development (USAID), 7, 80
- equal protection provision for international research, *in toto* standard for, 87, 89
  - equal protection provision for international research, role of, 87–89
  - ethics review for protection of participants in international clinical trials, U.S. provisions for, 81, 82
  - host country capacity for international research, building, national/international guidelines reviewed by NBAC, 93
- Agreement on Trade-Related Aspects of Intellectual Property Rights, 73
- Agreements. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights; Prior agreements
- AIDS/HIV. *See* Human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS)
- AIDSVAX, 106
- Alphavax Human Vaccines, Inc., 105
- AMA. *See* American Medical Association (AMA)
- American Home Products, 73
- American Medical Association (AMA), 24
- Argentina
- informed consent documentation requirements, issues, 49
- Asia
- health care services, 12
  - HIV perinatal transmission, placebo-controlled trials in, controversy, 1
- Assurances of compliance
- independent evaluation of procedures for protection of participants in international clinical trials, NBAC recommendations, xi, 80
  - protection of participants in international clinical trials, U.S. procedures for, xi, 14, 78–80
  - protection of participants in international clinical trials, U.S. procedures for, OHRP proposed revisions to, 80
- See also* Cooperative Project Assurance (CPA); Federalwide Assurance (FWA); International Cooperative Project Assurance; Multiple Project Assurances (MPAs); Single Project Assurances (SPAs)
- Australia
- ethics review for international clinical trials, 82
  - National Statement on Ethical Conduct in Research Involving Humans*, 93
  - protection of participants in international research, xiii, 14, 100
- Aventis Pharma, 73
- AZT, 2
- B**
- Barriers. *See* Cultural barriers
- Benefits
- AIDS vaccines development, prior agreements on post-trial benefits, 66, 106–108
  - disclosure requirements for participants informed consent, in international clinical trials, v–vi, 37
  - equitable distribution for U.S. government-sponsored international clinical trials, NBAC recommendations, iii, 6
  - post-trial, and researcher-participant relationship in international research, ethical issues, 58–59
  - post-trial, disclosure requirements for informed consent in international research, NBAC recommendations, vi, 40
  - post-trial, ethical issues for in international research, viii–x, 12–13, 55–74
  - post-trial, for host country from international research, NBAC recommendations, x, 74
  - post-trial, for host country from international research, prior agreements on, NBAC recommendations, x, 74
  - post-trial, for others from international research, ethical issues, x, 12–13
  - post-trial, for participants in international research, justice as reciprocity and, 59–61

- post-trial, for participants in international research, NBAC recommendations, x, 74
- post-trial, IAVI prior agreements for international research, description, 66, 74, 104–106
- post-trial, obligations of public/private research sponsors in international research, 64–65
- post-trial, obligations of researchers in international research, 64
- post-trial, obligations to host community/country in international research, ethical concerns, 61–64
- post-trial, obligations to participants in international research, 56–58
- post-trial, prior agreements for international research, and breach of obligations potential, 72, 74
- post-trial, prior agreements for international research, and creation of double standard, issues, 71–72
- post-trial, prior agreements for international research, and delay/prevention of research, 68
- post-trial, prior agreements for international research, and funding/distribution problems, 67–69
- post-trial, prior agreements for international research, and health policy influence, issues, 70–71
- post-trial, prior agreements for international research, and prevailing international standard, issues, 70
- post-trial, UNAIDS prior agreements for international research, 66, 74, 108
- post-trial, VaxGen prior agreements for international research, 66, 74, 106–108
- post-trial, WHO prior agreements for international research, 66, 74, 103–104
- Thailand AIDS vaccine research, VaxGen prior agreements on post-trial benefits, description, 66, 106–108
- Benin
- post-trial benefits in, UNAIDS prior agreement for, 108
- Berkley, Seth, 105, 106
- Bill and Melinda Gates Foundation
- research initiatives of, timeline 2000–2001, 73
- Bioethics Commission. *See* National Bioethics Advisory Commission (NBAC)
- “Body Hunters,” 107
- Boehringer Ingelheim, 73
- Botswana
- HIV/AIDS prevention in, funding for, 73
- Brazil
- National Health Council (NHC), 57
  - post-trial benefits in, UNAIDS prior agreement for, 108
  - post-trial obligations to international research participants, provisions for, 57, 62, 70
  - protection of international research participants, documents concerning, comparative analysis of, 100
  - Resolution No 196/96 on Research Involving Human Subjects*, 90, 93
- Bristol-Myers Squibb, 73
- C**
- California, 66, 106
- Canada
- AIDS vaccine development funding for IAVI, 106
  - established effective treatment, example of, 10
  - ethics review for international clinical trials, 82
  - international research activities of, 3
  - post-trial obligations to international research participants, provisions concerning, 57, 70
  - protection of international research participants, xiii, 14, 100
  - Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, 57, 87, 93
- Capacity
- building, for design/review/conduct of international research by developing countries, strategies for, NBAC recommendations, xiv, 91
  - building, for ethics review of international clinical trials by developing countries, assistance for, NBAC recommendations, xiv, 94
  - building, for review/conduct of international clinical trials by host country, necessity of, xiii–xiv, 14, 89–94
- Caribbean
- HIV perinatal transmission, placebo-controlled trials in, controversy, 1
- CDC. *See* Centers for Disease Control and Prevention (CDC)
- Centers for Disease Control and Prevention (CDC), 7, 50, 79, 107
- informed consent process for international clinical trials, NBAC recommendations, viii, 50
- CEUs. *See* Clinical Epidemiology Units (CEUs)
- Chapel Hill, North Carolina, 73
- See also* North Carolina
- Children’s Hospital
- Children’s Research Institute, 105
- Chile
- informed consent documentation requirements, issues, 49–50
- China
- AIDS vaccine development efforts, 106
  - Committee on Research Involving Human Subjects, 93
  - Guidelines on Ethical Review of Medical Research*, 93
  - protection of international research participants, documents concerning, comparative analysis of, 100
- CIOMS. *See* Council for International Organizations of Medical Sciences (CIOMS)
- Clinical Epidemiology Units (CEUs), 91
- Clinical trials
- Add-on design for, description of, 22
  - AIDS vaccines development, prior agreements on post-trial benefits, 66
  - alternative therapies disclosure requirements, cultural barriers to, 39–40
  - assurances of compliance, for protection of international research participants, xi, 14, 78–80

- biomedical researchers in, ethical issues for, NBAC survey, 4
- capacity building for host country, variation in U.S./ international guidelines for, 92, 93–94
- capacity building for international research, need to, xiii–xiv, 14, 89–94
- capacity building for international research, strategies for, NBAC recommendations, xiv, 91, 94
- control groups treatment in developing countries, ethical concerns for, 26–28
- crossover design for, description of, 22
- design for protection of participants in international research, iii–iv, 8–10, 20–29
- design/implementation, community involvement in, for international research, iv–v, 30–31
- design issues for repeating trials, 31–32
- designs of, descriptions of, 22
- developing countries as setting for, reasons for, 6–7
- disclosure requirements for international research, cultural barriers to, 38–40
- efficacy (optimal care) vs. effectiveness, distinction, 28–29
- equivalence trials, description of, 22
- equivalent protections for participants in, procedures for, xiii, 14, 85–89
- established effective treatment for control groups in international research, iv, 9–10, 28
- ethical concerns for international research, papers commissioned on, 117
- ethical concerns for international research, public comments on, 111–113
- ethical concerns for international research, testimony, public/expert on, 115
- ethical conduct of, requirements for, NBAC recommendations on, 5–6
- ethical issues for developing countries as setting for, 3–4
- ethics review by host country for international research, challenges to, 82
- ethics review for protection of international research participants, requirements, xi–xii, 13–14, 81–85
- factorial design, description of, 22
- financial support for costs of ethical review of, requirements, NBAC recommendations, xiii, 85
- group sequential design, description of, 22
- health needs of host country, responsiveness of international research in developing countries to, iii, 7–8
- HIV perinatal transmission, placebo-controlled trials in developing countries for, controversy, 1, 2
- inducement (undue) for enrollment in, definition/concerns, 46–47
- informed consent disclosure requirements, for participants in international research, NBAC recommendations, v–vi, 37, 40
- informed consent in international research, ensuring comprehension, NBAC recommendations, vi, 42
- informed consent process, cultural variations for international research, NBAC recommendations, viii, 50
- informed consent role of family members for international research, vii, 44–45
- informed consent role of others for international research, NBAC recommendations, vi, 43
- multiple ethics review for international research, issues, 82–85
- parallel group design, description of, 22
- participant population selection for, 29
- participants fair/respectful treatment in international research, v–vii, 10–12
- participants in international research, ethical requirements for, 5–6
- participants standard of care in international research, 9, 26–28
- phases of, summary of, 21
- pivotal (confirmatory) trials, description of, 21
- post-trial benefits for host country in international research, NBAC recommendations, x, 74
- post-trial benefits for host country, prior agreements for international research, NBAC recommendations, x, 74
- post-trial benefits for others in international research, ethical issues, x, 12–13
- post-trial benefits for participants in international research, NBAC recommendations, x, 74
- post-trial benefits, and researcher-participant relationship, ethical issues, 58–59
- post-trial benefits, disclosure in informed consent documents for, NBAC recommendations, vi, 40
- post-trial benefits, IAVI prior agreements for international research, 66, 74, 104–106
- post-trial benefits, in international research, ethical issues, viii–x, 12–13, 55–74
- post-trial benefits, obligations of public/private research sponsors, 64–65
- post-trial benefits, obligations of researchers, 64
- post-trial benefits, obligations to host country of international research, ethical concerns, 61–64
- post-trial benefits, obligations to participants in international research, concerns, 56–58
- post-trial benefits, prior agreements on international research, discussion, 66–72, 74, 103–108
- post-trial benefits, prior agreements on, and breach of obligations potential, 72, 74
- post-trial benefits, prior agreements on, and creation of double standard, issues, 71–72
- post-trial benefits, prior agreements on, and delay/prevention of research, 68
- post-trial benefits, prior agreements on, and funding/distribution problems, 67–69
- post-trial benefits, prior agreements on, and health policy influence, issues, 70–71
- post-trial benefits, prior agreements on, and prevailing international standard, issues, 70
- post-trial benefits, UNAIDS prior agreements for international research, 66, 74, 108
- post-trial benefits, VaxGen prior agreements for international research, 66, 74, 106–108
- post-trial benefits, WHO prior agreements for international research, 66, 74, 103–104
- post-trial treatment for research participants, justice as reciprocity and, 59–61

