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NEONATAL HIV TESTING: GOVERNMENTAL INSPECTION OF THE BABY FACTORY

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The opinions expressed in this article belong to the author alone and contrast with government agencies' views.

This article stems from the indignation of my classmate, friend and nurse midwife, Lisa Miller. The author is grateful for the comments and criticism of: Deborah Galen, Carol Heise, Loriann Stanislawski, and Christina Schneider. To all my patients at the Englewood Sexually Transmitted Disease clinic, this article is an elaborate apology for the HIV testing, without notice or consent, performed on the specimens obtained for serologic tests for syphilis. *See* Onorato, McCray, Pappaioanou, Johnson, Aral, Hardy and Dondero, *HIV Seroprevalence Surveys in Sexually Transmitted Disease Clinics*, 105 PUB. HEALTH REP. 119-124 (1990). This article is dedicated to the honesty and trust essential to the intimate relationship between patients and health care providers.

I. INTRODUCTION

In 1986, the government covertly began to examine newborn infants for the human immunodeficiency virus (HIV).[1] At first only the Massachusetts and New York state departments of health tested newborns for HIV without notice, without consent, and without specific legal authorizaton. Few people, outside of those reading medical journals, knew or know about the babies' HIV testing. The agencies never gave parents the results of the HIV testing, even when the test for HIV was positive.

Shorlty thereafter, the Centers for Disease Control (CDC), part of the Public Health Service (PHS), which is controlled by the United States Department of Health and Human Services (DHHS),

1. *HIV Antibody Prevalence Data Derived From Study of Massachusetts Infants*, 258 J. A.M.A. 171 (1987)(Massachusett's department of health began study of infants in December, 1986). Centers for Disease Control, *Report on National HIV Seroprevalence Surveys*, 39 MORBIDITY & MORTALITY WEEKLY REP. 884 (1990)("CDC collaborates with state and local health departments, other federal agencies, blood collection agencies, and medical research institutions to conduct human immunodeficiency virus ("HIV") seroprevalence surveys in a variety of sentinel populations"). *See also* Marwick, *HIV Antibody Prevalence Data Derived from Study of Massachusetts Infants*, 258 J. A.M.A. 2609, 2609-11 (1987); Centers for Disease Control, *Human Immunodeficiency Virus Infection in the United States: A Review of Current Knowledge*, 36 MORBIDITY & MORTALITY WEEKLY REP. 6, 7 (Supp. 6 1987). This is somewhat remarkable, considering the antibody test for HIV became available March 2, 1985. *See also* Dondero, Pappaioanou & Curran, *Monitoring the Levels and Trends of HIV Infection: The Public Health Service's HIV Surveillance Program*, 103 PUB. HEALTH REP. 213, 213-20 (1988); Centers for Disease Control, *Quarterly Report to the Domestic Policy Council on the Prevalence and Rate of Spread of HIV and AIDS in the United States*, 37 MORBIDITY & MORTALITY WEEKLY REP. 223, 223-26 (1988); Centers for Disease Control, *Quarterly Report to the Domestic Policy Council on the Prevalence and Rate of Spread of HIV and AIDS in the United States*, 37 MORBIDITY & MORTALITY WEEKLY REP. 551, 551-54, 559 (1988).

decided to copy these studies.[2] Thus, State and federal agencies now jointly intrude upon the family to assess the rate of HIV infection in reproductively active women.[3] An agency will test a newborn's blood; whether the infant blood specimen demonstrates antibodies to HIV depends on whether the mother is infected with HIV.[4] State laws which mandate newborn screening for other diseases provide parents with notice and an opportunity to refuse testing,[5] yet childbearing women are not given notice of this intrusion and have no opportunity to refuse HIV testing. And, there is no statute mandating HIV screening of newborns.

Since 1987,[6] in a cooperative venture between the PHS and state/territorial health departments,[7] newborn blood specimens have been analyzed for the presence of antibodies to HIV.[8] Blood

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2. Pappaioanou, George, Hannon, Gwinn, Dondero, Grady, Hoff, Willoughby, Wright, Novello & Curran, *HIV Seroprevalence Surveys of Childbearing Women — Objectives, Methods, and Uses of the Data*, 105 PUB. HEALTH REP. 147, 148 (1990).

3. *See generally* Pappaioanou, *supra* note 2, at 147-52; Dondero, *supra* note 1, at 213-20 (1988). *See also Centers for Disease Control, AIDS and Human Immunodeficiency Virus Infection in the United States: 1988 Update*, 38 MORBIDITY & MORTALITY WEEKLY REP. 24, 25 (Supp. 4 1989).

4. The antibody reaction from testing neonatal blood specimens reflects the mother's antibody status because of the transplacental transmission of maternal antibodies. As noted by the CDC:

> The prevalence of HIV infection among childbearing women was determined by anonymously testing blood for antibodies to HIV by the enzyme immunoassay (EIA) and Western blot methods. Blood samples were routinely collected from newborn infants for diagnosis of hereditary metabolic disorders. The prevalence of HIV antibody in these samples measures the prevalence of HIV infection among childbearing women because maternal antibody is transferred to the infants before birth, sample selection is relatively unbiased, and blood specimens are available for >90% of births.

Gayle, Selik & Chu, *Surveillance for AIDS and HIV Infection Among Black and Hispanic Children and Women of Childbearing Age, 1981-1989*, 39 MORBIDITY & MORTALITY WEEKLY REP. 23, 24 (Supp. 3 1990). Unfortunately, with the currently licensed tests maternal infection cannot be distinguished from infant infection. Andiman, *Virologic and Serologic Aspects of Human Immunodeficiency Virus Infection in Infants and Children*, 13 SEMINARS PERINATOLOGY 16, 21-22 (1989).

5. *See, e.g.*, CAL. HEALTH & SAFETY Code § 308 (West 1990); FLA. STAT. ANN. § 383.14(3) (West 1991); ILL. REV. STAT. ch. 111, paras. 4801, 4905 (1989); N.Y. PUBLIC HEALTH LAW § 2500-a(b) (McKinney 1991); TEX. HEALTH & SAFETY CODE ANN. §§ 33.001, 3.03, 34.002(e) (Vernon 1991).

6. For sources discussing the origin of governmental testing of newborns for HIV, see *supra* note 1.

7. Pappaioanou, *supra* note 2, at 148 ("[i]n 1987-88, the CDC, in collaboration with state and local health departments, developed and implemented the family of HIV seroprevalence surveys, a comprehensive, national, sentinel surveillance system for HIV."); Dondero, *supra* note 1, at 213-20; Centers for Disease Control, Announcement No. 901, Cooperative Agreements for Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Virus Syndrome (AIDS); Prevention and Surveillance Projects; Availability of Funds for Fiscal Year 1989, 53 Fed. Reg. 36492 (1988).

8. Pappaioanou, *supra* note 2, at 148.

specimens, initially obtained under the guise of legislatively mandated newborn screening tests,[9] are appropriated for nonmandated HIV testing. Almost all U.S. states and territories participate in the neonatal HIV serosurveillance program.[10] Infants from rural and urban areas, from affluent and poverty stricken families, are tested for HIV.[11] Somewhere between thirteen percent and thirty percent of infants born to HIV infected mothers become infected from in utero exposure to the maternal infection.[12] And, because the currently licensed HIV testing procedure relies on detecting the presence of antibodies to HIV,[13] any HIV antibodies from the infant blood specimen actually belong to the mother.[14] In contrast to other newborn screening tests which detect abnormalities in the infants, the neonatal HIV screening allows investigators to determine the mother's HIV status without directly removing her blood.

On a previous occasion, the PHS and a state health department collaborated in a serological study,[15] known as the Tuskegee Syphilis Study. This study serves as a monument of unethical medical investigation and experimentation on human subjects. Black men were serologically tested for syphilis to observe and record what happens to persons infected with Treponema pallidum, the causative agent of syphilis. Tragically, no one in the study received treatment, medical referral or counseling. The natural history of

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9. *See, e.g.*, CAL. HEALTH & SAFETY CODE §§ 304.1, 309 (West 1990); FLA. STAT. ANN. §§ 383.14, 383.31 (West 1991); ILL. REV. STAT. ch. 111, para. 4903 (1989); N.Y. PUBLIC HEALTH LAW § 2500-a (McKinney 1991); TEX. HEALTH & SAFETY CODE ANN. § 33.001 (Vernon 1991).

10. The government hopes to involve all fifty states soon. Dep't Health & Human Serv., *Dear Colleague Letter*, Jan. 1, 1991, at 3.

11. Pappaioanou, *supra* note 2, at 149; Hoff, Berardi, Weiblen, Mahoney-Trout, Mitchell & Grady, *Seroprevalence of Human Immunodeficiency Virus Among Childbearing Women: Estimation by Testing Samples of Blood from Newborns*, 318 NEW ENG. J. MED. 525, 526 (1988).

12. Blanche, Rouzioux, Moscato, Veber, Mayauz, Jacomet, Tricoire, Deville, Vial, Firtion, Crepy, Douard, Robin, Courpotin, Ciraru-Vigneron Deist & Griscelli, *A Prospective Study of Infants Born to Women Seropositive for Human Immunodeficiency Virus Type 1*, 320 NEW ENG. J. MED. 1643 (1989); EUROPEAN COLLABORATIVE STUDY, *Children Born to Women with HIV-1 Infection: Natural History and Risk of Transmission*, 337 LANCET 253 (1991) [hereinafter EUROPEAN COLLABORATIVE STUDY].

13. Hannon, Lewis, Jones & Powell, *A Quality Assurance Program for Human Immunodeficiency Virus Seropositivity Screening of Dried-Blood Spot Specimens*, 10 INFECTION CONTROL HOSP. EPIDEMIOLOGY 8 (1989).

14. Pyun, Ochs, Dufford & Wedgwood, *Perinatal Infection with Human Immunodeficiency Virus: Specific Antibody Responses by the Neonate*, 317 NEW ENG. J. MED. 611, 611-14 (1987). *See generally* Johnson, Nair, Hines, Seiden, Alger, Revie, O'Neil & Hebel, *Natural History and Serologic Diagnosis of Infants Born to Human Immunodeficiency Virus-Infected Women*, 143 AM. J. DISEASES CHILDREN 1147 (1989); Nicholas, Sondheimer, Willoughby, Yaffe & Katz, *Human Immunodeficiency Virus Infection in Childhood, Adolescence, and Pregnancy: A Status Report and National Research Agenda*, 83 PEDIATRICS 293, 295 (1989).

15. J. JONES, BAD BLOOD 1, 7 (1981).

syphilis, already well understood from earlier research, took its toll for forty years on the men in the study,[16] their sexual partners, and their families, before public outrage and claims of racism halted the observation.[17]

Now the same federal agency is observing the spread of HIV. Again, none of the human subjects in this medical investigation receive adequate notice or give fully informed consent to the serologic testing. Again, none of the human subjects whose serologic test is positive[18] receive treatment, medical referral or counseling. History is now repeating itself with the serologic investigation of HIV infection in reproductively active women.

HIV infection in reproductively active women is not an isolated event but rather is a disease of the family. Generally, the woman is the family's primary caretaker. Her infection leads to illness, incapacitation and death. As her state of health declines, so does her ability to care for her family. In addition, her infection may be accompanied by the newborn infant's infection, other children's infection, and probably a husband/lover's infection. As the mother becomes ill, then requires hospitalization and dies, her family suffers economic, emotional and developmental injury.

Additionally, HIV infection in infants is usually not an isolated event; more often, it too is a family illness. Physicians first recognized infant infection following the development of illness after transfusions during intensive care.[19] Now, perinatal infection is predominantly the result of vertical transmission[20] from an HIV-infected mother.[21] Identifying an infant with HIV usually leads to identifying a mother who is HIV-infected, and may also lead to

16. Shafer, Usilton & Gleeson, *Untreated Syphilis in the Male Negro: A Prospective Study of the Effect on Life Expectancy*, 69 PUB. HEALTH REP. 684 (1954); Rivers, Schuman, Simpson & Olansky, *Twenty Years of Followup Experience In a Long-Range Medical Study*, 68 PUB. HEALTH REP. 391 (1953); Heller & Bruyere, *Untreated Syphilis in the Male Negro: II. Mortality During 12 Years of Observation*, 27 J. VENEREAL DISEASE INFO. 34 (1946); Vonderlehr, Clark, Wenger & Heller, *Untreated Syphilis in the Male Negro: A Comparative Study of Treated and Untreated Cases*, 17 J. VENEREAL DISEASE INFO. 260 (1936).

17. Brandt, *Racism, Research and the Tuskegee Syphilis Study*, 8 HASTINGS CENTER REP. 21 (1978).

18. These individuals are referred to as seropositives.

19. Centers for Disease Control, *Unexplained Immunodeficiency and Opportunistic Infections in Infants — New York, New Jersey, California*, 31 MORBIDITY & MORTALITY WEEKLY REP. 665, 665-67 (1982); Ammann, Cowan, Wara, Weintrub, Dritz, Goldman & Perkins, *Acquired Immunodeficiency Syndrome in an Infant: Possible Transmission by Means of Blood Product Administration*, 1 LANCET 956, 956-58 (1983).

20. Vertical transmission refers to the spread of a disease from mother to child through breast feeding, the birthing process, or transplacental transmission. Horizontal transmission refers to the spread between individuals through shared high risk activities.

21. Centers for Disease Control, HIV/AIDS SURVEILLANCE REP. 8, 8-9 (Feb. 1991); Rogers, Thomas, Starcher, Noa, Bush & Jaffe, *Acquired Immu-*

identifying other family members with the disease. Everyone with HIV will become ill and die (unless some other supervening catastrophe occurs). Children suffer and die or, if they are uninfected, experience the suffering of family members, and ultimately face orphanhood. The United Nations World Health Organization estimates that, by the year 2000, there will be ten million infants and children infected with HIV and ten million others who will be left orphaned from parental infection.[22] HIV devastates families.

The rising number of HIV-infected women[23] and children[24] concern the medical community,[25] public health agencies,[26] and the legal community as well.[27] Whether physicians should screen preg-

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nodeficiency Syndrome in Children: Report of the Centers for Disease Control National Surveillance, 1982-1985, 79 PEDIATRICS 1008, 1008-14 (1987).

22. *Pediatric AIDS Now Considered a Global Threat, Millions Expected to Become Orphans*, 27(4) UN MONTHLY CHRON. 69 (1990).

23. The CDC tallied more than 15,000 cases and noted a disproportionate amount of women belonging to racial and ethnic minority groups. Centers for Disease Control, *AIDS in Women — United States*, 39 MORBIDITY & MORTALITY WEEKLY REP. 845, 845-46 (1990). Current reporting misses cases of asymptomatic HIV infection so that the quoted numbers underestimate the actual extent of HIV infection in reproductively active women. *See generally*, Centers for Disease Control, *HIV Infection Reporting - United States*, 38 MORBIDITY & MORTALITY WEEKLY REP. 496, 496-99 (1989).