- protection of participants in international research, ethical requirements, ii–iii, 5–6
- protection of participants in international research, mechanisms for, xi–xiv, 13–14, 78–89
- randomized withdrawal design, description of, 22
- recruitment issues for international research, 10–12
- repeating study, design issues, 31–32
- resources (funding) support for ethics review of international research, xiii, 85
- risk disclosure requirements for, cultural barriers to, 38–39
- sample size selection for, 29
- Single Project Assurances for protection of research participants in, criticisms of, 79–80
- superiority trials, description of, 22
- Thailand AIDS vaccines testing, prior agreement on post-trial benefits, 66
- therapeutic misconception minimization, for participants in international research, vii–viii, 48
- voluntary consent process for international research, v–vii, 11, 36–38
- voluntary consent process, role of others, for international research, vi–vii, 42–45
- voluntary informed consent, ethical issues, 35
- voluntary participation and undue inducement for, involvement of community leaders, NBAC recommendations, vi, 44
- women's informed consent, role of husband in international research, vii, 45
- See also* Research
- Clinton, William J., 72, 73
- State of the Union address, 72
- Code of Federal Regulations, Title 45, Part 46 (45 CFR 46), 3, 35, 36, 48, 55
- assurances for protection of participants in international clinical trials, 78, 79
- disclosure requirements for international research participants, v–vi, 37
- equivalent protections for international research participants, provision for, 85, 86, 87, 88, 89
- ethics review for protection of international research participants, 81, 82
- host country capacity building for international clinical trials, U.S./international guidelines on, 93
- protection of international research participants, U.S./international policy/regulatory issues for, 14
- protection of international research participants, U.S. procedures for, 78, 79, 81, 82, 85, 86, 87, 88, 89
- Coercion
- community leaders role in participation in international clinical trials, NBAC recommendations, vi, 44
- inducement (undue) for enrollment in international research, definition and concerns, 46–48
- Columbia Laboratories, 108
- Columbus, Ohio, 105
- Comments. *See* Public comments
- Commission. *See* National Bioethics Advisory Commission (NBAC)
- Commissioned papers. *See* Papers commissioned
- Common Rule. *See* Code of Federal Regulations, Title 45, Part 46 (45 CFR 46)
- Communities
- design/implementation of international clinical trials, involvement in, iv–v, 30–31
- education on scientific/technical aspects of research protocols, innovative methods, 41
- leaders, involvement in informed consent process for international clinical trials, issues for, 42–44
- leaders, involvement in voluntary participation in international clinical trials, NBAC recommendations, vi, 44
- post-trial benefits of international research, access to, ethical issues, 55–74
- post-trial benefits of international research for host countries, prior agreements on, x, 74
- post-trial benefits of international research, obligations of public/private research sponsors, 64–65
- post-trial benefits of international research, obligations of researchers, 64
- post-trial benefits of international research, obligations to host community, ethical concerns, 61–64
- Uganda, leaders involvement in informed consent guidelines for international research, 44
- Compensation
- participants in international clinical trials, ethical requirements for, 6
- participants in international research, documents concerning protection of, comparative analysis of, 100–101
- participants in U.S. government-sponsored clinical trials, care/compensation for, NBAC recommendations, iii, 6
- Confidentiality. *See* Privacy and confidentiality
- Congress, U.S. *See* U.S. Congress
- Consent. *See* Informed consent
- Consent forms. *See* Documentation; Informed consent
- Consent process. *See* Informed consent
- Contraceptive devices
- female condom, international research on, UNAIDS prior agreement for post-trial benefits in selected countries, 108
- Control groups
- dose-comparison concurrent control, 23
- established effective treatment in international clinical trials, iv, 9–10, 28
- established effective treatment vs. best current methods in developing countries, standard definition, 28
- external control, 23
- interventions for, cultural barriers to disclosure requirements, 39
- nature of, ethical design issues, 23–26
- no treatment concurrent control, 23
- randomization of, cultural barriers to disclosure requirements, 39
- treatment of, ethical design issues, 22, 26–28

- types of, summary, 23–26  
 See also Active treatment concurrent control; Clinical trials; Placebo concurrent control
- Cooperative Project Assurance (CPA), 79, 80  
 See also Assurances of compliance; International Cooperative Project Assurance; Office for Human Research Protections (OHRP)
- Cooperative Protocol Research Program, 79
- Cornell University  
 Medical School, 41
- Côte d'Ivoire  
 UNAIDS prior agreement for post-trial benefits in, 108
- Council for International Organizations of Medical Sciences (CIOMS), 3  
*International Ethical Guidelines for Biomedical Research Involving Human Subjects*, 5, 8, 9, 11, 14, 36, 38, 46, 62, 70, 74, 90, 93  
*International Guidelines for Ethical Review of Epidemiological Studies*, 93  
 international research participants protection, documents concerning, comparative analysis of, 100  
 “Obligations of Sponsoring and Host Countries,” 62  
 “Research Involving Subjects in Underdeveloped Communities,” 62
- Council of Europe  
*Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine*, 93  
 international research participants protection, documents concerning, comparative analysis of, 100
- CPA. See Cooperative Project Assurance (CPA)
- Cultural barriers  
 alternative therapies, disclosure requirements for international clinical trials and, 39–40  
 control interventions, disclosure requirements for international clinical trials and, 39  
 control randomization, disclosure requirements for international clinical trials and, 39  
 diagnosis/prognoses, disclosure requirements for international clinical trials and, 38–39  
 disclosure requirements for international clinical trials, and, 38–40  
 informed consent documentation for international clinical trials, issues, 48–50  
 informed consent process for international clinical trials, variations due to, viii, 50  
 informed consent process for women in international clinical trials, issues, 45  
 informed consent process involvement of community leaders for international clinical trials, issues, 43  
 informed consent process involvement of family members for international clinical trials, issues, 44–45  
 informed consent process involvement of others for international clinical trials, issues, 42–45  
 post-trial benefits, disclosure requirements for international clinical trial and, 40  
 risk information, disclosure requirements for international clinical trials and, 38–39  
 scientific/technical information explanation for informed consent for international research, innovative methods, 40–42  
 voluntary consent process, role of others, for international clinical trials, vi–vii, 42–45
- D**
- Data and Safety Monitoring Board (DSMB), 31
- Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, 5, 8, 9, 10, 25, 26, 36, 37, 56, 57, 62, 70, 74, 80, 82, 88, 93, 100  
 See also World Medical Association (WMA)
- Denmark  
*Act on a Scientific Ethical Committee System and the Handling of Biomedical Research Subjects*, 93  
 international clinical trials, ethics review for, 82  
 international research participants protection, documents concerning, comparative analysis of, 100
- Department of Health and Human Services (DHHS)  
 international clinical trials, assurance regulations for protection of participants, 79, 80  
 international clinical trials, ethics review regulations for protection of participants, 81, 82  
 international research participants, equal protection provision for, xiii, 14, 85–89
- Department of the Treasury  
 Secretary, 72
- Design. See Research design
- Developing countries. See Research involving developing countries
- DHHS. See Department of Health and Human Services (DHHS)
- Dickens, Bernard, 88
- Disclosure of information  
 alternative therapies for international research and, cultural barriers to requirements, 39–40  
 community representatives involvement to ensure comprehension in international clinical trials, vi, 42  
 control interventions for international research and, cultural barriers to requirements, 39  
 control randomization for international research and, cultural barriers to requirements, 39  
 cultural barriers to clinical trial requirements, 38–40  
 diagnosis/prognoses for international research and, cultural barriers to requirements, 38–39  
 participants in international clinical trials, informed consent requirements for, v–vi, 37, 40  
 post-trial benefits from international research, informed consent requirements for, vi, 40  
 risk to participants of international clinical trials and, cultural barriers to requirements, 38–39  
 scientific/technical information explanation for international clinical trials, innovative methods, 40–42  
 See also Information; Informed consent

## Diseases and disorders

- diagnosis disclosure requirements for international clinical trials, cultural barriers to, 38–39
- disclosure requirements for participants in international clinical trials, v–vi, 37, 40
- See also* Human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS); Respiratory Distress Syndrome (RDS)

## Documentation

- Haiti informed consent requirements for international research, 49
- informed consent process for international research, concerns for, 48–50
- informed consent requirements for international research, examples of, 49
- Malawi informed consent requirements for international research, 49
- Nigeria informed consent requirements for international research, 49
- Uganda informed consent requirements for international research, 49

Double standards. *See* Standards

## Drugs and drug testing

- Biologic License Application, 21
- development phases, summary of, 21
- discovery process for, 21
- investigational device exemption (IDE), 21
- investigational new drug (IND) application, 21
- New Drug Application (NDA), 21
- pivotal trials (confirmatory trials), 21
- post-trial access and prior agreements for international research, funding/distribution issues, 67–69
- preclinical testing, 21
- Product License Application, 21
- See also* Clinical trials; Placebos; Vaccines and vaccination

DSMB. *See* Data and Safety Monitoring Board (DSMB)**E**Effectiveness studies. *See* Clinical trialsEfficacy studies. *See* Clinical trials

## Elizabeth Glaser Pediatric AIDS Foundation

- Call to Action project, 73

EO 13155. *See* Executive Order 13155

## Equipoise

- clinical trials and, requirement for, 22–23
- definition of, 22
- See also* Clinical trials; Research design

Equivalent protections. *See* Protections for human participantsEstablished effective treatment. *See* Active treatment concurrent control; Health care

## Ethics

- AIDS vaccines development, prior agreements on post-trial benefits, 66
- biomedical researchers in developing countries and U.S., issues for, NBAC survey, 4
- clinical trials in developing countries and, papers commissioned on, 117
- clinical trials in developing countries and, public comments on, 111–113
- clinical trials in developing countries and, testimony, public/expert on, 115
- clinical trials in developing countries, issues for, 3–4
- clinical trials participants, obligations owed to during, 20
- control groups treatment in clinical trials in developing countries, concerns, 26–28
- design/conduct of international clinical trials, concerns, 19–32
- HIV perinatal transmission, placebo-controlled trials in developing countries, controversy, 1, 2
- informed consent, standard of, definitions, 36–38
- Latin America proposed placebo use in study, concerns, 25
- participants in international clinical trials, fair/respectful treatment of, v–vii, 10–12
- post-trial benefits for international research, issues, viii–x, 12–13, 55–74
- post-trial benefits for others in international research, issues, x, 12–13
- post-trial benefits, and researcher-participant relationship in international research, issues, 58–59
- post-trial benefits, IAVI prior agreements for international research, 66, 74, 104–106
- post-trial benefits, obligations of public/private research sponsors for international research, 64–65
- post-trial benefits, obligations of researchers in international research, 64
- post-trial benefits, obligations to host community/country of international research, concerns, 61–64
- post-trial benefits, obligations to participants in international clinical trials, concerns, 56–58
- post-trial benefits, prior agreements for international research, discussion, 66–72, 74
- post-trial benefits, prior agreements for international research, and health policy influence, issues, 70–71
- post-trial benefits, prior agreements for international research, and prevailing international standard, issues, 70
- post-trial benefits, prior agreements for international research, funding/distribution problems for, 67–69
- post-trial benefits, UNAIDS prior agreements for international research, 66, 74, 108
- post-trial benefits, VaxGen prior agreements for international research, 66, 74, 106–108
- post-trial benefits, WHO prior agreements for international research, 66, 74, 103–104
- post-trial treatment for participants in international research, justice as reciprocity and, 59–61
- protection of participants in international clinical trials, requirements for, ii–iii, 5–6

- protection of participants in international clinical trials, U.S./international policy/regulatory issues, 14
- protections for participants in U.S. government-sponsored international clinical trials, NBAC recommendations, ii–iii, 6
- recruitment for international clinical trials, issues, 10–12
- Thailand AIDS vaccines testing, prior agreement on post-trial benefits, 66
- voluntary informed consent, substantive standard of, recommendations, 38
- See also* Ethics review and review committees
- Ethics review and review committees, 6
- assurance process for protection of participants in international research, U.S. procedures for, xi, 80
- capacity building for developing countries, for international clinical trials, strategies for, NBAC recommendations, xiv, 91
- capacity building, for host country in international clinical trials, need to, xiii–xiv, 14, 89–94
- capacity building, for host country in international clinical trials, U.S./international guidelines reviewed by NBAC on, 93
- clinical trials involving human participants in developing countries, requirements for, xi–xii, 13–14, 81–85
- design involvement of community and study participants, for international clinical trials, v, 30–31
- design justification to, for protection of participants in international clinical trials, iv, 20
- equal protection provision, for participants in international clinical trials, role of, 88, 89
- established effective treatment for control groups in developing countries, concerns for, iv, 9–10, 28
- financial support for costs of, for research in developing countries, xiii, 85
- informed consent for international clinical trials, ensuring comprehension for, vi, 42
- informed consent for participants in international clinical trials, disclosure for, NBAC recommendations, vi, 40
- informed consent, procedural requirement for international research, cultural barriers to, NBAC recommendations, viii, 50
- multiple, for international clinical trials, considerations, 82–84
- post-trial benefits for host country population, for international research, NBAC recommendations, x, 74
- post-trial benefits, in international research, disclosure in informed consent documents, NBAC recommendations, vi, 40
- post-trial treatment/benefits for participants in international research, NBAC recommendations, x, 74
- protection of international research participants, challenges to host country review, 82
- protection of international research participants, U.S. provisions for, 81, 82, 83, 84, 85
- U.S. government-sponsored clinical trials in developing countries, requirements for, NBAC recommendations, xii, 83, 84
- voluntary informed consent for participants in international clinical trials, NBAC recommendations, v, 38
- women's informed consent process, role of husband, in international clinical trials, vii, 45
- See also* Ethics; Institutional Review Boards (IRBs)
- Europe
- AIDS vaccine research, 91
- established effective treatment in international research, example of, 10
- Evaluation
- international research participants, assurance process for protection of, independent evaluation, NBAC recommendations, xi, 80
- See also* Ethics review and review committees
- Executive Order 13155, 73
- Expert testimony. *See* Testimony and speakers
- F**
- Faden, R.R., 36
- Families
- husbands involvement in informed consent of women, for international clinical trials, cultural issues, 45
- informed consent process involvement of, for international clinical trials, vii, 44–45
- Uganda informed consent guidelines for involvement, 44
- See also* Marriage
- FDA. *See* Food and Drug Administration (FDA)
- Federal departments and agencies
- financial support for ethical review costs of research in developing countries, requirements, xiii, 85
- informed consent documentation for international clinical trials, and, recommendations, viii, 50
- See also* Agency for International Development (USAID); Department of Health and Human Services (DHHS); Department of the Treasury; Federal government; Federal regulation; Food and Drug Administration (FDA)
- Federal Food, Drug, and Cosmetic Act, 81
- Federal funding for research
- ethics review of U.S. government-sponsored international clinical trials, NBAC recommendations, xii, 83, 84
- financial support for costs of ethical review of research in developing countries, NBAC recommendations, xiii, 85
- post-trial obligations of public sponsors, 64–65
- protections for participants in U.S. government-sponsored international clinical trials, NBAC recommendations, ii–iii, 6
- See also* Federal government; Research funding
- Federal government
- assurances for protection of participants in international clinical trials, explanation, 78–80
- ethics review of U.S. government-sponsored clinical trials in developing countries, requirements, NBAC recommendations, xii, 83
- protection of participants in international research, documents concerning, comparative analysis of, 101
- protection of participants in U.S. government-sponsored international clinical trials, NBAC recommendations, ii–iii, 6
- Single Project Assurances for protection of international research participants, criticisms of, 79–80

- See also* Federal departments and agencies; Federal funding for research; Federal legislation; Federal regulation; Health policy; Public policy; U.S. Congress
- Federal legislation  
 Vaccines for the New Millennium Act of 2000 (S. 2132/H.R. 3812), 72  
 World Bank AIDS Prevention Trust Fund Act (S. 2033/H.R. 3519), 72  
*See also* Federal Food, Drug, and Cosmetic Act; Federal government; Federal regulation; Public Health Service Act; Public Law 106-264; Public Law 106-429; U.S. Congress
- Federal oversight. *See* Federal regulation
- Federal policy. *See* Federal government; Federal regulation; Health policy; Public policy
- Federal Policy for the Protection of Human Subjects. *See* Code of Federal Regulations, Title 45, Part 46 (45 CFR 46)
- Federal regulation  
 assurances for protection of participants in international clinical trials, explanation, 78–80  
 equal protection for participants in international research, provision of DHHS, explanation, xiii, 14, 85–89  
 ethics review for protection of participants in international clinical trials, U.S. procedures, 81–85  
 host country capacity for international research, variation in U.S./international guidelines for, 92, 93–94  
 protection of participants in international clinical trials, U.S. procedures for, 78–89  
 protection of participants in international clinical trials, U.S./international policy/regulatory issues, 14  
 Single Project Assurances for protection of international research participants, criticisms of, 79–80  
*See also* Federal departments and agencies; Federal government; Public policy
- Federalwide Assurance (FWA), 87, 89  
 Federalwide Domestic Assurance, xi, 80  
 Federalwide International Assurance, xi, 80  
 international research participants protection, OHRP proposed revisions to, 80  
*See also* Assurances of compliance
- FIC. *See* Fogarty International Center (FIC)
- Finland  
*Decrees 785/1992, 494/1998, and 986/1999 on international research guidelines, 93*  
 international research participants protection, documents concerning, comparative analysis of, 100
- Flaherty, M.P., 108
- Fogarty International Center (FIC)  
 International Bioethics Education and Career Development Award Program, 91  
*See also* National Institutes of Health (NIH)
- Food and Drug Administration (FDA), 3, 23, 25, 36, 50, 80, 87, 93  
 drug development phases and, 21  
 ethics review of international clinical trial, requirements of, xii, 81, 82, 83, 84  
 protection of participants in international clinical trials, U.S./international policy/regulatory issues, 14  
 protection of participants in U.S. government-sponsored international clinical trials, requirements of, NBAC recommendations, iii, 6
- Foreign countries. *See* Developing countries; International research
- Fost, N.C., 39
- France  
 international research activities of, 3  
*Law 88-1138 Regarding the Protection of Persons Agreeing to Biomedical Research, 93*  
 protection of international research participants, documents concerning, comparative analysis of, 100
- Freedom of choice  
 inducement (undue) for research enrollment, definition and concerns, 46–48  
 informed consent process involvement of community leaders, issues, 42–44  
 informed consent process involvement of family members, issues, 44–45  
 informed consent process involvement of others, issues, 42–45  
 voluntary informed consent and, issues, 45–48  
 women's voluntary informed consent, issues, 45
- FWA. *See* Federalwide Assurance (FWA)
- FY 2001 Foreign Operations Appropriations Act. *See* Public Law 106-429
- ## G
- Gambia  
 clinical trial, community education for informed consent, 41
- Gates Foundation. *See* Bill and Melinda Gates Foundation
- Germany  
 international research activities of, 3
- Glantz, L.H., 67
- Glaser Foundation. *See* Elizabeth Glaser Pediatric AIDS Foundation
- Glaxo SmithKline Beecham, 73
- Glaxo Wellcome, 73
- Global AIDS and Tuberculosis Relief Act of 2000. *See* Public Law 106-264
- Global Alliance for Vaccines and Immunization, 72  
 Global Fund for Children's Vaccines, 73
- Government funding for research. *See* Federal funding for research
- ## H
- Haemophilus influenzae* type b, 4, 73
- Haiti  
 established effective treatment, example of, 10  
 ethics review process in international research, comments on, 84  
 HIV vaccine trials, scientific information explanation for informed consent, 41  
 informed consent documentation requirements, 49