24. *See Global Pediatric AIDS Estimates at 10 Million by Year 2000*, 2 PAACNOTES 232, 259 (1990)(summary of World Health Organization analysis); FINAL REPORT OF THE SECRETARY'S WORK GROUP ON PEDIATRIC HIV INFECTION AND DISEASE, Dep't Heath & Human Serv. (Nov. 18, 1988).

25. INSTITUTE OF MEDICINE, HIV SCREENING OF PREGNANT WOMEN AND NEWBORNS, (Leslie M. Hardy ed. 1991); Working Group on HIV Testing of Pregnant Women and Newborns, *HIV Infection, Pregnant Women, and Newborns: A Policy Proposal for Information and Testing*, 264 J. A.M.A. 2416, 2416-20 (1990) ("Infants born to HIV-infected women present a growing concern for the medical community."). *See also* AMERICAN MEDICAL ASSOCIATION, HIV POLICY FOR THE 90'S, REPORT OF THE BOARD OF TRUSTEES (REPORT X: AMA HIV UPDATE) 11 (1989).

26. NATIONAL INSTITUTE OF HEALTH, THE NEW FACE OF AIDS: A MATERNAL AND PEDIATRIC EPIDEMIC, U.S. DEP'T HEALTH & HUMAN SERV. (June 1990); PEDIATRIC, ADOLESCENT AND MATERNAL AIDS BRANCH, CENTER FOR RESEARCH FOR MOTHERS AND CHILDREN, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT, REPORT TO THE NATIONAL ADVISORY CHILD HEALTH AND HUMAN DEVELOPMENT COUNCIL, (June 1990); Samuels, Mann & Koop, *Containing the Spread of HIV Infection: a World Health Priority*, 103 PUB. HEALTH REP. 221 (1988); Bowen, *In Pursuit of the Number One Public Health Problem*, 103 PUB. HEALTH REP. 211 (1988).

27. Isaacman, *Are We Outlawing Motherhood for HIV-Infected Women*, 22 LOY. U. CHI. L.J. 479 (1991); Closen, *A Call for Mandatory Testing and Restriction of Certain Health Care Professionals*, 9 ST. LOUIS U. PUB. L. REV. 421 (1990); Isaacman, *The Other Side of the Coin: HIV-Infected Health Care Workers*, 9 ST. LOUIS U. PUB. L. REV. 439 (1990); American Bar Association, *Policy and Report on AIDS*, 21 U. TOL. L. REV. 9 (1989); Gostin, *The Politics of AIDS: Compulsory State Powers, Public Health, and Civil Liberties*, 49 OHIO ST. L.J. 1017 (1989); Parmet, *The Police Power and AIDS: The Limits of Legal Precedent*, 11 J.H.H.R.A. 444-57 (1989); Holzhauer, *AIDS Testing in the Health Care Setting*, 4 ISSUES LAW & MED. 345 (1988); Spece, *AIDS: Due Process, Equal Protection, and the Right to Treatment*, 4 ISSUES LAW & MED. 283 (1988); Sullivan

nant women for HIV infection is a topic of current public health debate.[28] The debate concerns whether newborn screening should be mandatory,[29] voluntary but with specific informed consent,[30] or simply voluntary.[31] Numerous scholarly papers discuss testing in the medical literature,[32] and professional associations' position statements may herald legislative recommendations.[33] In addition, several groups advocate HIV counseling and testing as part of routine health care.[34] What these statements and articles fail to debate

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& Field, *AIDS and the Coercive Power of the State*, 23 HARV. C.R.-C.L. L. REV. 139 (1988); Comment, *The Constitutional Implications of Mandatory AIDS Testing in the Health Care Industry*, 17 SW. U.L. REV. 787 (1988); Merritt, *Communicable Disease and Constitutional Law: Controlling AIDS*, 61 N.Y.U. L. REV. 739 (1986); Closen, Connor, Kaufman & Wojcik, *AIDS: Testing Democracy - Irrational Responses to the Public Health Crisis and the Need for Privacy in Serologic Testing*, 19 J. MARSHALL L. REV. 835 (1986).

28. *See* Thomas, *AMA Endorsed Involuntary HIV Testing — Or Did It?*, 32 MED. WORLD NEWS 41 (1991); U.S. Preventive Services Task Force, *Screening for HIV*, 40 AM. FAM. PRAC. 123-29 (1989); Shere, *Physician Use of the HIV Antibody Test: The Need for Consent, Counseling, Confidentiality, and Caution*, 259 J. A.M.A. 264, 265 (1988)(perils of misuse of HIV testing); Task Force on Pediatric AIDS, *Perinatal Human Immunodeficiency Virus Infection*, 82 PEDIATRICS 941-43 (1988)(serologic testing should be offered to pregnant women at increased risk for HIV infection).

29. Mandatory screening means that all individuals within a defined population are tested without an opportunity for refusal. INSTITUTE OF MEDICINE, HIV SCREENING OF PREGNANT WOMEN AND NEWBORNS 23 (Leslie M. Hardy ed. 1991) [hereinafter "*HIV Screening of Pregnant Women*").

30. Voluntary screening with right of refusal means that each individual within a defined population is informed that the test will be performed unless he or she explicitly refuses. *Id.*

31. Voluntary screening with specific informed consent means that each individual within a defined population is informed that the test is available but that it will be performed only with a person's specific informed consent. *Id.*

32. Bayer, *Perinatal Transmission of HIV Infection: The Ethics of Prevention*, 32 CLINICAL OBSTETRICS & GYNECOLOGY 497-505 (1989); Bayer & Levine, *The Ethics of Screening for Early Intervention in HIV Disease*, 79 AM. J. PUB. HEALTH 1661-67 (1989); Gostin, *Public Health Strategies for Confronting AIDS*, 261 J. A.M.A. 1621 (1989); Listernick, *The Case Against Mandatory Prenatal Testing for HIV*, 32 CLINICAL OBSTETRICS & GYNECOLOGY 506-15 (1989); Rhame & Maki, *The Case for Wider Testing for HIV Infection*, 320 NEW ENG. J. MED. 1248 (1989); Cates & Handsfield, *HIV Counseling and Testing: Does it Work?*, 78 AM. J. PUB. HEALTH 1533 (1988); Bayer, Levine & Wolf, *HIV Antibody Screening: An Ethical Framework for Evaluating Proposed Programs*, 256 J. A.M.A. 1768-74 (1986).

33. *See, e.g.*, R.I. GEN. LAWS § 23-6-14(a) (1989).

34. *HIV Screening of Pregnant Women*, *supra* note 29, at 23 (the committee recommends voluntary HIV screening (with specific informed consent) for all pregnant women in high prevelance areas); Working Group on HIV Testing of Pregnant Women and Newborns, *HIV Infection, Pregnant Women, and Newborns: A Policy Proposal for Information and Testing*, 264 J. A.M.A. 2416 (1990)("[w]e advocate a policy of informing all pregnant women and newborn mothers about the epidemic of HIV infection and the availability of testing"); AMA Policy Compendium 11 (1990)((22b) continues to support voluntary, routine HIV antibody testing of the newborn in areas with a high prevalence of HIV infection, and encourages that confidentiality of test results be strictly observed; (22c) supports mandatory HIV testing of all newborns in high preva-

is the legitimacy of the ongoing newborn screening program — the neonatal HIV surveillance program engineered by the CDC.[35]

The neonatal HIV serosurveillance program represents the systematic collection of information from mothers[36] and their infants[37] to further scientists' knowledge and understanding of HIV infection.[38] However, what does this medical research[39] using human subjects[40] without voluntary assent do for the women and infants? This article examines the neonatal HIV serosurveillance program, reviews the rationale behind the study, and articulates objections to

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lence areas when treatment modalities with proven benefits for infected neonates are available); Report of the Board of Trustees, Report Q (A-89), Neonatal HIV Antibody Screening, American Medical Association (1989); Committee on Infectious Diseases, Report of the Committee on Infectious Diseases, American Academy of Pediatrics 94 (21st ed. 1988)("The use of special consent procedures for the diagnosis of HIV infection in infants and children is strongly discouraged") (bold emphasis in the original]; ACOG Technical Bulletin No. 123 (Dec. 1988)("Testing and counseling are recommended in any medical setting in which women at risk are encountered, including clinics offering services for gynecologic and prenatal care, family planning, and diagnosis and treatment of sexually transmitted diseases").

35. *See supra* notes 2-5 and accompanying text for an historical account of the CDC's neonatal HIV surveillance program.

36. The information from mothers includes "demographic or residential information or hospital geographic location or both." Pappaioanou, *supra* note 2, at 149.

37. The data which accompanies the specimen includes: the infant's name, hospital name, hospital record number, date of birth, sex, multiple or single gestation, prematurity, weight, geographical location, and whether the mother is on public aid. *See* Appendix. According to the CDC, personal identifiers are later removed. Pappaioanou, *supra* note 2, at 149; Dondero, *supra* note 1, at 215.

38. This conduct falls within the statutory definition of research using human subjects. 45 C.F.R. §§ 46.102(e) and (f) (1989).

39. The Federal Regulations state:

> 'Research' means a systematic investigation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute 'research' for purposes of these regulations, whether or not they are supported or funded under a program which is considered research for other purposes.

45 C.F.R. § 46.102(e)(1989).

40. The Federal Regulations state:

> 'Human subject' means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. 'Intervention' includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. 'Interaction' includes communication or interpersonal contact between investigator and subject. 'Private information' includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonable expect will not be made public.

45 C.F.R. § 46.102(f)(1989).

testing newborn infants without notice, without consent,[41] and without legislative mandate. The impact of the neonatal HIV serosurveillance study and the risks to HIV-infected families become clearer after first reviewing some basic facts about HIV disease.

1. Medical Principles

HIV is the internationally accepted name[42] for the causative agent of Acquired Immunodeficiency Disease Syndrome (AIDS).[43] The hallmark of HIV infection is a progressive decline in the immune function. When the decline results in the abnormal functioning of the immune system and the HIV-infected person develops symptoms of illness, the person meets the World Health Organization (WHO) and CDC definition for AIDS.[44]

The virus usually spreads from person-to-person through the exchange of blood, semen, and vaginal secretions.[45] An HIV-infected individual who engages in certain types of sexual contact[46] or shares unsterile needles,[47] may thereby expose another uninfected individual to the virus. Some individuals become infected after one at-risk exposure, others do not.[48]

When an exposed individual becomes infected with HIV, symp-

41. The law appears to require informed consent. As the regulations state: "[N]o investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative." 45 C.F.R. § 46.116 (1989).

42. *Human Immunodeficiency Viruses*, 232 SCIENCE 697 (1986).

43. Montagnier, *Lymphadenopathy-Associated Virus: From Molecular Biology to Pathogenicity*, 103 ANNALS INTERNAL MED. 689-93 (1985); Francis, Jaffe, Fultz, Getchell, McDougal & Feorino, *The Natural History of Infection with the Lymphadenopathy-Associated Virus Human T-Lymphotropic Virus Type III*, 103 ANNALS INTERNAL MED. 719-22 (1985); Levy, Kaminsky, Morrow, Steimer, Luciw, Dina, Hoxie & Oshiro, *Infection by the Retrovirus Associated with the Acquired Immunodeficiency Syndrome*, 103 ANNALS INTERNAL MED. 694-99 (1985).

44. Centers for Disease Control, *Revision of the CDC Surveillance Case Definition for Acquired Immunodeficiency Syndrome*, 36 MORBIDITY & MORTALITY WEEKLY REP. 3-15 (Supp. 1S 1987).

45. *See generally* M. CLOSEN, D. HERMANN, P. HORNE, S. ISAACMAN, R. JARVIS, A. LEONARD, R. RIVERA, M. SCHERZER, G. SCHULTZ & M. WOJCIK, AIDS: CASES AND MATERIALS 111-34 (1989) [hereinafter AIDS: CASES AND MATERIALS]; Friedland, Kahl, Saltzman, Rogers, Feiner, Mayers, Schable & Klien, *Additional Evidence for Lack of Transmission of HIV Infection by Close Personal (Casual) Contact*, 4 AIDS 639-44 (1990).

46. This includes any sexual conduct whereby an uninfected individual is exposed to the blood, semen, or vaginal secretions of the HIV-infected individual. Common examples are oral-genital, genito-genital, or ano-genital intercourse.

47. The needle must be unsterile because of prior use by an HIV-infected individual for this to apply.

48. Osmond, *Heterosexual Transmission of HIV*, in P. COHEN, M. SANDE & P. VOLBERDING, THE AIDS KNOWLEDGE BASE 1.2.4-3 (1990).

toms of illness may appear in as little as two to three weeks[49] or as late as several years.[50] Studies demonstrate the inevitable progression from asymptomatic HIV infection to AIDS.[51] Because HIV infection eventually progresses from asymptomatic HIV infection to AIDS, a new term — HIV disease — better reflects the underlying pathology and more accurately describes the medical disorder.[52]

HIV disease targets entire families. Infected mothers are the index source for vertical transmission of HIV. These women must simultaneously cope with raising a child (or children) while dying of an incurable disease. Sometimes these women bear an added emotional burden of guilt from infecting their babies with HIV. Inevitably, these women cannot physically or emotionally provide the care their families need.

Children of HIV-infected women comprise a growing population of orphans.[53] The tragedies posed to infected children have often appeared in the press.[54] Uninfected children of HIV-infected mothers also face burdens. These children, if they have a family to begin with, witness the deterioration and destruction of their fam-

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49. Cooper, Gold, Maclean, Donovan, Finlayson, Barnes, Michelmore, Brooke & Penny, *Acute AIDS Retrovirus Infection : Definition of a Clinical Illness Associated with Seroconversion*, 1 LANCET 537, 537-40 (1985).

50. Schecter, Craib, Montaner, Maynard, Broughton, Voight & O'Shaughnessy, *The Modeling of Progression to AIDS: Is It Wise to Combine Different AIDS Manifestations?* Sixth International Conference on AIDS Th.C.622 (June 21, 1990); Hessol, Byers, Lifson, O'Malley, Cannon, Buchbinder, Harrison & Rutherford, *Relationship Between AIDS Latency Period and Survival Time*, Sixth International Conference on AIDS Th.C.621 (June 21, 1990).

51. Chaission & Volberding, *Clinical Manifestations of HIV Infection* in G. MANDELL, R. DOUGLAS & J. BENNETT, PRINCIPLES AND PRACTICE OF INFECTIOUS DISEASES 1059, 1062 (3d ed. 1990).

52. REPORT OF THE PRESIDENTIAL COMMISSION ON THE HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC xvii (June 24, 1988)("The term 'AIDS' is obsolete"). In addition, according to the Institute of Medicine:

> Today, with a better understanding of the natural history of HIV infection and with more precise laboratory assessments of disease progression, the committee believes that the term ARC is no longer useful, either from a clinical or public health perspective, and that HIV infection itself should be considered a disease. It is more accurate to describe HIV infection as a continuum of conditions.