Health and Human Services Department. *See* Department of Health and Human Services (DHHS)

#### Health care

AIDS vaccines development, prior agreements on post-trial benefits, 66

control groups of U.S. researchers in developing countries, ethical concerns, 26–28

design and routine care, relevance for participants in international clinical trials, iii–iv, 8–10, 20–29

disclosure requirements for control interventions in international clinical trials, cultural barriers, 39–40

established effective treatment for control groups in international clinical trials, iv, 9–10, 28

established effective treatment vs. best current methods, for international clinical trials, 28

HIV perinatal transmission, placebo-controlled trials in developing countries, controversy, 1, 2

host country needs, responsiveness of clinical trials in developing countries to, iii, 7–8

post-trial benefits for host country population, for international research, NBAC recommendations, x, 74

post-trial benefits for international clinical trials, ethical issues, viii–x, 12–13, 55–74

post-trial benefits for participants in international clinical trials, justice as reciprocity and, 59–61

post-trial benefits, IAVI prior agreements for international research, 66, 74, 104–106

post-trial benefits, obligations of public/private research sponsors, 64–65

post-trial benefits, obligations of researchers, 64

post-trial benefits, obligations to host community/country, ethical concerns, 61–64

post-trial benefits, obligations to participants, ethical concerns, 56–58

post-trial benefits, prior agreements for international research, and breach of obligations potential, 72, 74

post-trial benefits, prior agreements for international research, and creation of double standard, issues, 71–72

post-trial benefits, prior agreements for international research, and delay/prevention of research, 68

post-trial benefits, prior agreements for international research, and prevailing international standard, issues, 70

post-trial benefits, prior agreements for international research, discussion, 66–72, 74

post-trial benefits, prior agreements for international research, funding/distribution problems, 67–69

post-trial benefits, prior agreements for international research, health policy influence of, issues, 70–71

post-trial benefits, UNAIDS prior agreements for international research, 66, 74, 108

post-trial benefits, VaxGen prior agreements for international research, 66, 74, 106–108

post-trial benefits, WHO prior agreements for international research, 66, 74, 103–104

post-trial obligations, and researcher-participant relationship, ethical issues for, 58–59

post-trial treatment/benefits for participants in international research, NBAC recommendations, x, 74

protection of participants in international research, documents concerning, comparative analysis of, 100–101

standard of, for participants in international clinical trials, 9, 26–28

Thailand AIDS vaccines testing, prior agreement on post-trial benefits, 66

therapeutic misconception minimization, for participants in international clinical trials, vii–viii, 48

*See also* Active treatment concurrent control; Health care costs; Health policy; Placebo concurrent control

#### Health care costs

post-trial benefits for international research, prior agreements for, funding issues for, 68–69

*See also* Health care

#### Health policy

prior agreements on post-trial benefits in international research, unrealistic influence on, 70–71

*See also* Health care; Health care costs; Public policy

#### Heavily Indebted Poor Countries, 73

Helsinki, Finland. *See* *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*; Finland

#### Hippocratic oath, 58

HIV/AIDS. *See* Human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS)

#### H.M.S. Salisbury, 23

#### HUGO. *See* Human Genome Organization (HUGO)

#### Human Genome Organization (HUGO)

Ethics Committee, 63, 70

Human Genome Project, 63

post-trial benefits access for international research participants, provisions for, 63, 70

*Statement on Benefit Sharing*, 63, 70

#### Human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS)

maternal-to-infant transmission of, placebo-controlled trials in developing countries, controversy, 1, 2

Thailand vaccines testing, prior agreement on post-trial benefits, 66, 106–108

vaccine development, IAVI prior agreements on post-trial benefits, 66, 74, 104–106

vaccine development, VaxGen prior agreements on post-trial benefits, 66, 74, 106–108

vaccine initiatives timeline 2000–2001, 72–73

vaccine trials, 30, 41

#### Human participants. *See* Participants; Protections for human participants

#### Husbands. *See* Families; Marriage

Hyder, Adnan, 26, 27, 38, 41, 42, 47, 48, 50, 55, 57, 64, 66, 80, 82, 83, 85, 86, 89–90, 92

- I**
- IAVI. *See* International AIDS Vaccine Initiative (IAVI)
- ICH. *See* International Conference on Harmonisation (ICH)
- IDE. *See* Investigational device exemption (IDE)
- Ijsselmuiden, C.B., 36
- Illinois, 73
- Immtech International, Inc., 73
- INCLEN. *See* International Clinical Epidemiology Network (INCLEN)
- IND. *See* Investigational new drug (IND) application
- Independent bodies
  - international research participants, assurance process for protection of, evaluation by, NBAC recommendations, xi, 80
- India
  - AIDS vaccine development efforts, 106
  - Ethical Guidelines on Biomedical Research Involving Human Subjects*, 87, 93
  - Indian Council of Medical Research, 87, 93
  - international clinical trials, ethics review for, 82
  - international research ethics and voluntary informed consent, 11, 35
  - international research participants protection, documents concerning, comparative analysis of, 101
- Inducement. *See* Coercion
- Infants
  - Latin America Respiratory Distress Syndrome proposed study, 25
  - See also* Maternity
- Influence. *See* Coercion
- Information
  - scientific/technical, explanation for informed consent, innovative methods, 40–42
  - See also* Disclosure of information; Informed consent
- Informed consent
  - biomedical researchers in developing countries and U.S., ethical issues for, NBAC survey, 4
  - community leaders involvement in process, cultural issues, 42–44
  - comprehension of, ensuring, for international clinical trials, vi, 42
  - cultural issues relating to process of, 40–45
  - cultural variations to process, for international clinical trials, NBAC recommendations, viii, 50
  - documentation requirement for, discussion, 37, 38, 48–50
  - documentation requirement for, examples, 49
  - documents concerning protection of international research participants, comparative analysis of, 100–101
  - ethical issues for international research by U.S. researchers, 35–51
  - ethical standard of, definitions of, 36–38
  - family members role in process for international clinical trials, vii, 44–45
  - others involvement in process for international clinical trials, vi, 42–45
  - post-trial benefits from international research, disclosure for, NBAC recommendations, vi, 40
  - process of, discussion, 36, 37, 38
  - recruitment issues for international clinical trials, 10–12
  - scientific/technical information explanation for, innovative methods, 40–42
  - substantive standard of, definition, 37–38
  - therapeutic misconception minimization, for participants in international clinical trials, vii–viii, 48
  - Uganda involvement of others, new guidelines for, 44
  - voluntary, for participants in international clinical trials, v–vii, 11, 36–38
  - voluntary, role of others, for international clinical trials, vi–vii, 42–45
  - women, role of husband in process for international clinical trials, vii, 45
  - See also* Disclosure of information; Information
- Institute of Human Virology, 105
- Institutional Review Boards (IRBs), xiv, 6, 13, 19, 20, 24, 39, 41, 50, 65, 66, 92, 94
  - disclosure requirements for international clinical trials, and, 37
  - equal protection provision, for research participants in international clinical trials, role of, 87, 88, 89
  - ethics review for international clinical trials, U.S. procedures concerning, 81, 82, 83, 84, 85
  - ethics review of U.S. government-sponsored clinical trials in developing countries, requirements, xii, 83, 84
  - protection of participants in international research participants, U.S. procedures concerning, 78, 79
  - registration process, for assurances protection of international research participants, and proposed revisions 80, 81
  - See also* Ethics review and review committees
- International AIDS Vaccine Initiative (IAVI)
  - AIDS vaccine development efforts, 72, 73, 104–106
  - AIDS Vaccines for the World: Preparing Now to Assure Access*, 106
  - international research, prior agreements for post-trial benefits from, 66, 74, 104–106
  - Scientific Blueprint 2000: Accelerating Global Efforts in AIDS Vaccine Development*, 106
  - Scientific Blueprint for AIDS Vaccine Development*, 104–105
  - Uganda research capacity building, efforts of, 91
- International Clinical Epidemiology Network (INCLEN), 91
  - See also* Rockefeller Foundation
- International Conference on Harmonisation (ICH), 3, 24
  - Harmonised Tripartite Guideline, Guideline for Good Clinical Practice (GCP)*, 36, 37, 38, 87, 88, 93
  - international research participants protection, documents concerning, comparative analysis of, 100
- International Cooperative Project Assurance, 79
  - See also* Assurances of compliance; Cooperative Project Assurance (CPA); Office for Human Research Protections (OHRP)

International Covenant on Civil and Political Rights, 35

#### International regulation

- equal protection for research participants in international research, DHHS provision for, explanation, xiii, 14, 85–89
- host country capacity for international research, variation in U.S./international guidelines for building, 92, 93–94
- host country review for international research, challenges to, 82
- post-trial obligations to international research participants, existing guidelines, 56–58
- protection of participants in international clinical trials, comparative analysis of relative documents, 99–101
- protection of participants in international clinical trials, U.S./international policy/regulatory issues, 14