INSTITUTE OF MEDICINE, CONFRONTING AIDS: UPDATE 1988 37 (1988).

53. Doan-Johnson & McGinley, *Filling the Void: Boarder Babies and the Nurses Who Love Them*, 20 NURSING 90 44 (1990); Dept. of Health & Human Serv., Final Report of the Secretary's Work Group on Pediatric HIV Infection and Disease 7-8 (Nov. 18, 1988). *See supra* note 22 and accompanying text for statistics regarding the number of potential orphaned children by the year 2000, due to the HIV disease.

54. Gorman, *Plague of the Innocents*, TIME, Jan. 25, 1988, at 59; Seligman, *Babies Born with AIDS: In Its Youngest Victims, the Heartbreaking Disease Takes a Unique Form*, NEWSWEEK, Sept. 22, 1986, at 70; Rudinger, Crocker & Cohen, *The Dilemmas of Childhood HIV Infection*, 19 CHILDREN TODAY 26-29 (July-Aug. 1990); *AIDS Young Victims*, U.S. NEWS & WORLD REPORT, July 3, 1989, at 62.

ily. These children often must cope with the loss of siblings and the loss of parents as HIV disease reaches its ultimate conclusion: death. Extended family members are not spared from the horrors of this disease either. Anyone who provides physical and emotional support to infected families experiences tragedy.

Not all the news about HIV disease is bad. First, not all infants born to HIV-infected mothers develop HIV infection.[55] In the USA, approximately one-third of newborns born to HIV infected mothers become HIV infected.[56] Second, health providers can offer more than education and counseling to persons with HIV. While there is no cure for HIV infection, therapy can combat HIV[57] and improve both the length and quality of life for those with HIV disease.[58] Early intervention delays progression of HIV disease.[59] Dramatic achievements have been made in the management and therapy of infections which plague persons with HIV disease.[60] Improvements in therapeutic management have benefitted women[61] and chil-

55. Recent research suggests only 13% of infants born to HIV infected mothers develop HIV disease. EUROPEAN COLLABORATIVE STUDY, at 253.

56. Blanche, *supra* note 12, at 1643-48; Johnson, *supra* note 14, at 1147; Nicholas, *supra* note 14, at 295. *See also* Peckham & Newell, *HIV-1 Infection in Mothers and Babies*, 2 AIDS CARE 205, 205-11 (1990). In Africa the rates are higher than in the USA. The differences in transmission rates between Europe, USA, and Africa probably stem from the respective health of the populations within those continents. Overall infant mortality rates demonstrate the disparity in health. Europeans fare better than Americans (ranked 24th globally) and African countries fare worse than the USA.

57. American Foundation for AIDS Research, 4 AIDS/HIV Treatment Directory (Dec. 1990).

58. Lemp, Payne, Neal, Temelso & Rutherford, *Survival Trends for Patients with AIDS*, 263 J. A.M.A. 402, 402-06 (1990); Altman, *Experts on AIDS, Citing New Data Push for Testing Gains in Treatment Seen, Doctors Say Earlier Diagnosis Can Prolong Some Lives and Relieve Suffering*, N.Y. Times, Apr. 24, 1989, §A, at 1, col. 1.

59. AIDS Clinical Trials Group of the National Institute of Allergy and Infectious Diseases, *Zidovudine in Asymptomatic Human Immunodeficiency Virus Infection*, 322 NEW ENG. J. MED. 941, 941-49 (1990); Fischl, Richman, Hansen, Collier, Carey, Para, Hardy, Dolin, Powderly, Allan, Wong, Merigan, McAuliffe, Hyslop, Rhame, Balfour Jr., Spector, Volberding, Pettinelli & Anderson, *The Safety and Efficacy of Zidovudine (AZT) in the Treatment of Subjects with Mildly Symptomatic Human Immunodeficiency Virus Type 1 (HIV) Infection*, 112 ANNALS INTERNAL MED. 727, 727-37 (1990).

60. Centers for Disease Control, *Guide for Prophylaxis Against Pneumocystis carinii Pneumonia for Persons Infected with Human Immunodeficiency Virus*, 38 MORBIDITY & MORTALITY WEEKLY REP. 1, 1-9 (Supp. 5 1989); Viscarello, *AIDS: Natural History and Prognosis*, 17 OBSTETRICS GYNECOLOGY CLINICS N. AM. 545, 545-55 (1990); Lemp, Payne, Neal, Temelso & Rutherford, *Survival Trends for Patients with AIDS*, 263 J. A.M.A. 402, 402-06 (1990).

61. Gloeb, Efantis & O'Sullivan, *Longitudinal Evaluation of Human Immunodeficiency Virus Infection in Pregnant Women*, 164 AM. J. OBSTETRICS & GYNECOLOGY 248 (1991); Minkoff & Moreno, *Drug Prophylaxis for Human Immunodeficiency Virus-Infected Pregnant Women: Ethical Considerations*, 163 AM. J. OBSTETRICS & GYNECOLOGY 1111, 1111-14 (1990); Viscarello, DeGennaro & Hobbins, *Preliminary Experience with the Use of Zidovudine (AZT) During Pregnancy*, 164 AM. J. OBSTETRICS & GYNECOLOGY 248 (1991).

dren.[62] Finally, special care with immunizations,[63] immunoglobulins,[64] and ambulatory management[65] improves or maintains the health of affected children.

The good news must be tempered with a caveat. HIV infection in infancy rapidly progresses to severe immunodeficiency, making early diagnosis crucial.[66]

2. *Neonatal HIV Serosurveillance*

The neonatal HIV serosurveillance program is one of several[67] ongoing HIV research[68] studies conducted by government health of-

62. *See* National Institute of Child Health and Human Development, AIDS Clinical Trials Alert, Results of the NICHD Clinical Trial of the Efficacy of Intravenous Immunoglobulin (IVIG) for the Prophylaxis of Serious Bacterial Infections in Symptomatic HIV-Infected Children (Jan. 16, 1991); Pizzo, Butler, Balis, Brouwers, Hawkins, Eddy, Einloth, Falloon, Husson, Jarosinski, Meer, Moss, Poplack, Santacroce, Wiener & Wolters, *"Dideoxycytidine Alone and in an Alternating Schedule with Zidovudine in Children with Symptomatic Human Immunodeficiency Virus Infection*, 117 J. PEDIATRICS 799, 799-08 (1990); Working Group on PCP Prophylaxis in Children, *Guidelines for Prophylaxis Against Pneumocystis carinii Pneumonia For Children Infected With Human Immunodeficiency Virus*, 40 MORBIDITY & MORTALITY WEEKLY REP. 1, 1-13 (RR-2 1991); U.S. Dep't Health and Human Serv., HHS News, Release No. P90-28 (May 3, 1990)(HHS Secretary Sullivan announced FDA approval of AZT to treat children, following culmination of the pediatric trials of AZT started in 1986); *HIV Babies Need Pneumonia Protection*, 138 SCIENCE NEWS, Sept 1, 1990, at 141.

63. American Academy of Pediatrics, Report of the Committee on Infectious Diseases, 94, 94-98 (21st ed 1988); *Immunization Practices Advisory Committee, General Recommendations on Immunization*, 38 MORBIDITY & MORTALITY WEEKLY REP. 205, 205-27 (1989); Centers for Disease Control, *Immunization of Children Infected with Human Immunodeficiency Virus - Supplementary ACIP Statement*, 37 MORBIDITY & MORTALITY WEEKLY REP. 181, 181-83 (1988); Joint WHO/UNICEF Statement on Early Immunization for HIV-Infected Children, 64 WEEKLY EPIDEMIOLOGIC RECORD 48, 48-49 (1989); Joint WHO/UNICEF Statement on Early Immunization for HIV-Infected Children, 62 WEEKLY EPIDEMIOLOGIC RECORD 297, 297-99 (1987).

64. *See* National Institute of Child Health and Human Development, AIDS Clinical Trials Alert, Results of the NICHD Clinical Trial of the Efficacy of Intravenous Immunoglobulin (IVIG) for the Prophylaxis of Serious Bacterial Infections in Symptomatic HIV-Infected Children (Jan. 16, 1991).

65. Ambulatory management refers to well child care and the care of problems not requiring hospitalization. *See, e.g.*, Mendez, *Ambulatory Care of Infants and Children Born to HIV-Infected Mothers*, 19 PEDIATRIC ANNALS 439 (1990)(recommending that special clinics be established where children and their families may be treated).

66. EUROPEAN COLLABORATIVE STUDY, *supra* note 12, at 258; Blanche, *supra* note 12, at 1647.

67. Pappaioanou, Donder, Peterson, Onorato, Sanchez & Curran, *The Family of HIV Seroprevalence Surveys: Objectives, Methods, and Uses of Sentinel Surveillance for HIV in the United States*, 105 PUB. HEALTH REP. 113, 113-19 (1990)[hereinafter Pappaioanou, *The Family of HIV Seroprevalence Surveys*]; Pappaioanou, *supra* note 2, at 152.

68. *See* 45 C.F.R. § 46.102(e)(1989)(defining "research").

ficials and involving human subjects.[69] Regardless of the family's income, color, or geographical location, nearly all live births from nearly all states are included in this study to determine the number of HIV-infected reproductively active women. In essence, health officials are examining the serostatus[70] of the nuclear family.[71]

At the outset, it must be clear that this medical research project is nontherapeutic.[72] No one receives any information regarding his or her infective status. No one receives any referral for medical treatment. The experiment simply compiles and analyzes data to determine the rate of HIV infection in reproductively active women.[73]

The term "neonatal" means within the newborn period, an arbitrary time interval that includes the first three months of life. "HIV" refers to the human immunodeficiency virus. "Serosurveillance" is a neologism from the components serum and surveillance. "Serum" refers to the fluid portion of the blood which remains after removal of the fibrin clot and blood cells.[74] "Surveillance" means to: (1) inspect; (2) watch or observe a person under suspicion.[75] Hence the title of this article, *Governmental Inspection of the Baby Factory*, accurately reflects the agent of this policy, and the policy itself.

The current program must be distinguished from legitimate testing and screening programs. Testing programs, in colloquial medical usage, are individually tailored examinations.[76] Screening programs, in colloquial medical usage, are general or subpopulation examinations.[77] Surveillance programs may not be new to law enforcement agencies, but they are new in modern medicine.[78] Both

69. *See* 45 C.F.R. § 46.102(f)(1989)(defining "human subject").

70. Serostatus refers to the reactivity, positive or negative, of blood (serum). A person whose blood test is positive for antibodies to HIV is HIV seropositive.

71. The nuclear family refers to the father, mother and children. In this article, the nuclear family refers to the simplest family unit — the mother and child(ren).

72. No one receives any therapy to allay, improve, or cure their condition.

73. Pappaioanou, *supra* note 2, at 149.

74. STEDMAN'S MEDICAL DICTIONARY 1276 (23rd ed. 1976).

75. WEBSTER'S UNABRIDGED DICTIONARY 1837 (2nd ed. 1983). The CDC defines surveillance as: "(a) gathering high-quality interpretable data on the occurrence of diseases or infections, and (b) analyzing and using those data to target and evaluate public health interventions, such as health education, HIV-antibody testing, and counseling." Dondero, *supra* note 1, at 214.

76. An example of this practice is the diagnostic use of a chest x-ray on a patient after the physician detects abnormal breath sounds through auscultaion.

77. The most familiar examples are testing African-Americans for the sickle cell trait and testing Jewish people for the Tay-Sachs trait.

78. Surveillance programs using human subjects are novel, in contrast to surveillance programs involving hospital equipment and environmental sampling to determine the adequacy of sterilization procedures.

testing and screening programs provide notice to the human subjects and may require prior consent, depending on whether screening is legislatively mandated or voluntary. Examples of legislatively mandated screening programs[79] are programs testing for phenylketonuria[80] (PKU) and syphilis;[81] examples of voluntary screening programs are programs involving blood pressure and cholesterol examinations.

Screening programs serve four major purposes. First, screening identifies asymptomatic individuals so that the disease can be treated or prevented. Second, screening provides an added opportunity for individual counseling about conduct.[82] Third, screening provides a population base for enrollment into treatment. Fourth, screening provides data for scientific studies.[83]

Metabolic screening tests on newborn infants typify legislatively mandated screening programs. Towards the end of the first week of the baby's life, medical personnel remove blood from a newborn infant, usually through a procedure referred to as a "heelstick". At no cost to the parents, the blood is analyzed in a specialized laboratory. All abnormal results are promptly reported to the parents along with a referral to centers specializing in caring for infants with metabolic abnormalities. At these medical centers, parents receive counseling and education regarding the metabolic abnormality. The child, with parental consent, receives therapy once the diagnosis is confirmed. The respective states tally the numbers and thereby provide data for determining disease rates.[84]

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79. L. ANDREWS, STATE LAWS AND REGULATIONS GOVERNING NEWBORN SCREENING (1985).

80. Phenylketonuria is an inherited genetic disorder of metabolism involving the breakdown of phenylalanine to tyrosine. Untreated children show progressive deterioration of mental ability, and seizures, skin disorders and a particular odor. The overall incidence is approximately 100 per million livebirths. Scriver, Kaufman & Woo, *The Hyperphenylalaninemias*, in THE METABOLIC BASIS OF INHERITED DISEASE 495 (C. Scriver, A. Beaudet, W. Sly & D. Valle 6th ed. 1990).

81. *See* AIDS: CASES AND MATERIALS *supra* note 45, at 30-33. The CDC recorded over 45,000 reported cases of syphilis in the civilian population during 1989. *See* Centers for Disease Control, *Summary of Notifiable Diseases*, 38 MORBIDITY & MORTALITY WEEKLY REP. 3 (1989).

For examples of screening statutes, see CAL. HEALTH & SAFETY CODE § 3222 (West 1990); FLA. STAT. ANN. § 384.31 (West 1991); ILL. REV. STAT. ch. 111, para. 4801 (1989); N.Y. PUBLIC HEALTH LAW § 2308-a (McKinney 1985).

82. In the context of HIV infection, this counseling would cover family planning decisions, sexual conduct, and intravenous needle sharing practices.

83. In the context of HIV infection, this information would include demographic statistics and natural history studies.

84. Rates are commonly expressed in terms of prevalence or incidence. The following definitions apply:

> Prevalence is the level of infection in a given population at a particular time. It is usually expressed as a rate, such as percent of the population infected or number of infected persons per 1,000 or 10,000 persons in the

The neonatal HIV surveillance program does not fulfill the purposes of a screening program. The neonatal HIV surveillance program removes[85] personal identifiers and thereby fails to identify asymptomatic persons to treat or prevent HIV infection in such individuals. Since the neonatal HIV surveillance program removes personal identifiers, the program also fails to provide HIV-infected mothers with referrals to medical therapy and social services. This ignores the current medical capability to improve the quality and quantity of life of HIV-infected individuals by early initiation of medical therapy.[86] Furthermore, the neonatal HIV surveillance program is performed without notice to mothers. Finally, there is no individual counseling about conduct. Nothing is done to discourage an infected individual from engaging in activities which spread HIV. Thus, the sole screening purpose served by the current neonatal HIV surveillance programs is to merely provide data for tabulating disease demographics.

Defining the words and describing the procedures employed only begins to detail the mechanics of this PHS project operated by an agency branch, the CDC. The serosurveillance program does not

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population. This statistic requires only that the number of infected and noninfected persons be determined in a given population, or an appropriate sample of that population, on one occasion. Incidence is the rate of new infection occurring in a given population during a given period and is typically expressed as the percent of susceptibles becoming infected per year or the number of new infections per 1,000 or 10,000 persons per year. Incidence is difficult to measure; it requires that the same persons be tested on more than one occasion, which is logistically complex and introduces potentially serious self-selection bias.

Dondero, *supra* note 1, at 213.

85. In the medical literature, the removal of patient identifiers is referred to as 'unlinking'.

86. American Foundation for AIDS Research, AIDS/HIV Treatment Directory (Dec. 1990); Gloeb, Lai, Efantis & O'Sullivan, *Longitudinal Evaluation of Human Immunodeficiency Virus Infection in Pregnant Women*, 164 AM. J. OBSTETRICS & GYNECOLOGY 248 (Supp. 1991); Nat'l Institute of Child Health and Human Dev., AIDS Clinical Trials Alert, Results of the NICHD Clinical Trial of the Efficacy of Intravenous Immunoglobulin (IVIG) for the Prophylaxis of Serious Bacterial Infections in Symptomatic HIV-Infected Children (Jan. 16, 1991); Settlage, *AIDS in Obstetrics: Diagnosis, Course, and Prognosis*, 32 CLINICAL OBSTETRICS & GYNECOLOGY 437, 442 (1989); Viscarello, DeGennaro & Hobbins, *Preliminary Experience with the Use of Zidovudine (AZT) During Pregnancy*, 162 AM. J. OBSTETRICS & GYNECOLOGY 248 (Supp. 1991); Volberding, Lagakos, Koch, Pettinelli, Myers, Booth, Balfour, Reichman, Bartlett, Hirsch, Murphy, Hardy, Soeiro, Fischl, Bartlett, Merigon, Hyslop, Richman, Valentine, Corey, and the AIDS Clinical Trials Group of the National Institute of Allergy and Infectious Diseases, *Zidovudine in Asymptomatic Human Immunodeficiency Virus Infection*, 322 NEW ENG. J. MED. 941, 941-49 (April 5, 1990); U.S. Dep't of Health & Human Serv., HHS News, Food & Drug Admin., P90-28 (May 3, 1990)(HHS Secretary Sullivan announced FDA approval of AZT to treat children, following culmination of the pediatric trials of AZT started in 1986); Altman, *Experts on AIDS, Citing New Data Push for Testing Gains in Treatment Seen, Doctors Say Earlier Diagnosis Can Prolong Some Lives and Relieve Suffering*, N.Y. Times, Apr. 24, 1989, A1, at 1, col. 1.

exist in a vacuum. This program operates within society and has important political, legal, and social ramifications.

Surveillance conducted by an agency other than the CIA or FBI and subjecting all liveborn infants to its scrutiny is something extraordinary in the United States.[87] Besides the novelty of a national surveillance program involving ordinary citizens,[88] the current neonatal HIV serosurveillance studies are surprising for two other reasons. First, since the HIV testing is done without notice and consent, the testing is involuntary and appears to violate various laws. Second, the HIV testing is unlinked (or blinded)[89] and is, therefore, incapable of offering any tangible benefit to those who are tested.

Nonconsensual HIV testing of ordinary citizens must be considered extraordinary given the plethora of state statutes which specifically require informed consent to such testing.[90] Most reproductively active women do not belong to the select populations of which statutory exceptions allow involuntary testing.[91]

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87. Other countries have adopted draconian measures. *See* Rich, *AIDS Test Backlash*, 339 NATURE 326 (1989); Bayer & Healton, *Controlling AIDS in Cuba: The Logic of Quarantine*, 320 NEW ENG. J. MED. 1022 (1989).

88. Reproductively active women and their newborns are not quite ordinary citizens, but are not in the same league as prisoners, military personnel, immigrants, and federal foreign service employees. *See infra* notes 146-48 and accompanying text for a slippery slope argument regarding the different groups subjected to governmental non-consensual testing.

89. "In blinded surveys, blood specimens collected for other purposes are permanently stripped of personal identifiers, then serologically tested for HIV." Dondero, *supra* note 1, at 215. The terms "blinded" and "unlinked" are often used incorrectly as synonyms. *Unlinked* refers to the permanent removal of patients identified in a clinical investigation wherein the human subjects are unaware of their participation, never give consent, and never receive study results. *Blinded* refers to the temporary lack of knowledge during a medical experiment, wherein the patient is aware of participating in a clinical investigation, gave informed consent, and receives the results when (at the study's conclusion) researchers remove the blinding to compare study groups.

90. *See, e.g.*, CAL. HEALTH & SAFETY CODE §§ 199.21, 199.22 (West 1990); DEL. CODE ANN. tit. 16, § 1202 (1988); FLA. STAT. ANN. § 381.609(3) (West 1990); ILL. REV. STAT. ch. 111, para. 7304 (1989); MD. HEALTH-GENERAL CODE ANN. § 18-336(b)(1) (1990); MONT. CODE ANN. § 50-16-1007 (1989); N.M. STAT. ANN. § 24-2B-2 (1989); N.Y. PUB. HEALTH LAW § 2781 (McKinney 1990); N.D. CENT. CODE § 23-07.5-02 (1989); OHIO REV. CODE ANN. § 3701.242 (Anderson 1989); OR. REV. STAT. § 433.045 (1990); R.I. GEN. LAWS § 23-6-12 (1989); TEX. HEALTH & SAFETY CODE ANN. 81.102 (Vernon 1991); VA. CODE ANN. § 32.1-37.2 (1990); WASH. REV. CODE ANN. § 70.24.330 (1990); WIS. STAT. ANN. § 146.025 (West 1990).

91. Army Reg. 600-110, Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus (HIV) (Mar. 11, 1988); Deputy Sec'y of Defense, Memorandum on Policy, Identification, Surveillance, and Admin. of Personnel Infected with Human Immunodeficiency Virus (HIV) (Aug. 4, 1988); Medical Examination of Aliens, 52 Fed. Reg. 31,540, 32,540 (1987); Report of the Presidential Comm'n on the Human Immunodeficiency Virus Epidemic 134-35 (June 1988); U.S. Dep't of Justice, National Institute of Justice, AIDS in Correctional Facilities: Issues and Options (T. Hammett 3rd

Removing blood from someone's circulation is a medical procedure, an invasion of bodily integrity.[92] The general rule is that such personal contact requires both notice and consent, or else the contact can be considered a battery.[93] To quote the Supreme Court: "[n]o right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law"[94].

Performing medical procedures without notice and consent as part of a medical study affronts the common law,[95] affronts regulations governing experiments using human subjects,[96] and affronts common courtesy. Additionally, both the United State's constitution and the individual state constitutions recognize the right of persons to remain free from such unreasonable searches and seizures.[97]

Unlinked HIV seroprevalence studies are also extraordinary in that these studies remove specific patient identifiers. Hence the study's descriptive name, "unlinked". Unlinked means, in practical terms, that the individuals being tested cannot be matched to their test results. All positive test results are merely recorded, along

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ed. 1988); *But see* Glover v. E. Neb. Community Office of Retardation, 867 F.2d 461 (8th Cir. 1989)(forced AIDS testing held violation of health service agency employee's fourth amendment rights); Dunn v. White, 880 F.2d 1188 (10th Cir 1989)(prisoners' rights not violated by forced AIDS testing); Haywood County v. Hudson, 740 S.W.2d 718 (Tenn. 1987)(arrestee's rights not violated by forced AIDS testing); Local 1812, Am. Fed'n of Gov't Employees v. United States Dep't of State, 662 F. Supp. 50 (D.D.C. 1987)(inclusion of AIDS test for foreign service employees did not warrant preliminary injunction); 42 C.F.R. § 34.2(a)(b)(4) (1988)(altered by Part 34-Medical Examination of Aliens, 56 Fed. Reg. 2484-86 (Jan. 23, 1991)). *See also* Gostin, Cleary, Mayer, Brandt & Chittenden, *Screening Immigrants and International Travelers for the Human Immunodeficiency Virus*, 322 NEW ENG. J. MED. 1734 (1990).

92. *See infra* notes 240-67 and accompanying text for a discussion of possible conversion, misrepresentation, fraud, and invasion of privacy.

93. Kohoutek v. Hafner, 383 N.W.2d 295, 298-99 (Minn. 1986); PROSSER & KEETON, THE LAW OF TORTS § 18 (5th ed. 1984); RESTATEMENT (SECOND) OF TORTS § 13 (1965).

94. Union Pac. R.R. Co. v. Botsford, 141 U.S. 250, 251 (1891). However, recently the Supreme Court allowed the state to override the patient's interests, when balanced against the state's interests, to preserve a citizen's vegetative life. Cruzan v. Missouri, 110 S.Ct. 2841 (1990).

95. "Every human being of adult years and sound mind has a right to determine what shall be done with his own body." Schloendorff v. Society of N.Y. Hospital, 211 N.Y. 125, 129-30, 105 N.E. 92, 93 (1914).

96. *See infra* text at II., 1., A., *Regulations Protecting Human Subjects in Research* for a discussion of various relevant federal statutes which may be violated by the CDC's HIV seroprevalence studies.

97. U.S. Const. amend IV. *See also* Schmerber v. California, 384 U.S. 757, 767 (1966). The fourth amendment applies to the states through the fourteenth amendment. Wolf v. Colorado, 338 U.S. 25, 27-28 (1949).

with various demographic factors, and serve as a valuable tally for gauging the extent of HIV infection. Performing the HIV testing over a period of time gives useful data for projecting the trend of HIV progression in families.

Without matching a positive test result to a specific person, no one is labeled and no one suffers from discrimination. In short, no one is harmed through notification of the test results. On closer inspection, can we really say this is truly a situation where there is no foul, no harm? Without matching a positive test result to a specific person, those who are HIV-infected are deprived of the potential benefits of being informed. Individuals who are unknowingly HIV-infected cannot enroll in AIDS treatment programs, and cannot make fully informed decisions regarding childbearing or childrearing. In addition, they may continue to engage in sexual or other activities and further spread HIV. This end result seems particularly odd when the agency involved in the serosurveillance program has a statutory mandate[98] to prevent the spread of disease and promote health. Ironically, in 1986, the PHS designated the CDC as "the lead agency within the Public Health Service (PHS) to inform and educate the American public about AIDS."[99]

3. History of Neonatal HIV Testing

Early HIV seroprevalence studies began by following PHS guidelines.[100] Those guidelines state: "All women of childbearing age with identifiable risks for HIV infection should be routinely counseled and tested for HIV antibody, regardless of the health-care setting."[101] A thorough reading of the recommendations reveals explicit and implicit recognition of the need to provide patients with notice and consent to testing during counseling.

The 1987 guidelines specifically state: "These guidelines are based on public health considerations for HIV testing, including the principles of counseling before and after testing, confidentiality of personal information, and the understanding that a person may de-

98. 42 U.S.C. § 241(a) (1988). *See also* 42 U.S.C. § 242b(a) (1988).

99. Mason, Noble, Lindsey, Kolbe, Ness, Bowen, Drotman & Rosenberg, *Current CDC Efforts to Prevent and Control Human Immunodeficiency Virus Infection and AIDS in the United States Through Information and Education*, 103 PUB. HEALTH REP. 255, 256 (1988).

100. Centers for Disease Control, *Recommendations for Assisting in the Prevention of Perinatal Transmission Of Human T-Lymphotrophic Virus Type (III) Lymphadenopathy Associated Virus and the Acquired Immune Deficiency Syndrome*, 34 MORBIDITY & MORTALITY WEEKLY REP. 721, 721-31 (1985); Centers for Disease Control, *Public Health Service Guidelines for Counseling and Antibody Testing to Prevent HIV Infection and AIDS*, 36 MORBIDITY & MORTALITY WEEKLY REP. 509, 509-15 (1987)[hereinafter *Counseling and Antibody Testing*].

101. *Counseling and Antibody Testing*, *supra* note 100, at 512.

cline to be tested without being denied health care or other services, except where testing is required by law."[102] Later recommendations reaffirmed the basic principles of notice and consent.[103]

Despite the above PHS guidelines, the current neonatal HIV serosurveillance program omits counseling both before and after testing. This way no one declines testing and no one complains about being tested against her will. Additionally, infected third parties can hardly hold the agency responsible for its failure to notify or warn,[104] because the infected persons are unaware of the testing.

The same 1987 recommendations explicitly discuss what procedures health care personnel should follow when there is no counseling before testing, as when dealing with blood, organ, and tissue donors, prisoners, and immigrants.[105] The PHS/CDC guidelines state:

> When there is no counseling before testing, persons should be informed that testing for HIV antibody will be performed, that individual results will be kept confidential to the extent permitted by law, and that appropriate counseling will be offered. *Individual counseling of those who are HIV-antibody positive or at continuing risk for HIV infection is critical for reducing further transmission and for ensuring timely medical care.*[106]

Yet childbearing women, ordinary American families, receive less than what health officials offer prisoners and immigrants.

In 1985, articles appeared in medical journals describing vertical transmission to newborns.[107] In 1986, researchers began testing newborn infants without notice to parents and, obviously, without parental consent.[108] In 1987, articles appeared in medical journals describing studies of HIV infection in pregnant women.[109] Evi-

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102. *Id.* at 511.

103. Centers for Disease Control, *Recommendations for Prevention of HIV Transmission in Health-Care Settings*, 36 MORBIDITY & MORTALITY WEEKLY REP. 15 (Supp. 1987).

104. Closen & Isaacman, *The Duty to Notify Private Third Parties of the Risks of HIV Infection*, 21 J. HEALTH & HOSP. L. 295 (1988); Isaacman & Closen, *Lose a Piece of the Rock: Physician Liability for Failing to Notify Private Third Parties of HIV Risk*, 91 J. AM. OSTEOPATHIC A. 45 (1991).

105. *Counseling and Antibody Testing*, *supra* note 100, at 511.

106. *Id.* (emphasis added).

107. Jovaisas, Koch, Schafer, Stauber & Lowenthal, *LAV/HTLV-III in 20-Week Fetus*, 2 LANCET 1129 (1985); LaPointe, Michaud, Pekovic, Chausseau & Dupuy, *Transplacental Transmission of HTLV-III Virus*, 312 NEW ENG. J. MED. 1325 (1985).

108. Marwick, *HIV Antibody Prevalence Data Derived From Study of Massachusetts Infants*, 258 J. A.M.A. 171, 171-72 (1987)(Massachusetts' department of health began study of infants in December, 1986). *See also* Centers for Disease Control, *AIDS and Human Immunodeficiency Virus Infection in the United States: 1988 Update*, 38 MORBIDITY & MORTALITY WEEKLY REP. 32 (Supp. 1989).