#### International research

- AIDS vaccines development, prior agreements on post-trial benefits, 66
- alternative therapies disclosure requirements, cultural barriers to, 39–40
- assurances of compliance, for protection of participants, xi, 14, 78–80
- biomedical researchers in, ethical issues for, NBAC survey, 4
- capacity building for host country, variation in U.S. international guidelines for, 92, 93–94
- capacity building for, need to, xiii–xiv, 14, 89–94
- capacity building for, strategies for, NBAC recommendations, xiv, 91, 94
- clinical trials in developing countries, ethical issues for, 3–4
- clinical trials in developing countries, reasons for, 6–7
- clinical trials in developing countries, recruitment issues, 10–12
- control groups treatment in developing countries, ethical concerns for, 26–28
- design for protection of participants in, iii–iv, 8–10, 20–29
- design issues for repeating trials, 31–32
- design/implementation, community involvement in, for, iv–v, 30–31
- disclosure requirements for, cultural barriers to, 38–40
- efficacy (optimal care) vs. effectiveness, distinction, 28–29
- equivalent protections for participants in, procedures for, xiii, 14, 85–89
- established effective treatment for control groups in, iv, 9–10, 28
- ethical concerns for, papers commissioned on, 117
- ethical concerns for, public comments on, 111–113
- ethical concerns for, testimony, public/expert on, 115
- ethical conduct of, requirements for, NBAC recommendations on, 5–6
- ethics review by host country for, challenges to, 82
- ethics review for protection of participants, requirements, xi–xii, 13–14, 81–85
- financial support for costs of ethical review of, requirements, NBAC recommendations, xiii, 85
- health needs of host country, responsiveness of clinical trials in developing countries to, iii, 7–8
- HIV perinatal transmission, placebo-controlled trials in developing countries, controversy, 1, 2

inducement (undue) for enrollment in, definition/concerns, 46–47

- informed consent in, ensuring comprehension, NBAC recommendations, vi, 42
- informed consent process, cultural variations for, NBAC recommendations, viii, 50
- informed consent role of family members for, vii, 44–45
- informed consent role of others for, NBAC recommendations, vi, 43
- informed consent, disclosure requirements for participants in, NBAC recommendations, v–vi, 37, 40
- multiple ethics review for international research, issues, 82–85
- participants fair/respectful treatment in, v–vii, 10–12
- participants in, ethical requirements for, 5–6
- participants standard of care in, 9, 26–28
- post-trial benefits for host country in, NBAC recommendations, x, 74
- post-trial benefits for host country, prior agreements for, NBAC recommendations, x, 74
- post-trial benefits for others in, ethical issues, x, 12–13
- post-trial benefits for participants in, NBAC recommendations, x, 74
- post-trial benefits, and researcher-participant relationship, ethical issues, 58–59
- post-trial benefits, disclosure in informed consent documents for, NBAC recommendations, vi, 40
- post-trial benefits, IAVI prior agreements for, 66, 74, 104–106
- post-trial benefits, in, ethical issues, viii–x, 12–13, 55–74
- post-trial benefits, obligations of public/private research sponsors, 64–65
- post-trial benefits, obligations of researchers, 64
- post-trial benefits, obligations to host country of, ethical concerns, 61–64
- post-trial benefits, obligations to participants in, concerns, 56–58
- post-trial benefits, prior agreements on, and breach of obligations potential, 72, 74
- post-trial benefits, prior agreements on, and creation of double standard, issues, 71–72
- post-trial benefits, prior agreements on, and delay/prevention of research, 68
- post-trial benefits, prior agreements on, and funding/distribution problems, 67–69
- post-trial benefits, prior agreements on, and health policy influence, issues, 70–71
- post-trial benefits, prior agreements on, and prevailing international standard, issues, 70
- post-trial benefits, prior agreements on, discussion of, 66–72, 74, 103–108
- post-trial benefits, UNAIDS prior agreements for, 66, 74, 108
- post-trial benefits, VaxGen prior agreements for, 66, 74, 106–108
- post-trial benefits, WHO prior agreements for, 66, 74, 103–104
- post-trial treatment for participants, justice as reciprocity and, 59–61
- protection of participants in, ethical requirements, ii–iii, 5–6

- protection of participants in, mechanisms for, xi–xiv, 13–14, 78–89
- resources (funding) support for ethics review of, xiii, 85
- risk disclosure requirements for, cultural barriers to, 38–39
- Single Project Assurances for protection of participants in, criticisms of, 79–80
- standard of care for participants in, 9, 26–28
- Thailand AIDS vaccines testing, prior agreement on post-trial benefits, 66
- therapeutic misconception minimization, for participants in, vii–viii, 48
- voluntary consent process for, role of others, vi–vii, 42–45
- voluntary consent process for, v–vii, 11, 36–38
- voluntary informed consent for, ethical issues, 35
- voluntary participation and undue inducement for, involvement of community leaders, NBAC recommendations, vi, 44
- women's informed consent for, role of husband in, vii, 45
- See also* Research
- Interventions. *See* Health care
- Investigational device exemption (IDE), 82, 83
- Investigational new drug (IND) application, 82, 83
- IRBs. *See* Institutional Review Boards (IRBs)
- J**
- Japan
- international research activities of, 3
- Johns Hopkins University, 4
- School of Hygiene and Public Health, 40–41
- Joint United Nations Programme on HIV/AIDS (UNAIDS), 73, 107
- Community Involvement and Impact, 30
  - Ethical Considerations in HIV Preventive Vaccine Research*, 8, 14, 57, 93
  - Ethical Review Committee, 30
  - Guidance Document for Preventive HIV/AIDS Vaccine Trials*, 62, 68, 70, 74, 90, 92
  - HIV vaccine research in developing countries, capacity building mechanisms for, listing, 90
  - post-trial benefits for international research, prior agreements for, 66, 74, 108
  - protection of international research participants, documents concerning, comparative analysis of, 100
  - See also* United Nations (UN)
- Justice
- distributive, ethical obligation for international clinical trials, summary, 77
  - fairness principle, and post-trial obligations to host community/country, ethical concerns, 61–64
  - reciprocity principle in clinical trials, and participants post-trial access to benefits, 59–61
- K**
- Kass, Nancy, 26, 27, 38, 41, 42, 47, 48, 50, 55, 57, 64, 66, 80, 82, 83, 85, 86, 89–90, 92
- Kenya
- Nairobi, AIDS vaccine development efforts, 105
  - Trypanosomiasis Research Institute, 73
  - See also* University of Nairobi
- Kerry, John, 72
- L**
- Languages
- Creole, informed consent for international research, form in, 41
  - English, informed consent for international research, form in, 41
  - French, informed consent for international research, form in, 41
  - translation of scientific/technical aspects of research protocols for informed consent, innovative methods, 41
- Latin America
- informed consent documentation requirements, issues, 49–50
  - placebo vs. established effective treatment in proposed study, ethical concerns, 25
- Leach, Jim, 72
- Lesotho
- UNAIDS prior agreement for post-trial benefits in, 108
- Lind, James, 23
- London School of Hygiene and Tropical Medicine, 73
- See also* United Kingdom
- Loue, Sana, 44, 92
- Love, R.R., 39
- M**
- Mali
- informed consent process involvement of community leaders, issues for, 43
- Malawi
- informed consent documentation requirements, 49
  - informed consent process involvement of community leaders, issues for, 43
  - malaria drugs clinical trials, 43, 49, 62
  - Ministry of Health, 62
- Malenga, Grace, 49, 62
- Maternity
- HIV perinatal transmission, placebo-controlled trials in developing countries, controversy, 1, 2
  - See also* Infants; Women
- Marriage
- husbands involvement in informed consent of women, for international clinical trials, vii, 45
  - See also* Families

Marshall, Patricia, 40, 41, 44, 49, 84, 85  
 Maryland. *See* University of Maryland  
 Medicaid, 71  
 Medical costs. *See* Health care costs  
 Medical interventions/treatment. *See* Health care  
 Medicare, 55  
 Merck, 72, 73  
 Millennium Vaccine Initiative, 72  
 MPAs. *See* Multiple Project Assurances (MPAs)  
 Multiple Project Assurances (MPAs), 79, 80, 89  
*See also* Assurances of compliance; Office for Human Research Protections (OHRP)

## N

National Bioethics Advisory Commission (NBAC), i, 3, 9, 10, 11, 13, 14, 15, 19, 24, 26, 32, 36, 37, 39, 41, 46, 47, 49, 51, 55, 56, 57, 60, 61, 62, 63, 64, 65, 67, 68, 70, 71, 77, 78, 81, 82, 86, 87, 88, 92  
 assurance process for protecting international research participants, recommendations, xi, 80  
 biomedical researchers in developing countries and U.S., ethical issues for, survey, 4  
 capacity building for design/review/conduct of clinical trials by developing countries, strategies for, recommendations, xiv, 91  
 capacity building for international research, for ethics review committees in developing countries, assistance for, recommendations, xiv, 94  
 design/conduct of international clinical trials, ethical concerns, recommendations, iv, 20, 28, 30–31  
 design/implementation of international clinical trials, involvement of community, recommendations, v, 30–31  
 equivalent protections for participants in international research, determination of, recommendations, xiii, 89  
 established effective treatment for control groups in international clinical trials, recommendations, iv, 28  
 ethics review of U.S. government-sponsored clinical trials in developing countries, requirements, recommendations, xii, 83  
 financial support for costs of ethical review of research in developing countries, requirements, recommendations, xiii, 85  
 health needs of host country, responsiveness of clinical trials in developing countries, iii, 8  
 host country capacity building, for international research, review of U.S./international guidelines on, 93  
 inducement (undue) and voluntary participation in international clinical trials, involvement of community leaders, vi, 44  
 informed consent for participants in U.S. government-sponsored international clinical trials, recommendations, iii, 6  
 informed consent process for international clinical trials, cultural variations for, recommendations, viii, 50  
 informed consent process for international clinical trials, disclosure requirements, recommendations, vi, 40  
 informed consent process for international clinical trials, ensuring comprehension for, recommendations, vi, 42  
 informed consent process for international clinical trials, involvement of family members, recommendations, vii, 45