109. Landesman, Minkoff, Holman, McCalla & Sijin, *Serosurvey of Human Immunodeficiency Virus Infection in Parturients: Implications for Human*

dently, medical researchers paid little heed to federal guidelines, to existing laws, or to professional guidelines. Medical journals publishing the researchers' work paid little heed to consent requirements adopted by the International Committee of Medical Journal Editors[110] or to their own requirements.[111] Several articles which investigated the HIV status of women who were tested without consent concluded that women could not be relied on to give accurate histories, accept counseling, and consent to HIV testing.[112]

Physicians and nurses at the State University of New York at Brooklyn and New York University conducted the first major study on HIV seroprevalence in childbearing women.[113] These health care professionals initially examined umbilical cord blood samples without the mother's knowledge or consent.[114] From their preliminary sampling, the physicians determined that the hospital catchment population had a high rate of HIV infection.[115] In summarizing their findings, the clinicians suggested that the two percent seroprevalence rate of HIV infected women far exceeded that of other conditions for which screening procedures exist. They stated: "[h]ospital facilities throughout the country, in areas of low and high prevalence rates of HIV infection, should perform similar surveillance studies in obstetric and family planning clinics, sexually transmitted diseases clinics, and abortion clinics."[116]

In the same published report, the group reported testing (again without the mother's knowledge or consent) umbilical cord blood

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Immunodeficiency Virus Testing Programs of Pregnant Women, 258 J. A.M.A. 2701, 2701-03 (1987); Marwick, *supra* note 108, at 2609-11; Centers for Disease Control, *Human Immunodeficiency Virus Infection in the United States: A Review of Current Knowledge*, 36 MORBIDITY & MORTALITY WEEKLY REP. 6, 7 (Supp. 1987).

110. International Committee of Medical Journal Editors, *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, 96 ANNALS OF INTERNAL MED. 766, 767 (1982). *See infra* text at III., 2., *Uniform Requirements for Manuscripts Submitted to Biomedical Journals.*

111. *Instructions for Authors*, 261 J. A.M.A. 3253 (1989). *See infra* text at III., 2., Uniform Requirements for Manuscripts Submitted to Biomedical Journals.

112. Landesman, *supra* note 109, at 2703; Donegan, Edelin & Craven, *HIV Seroprevalence Rate at the Boston City Hospital*, 319 NEW ENG. J. MED. 653 (1988); Grady & Hoff, *Reply to Donegan*, 319 NEW ENG. J. MED. 653, 653-54 (1988); Krasinski, Borkowsky, Bebenroth & Moore, *Failure of Voluntary Testing for Human Immunodeficiency Virus to Identify Infected Parturient Women in a High-Risk Population*, 318 NEW ENG. J. MED. 185 (1988); Minkoff, Holman, Beller, Delke, Fishbone & Landsman, *Routinely Offered Prenatal HIV Testing*, 319 NEW ENG. J. MED. 1018 (1988); Wenstrom & Zuidema, *Determination of the Seroprevalence of Human Immunodeficiency Virus Infection in Gravidas by Non-Anonymous Versus Anonymous Testing*, 74 OBSTETRICS & GYNECOLOGY 558, 560 (1989).

113. Landesman, *supra* note 109, at 2701-03.

114. *Id.* at 2701-02.

115. *Id.* at 2703.

116. *Id.*

from newborn infants delivered between December 8, 1986, and January 31, 1987, while concurrently trying to solicit maternal consent to HIV testing. The blood sample results were grouped into those consenting to counseling and testing and those not consenting.[117] The paper stated: "After the demographic and risk group data were obtained, they were matched to the cord blood sample. All identifiers were then removed, and HIV testing was performed."[118] Clinicians paired the umbilical cord blood HIV test results with patient information and voluntary HIV test results with 602 patients.

Twelve women from the entire group tested positive. Of the twelve, four self-identified as at risk, seven were identified by clinicians as at risk, and five patients had no identifying factors. Since only one-third of the women self-identified, two-thirds of HIV infected women were missed by relying on voluntary testing alone. These factual premises allow one to conclude that either clinicians were inept at assessing patient HIV risk and soliciting voluntary compliance with HIV testing or that childbearing women cannot be relied upon to voluntarily provide honest information about their sexual conduct and drug use and to consent to HIV testing.[119] Of course, the clinicians did not conclude that they were inept, and "[i]n an attempt to circumvent patient reluctance to acknowledge socially unacceptable behavior, the State University of New York Health Science Center at Brooklyn developed a program of routine prenatal counseling and testing."[120]

The New York study pioneered research in this area and served as a role model for similar studies and for the CDC.[121] Other published reports confirmed that mothers-to-be misidentify and misreport risk factors.[122] Perhaps mothers do not trust their doctors to keep such information confidential, or fear that such disclosures will impact on the delivery of medical services.[123] Nonetheless, medical scientists cavalierly concluded that professionals should routinely test all female patients for HIV.[124]

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117. *Id.* at 2702.

118. *Id.*

119. Doctors who perform experiments on patients without notice to patients and without the consent of patients sow the seeds of mistrust.

120. Minkoff, *supra* note 112, at 1018.

121. Pappaioanou, *supra* note 2, at 148.

122. Wenstrom, *supra* note 112, at 558-61.

123. ACLU AIDS Project, *Epidemic of Fear: A Survey of AIDS Discrimination in the 1980's and Policy Recommendations for the 1990's* 31-32 (1990); Chavkin, *Drug Addiction and Pregnancy: Policy Crossroads*, 80 AM. J. PUB. HEALTH 483, 485 (1990); Gostin, *The AIDS Litigation Project: A National Review of Court and Human Rights Commission Decisions, Part II: Discrimination*, 263 J. A.M.A. 2086, 2089 (1990).

124. Landesman, *supra* note 109, at 2703.

While there are merits to HIV testing of any population, there are also detriments. HIV testing is a social and political issue, as well as a medical issue. Medical literature devotes scant attention to the social and political repercussions of HIV serosurveillance. These issues have not been adequately aired, partly because unless a person has read the studies published in biomedical journals or participated as a researcher, most people are unaware that infants are being tested for HIV.

Legislatively mandated metabolic screening does not include HIV testing.[125] Therefore, according to the PHS guidelines, according to state statutes requiring written informed consent to HIV testing,[126] and according to the common law,[127] parental notice of testing and parental consent to testing should be a prerequisite to HIV testing infant blood specimens.[128] Nevertheless, the CDC modeled the current neonatal HIV surveillance program after the New York and Massachusetts programs[129] and purposefully omitted[130] giving parents notice and obtaining parental consent. Despite the recommendation in their own 1987 guidelines,[131] the PHS neonatal surveillance program omits individual counseling of those who test HIV-antibody positive. After tallying the numbers of HIV positive mothers, nothing further is done to reduce transmission and to ensure timely medical care for those who are HIV-infected under the neonatal HIV surveillance program.

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125. Florida and Rhode Island regulations include HIV testing with sexually transmitted disease screening regulations. *See* Intergovernmental Health Policy Project, *AIDS/HIV in Women: State Legislative Initiatives*, 3 INTERGOVERNMENTAL AIDS REP. 4 (Oct. 1990).

126. For a listing of state statutes which require informed consent to testing, see *supra* note 90.

127. *See infra* text at II., 5., Common Law.

128. There are exceptions to consent. Certain populations, by statute, are involuntarily tested. *See supra* note 91. Under certain circumstances, by statute, medical personnel may test an individual without consent. These include: high risk exposure of safety workers or health care providers, physician judgment, and research studies where personal identifiers are removed. *See, e.g.*, CAL. HEALTH & SAFETY CODE §§ 199.22(a), (c) (West 1990); DEL. CODE ANN. tit. 16, § 1202(c) (1988); FLA. STAT. ANN. § 381.609(i)(11) (West 1990); ILL. REV. STAT. ch. 111, paras. 7307, 7308 (1989); MONT. CODE ANN. 50-16-1007(7)(b) (1989); N.M. STAT. ANN. § 24-2B-5 (1989); N.Y. PUBLIC HEALTH LAW § 2781(6) (McKinney 1990); OHIO REV. CODE ANN. § 3701.242(E) (1989); R.I. GEN. LAWS § 23-6-14 (1989); TEX. HEALTH & SAFETY CODE ANN. § 81.102 (Vernon 1991); WASH. REV. CODE ANN. § 70.24.330 (1990); WIS. STAT. ANN. §§ 146.025(2)-(4) (West 1990).

129. Pappaioanou, *supra* note 2, at 148.

130. *Id.* ("obviates the need for informed consent"); Dondero, *supra* note 1, at 217.

131. Centers for Disease Control, *Public Health Service Guidelines for Counseling and Antibody Testing to Prevent HIV Infection and AIDS*, 36 MORBIDITY & MORTALITY WEEKLY REP. 509, 511 (1987).

4. CDC Justification for the Neonatal HIV Serosurveillance Project

The CDC outlined several purposes for the HIV surveillance programs.[132] These include: (1) targeting geographical areas for resource allocations;[133] (2) targeting population groups for services;[134] (3) tracking disease trends;[135] (4) assessing completeness of reporting;[136] (5) estimating the population of HIV-infected persons in the USA;[137] (6) monitoring the impact of programs;[138] and (7) convincing health professionals, community leaders, and politicians of the need for additional resources, personnel and clinics to serve infected individuals.[139]

The systematic collection of demographic information coupled with HIV testing of newborn blood by public health officials is governmental action. Governmental action must serve some legitimate purpose.[140] While the seven items are rational goals, common courtesy dictates that patients be forewarned about what procedures will be performed on them and why. Apart from common decency, none of the seven items have been balanced against the rights of: patient self-determination, individual autonomy, bodily security, and personal, family, and informational privacy. Having a rational goal does not justify ignoring individual rights. Some attention must be given to the means of reaching the goal.

5. Issues of Concern

Why make a fuss over state and federal health agencies' cooperative appropriation of one drop of infant blood? There are individual and social issues which make this little procedure a matter of major concern.

On an individual level, the extra squeeze of the infant's heel and the subsequent HIV testing may be seen by a parent as a theft

132. U.S. Dept. of Health and Human Serv., National HIV Seroprevalence Surveys, Summary of Results: Data From Serosurveillance Activities Through 1989, HIV/CID/9-90/006, 1, 1-2 (1990).

133. Dondero, *supra* note 1, at 213.

134. *Id.*

135. Onorato, Jones & Forrester, *Using Seroprevalence Data in Managing Public Health Programs*, 103 PUB. HEALTH REP. 163, 164 (1990); Pappaioanou, *The Family of HIV Seroprevalence Surveys*, *supra* note 67, at 113.

136. Buehler, Berkelman, Stehr-Green, & Leary, *Completeness of AIDS Surveillance, United States, Sixth International Conference on AIDS* Th.C.698 (June 21, 1990).

137. Pappaioanou, *The Family of HIV Seroprevalence Surveys*, *supra* note 67, at 118.

138. Onorato, *supra* note 135, at 164.

139. *Id.* at 166.

140. City of Cleburne, Tex. v. Cleburne Living Center, 473 U.S. 432, 432-33 (1985).

and an informational rape. The agencies, by taking the blood without legal authority or parental permission, obtain something that rightfully belongs to someone else. The agencies, by testing the blood and retaining demographic data, obtain personal information relating to age, sex, race, ethnicity, alienage, and conduct.[141] This personal information is used by the government for a purpose other than recording vital statistics. Mothers may feel a loss of autonomy and trust in the medical establishment because of the nonconsensual HIV testing, irrespective of the removal of individual identifiers.

Removal of individual identifiers adds injury to insult. Mothers who are HIV-infected may feel that they could have stayed healthier and lived longer if they knew their serostatus earlier.[142] Mothers who are HIV-infected may feel that their children could have stayed healthier and lived longer if they received appropriate medical care earlier.[143] Present and future lovers who become infected as a result of a mother's sexual conduct may wish the government agencies had informed their partner of her serostatus. Subsequent children who are HIV-infected may claim wrongful birth.[144] Subsequent children who are not HIV-infected may resent the early death of their mother from a disease whose stigma surpasses that of leprosy.

On a social level, the slippery slope argument comes into play, albeit at a point other than the slope's crest. Nonconsensual HIV testing first included military personnel,[145] prisoners,[146] and

141. The conduct alluded to is sex and drug use. *See*, Centers for Disease Control, *Update: Heterosexual Transmission of AIDS and HIV Infection - United States*, 38 MORBIDITY & MORTALITY WEEKLY REP. 423, 429-34 (1989); Centers for Disease Control, *Update: Acquired Immunodeficiency Syndrome Associated with Intravenous-Drug Use - United States, 1988*, 38 MORBIDITY & MORTALITY WEEKLY REP. 165-70 (1989).

142. Studies show that early intervention and medical management not only improves the quality of life for HIV-infected persons, but also extends their longevity. *See supra* text at I., 1., Medical Principles.

143. As long ago as 1987, the media publicized the infant's need for early treatment. Clark & Gosnell, *When a Child Has AIDS: The Need for Early Treatment Is Critical*, NEWSWEEK, Sept. 7, 1987, at 57.

144. Although wrongful birth as a compensable legal claim is not widely recognized, the emotional and physical suffering that accompanies individual circumstances must be acknowledged as very real.

145. Deputy Sec'y of Defense, Memorandum on Policy, Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus (HIV) (Aug. 4, 1988); Army Reg. 600-110, Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus (HIV) (Mar. 11, 1988).

146. U.S. Dep't of Justice, National Institute of Justice, AIDS in Correctional Facilities: Issues and Options (T. Hammett 3rd ed. 1988); Report of the Presidential Commission on the Human Immunodeficiency Virus Epidemic 134-35 (June 1988).

aliens.[147] Next came occupational testing.[148] Now we are at the nadir, testing ordinary citizens without notice and without consent. We seem to be at the end of the parade of horribles with indiscriminate surveillance of ordinary citizens.

There are other social concerns unique to this testing. Testing newborn infants for HIV without notice and consent takes advantage of two subpopulations, women and children, which have historically endured disparate treatment. Because women and children are captives of "the system" during and immediately following childbirth, they become involuntary participants in the neonatal HIV surveillance program.

The infant's HIV test reflects only the mother's serostatus. The sexism of testing is very apparent. Since over seventy-five percent of the women with HIV disease are women of color,[149] some believe the testing also has racist underpinnings.

Most of the seropositive patients are poor and poorly educated.[150] In contrast, the study designers are predominantly male, predominantly white, well educated and well past poverty level income. These demographics, these disparate social positions, promote social divisiveness, alienation, and mistrust. Simply experimenting on people without notice and without consent invites alienation and mistrust of the health care system.

From a social and medical perspective, nonconsensual HIV testing represents a giant step backwards from the recognition of patient rights and the involvement of patients in medical decisionmaking. Since the testing is not ordered by the mother's physician or the infant's physicians, arguably medical decisionmaking is absent. The testing program is an independent creation of a government agency and represents a frightening bureaucratic intrusion into family life.

Identification, treatment, and containment of infectious diseases are basic goals of public health services. From a public health

147. Medical Examination of Aliens, 52 Fed. Reg. 31,540, 32,540 (1987).

148. *See* Dep't of State, Local 1812, Am. Fed'n of Gov't Employees v. United States, 662 F. Supp 50 (D.D.C. 1987)(foreign service employees); *see also* Closen, *A Call for Mandatory Testing and Restriction of Certain Health Care Professionals*, 9 ST. LOUIS U. PUB. L. REV. 421 (1990); Centers for Disease Control, *Update: Transmission of HIV Infection During an Invasive Dental Procedure - Florida*, 40 MORBIDITY & MORTALITY WEEKLY REP. 21, 27 (1991); Comment, *The Constitutional Implications of Mandatory AIDS Testing in the Health Care Industry*, 17 SW. L.J. 787 (1988).

149. Virtually all live newborns are tested, so there is no racial discrimination. However, the results of the study may lead to stigmatization of women of color. See notes 338-39 and accompanying text.

150. Krueger, Wood, Diehr & Maxwell, *Poverty and HIV Seropositivity: The Poor Are More Likely to be Infected*, 4 AIDS 811-14 (1990).

perspective, the current program of widespread testing[151] purposefully fails to promote traditional public health communicable disease objectives.[152] The neonatal HIV surveillance program does not identify and notify HIV-infected individuals.[153] No one receives early treatment or education regarding behaviors which contribute to the spread of HIV, goals elaborated by the very same public health organization.[154] The current program consumes limited manpower and monies to tally numbers.[155]

Public health agency conduct is questioned because, unlike the metabolic screening tests, there is no express state or federal legislative mandate for HIV testing without notice and consent when the population tested consists of civilian populations.[156] The very same agency that designed the HIV testing without notice and consent[157] also states that patients should receive notice and give consent prior to testing.[158] Public health agency conduct is also questioned because various laws and professional codes mandate that human subjects of medical research receive notice of the study and receive all the formalities that go with informed consent.

Once the public becomes aware of the current program, the likely result may be to increase mistrust of the health care system. Those that need services may avoid them because of social divisiveness. This article does not deny the utility of tabulating HIV infection in reproductively active women. This article criticizes how this is being done. Should the government enter the nuclear family and abrogate the parental right of deciding whether infants should be

151. *See supra* notes 1-4 and accompanying text for an introductory synopsis of the various agencies which have conducted non-consensual HIV testing programs.

152. Dondero, *supra* note 1, at 215. To be interpretable, data on levels and trends of HIV infection must be as free from bias as possible. Self-selection bias — the impact of persons who are at risk or know they are infected being either more or less likely to be tested than persons who are otherwise similar but without recognized risk — poses a methodological problem because of its quantitatively unpredictable impact on the data. *Id.*

153. Pappaioanou, *supra* note 2, at 149. The CDC stated unlinking: "obviates the need for informed consent, thereby eliminating the self-selection bias in most voluntary (nonblinded) HIV seroprevalence surveys." *Id.*

154. Centers for Disease Control, *HIV Infection Reporting - United States*, 38 MORBIDITY & MORTALITY WEEKLY REP. 496, 497 (1989); Centers for Disease Control, *Partner Notification for Preventing Human Immunodeficiency Virus (HIV) Infection — Colorado, Idaho, South Carolina, Virginia*, 37 MORBIDITY & MORTALITY WEEKLY REP. 393, 393-96, 401-02 (1988).

155. A more cost effective method to estimate seroprevalence of HIV would be to test representative populations from urban and rural regions rather than include virtually every state and territory.

156. *Cf.*, *supra* note 90 and accompanying text.

157. *See infra* text at II., 1., B., *Administrative Procedure Act.*

158. Centers for Disease Control, *Public Health Service Guidelines for Counseling and Antibody Testing to Prevent HIV Infection and AIDS*, 36 MORBIDITY & MORTALITY WEEKLY REP. 509, 511 (1987).

tested for HIV? And, if the government supplants this right, should the abrogation of a family's decisionmaking autonomy occur at the behest of HIV-specific legislation promulgated by elected officials or should it occur as a result of an administrative agency's decision?

II. RELEVANT LAWS

Governmental use of medical procedures on human subjects, such as a laboratory analysis of newborn blood specimens, can be questioned under federal statutes, state and federal constitutions, human rights laws, and the common law. This body of law stems from past practices which caused patient suffering and death.

1. Federal Statutes

Several federal laws protect citizens from becoming involuntary participants in medical studies.[159] In addition, various international laws[160] apply to the practice of using humans as subjects in medical investigations.[161]

A. Regulations Protecting Human Subjects in Research

The applicable section of the Code of Federal Regulations dealing with research on human subjects is entitled: "Protection of Human Subjects."[162] Subpart A defines the terms, jurisdiction, purpose and policy. The section also details which research areas are exempt from the regulations.[163] The Department of Health and Human Services, of which the CDC is a branch, must follow enacted federal regulations governing research on human subjects.[164] The regulations define research[165] and human subjects.[166] The

159. Protection of Human Subjects, 45 C.F.R. §§ 46.101, 46.101-.409 (1989); The Nuremberg Code, Trials of War Criminals before the Nuernberg Military Tribunals under Control of Council Law No. 10, vol.2 , 181, 181-83 (1949).

160. *See* U.S. Const. art. III. (some international laws became federal laws through the treaty provision).

161. *See infra* text at II.4., International Laws.

162. 45 C.F.R. §§ 46.101-.409 (1989).

163. 45 C.F.R. § 46.101(b) (1989).

164. The federal regulations state:

> (a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving human subjects conducted by the Department of Health and Human Services or funded in whole or in part by a Department grant, contract, cooperative agreement or fellowship.
>
> (1) This includes research conducted by Department employees, except each Principal Operating Component head may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

45 C.F.R. § 46.101(a)(1) (1989).

165. 45 C.F.R. § 46.102(e) (1989).

166. 45 C.F.R. § 46.102(f) (1989).

regulation's definitions include an example using venipuncture and blood removal.[167] The example demonstrates that the withdrawal of blood through using a sharp instrument[168] applies to pricking an infant's heel with a lancet and removing blood.[169]

Apparently the CDC realized that the medical research study of the rate of HIV infection in reproductively active women which uses newborn blood specimens falls within the purview of these regulations. The Human Subjects Review Commission at the CDC, and institutional review boards looked at the protocol.[170] The CDC claims that unlinked serosurveillance is exempt from coverage under section 46.101(b)(5).[171] No one really questioned the CDC.

This claimed exemption cannot be used because "the research is covered by other subparts of this part."[172] In fact, several subparts of part A clearly apply. Newborn HIV testing detects HIV infection in the mother. HIV infection in reproductive-aged women is clearly linked with intravenous drug use and sex.[173] Sections 46.101(b)(3)(iii)[174] and 46.101(b)(4)(iii)[175] explicitly include drug

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167. *Id.*

168. A lancet is used in place of a needle when removing a blood specimen from infants.

169. The argument is sometimes advanced that the blood used is "surplus" specimen materials. Clear instructions are given with the neonatal filter specimens to fill each space with blood in mandatory, not precatory, language. The person performing the testing squeezes the amount specified, no more, which by design includes one circle for HIV. *See* Appendix.

170. Pappaioanou, *supra* note 2, at 152.

171. Pappaioanou, *The Family of HIV Seroprevalence Surveys*, *supra* note 67, at 115. Section 46.101(b)(5) states: "[r]esearch involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects." 45 C.F.R. § 46.101(b)(5).

172. The federal regulation states: "[r]esearch activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from these regulations unless the research is covered by other subparts of this part[.]" 45 C.F.R. § 46.101(b).

173. Gayle, Selik & Chu, *Surveillance for AIDS and HIV Infection Among Black and Hispanic Children and Women of Childbearing Age, 1981-1989*, 39 MORBIDITY & MORTALITY WEEKLY REP. 23, 23-30 (Supp. 3 1990); Guinan & Hardy, *Epidemiology of AIDS in Women in the United States*, 257 J. A.M.A. 2039, 2039-42 (1987); Centers for Disease Control, *Update: Acquired Immunodeficiency Syndrome Associated with Intravenous-Drug Use - United States*, 1988, 38 MORBIDITY & MORTALITY WEEKLY REP. 165-70 (1989); Centers for Disease Control, *Update: Heterosexual Transmission of AIDS and HIV Infection - United States*, 38 MORBIDITY & MORTALITY WEEKLY REP. 423, 423-24, 429-34 (1989).

174. "Research involving survey or interview procedures, except where all of the following conditions exist: . . . (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol." 45 C.F.R. § 46.101(b)(3)(iii) (1989).

175. Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist: ". . . (iii) the research deals with sensitive aspects of the subject's own behavior, such

use and sexual behavior within the purview of the regulations. In addition, sections 46.101(b)(3)(ii)[176] and 46.101(b)(4)(ii)[177] also apply because under current criminal laws[178] and civil laws,[179] the woman could face liability if her status "became known outside the research."[180] In addition, subpart D, "Additional Protections for Children Involved as Subjects in Research," should also apply because the samples are obtained from children.[181]

B. Administrative Procedure Act

Throughout this article the Neonatal HIV Serosurveillance project is referred to as a federal policy. The published neonatal HIV serosurveillance reports are authored by members of the CDC[182] and carry titles such as "Monitoring the Levels and Trends of HIV Infection: The Public Health Service's HIV Surveillance Program."[183] Funding for the testing, which influences states to cooperate with the project, comes from federal monies.[184] CDC per-

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as illegal conduct, drug use, sexual behavior, or use of alcohol." 45 C.F.R. § 46.101(b)(4)(iii) (1989).

176. "Research involving survey or interview procedures, except where all of the following conditions exist: . . . (ii) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability." 45 C.F.R. § 46.101(b) (3) (ii) (1989).

177. "Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist: . . . (ii) The observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability." 45 C.F.R. § 46.101(b)(4)(ii) (1989).

178. 1989 Ark. Acts § 5-14-123; IDAHO CODE § 39-608 (1988); ILL. REV. STAT. ch. 38, para. 12-16.2 (1989); IND. CODE ANN. § 35-42-1-7 (Burns 1989); OKLA. STAT. ANN. tit. 21, § 1192.1 (West 1990); S.C. CODE ANN. § 44-29-145 (Law. Coop. 1989). *See* Isaacman, *Are We Outlawing Motherhood for HIV-Infected Women?*, 22 LOY. U. CHI. L.J. 479 (1991); Closen & Isaacman, *Criminally Pregnant*, 76 A.B.A. J. 76, 76-78 (1990).

179. *Suit Claims Hudson Concealed Illness From Lover*, 72 A.B.A. J. 40 (1986); *Jury Makes Award to Woman After Death of Ex-Husband*, AIDS Policy & Law (BNA) at 5 (Jan. 25, 1989); *Florida Man Sues Male Lover Over Transmission of HIV*, AIDS Policy & Law (BNA) at 4 (July 25, 1990).

180. *See* 45 C.F.R. §§ 46.101(b)(3)(ii), 46.101(b)(4)(ii).

181. *See* 45 C.F.R. §§ 46.401(a), 46.402(a).

182. Allen, Lee, Schulz, Pappaioanou, Dondero & Onorato, *Determining HIV Seroprevalence Among Women in Women's Health Clinics*, 105 PUB. HEALTH REP. 130 (1990); Dondero, *supra* note 1, at 213-20; Onorato, *supra* note 135, at 163; Pappaioanou, *supra* note 2, at 147; Pappaioanou, *The Family of Seroprevalence Surveys*, *supra* note 67, at 113.

183. Dondero, *supra* note 1, at 213-20.

184. Centers for Disease Control, Announcement No. 901, Cooperative Agreements for Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Virus Syndrome (AIDS); Prevention and Surveillance Projects; Availability of Funds for Fiscal Year 1989, 53 Fed. Reg. 36,492 (Sept. 20, 1988).

sonnel coordinate and compile all the state results. Thus, the neonatal HIV testing program appears to be a federal policy.

Federal policies must be published in the Federal Register.[185] A thorough search of the register for a public notice, a statement of purpose, and an opportunity for public comment revealed nothing. Did the CDC ignore the Administrative Procedure Act? When asked, an agency official explained that this was not a federal policy, but a state policy.[186] The CDC lacks authority to order testing. The CDC lacks authority to independently appropriate state blood specimens intended for state mandated neonatal screening tests. Allegedly, the existing program is really a state program. By coincidence, nearly every state has the same program. By coincidence, state programs do not need to be published in the Federal Register. By coincidence, this same argument was used by the PHS to abrogate responsibility for the Tuskegee Syphilis studies.[187]

C. *Privacy Act*

In response to growing anxiety about governmental collection of personal information,[188] Congress enacted the Privacy Act[189] to "promote governmental respect for the privacy of citizens by requiring all departments and agencies of the executive branch and their employees to observe certain constitutional rules in the computerization, collection, management, use, and disclosure of personal information about individuals."[190] The statute meant to curb "the kind of illegal, unwise, overbroad, investigation and record surveillance of law-abiding citizens produced in recent years from actions of some over-zealous investigators, and the curiosity of some governmental administrators."[191] Seventeen years later, these con-

185. 5 U.S.C. § 552 (1988).

186. Personal communication with Timothy Dondero, MD (Dec. 21, 1990).

187. J. JONES, BAD BLOOD 7 (1981).

188. Personal information means:

> [a]ny information about the individual that identifies or describes any characteristic including but not limited to education, financial transactions, medical history, criminal or employment record, or any personal information that affords a basis for inferring personal characteristics such as finger and voice prints, photographs, or things done by or to such individual. Such a definition includes the record or present registration, or membership in an organization or activity, or admission to an institution. It is intended to include within these terms any symbol, number, such as a social security number or character, address, by which the individual is indexed in a file or retrievable from it.

1974 U.S. CODE CONG. & ADMIN. NEWS 6992, 6993.

189. The Privacy Act, Pub. L. No. 579, 88 Stat. 1896 (1974) (codified at 5 U.S.C. § 552 (1988)).

190. S. Rep. No. 1183, 93rd Cong., 2nd Sess., *reprinted in* 1974 U.S. CODE CONG. & ADMIN. NEWS 6916.

191. *Id.*

cerns are still poignant.

The neonatal HIV serosurveillance program uses personal information *and* medical specimens obtained for an entirely different purpose to collect data and analyze HIV infection in reproductively active women. The decision to perform these studies rests not with parents, not with legislators, and not with courts, but with administrators of government agencies.

Although well intentioned, the Privacy Act contains exceptions which emasculate the statute.[192] One exception allows the release of information for statistical research.[193] HIV related data which is unlinked can therefore be released to epidemiologists. The unlinking allows the agency to utilize the exception for the management, use and disclosure of personal information. The unlinking does not, however, excuse the means used in the collection of personal medical information.