informed consent process for international clinical trials, involvement of community leaders, recommendations, vi, 42, 43, 44  
 informed consent process for international clinical trials, involvement of others, recommendations, vi, 43, 44, 45  
 post-trial benefits for host country from international research, recommendations, x, 74  
 post-trial benefits for host country from international research, prior agreements on, recommendations, x, 74  
 post-trial benefits from international research, disclosure in informed consent documents, recommendations, vi, 40  
 post-trial benefits/treatment for participants in international research, recommendations, x, 74  
 protections for participants in U.S. government-sponsored international clinical trials, recommendations, ii–iii, 6  
 risk minimization, for participants in U.S. government-sponsored international clinical trials, recommendations, iii, xii, 6, 84  
 scientific/technical aspects of research protocols, explanation for informed consent, innovative methods, recommendations, 42  
 therapeutic misconception minimization, for participants in international clinical trials, recommendations, viii, 48  
 voluntary informed consent for participants in international clinical trials, recommendations, v, 38  
 women's informed consent process for international clinical trials, role of husband, recommendations, vii, 45  
 National Commission. *See* National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research  
 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 63, 80  
*Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, ii, 5, 10, 27, 62–63, 80  
 National Consensus Conference on Bioethics and Health Research in Uganda, 44  
 National Institutes of Health (NIH), viii, 2, 7, 50, 85, 91  
*See also* Fogarty International Center (FIC)  
 NBAC. *See* National Bioethics Advisory Commission (NBAC)  
 Netherlands  
 AIDS vaccine development funding for IAVI, 106  
 informed consent documentation requirements, issues, 49–50  
 international research activities of, 3  
 protection of international research participants, documents concerning, comparative analysis of, 101  
*Law Regarding Medical-Scientific Research on Humans*, 93  
 New Zealand  
*HRC Guidelines on Ethics in Health Research*, 93  
 international clinical trials, ethics review for, 82  
 international research participants protection, documents concerning, comparative analysis of, 101  
 NGOs. *See* Nongovernmental organizations (NGOs)  
 Nigeria  
 informed consent documentation requirements, 49  
 informed consent involvement of women's husbands, issues for, 44

Lagos, ethics review committees, comments on, 84  
 research disclosure requirements, cultural barriers to, 39  
 scientific/technical information explanation for informed consent, translation for, 41

NIH. *See* National Institutes of Health (NIH)

Nongovernmental organizations (NGOs), 7, 69, 72

North Carolina, 105

*See also* Chapel Hill, North Carolina; University of North Carolina

Nuffield Council on Bioethics, 90

Nuremberg Code, v, 11, 93

international research participants protection, documents concerning, comparative analysis of, 100

## O

Obligations

AIDS vaccines development, prior agreements on post-trial benefits, 66  
 clinical trial participants and, ethical considerations, 20  
 post-trial benefits for host community/country of international research, ethical concerns, 61–64  
 post-trial benefits for international research participants, ethical concerns, 55–74  
 post-trial benefits in international research, and researcher-participant relationship, ethical concerns, 58–59  
 post-trial benefits in international research, prior agreements for, and delay/prevention of research, 68  
 post-trial benefits in international research, prior agreements for, and prevailing international standard, 70  
 post-trial benefits in international research, prior agreements for, discussion of, 66–72, 74, 104–106  
 post-trial benefits in international research, prior agreements for, double standard creation, 71–72  
 post-trial benefits in international research, prior agreements for, potential breach of, 72, 74  
 post-trial benefits in international research, prior agreements for, health policy influence of, issues, 70–71  
 post-trial benefits in international research, prior agreements for, funding/distribution problems for, 67–69  
 post-trial benefits in international research, public/private research sponsors and, 64–65  
 post-trial benefits in international research, researchers and, 64  
 post-trial treatment for international research participants, justice as reciprocity and, 59–61  
 protection of participants in international research, comparison of documents concerning, 100–101  
 Thailand AIDS vaccines testing, prior agreement on post-trial benefits, 66

Office for Human Research Protections (OHRP), 81

assurance system for protection of international research participants, current practices of, 79, 80  
 assurance system for protection of international research participants, proposed revisions of, 80  
 equal protection provision, for international research participants, implementation by, xiii, 14, 85, 87–89

*See also* Cooperative Project Assurance (CPA); International Cooperative Project Assurance; Multiple Project Assurances (MPAs); Office for Protection from Research Risks (OPRR); Single Project Assurances (SPAs)

Office for Protection from Research Risks (OPRR), xiii, 14, 79, 84, 87, 88

*See also* National Institutes of Health (NIH); Office for Human Research Protections (OHRP)

Ohio. *See* Columbus, Ohio

OHRP. *See* Office for Human Research Protections (OHRP)

Okello, D., 44

OPRR. *See* Office for Protection from Research Risks (OPRR)

Oversight. *See* Federal regulation; International regulation

Oxford University. *See* University of Oxford

## P

Pape, Jean, 41, 42, 49, 84

Papers commissioned

international clinical trials, protection of participants, ethical concerns, 117

Participants. *See* Protections for human participants

Pelosi, Nancy, 72

P.L. 106-264. *See* Public Law 106-264

P.L. 106-429. *See* Public Law 106-429

Placebo concurrent control

active treatment concurrent control vs., ethical concerns, 25  
 explanation of, 23–26

Latin America proposed study use, ethical concerns, 25  
*See also* Clinical trials; Control groups; Placebos

Placebos

effect, explanation of, 23–24

HIV perinatal transmission, controversial trials in developing countries, 1, 2

*See also* Drugs and drug testing; Placebo concurrent control

Plowe, Christopher, 62

Policy. *See* Health policy; Public policy

Positive control. *See* Active treatment concurrent control

Presidential Advisory Council on HIV/AIDS, 73

Prevailing standards. *See* Standards

Prior agreements

AIDS vaccines development, post-trial benefits and, 66

IAVI, for post-trial benefits in international research, description, 66, 74, 104–106

post-trial benefits access to others in international research, ethical issues, x, 12

post-trial benefits for host country population in international research, and, NBAC recommendations, x, 74

post-trial benefits in international research and, discussion, 66–72, 74, 104–108

- post-trial benefits in international research and, double standard creation, issues, 71–72
- post-trial benefits in international research and, funding/distribution problems, 67–69
- post-trial benefits in international research and, health policy influence, issues, 70–71
- post-trial benefits in international research and, potential breach of obligations, 72, 74
- post-trial benefits in international research and, prevailing international standard and, issues, 70
- post-trial benefits in international research and, research delay/prevention and, 68
- Thailand AIDS vaccines testing, and post-trial benefits, 66, 106–108
- UNAIDS, for post-trial benefits in international research, description, 66, 74, 108
- VaxGen, for post-trial benefits in international research, description, 66, 74, 106–108
- WHO, for post-trial benefits in international research, description, 66, 74, 103–104
- Privacy and confidentiality
  - protection of participants in international research, comparison of documents concerning, 100–101
- Private sector
  - post-trial obligations of international research sponsors from, 64–65
- Protections for human participants
  - AIDS vaccines development, prior agreements on post-trial benefits, 66
  - assurances of compliance, for international clinical trials, xi, 14, 78–80
  - biomedical researchers in, ethical issues for, NBAC survey, 4
  - clinical trials in developing countries and, mechanisms for, xi–xiv, 13–14, 78–89
  - clinical trials in developing countries and, U.S./international policy/regulatory issues, 14
  - clinical trials in developing countries sponsored by U.S. government and, NBAC recommendations, ii–iii, 6
  - clinical trials in developing countries, ethical requirements for, ii–iii, 5–6
  - clinical trials in developing countries, recruitment issues, 10–12
  - control groups treatment in developing countries, ethical concerns for, 26–28
  - design and routine care for, in international clinical trials, iii–iv, 8–9, 20–29
  - design involvement of, for international clinical trials, 30–31
  - equivalent protections for, procedures for, xiii, 14, 85–89
  - ethical concerns for, papers commissioned on, 117
  - ethical concerns for, public comments on, 111–113
  - ethical concerns for, testimony, public/expert on, 115
  - ethics review by host country for, challenges to, 82
  - ethics review for protection of participants, requirements, xi–xii, 13–14, 81–85
  - existential loss of, in international research, 58–59
  - fair/respectful treatment of, in international clinical trials, v–vii, 10–12
  - HIV perinatal transmission, placebo-controlled trials in developing countries, controversy, 1, 2
  - inducement (undue) for enrollment in, definition/concerns, 46–47
  - informed consent process for international research, cultural variations for, NBAC recommendations, viii, 50
  - informed consent process for international research, ensuring comprehension, NBAC recommendations, vi, 42
  - informed consent process for international research, role of family members for, vii, 44–45
  - informed consent process for international research, role of others for, NBAC recommendations, vi, 43
  - informed consent, disclosure requirements for international research, cultural barriers to, 38–40
  - informed consent, disclosure requirements for international research, NBAC recommendations, v–vi, 37, 40
  - international documents concerning, comparative analysis of, 99–101
  - multiple ethics review for international clinical trials, issues for, 82–85
  - post-trial benefits for host country in, NBAC recommendations, x, 74
  - post-trial benefits for host country population, for international research, NBAC recommendations, x, 74
  - post-trial benefits, IAVI prior agreements for, 66, 74, 104–106
  - post-trial benefits, in international research, ethical issues, viii–x, 12–13, 55–74
  - post-trial benefits, obligations of public/private research sponsors, 64–65
  - post-trial benefits, obligations of researchers, 64
  - post-trial benefits, prior agreements for international research, and breach of obligations potential, 72, 74
  - post-trial benefits, prior agreements for international research, and creation of double standard, issues, 71–72
  - post-trial benefits, prior agreements for international research, and delay/prevention of research, 68
  - post-trial benefits, prior agreements for international research, and funding/distribution problems, 67–69
  - post-trial benefits, prior agreements for international research, and health policy influence, issues, 70–71
  - post-trial benefits, prior agreements for international research, and prevailing international standard, issues, 70
  - post-trial benefits, prior agreements for international research, discussion of, 66–72, 74, 103–108
  - post-trial benefits, UNAIDS prior agreements for, 66, 74, 108
  - post-trial benefits, VaxGen prior agreements for, 66, 74, 106–108
  - post-trial benefits, WHO prior agreements for, 66, 74, 103–104
  - post-trial obligations to, ethical concerns, 56–58
  - post-trial obligations to, relationship with researcher and, ethical issues, 58–59
  - post-trial treatment for participants, justice as reciprocity and, 59–61
  - post-trial treatment/benefits for participants in international research, NBAC recommendations, x, 74
  - Single Project Assurances for, criticisms of for research in developing countries, 79–80

- standard of care for, in international clinical trials, 9, 26–28  
 Thailand AIDS vaccines testing, prior agreement on post-trial benefits, 66  
 therapeutic misconception minimization, for international clinical trials, vii–viii, 48  
 voluntary consent, concerns for, 45–48  
 voluntary informed consent for international clinical trials, v–vii, 11, 36–38  
 voluntary participation and undue inducement for, involvement of community leaders, NBAC recommendations, vi, 44  
 women's informed consent for international clinical trials, role of husband in, vii, 45  
*See also* Research
- Public comments  
 international clinical trials, protection of participants, ethical issues, 111–113  
*See also* Testimony and speakers
- Public Health Service Act, 81, 91
- Public Law 106-264, 73
- Public Law 106-429, 73, 106
- Public policy  
 protection of participants in international clinical trials, U.S./international policy/regulatory issues, 14  
*See also* Federal government; Federal regulation; Health policy
- Public testimony. *See* Testimony and speakers
- R**
- Randomization  
 clinical trials, and, 22, 23  
 clinical trials, and disclosure requirements, cultural barriers to, 39  
*See also* Clinical trials; Research design
- RDS. *See* Respiratory Distress Syndrome (RDS)
- Reciprocity  
 justice as, and participants access to post-trial treatment in international research, 59–61
- Recommendations  
 assurance process for protecting international research participants, xi, 80  
 capacity for international research, for ethics review committees in developing countries, assistance for building, xiv, 94  
 capacity of developing countries to design/review/conduct clinical trials, strategies for building, xiv, 91  
 design/conduct of international clinical trials, ethical concerns, iv, 20, 28, 30–31  
 design/implementation of international clinical trials, involvement of community, v, 30–31  
 disclosure for informed consent of participants in international clinical trials, vi, 40  
 equivalent protections for participants in international research, determination of, xiii, 89  
 established effective treatment for control groups in international clinical trials, iv, 28  
 ethics review of U.S. government-sponsored clinical trials in developing countries, requirements, xii, 83  
 financial support for costs of ethical review of research in developing countries, requirements, xiii, 85  
 health needs of host country, responsiveness of clinical trials in developing countries, iii, 8  
 inducement (undue) and voluntary participation in international clinical trials, involvement of community leaders, vi, 44  
 informed consent for participants in U.S. government-sponsored international clinical trials, iii, 6  
 informed consent in international clinical trials, ensuring comprehension for, vi, 42  
 informed consent process for international clinical trials, involvement of family members, vii, 45  
 informed consent process for international clinical trials, involvement of community leaders, vi, 42, 43, 44  
 informed consent process for international clinical trials, involvement of others, vi, 43, 44, 45  
 informed consent process, cultural variations for international clinical trials, viii, 50  
 post-trial benefits for host country from international research, x, 74  
 post-trial benefits for host country from international research, prior agreements on, x, 74  
 post-trial benefits from international research, disclosure in informed consent documents, vi, 40  
 post-trial benefits/treatment for participants in international research, x, 74  
 protections for participants in U.S. government-sponsored international clinical trials, ii–iii, 6  
 risk minimization, for participants in U.S. government-sponsored international clinical trials, iii, xii, 6, 84  
 scientific/technical aspects of research protocols, explanation for informed consent, innovative methods, 42  
 therapeutic misconception minimization, for participants in international clinical trials, viii, 48  
 voluntary informed consent for participants in international clinical trials, v, 38  
 women's informed consent process for international clinical trials, role of others, 45  
 women's informed consent process for international clinical trials, role of husband, vii, 45
- Regulation. *See* Federal government; Federal regulation; International regulation
- Relationships. *See* Families; Marriage
- Relatives. *See* Families; Marriage
- Research  
 inducement (undue) for participation in, definition and concerns, 46–48  
 informed consent disclosure requirements, description, 37  
 therapeutic misconception of, minimization of, 48  
 voluntary participation in, concerns for, 45–48  
*See also* Clinical trials; International research; Protections for human participants; Research design; Research funding; Research involving developing countries; Research regulation; Science and technology

## Research design

capacity of developing countries to design/review/conduct clinical trials, strategies for building, NBAC recommendations, xiv, 91

clinical trials, chief considerations for, 20

community involvement in, for international clinical trials, iv–v, 30–31

community/participants involvement in, for international clinical trials, v, 30–31

ethical concerns for international clinical trials, 19–32

host country health needs, responsiveness of clinical trials in developing countries, NBAC recommendations, iii, 8

information disclosure for informed consent of participants in international clinical trials, NBAC recommendations, vi, 40

medical treatment for participants in clinical trials in developing countries, ethical concerns, 26–28

participants protection in international clinical trials, NBAC recommendations, iv, 20

participants routine care in international clinical trials, and, iii–iv, 8–9, 20–29

repeating study in developing country, issues for international research, 31–32

results (interim), monitoring issues for international research, 31

sample size determination for international critical trials, 29

*See also* Equipoise; Randomization; Research

## Research funding

capacity of developing countries to design/review/conduct clinical trials, strategies for building, NBAC recommendations, xiv, 91

post-trial obligations of public/private sponsors of international clinical trials, 64–65

resources support for ethics review of international clinical trials, xiii, 85

*See also* Federal funding for research; Research

## Research involving developing countries

AIDS vaccines development, prior agreements on post-trial benefits, 66

assurances of compliance, for protection of international research participants, xi, 14, 78–80

biomedical researchers in, ethical issues for, NBAC survey, 4

capacity building for host country, for international clinical trials, variation in U.S./international guidelines for, 92, 93–94

capacity building for international clinical trials, need to, xiii–xiv, 14, 89–94

capacity building for international clinical trials, strategies for, NBAC recommendations, xiv, 91, 94

clinical trials conducted in, reasons for, 6–7

control groups treatment in international clinical trials, ethical concerns for, 26–28

design for protection of participants in international clinical trials, iii–iv, 8–9, 20–29

design issues for repeating clinical trials, 31–32

design/implementation, community involvement in, for international clinical trials, iv–v, 30–31

efficacy (optimal care) vs. effectiveness trials, distinction, 28–29

equivalent protections for research participants in, procedures for, xiii, 14, 85–89

established effective treatment for control groups in international clinical trials, iv, 9–10, 28

ethical concerns for, papers commissioned on, 117

ethical concerns for, public comments on, 111–113

ethical concerns for, testimony, public/expert on, 115

ethical issues for clinical trials conducted in, 3–4

ethics review by host country for international research, challenges to, 82

ethics review for protection of participants in international clinical trials, requirements, xi–xii, 13–14, 81–85

financial support for costs of ethical review of, requirements, NBAC recommendations, xiii, 85

health needs of host country, responsiveness of international clinical trials, iii, 7–8

HIV perinatal transmission, placebo-controlled trials in, controversy, 1, 2

informed consent in international clinical trials, ensuring comprehension, NBAC recommendations, vi, 42

informed consent process, cultural variations for international clinical trials, NBAC recommendations, viii, 50

informed consent role of family members for international clinical trials, vii, 44–45

informed consent role of others for international clinical trials, NBAC recommendations, vi, 43

informed consent, disclosure requirements for participants in international clinical trials, NBAC recommendations, v–vi, 37, 40

multiple ethics review for international clinical trials, issues, 82–85

participants fair/respectful treatment in international clinical trials, v–vii, 10–12

participants in international clinical trials, ethical requirements for, 5–6

participants standard of care in international clinical trials, 9, 26–28

post-trial benefits for host country in international research, NBAC recommendations, x, 74

post-trial benefits for host country, prior agreements for international research, NBAC recommendations, x, 74

post-trial benefits for others in international research, ethical issues, x, 12–13

post-trial benefits for participants in international research, NBAC recommendations, x, 74

post-trial benefits, and researcher-participant relationship, ethical issues, 58–59

post-trial benefits, disclosure in informed consent documents for, NBAC recommendations, vi, 40

post-trial benefits, IAVI prior agreements for international clinical trials, 66, 74, 104–106

post-trial benefits, in international research, ethical issues, viii–x, 12–13, 55–74

post-trial benefits, obligations of public/private research sponsors, 64–65

post-trial benefits, obligations of researchers, 64

post-trial benefits, obligations to host country of international clinical trials, ethical concerns, 61–64

post-trial benefits, obligations to participants in international clinical trials, concerns, 56–58