D. Patient Self-Determination Act

In response to the Supreme Court's *Cruzan* decision,[194] representatives introduced the Patient Self-Determination Act of 1990.[195] Elected officials, reflecting the will of the people, attempted to protect the decision making powers of patients.[196] While many of the troubling and difficult decisions regarding treatment occur towards the end of life, troubling and difficult decisions also occur with conception and pregnancy. The principle of self-determination, whether at the end of life or at the beginning, remains manifested in the fundamental right of patients to accept or refuse medical treatment. Legislators exalted this common law principle to increase institutional and patient awareness in a statutory command.[197]

The new law demands that adults admitted to hospitals receive written information detailing: "an individual's rights . . . to make decisions concerning such medical care, including the right to ac-

192. *See* 5 U.S.C. §§ 552a(b)(1)-(12) (1988).

193. The exception allows disclosure "to a recipient who has provided the agency with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and the record is to be transferred in a form that is not individually identifiable." 5 U.S.C. § 552a(b)(5) (1988).

194. Cruzan v. Missouri, 110 S.Ct. 2841 (1990).

195. H.R. 5835, 101st Cong., 2nd Sess., *reprinted in* 1991 U.S. CODE CONG. & ADMIN. NEWS 291-97.

196. 136 CONG. REC. E943 (daily ed. Apr. 3, 1990)(statement of Rep. Levin).

197. Omnibus Budget Reconciliation Act of 1990, P.L. No. 101-508, (Nov. 5, 1990)(codified as amended in scattered sections of 42 U.S.C.).

cept or refuse medical or surgical treatment. . ."[198] When patients are not informed of testing, when patients are not given the opportunity to make decisions regarding testing, when patients cannot refuse testing, patient self-determination is violated. When the law takes effect, the law may also be violated.

2. Nuremberg Code

The United State's military developed a code governing human experimentation after World War II.[199] Nazi medical experiments, which included forced sterilization, mass murder, and various acts of torture, moved the world to adopt a standard for using human subjects in medical projects.

At first glance, the comparison to Nazi war crimes seems out of place. However, from the position of a person who becomes HIV-infected through sexual contact with a woman uninformed of her HIV serostatus, the comparison is apt. The HIV-infected contact now faces a lengthy debilitating disease which may result in cosmetic deformity,[200] various debilitating complications, and death.[201] Concomitant with the physical pain, suffering, and certain death this person will face, individuals with HIV-infection face significant discrimination and emotional distress. The emotional distress stems from: the social responses to this particular disease, least of which is outright ostracism; the effect this disease has on an individual's sex and family life choices; and, the lack of medical success and medical pessimism in finding a cure. Becoming HIV-infected is more than slightly inconvenient.

Similarly, the HIV-infected woman may feel victimized by the government's study. Perhaps after one of her children develops HIV disease or she develops symptoms, a mother may feel cheated by a bureaucracy that could have informed her much sooner about her condition. These women may feel their individual family's needs have been ignored by health care personnel, that they are just a number in a cold system. HIV-infected mothers may feel that their quality of life has been senselessly diminished and that their

198. Omnibus Budget Reconciliation Act of 1990, P.L. No. 101-508, § 4206(a)(A)(i), 1991 U.S. CODE CONG. & ADMIN. NEWS 292 (to be codified at 42 U.S.C. § 1395cc).

199. Mulford, *Experimentation on Human Beings*, 20 STAN. L. REV. 99 (1967).

200. Kaposi's sarcoma lesions characteristically appear on the skin and mucous membranes. In addition, weight loss, which often accompanies HIV disease, can give victims an 'Aushwitz' look.

201. Koop, *AIDS, An Overview of Current Issues*, 9 J. LEGAL MED. 489 (1988). The Surgeon General wrote: "[W]hen you look back at those persons who had AIDS in 1981, you discover that 92% of them have died of the disease." *Id.* at 490.

health deteriorated more rapidly because they were not referred to the appropriate medical treatment at the earliest possible moment.

The Nuremberg Military Tribunals elaborated the principle that: "voluntary consent of the human subject is absolutely essential . . . to satisfy moral, ethical and legal concepts."[202] At least four Supreme Court Justices have recognized the Nuremberg Code's requirement of voluntary consent for all citizens participating in experiments.[203] The neonatal HIV serosurveillance study deliberately omits soliciting consent from the human experimental subjects.[204] Performing a medical study without obtaining the voluntary informed consent of the human subject participants is at odds with the Nuremberg Code's very first principle.[205]

Other sections of the Nuremberg Code are also violated by the current PHS/CDC surveillance program. Principle four of the Code commands: "The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury."[206] Principle seven of the Code commands: "Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death."[207] Taken together, these principles demand that the safety and health of the human subjects be protected from even a remote chance of physical or mental harm.

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202. United States v. Stanley, 483 U.S. 669, 685 (1987)(J. O'Connor, concurring in part, dissenting in part) (*quoting* United States v. Brandt, 2 Trials of War Criminals Before the Nuremberg Military Tribunals Under Control of Council Law No. 10, vol. 2, at 181 (1949)).

203. *Stanley*, 483 U.S. at 685, 687.

204. Dondero, *supra* note 1, at 214.

205. The Code states:

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
>
> The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

Trials of War Criminals before the Nuernberg Military Tribunals under Control Council Law No. 10, vol. 2, at 181-82 (1949).

206. *Id.* at 182.

207. *Id.*

When the government intentionally strips the personal identifier from the blood specimens, the government intentionally avoids notifying HIV positive women of their infection. Those who are infected will not alter their high-risk behavior nor avail themselves of beneficial medical and social services. Their lives will be cut short as a result of not knowing. Their lives will contain more suffering as a result of not knowing, and they will probably infect others as a result of their ignorance. The analogy to experiments performed by Nazi doctors[208] or the PHS Tuskegee study[209] seem apt. Clearly there are physical and mental risks of harm which accompany the present practice.

3. Constitutions

The federal constitution explicitly recognizes the right of citizens to be secure in their persons.[210] Puncturing the infant's heel with a medal lancet is a physical invasion of the person. The withdrawal of a blood specimen is a seizure[211] and an invasion of the person.[212] Testing the blood for alcohol is a search.[213] Similarly, the withdrawal of a blood specimen by state and federal government agencies from an infant is a seizure, and the testing for HIV is a search under the Fourth Amendment.[214] However, the seizure and search of the infant's blood is conducted without probable cause, without individualized suspicion, and without specific legal authorization. Additionally, HIV is not destructible evidence or a metabolite likely to disappear over time. At the present time it is an incurable infection. Because the government causes the removal of blood and then uses the specimen, this is also a deprivation of property without due process of law and without just compensation.[215]

Until recently, Supreme Court decisions interpreting search

208. R. LIFTON, THE NAZI DOCTORS: MEDICAL KILLING AND PSYCHOLOGY OF GENOCIDE (1986).

209. Heller & Bruyere, *Untreated Syphilis in the Male Negro: II. Mortality During 12 Years of Observation*, 27 J. VENEREAL DISEASE INFO. 34 (1946); Rivers, Schuman, Simpson & Olansky, *Twenty Years of Followup Experience In a Long-Range Medical Study*, 68 PUB. HEALTH REP. 391 (1953); Shafer, Usilton & Gleeson, *Untreated Syphilis in the Male Negro: A Prospective Study of the Effect on Life Expectancy*, 69 PUB. HEALTH REP. 684 (1954); Vonderlehr, Clark, Wenger & Heller, *Untreated Syphilis in the Male Negro: A Comparative Study of Treated and Untreated Cases*, 17 VENEREAL DISEASE INFO. 260 (1936).

210. U.S. CONST. amend. IV.

211. Schmerber v. California, 384 U.S. 757, 767 (1966).

212. *Id.*

213. *Id. See also* Winston v. Lee, 470 U.S. 753, 759-60 (1985).

214. Glover v. E. Nebraska Community Office of Retardation, 686 F. Supp. 243, 250 (D. Neb. 1988), *aff'd* 867 F.2d 461 (8th Cir.), *cert. denied*, 110 S. Ct. 321 (1989). *Cf.* United States v. Jacobsen, 466 U.S. 109, 113-14 (1984).

215. U.S. CONST. amend. V.

and seizure cases required judicial review from their inception,[216] the existence of probable cause,[217] and the search had to be reasonable.[218] The fourth amendment also protects the privacy of individuals from unreasonable searches and seizures that were not part of a criminal investigation.[219]

Recent Supreme Court decisions have effectively modified the prerequisites of judicial review,[220] probable cause, and individualized suspicion,[221] have tolerated searches outside of criminal proceedings,[222] and have construed "reasonable" on the basis of judicial idiosyncrasy.[223] Nonetheless, childbearing women, as a class, are not suspects in any criminal activity.[224] Nor are they participants in a highly regulated industry. Although the Supreme Court noted that "society's judgment that blood tests do not constitute an unduly extensive imposition on an individual's privacy and bodily integrity,"[225] and allowed warrantless searches of transportation workers without probable cause and without individualized suspicion, extending this holding to all childbearing women appears unwarranted.

Because the fourth amendment applies to the states,[226] state constitutions can only add protection to individual rights. Strengthening the respect for the security of the person would increase individual protection from a government agency's searches and seizures. Further, several state constitutions explicitly protect privacy rights of citizens.[227] In so far as the HIV serosurveillance studies obtain demographic information by means of nonconsensual

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216. *See* United States v. Ventresca, 380 U.S. 102, 105-06 (1965).

217. Coolidge v. New Hampshire, 403 U.S. 443, 450 (1971).

218. Terry v. Ohio, 392 U.S. 1, 20-22 (1968).

219. Michigan v. Tyler, 436 U.S. 499, 504-05 (1978)(police investigation after a fire to find evidence of arson); Camara v. Municipal Court, 387 U.S. 523, 531-33 (1967)(inspection by city housing inspectors of an apartment without a warrant).

220. New York v. Burger, 482 U.S. 691, 702 (1987)(closely regulated junk yard industry held subject to "special need" exception to warrant requirement of fourth amendment); New Jersey v. T.L.O., 469 U.S. 325, 340 (1985)(public schools need to maintain control to permit warrantless searches of school lockers on less than probable cause).

221. Skinner v. Ry. Labor Executives' Assn., 489 U.S. 602 (1989)(urine test, not a blood test, for drugs allowed under 'special needs' exception without individualized suspicion).

222. *Id.* (transportation workers); *Burger*, 482 U.S. at 691 (business); O'Connor v. Ortega, 480 U.S. 709 (1987)(physician's office by employer); *T.L.O.*, 469 U.S. at 325 (students).

223. *Skinner*, 489 U.S. at 602. *Cf.*, Nat'l Treasury Employees Union v. Von Raab, 489 U.S. 656 (1989).

224. *But see* Isaacman & Closen, *Criminally Pregnant*, 76 A.B.A. J. 76 (1990).

225. Winston v. Lee, 470 U.S. 753, 762 (1985).

226. Wolf v. Colorado, 238 U.S. 25, 27-28 (1949).

227. CAL. CONST. art. I, 1; FLA. CONST. art. 1, 23; ILL. CONST. art. I, 6.

testing, these studies violate bodily integrity, as well as family, personal, and informational privacy.

4. International Laws

Human rights are matters of international concern. The United Nations' ("U.N.") charter itself recognizes and asserts fundamental human rights[228] which member states are bound to protect. The United States is a signatory to the U.N. Charter. Several U.N. declarations apply to sampling blood from persons and obtaining information concerning the nuclear family without notice to the individual.

A. Universal Declaration of Human Rights

The Universal Declaration of Human Rights ("Declaration") is analogous to our Bill of Rights and serves to protect individual freedoms. Two articles of the Declaration apply to the practice of involuntary testing of newborns for HIV. Article 3 states: "Everyone has the right to life, liberty and the security of person."[229] An uninvited withdrawal of blood from a person by a government agency violates the "security of person."[230]

Article 12 protects individuals from arbitrary interference with privacy, family, and reputation.[231] By obtaining blood specimens from newborn infants and compiling demographic information from patient records, government agencies invade an individual's right to personal, family, and informational privacy. In addition, the demographic information, regardless of its validity, stigmatizes people and thereby damages the reputation of persons who belong to minority groups.[232]

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228. The charter begins with "[w]e the peoples of the United Nations determined . . . to reaffirm faith in fundamental human rights, in the dignity and worth of the human person, in the equal rights of men and women and of nations large and small." UNITED NATIONS, Y.B. OF THE UNITED NATIONS 987 (1947-48).

229. UNITED STATES GOVERNMENT PRINTING OFFICE, INTERNATIONAL HUMAN RIGHTS 4 (1976)[hereinafter INT'L HUMAN RIGHTS].

230. The Supreme Court acknowledged that removal of blood invoked the security of the person in Schmerber v. State of California, 384 U.S. 757, 767 (1966).

231. Article 12 of the Universal Declaration of Human Rights states: "[n]o one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks." INT'L HUMAN RIGHTS, *supra* note 229, at 5.

232. At least the Canadian government recognized this risk. *See* Federal Centre for AIDS Working Group on Anonymous Unlinked HIV Seroprevalence, *Guidelines on Ethical and Legal Considerations in Anonymous Unlinked HIV Seroprevalence Research*, 143 CAN. MED. ASSOC. J. 625, 626-27 (1990).

B. Declaration of Rights of the Child

U.N. member nations recognized that children need special safeguards and voted overwhelmingly to memorialize principles to protect the rights of children.[233] Principle 4 obliges member nations to provide adequate prenatal and postnatal care to mothers and children.[234] Neither mothers nor children receive adequate care when they are deliberately not informed of their HIV serostatus. Principle 5 provides that treatment shall be offered for an infant's condition.[235] A positive blood test linked to an individual child would provide reason to investigate the child's serostatus further and to determine whether the infant has the infection.[236] If the follow-up examination demonstrated HIV disease, early intervention could begin promptly.[237] The current program fails to offer such a child anything.

C. Other Human Rights Declarations

Many other human rights declarations contain nearly identical language protecting the security of the person,[238] individual and family privacy, along with individual and family reputation.[239] The above analysis applies with equal force to these declarations as well.

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233. Declaration of the Rights of the Child, Resolution 1386(XIV) Y.B. OF THE UNITED NATIONS 198 (1959).

234. The principle states in full: The child shall enjoy the benefits of social security. He shall be entitled to grow and develop in health; to this end, special care and protection shall be provided both to him and to his mother, including adequate pre-natal and post-natal care. The child shall have the right to adequate nutrition, housing, recreation and medical services. *Id.*

235. Principle 5 states: "The child who is physically, mentally or socially handicapped shall be given the special treatment, education and care required by his particular condition." *Id.*

236. EUROPEAN COLLABORATIVE STUDY, *supra* note 12, at 253 (the diagnosis of HIV disease in infants born to HIV-infected mothers was possible on the basis of a variety of other laboratory tests and on the repeated clinical examination of the infant).