- post-trial benefits, prior agreements for, summary of, 103–108
- post-trial benefits, prior agreements on international research, discussion, 66–72, 74
- post-trial benefits, prior agreements on, and breach of obligations potential, 72, 74
- post-trial benefits, prior agreements on, and creation of double standard, issues, 71–72
- post-trial benefits, prior agreements on, and delay/prevention of research, 68
- post-trial benefits, prior agreements on, and funding/distribution problems, 67–69
- post-trial benefits, prior agreements on, and health policy influence, issues, 70–71
- post-trial benefits, prior agreements on, and prevailing international standard, issues, 70
- post-trial benefits, UNAIDS prior agreements for international clinical trials, 66, 74, 108
- post-trial benefits, VaxGen prior agreements for international clinical trials, 66, 74, 106–108
- post-trial benefits, WHO prior agreements for international clinical trials, 66, 74, 103–104
- post-trial treatment for research participants, justice as reciprocity and, 59–61
- protection of participants in international clinical trials, ethical requirements, ii–iii, 5–6
- protection of participants in international clinical trials, mechanisms for, xi–xiv, 13–14, 78–89
- recruitment issues for international clinical trials, 10–12
- resources (funding) support for ethics review of international clinical trials, xiii, 85
- Single Project Assurances for protection of research participants in, criticisms of, 79–80
- Thailand AIDS vaccines testing, prior agreement on post-trial benefits, 66
- therapeutic misconception minimization, for participants in international clinical trials, vii–viii, 48
- voluntary consent process for international clinical trials, v–vii, 11, 36–38
- voluntary consent process, role of others, for international clinical trials, vi–vii, 42–45
- voluntary informed consent, ethical issues, 35
- voluntary participation and undue inducement for, involvement of community leaders, NBAC recommendations, vi, 44
- women's informed consent, role of husband in international clinical trials, vii, 45
- See also* Research
- Research regulations
- equal protection for participants in international research, provision of DHHS, explanation, xiii, 14, 85–89
- ethics review for protection of participants in international clinical trials, U.S. procedures, 81–85
- host country capacity for international research, variation in U.S./international guidelines for, 92, 93–94
- protection of participants in international clinical trials, challenges to host country review, 82
- protection of participants in international clinical trials, U.S./international policy/regulatory issues, 14
- protection of participants in international clinical trials, U.S. procedures for, 78–89
- See also* Research
- Respiratory Distress Syndrome (RDS)
- Latin America infants proposed study using placebo vs. established effective treatment, 25
- See also* Diseases and disorders
- Review bodies. *See* Ethics review and review committees; Institutional Review Boards (IRBs)
- Risk
- disclosure requirements for clinical trials, cultural barriers to, 38–39
- disclosure requirements for participants informed consent, in international clinical trials, v–vi, 37, 40
- minimization of, for participants in U.S. government-sponsored clinical trials, NBAC recommendations, iii, 6
- Roche, 73
- Rockefeller Foundation, 91
- See also* International Clinical Epidemiology Network (INCLEN)
- S**
- Safeguards. *See* Protections for human participants
- Salmonella* bacteria, 105
- Scandinavia
- international research activities of, 3
- Science and technology
- information, explanation for informed consent in international clinical trials, innovative methods, 40–42
- Seattle, Washington, 105
- Senegal
- literacy rates, summary, 41
- scientific/technical information explanation for research study, 41
- Single Project Assurances (SPAs), 79, 80
- criticisms of, for research in developing countries, 79–80
- See also* Assurances of compliance; Office for Human Research Protections (OHRP)
- Sommer, Alfred, 40–41
- South Africa
- AIDS vaccine development efforts, 105, 106
- Guidelines on Ethics for Medical Research*, 90, 93
- Medical Research Council, 105
- National Institute of Virology, 105
- post-trial benefits access for international research participants, guidelines for, 57
- protection of participants in international research, comparative analysis of documents concerning, 101
- UNAIDS prior agreement for post-trial benefits in, 108
- See also* University of Capetown
- SPAs. *See* Single Project Assurances (SPAs)

## Standards

- double, prior agreements for post-trial benefits in international research, and creation of, issues, 71–72
- health care, for participants in international clinical trials, explanation of, 9
- prevailing, prior agreements for post-trial benefits in international research, problems, 70–71
- protection of participants in international research, documents concerning, comparative analysis of, 100–101

Statistics. *See* Randomization

Struck, D., 108

Substantive standard of informed consent. *See* Informed consent

Sugarman, Jeremy, 38, 49

## Surveys and questionnaires

- biomedical researchers in developing countries and U.S., ethical issues for, 4, 20, 26, 27, 55, 56, 57, 64, 80, 82, 83, 85, 86, 89–90, 92

## Switzerland

- informed consent documentation requirements for international research, issues, 49–50

**T**

## Tanzania

- National Institute for Medical Research, 73

Targeted Genetics Corporation (TGC), 105

Technology. *See* Science and technology

## Testimony and speakers

- international clinical trials, protection of participants in, ethical concerns, 115
- See also* Public comments

TGC. *See* Targeted Genetics Corporation (TGC)

## Thailand

- AIDS Call to Action project in, 73
- AIDS vaccine research, prior agreements on post-trial benefits, 66, 106–108
- Bangkok, 107, 108
- Bangkok Metropolitan Association, 107
- female condom research, UNAIDS prior agreement for post-trial benefits, 108
- HIV perinatal transmission, placebo-controlled trials in, controversy, 1, 2
- Mahidol University, 107
- Ministry of Public Health, 107
- protection of participants in international research, documents concerning, comparative analysis of, 101
- Rule of the Medical Council on the Observance of Medical Ethics*, 93
- Senate, 108
- voluntary informed consent and international research ethics, 11, 35

## Therapeutic misconception

- minimization of, for participants in international clinical trials, vii–viii, 48

Translation. *See* Languages

Treatment. *See* Active treatment concurrent control; Health care

Trials. *See* Clinical trials

**U**

## Uganda

- AIDS vaccine development efforts, 105
- capacity building efforts for international research in, 91, 93
- Guidelines for the Conduct of Health Research Involving Human Subjects in Uganda*, 44, 49, 57, 62, 93
- informed consent documentation requirements, 49
- informed consent process involvement of others, new guidelines for, 44
- Ministry of Health, 91
- Ministry of Justice, 93
- National Council of Science and Technology, 93
- National Drug Authority, 93
- post-trial obligations to international research participants, guidelines for, 57, 70
- protection of international research participants, documents concerning, comparative analysis of, 101
- voluntary informed consent and ethics in international research, 11, 35

UN. *See* United Nations (UN)

UNAIDS. *See* Joint United Nations Programme on HIV/AIDS (UNAIDS)

Undue influence. *See* Coercion

## United Kingdom

- AIDS vaccine development funding for IAVI, 106
- Guidelines for Good Clinical Practice in Clinical Trials*, 93
- Interim Guidelines for Research Involving Human Participants in Developing Societies: Ethical Guidelines for MRC-Sponsored Studies*, 57, 93
- international clinical trials, ethics review for, 82
- international research activities of, 3
- Medical Research Council (MRC), 48, 57
- post-trial obligations to international research participants, guidelines for, 57, 70
- protection of international research participants, documents concerning, comparative analysis of, 101
- See also* London School of Hygiene and Tropical Medicine; University of Oxford

United Nations (UN), 103, 104

- See also* Joint United Nations Programme on HIV/AIDS (UNAIDS); United Nations Children's Fund; United Nations Population Fund

United Nations Children's Fund, 73

- See also* United Nations (UN)

United Nations Population Fund, 73

- See also* United Nations (UN)

United Nations Programme on HIV/AIDS. *See* Joint United Nations Programme on HIV/AIDS (UNAIDS)

*Universal Declaration of Human Rights*, 10

Universities

*See also* Cornell University; Johns Hopkins University; London School of Hygiene and Tropical Medicine; University of Capetown; University of Maryland; University of Nairobi; University of North Carolina; University of Oxford; Vanderbilt University

University of Capetown, 105

*See also* South Africa

University of Maryland

Biotechnology Institute, 91

University of Nairobi, 105

*See also* Kenya

University of North Carolina, 73

*See also* North Carolina

University of Oxford, 105

*See also* United Kingdom

USAID. *See* Agency for International Development (USAID)

U.S. Congress, 72

House of Representatives, 73

Senate, 73

U.S. government. *See* Federal government; Federal regulation; Public policy; U.S. Congress

U.S. Public Health Service Act. *See* Public Health Service Act

## V

Vaccines and vaccination

AIDS/HIV, development, and prior agreements on post-trial benefits, 66, 74

AIDS/HIV, development, IAVI prior agreements on post-trial benefits, 66, 74, 104–106

AIDS/HIV, development, VaxGen prior agreements on post-trial benefits, 66, 74, 106–108

AIDS/HIV, trials for, 30, 41

*Haemophilus influenzae* type b, trial for, 41

initiatives timeline 2000–2001, 72–73

Thailand AIDS/HIV vaccine research, prior agreements on post-trial benefits, 66, 106–108

*See also* Drugs and drug testing

Vanderbilt University, 41

VaxGen

international research, and prior agreements for post-trial benefits, 66, 74, 106–108

Thailand AIDS/HIV vaccine research, prior agreements on post-trial benefits, 66, 74, 106–108

Vietnam

alternative therapies disclosure requirements for clinical trials, cultural barriers to, 39–40

Voluntary consent. *See* Coercion; Informed consent

## W

Washington. *See* Seattle, Washington; Washington, D.C.

Washington, D.C., 84

*Washington Post*, 107

Wellcome Trust Research Laboratories, 73

White House, 72

WHO. *See* World Health Organization (WHO)

WMA. *See* World Medical Association (WMA)

Women

condom (female), international research on, prior agreement for, 108

informed consent for international clinical trials, role of husband, vii, 45

informed consent for international clinical trials, role of others in, cultural issues, 45

*See also* Maternity

World Bank, 72, 105

World Bank AIDS Trust Fund, 73

World Health Organization (WHO), 3, 73, 85, 107

Compound for Distribution in both Public and Private Sectors, 104

*Guidelines on Interaction with Commercial Enterprises*, 103

Memorandum of Understanding (MOU), 103–104

*Operational Guidelines for Ethics Committees That Review Biomedical Research*, 62, 70, 92

*Policy on Patents: Information Paper on WHO Patents Policy*, 103

post-trial benefits for international research, prior agreements for, 66, 74, 103–104

World Medical Assembly Declaration, 86

World Medical Association (WMA), 3, 8, 36, 56, 80

*See also* Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects

## Z

Zambia

international research, UNAIDS prior agreement for post-trial benefits in, 108

Zimbabwe

international research, UNAIDS prior agreement for post-trial benefits in, 108