237. Blanche, *supra* note 12, at 1643-48 (the importance of early intervention).

238. INTERNATIONAL COVENANT ON CIVIL AND POLITICAL RIGHTS, RESOLUTION 2200A (XXI) Dec. 16, 1966 ARTICLE 9(1) INTERNATIONAL HUMAN RIGHTS 24 (1976); AMERICAN DECLARATION OF THE RIGHTS AND DUTIES OF MAN, ARTICLE V-VII INTERNATIONAL HUMAN RIGHTS 40 (1976); CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND FUNDAMENTAL FREEDOMS, ARTICLE 5(1) INTERNATIONAL HUMAN RIGHTS 44 (1976).

239. INTERNATIONAL COVENANT ON CIVIL AND POLITICAL RIGHTS, RESOLUTION 2200A (XXI) Dec. 16, 1966 ARTICLE 17(1) INTERNATIONAL HUMAN RIGHTS 26 (1976); AMERICAN DECLARATION OF THE RIGHTS AND DUTIES OF MAN, ARTICLES V, VI, VII INTERNATIONAL HUMAN RIGHTS 40 (1976); CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND FUNDAMENTAL FREEDOMS, ARTICLE 8 INTERNATIONAL HUMAN RIGHTS 46 (1976).

5. Common Law

Common law respects the dignity interest[240] of the individual. As John Stewart Mill noted, "[o]ver himself, over his own body and mind, the individual is sovereign."[241] Only consent of the individual[242] and authority of law[243] break this sovereignty. Squeezing blood from an infant's heel for HIV testing without notice to parents and without consent from parents disregards parental sovereignty.

The mere act of entering into a doctor-patient relationship does not vest a physician with authority to make decisions for patients. In fact, a patient's wish supersedes the physician's recommendation except in carefully circumscribed situations.[244] The common law has long recognized the right to be secure against unconsented touching;[245] thus, consent is required in order to use a person in a medical study.

Historically, courts have protected childbearing women from unwarranted intrusions[246] and nonconsensual procedures.[247] When a physician performs a procedure without consent, he or she commits a battery.[248] When a physician performs a procedure without full consent, he or she commits either a battery[249] or negligent nondisclosure.[250]

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240. RESTATEMENT (SECOND) OF TORTS § 1 (1977).

241. J. MILL, ON LIBERTY 15 (1954).

242. RESTATEMENT (SECOND) OF TORTS § 892 (1977).

243. W PROSSER, J. WADE & V SCHWARTZ, CASES AND MATERIALS ON TORTS 128-29 (8th ed. 1988).

244. *See* RESTATEMENT (SECOND) OF TORTS § 892A (1977) (mental and legal incapacity without an appointed guardian). If the patient is unconscious, as in many emergency situations, the patient's wishes are unknown and unexpressed. Without an expressed patient wish, there is no conflict.

245. Union Pac. Ry. Co. v. Botsford, 141 U.S. 250, 251 (1891). In *Botsford*, the Court states that "[n]o right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." *See also* W. KEETON, D. DOBBS, R. KEETON & D. OWEN, PROSSER & KEETON ON THE LAW OF TORTS 118-21 (5th ed. 1984).

246. De May v. Roberts, 46 Mich. 160, 165, 9 N.W. 146, 149 (1881) (doctor liable in deceit; court held that the patient "had a legal right to the privacy of her apartment").

247. Inderbitzen v. Lane Hosp., 124 Cal. App. 462, 12 P.2d 744 (1932) (where medical students examined patient over woman's protest, the court held that their conduct "constituted an assault upon her or trespass to her person").

248. Rubino v. De Fretias, 638 F.Supp. 182, 182-85 (D. Ariz. 1986); Bang v. Charles T. Miller Hosp., 251 Minn. 427, 88 N.W.2d 186 (1958); Mohr v. Williams, 95 Minn. 261, 104 N.W. 12 (1905).

249. Dow v. Kaiser Found., 12 Cal. App. 3d 488, 90 Cal. Rptr. 747 (1970).

250. Canterbury v. Spence, 464 F.2d 772, 780-83 (D.C. Cir. 1972); Kohoutek v. Haffner, 383 N.W.2d 295, 298-302 (Minn. 1986); Harnish v. Children's Hosp. Medical Center, 387 Mass. 152, 439 N.E.2d 240 (1982).

Justice Blackmun defined informed consent very simply as "the giving of information to the patient as to just what would be done and as to its consequences."[251] To fulfill these basic requirements, the neonatal HIV surveillance program would first need to communicate to the parent the following:

1) a sharp instrument will be used to cause the baby's heel to bleed;
2) the blood will be collected and tested for HIV antibodies;
3) if the HIV antibody test is positive, the results indicate that the mother is infected with HIV and that the infant may or may not be infected with HIV; and
4) regardless of whether the blood test is positive or negative for HIV, no one will inform the mother of the test results.

Second, the program would need to obtain the voluntary assent of the parent.

Because no one offers this information to parents, nor seeks their assent, the HIV serosurveillance is performed without prior informed consent. Additionally, because no state law requires indiscriminate testing of all newborns for HIV, the HIV serosurveillance study does not operate under authority of law. The HIV testing practice unlawfully violates the dignity interests of the family, the mother and the child.

Judge Cardozo's claim that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault,"[252] is technically incorrect. Because patients are ordinarily unconscious during surgery, there is no apprehension of offensive touching.[253] Thus, the surgeon commits battery[254] rather than assault and the courts hold physicians liable, regardless of the outcome.[255] Similiar to a doctor operating without consent, a nurse who jabs an infant's heel to remove blood for a test that is not required by law or that the parent does not consent to, commits a battery.

The problem with this analysis is its premise that the decision-making actor is the physician. But, the doctor is not responsible for the testing and may know nothing about the neonatal HIV testing. State public health agencies are responsible for the HIV testing. The nurses[256] who jab the baby's heel and collect the infant's blood are acting as agents of the state. The HIV specimen is obtained

251. Planned Parenthood of Cent. Missouri v. Danforth, 428 U.S. 52, 67, n.8 (1976).

252. Schloendorff v. Society of New York Hosp., 211 N.Y. 125, 129-30, 105 N.E. 92, 93 (1914).

253. RESTATEMENT (SECOND) OF TORTS § 21 (1965).

254. RESTATEMENT (SECOND) OF TORTS §§ 13, 18 (1965).

255. Pugsley v. Privette, 220 Va. 892, 901, 263 S.E.2d 69, 75 (1980).

256. Nurses ordinarily obtain the newborn blood specimens.

along with the specimens for the state's mandated screening tests.[257] Most nurses believe the specimens submitted to the state fulfill the legal requirements, no more and no less.[258]

Since nurses, physicians and hospitals actually are unwitting agents for the state/federal health agency programs, other causes of action should be entertained. The public health agency falsely represents that the newborn screening test includes only the legally mandated tests.[259] The agency does so with the intention of misleading the persons who are the focus of the testing.[260] Mothers, who justifiably believe health care personnel's representation that the testing is required by law, allow the nurse to lance and squeeze the baby's heel. The injury to the infant, the extra squeezing of the heel, may seem trivial but it is certainly cognizable.[261] This covers all the elements for a cause of action in deceit.[262] Moreover, the lancing and heel squeezing represents an unreasonable intrusion,[263] and so the common law action for invasion of privacy[264] also applies to the fact pattern.[265] Additionally, since the agency takes blood without permission or legal authority for its own purpose, this conduct represents conversion.[266] In theory, even a claim for reckless disregard of safety could be entertained.[267]

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257. These laws do not contain provisions for HIV testing. At least two states (Rhode Island and Florida) allow testing under other regulations.

258. There is nothing included with the screening materials to indicate otherwise. *See* Appendix A for a copy of the State of Illinois' Department of Public Health neonatal screening test form.

259. *Id.*

260. Disclosure of the HIV screening could create protest, refusal, and "selection bias." *See supra* notes 141-58 and accompanying text.

261. *See* Crosswhite v. Barnes, 139 Va. 471, 477, 124 S.E. 242, 244 (1924). The *Crosswhite* court held that "[t]he law is so jealous of the sanctity of the person that the slightest touching of another . . if done in a rude, insolent or angry manner, constitutes a battery for which the law affords redress." *Id.*

262. De May v. Roberts, 46 Mich. 160, 9 N.W. 146 (1881). *See also* W. KEETON, D. DOBBS, R. KEETON & D. OWEN, PROSSER & KEETON ON THE LAW OF TORTS § 105, at 728 (5th ed. 1984).

263. The intrusion is unreasonable because it is not legally authorized; parents are not given notice, nor do they consent to the HIV testing.

264. Bednarik v. Bednarik, 18 N.J. Misc. 633, 16 A.2d 80 (1940). *Cf.*, Froelich v. Werbin, 219 Kan. 461, 548 P.2d 482 (1976). *See also* W. KEETON, D. DOBBS, R. KEETON & D. OWEN, PROSSER & KEETON ON THE LAW OF TORTS § 117, at 854-56 (5th ed. 1984); RESTATEMENT (SECOND) OF TORTS § 652A (1977).

265. Bednarik v. Bednarik, 18 N.J. Misc. 633, 16 A.2d 80 (1940).

266. RESTATEMENT (SECOND) OF TORTS §§ 222A and 228 (1965). In the recent case of Moore v Regents University of California, 51 Cal. 3d 120, 271 Cal. Rptr. 146, 793 P.2d 479 (1989), in which Moore consented to the procedure, the court upheld the negligent disclosure claim but dismissed the conversion claim.

267. RESTATEMENT (SECOND) OF TORTS § 500 (1965). The unlinking of test results is intentional and the failure to notify infected persons of the results certainly contributes to delay in diagnosis, delay in treatment, and the spread of the infection to others. Subsequent pregnancies and infection of those infants also constitutes harm.

III. RELEVANT PROFESSIONAL GUIDELINES

Nonmedical individuals are somewhat familiar with the Hippocratic Oath, but few realize that physicians need not recite this Oath and that the words only carry ceremonial value at graduation. In contrast, professional associations' guidelines are not ceremonial. Professional association guidelines specifically address biomedical research. In addition to professional association guidelines, biomedical research is also subjected to editorial scrutiny.

1. Professional Ethics

Ethical problems frequently arise in the medical setting. To guide professionals, leaders and experts from various associations have drafted comprehensive ethical guidelines. Several apply to HIV testing.

A. World Medical Association

In July 1945, physicians from allied countries formed an international medical association to be concerned with the ethics of medical practice. The stimulus for this organizational focus was the Nazi physicians' forced sterilization and eugenics programs. The World Medical Association is widely recognized for its pioneering guidelines on medical ethics.

In the 1948 Declaration of Geneva, the Association clearly stated that the interest and well being of the patient is paramount to that of scientific research.[268] When patients are tested for HIV without their knowledge, without their assent, and never informed of the results, patient interests are not paramount; patient interests are ignored. Epidemiological research is exalted over patient care.

In 1949, the Association issued the International Code of Medical Ethics which commands that "[a] physician shall deal honestly with patients."[269] Taking blood for one purpose (legislatively mandated metabolic screening) and using the blood for another purpose (HIV testing) without informing the patients of the results cannot be considered dealing honestly with patients.

In the Declaration of Helsinki,[270] the Association specifically addressed biomedical research practices. Several of the Helsinki principles outlined below apparently are being ignored by the neonatal serosurveillance study. First is the command to place patient

268. "The health of my patient will be my first consideration." WORLD MEDICAL ASSOCIATION, HANDBOOK OF DECLARATIONS 3 (1985) [hereinafter HANDBOOK OF DECLARATIONS].

269. *Id.* at 4.

270. *Id.* at 9.

interests first.[271] The study's principal goal is to determine the rate of HIV infection in reproductively active women. In that pursuit, no consideration is being given to women's interests. Second is the command to respect the person and the individual's autonomy in medical decisions.[272] In fact, the study is designed to circumvent notice to the women in order to avoid any individual protest to the testing.[273] No respect is given to the women's wishes. Third, the command for informed consent is ignored along with the command to offer the patient the opportunity to abstain from participation in the study.[274]

An additional four part section of the Helsinki Declaration covers non-therapeutic biomedical research.[275] The neonatal HIV serosurveillance violates each of the four articles. The first article obliges the physician to "remain the protector of the life and health of that person on whom biomedical research is being carried out."[276] In actual practice, the physician never receives the HIV test results and so never instigates any therapeutic measures on behalf of his or her patient. Consequently, the physician cannot provide such measures as protection against opportunistic infections or early initiation of antiviral medicines[277] to delay the onset of disease. The second article states that "[t]he subjects should be volunteers."[278] As mentioned earlier,[279] parents are never given notice of the testing and so they never assent to participation in the research experiment. The third article states that research should be sus-

271. "Concern for the interests of the subject must always prevail over the interests of science and society." *Id.* at 10 (directive No. 5).

272. "The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject." *Id.* (directive No. 6).

273. Dondero, *supra* note 1, at 215.

274. Article 9 of the Declaration of Helenski proposes:

> In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely given informed consent, preferably in writing.

HANDBOOK OF DECLARATIONS, *supra* note 268, at 10.

275. *Id.* at 11 (non-therapeutic biomedical research involving human subjects).

276. *Id.*

277. NIH Conference, *Antiviral Therapy in AIDS*, 113 ANNALS INTERNAL MED. 604-18 (1990).

278. *Id.*

279. *See supra* notes 261-63 and accompanying text.

pended if there might be potential harm to the subject.[280] As discussed earlier, there is harm to the family as a whole and to both mother and child in the delay of therapy. Additionally, there is the potential of harm through the unwitting administration of live viral immunizations to an HIV-infected child.[281] Besides the direct harm to the mother and infant, harm to others may result through inadvertent transmission. Without notifying patients of their serostatus and without any individual counseling, there is no impetus to change conduct.[282] This, in turn, may lead to horizontal[283] or vertical transmission.[284] The fourth article restates the principle that the interest of science and society does not supersede the consideration of the patient.[285]

B. American Medical Association

Throughout American history several studies trammeled the rights of patients and actually caused illness and death.[286] In response, the American Medical Association addressed research situations in its discussion of medical ethics and medical practice.[287] The recent edition of *Current Opinions* states:

> (4) In clinical investigation primarily for the accumulation of scientific knowledge-
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> A. Adequate safeguards must be provided for the welfare, safety and comfort of the subjects. It is fundamental social policy that the

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280. "The investigator or the investigating team should discontinue the research if in his/her judgement it may, if continued, be harmful to the individual." HANDBOOK OF DECLARATIONS, *supra* note 268, at 11 (directive No. 3).

281. REPORT OF THE COMMITTEE ON INFECTIOUS DISEASES, AMERICAN ACADEMY OF PEDIATRICS 96-98 (21st ed 1988).

282. Becker & Joseph, *AIDS and Behavioral Change to Reduce Risk: A Review*, 78 AM. J. PUB. HEALTH 394, 394-410 (1988); Francis & Chin, *Prevention and Control of Acquired Immunodeficiency Syndrome in the United States*, 257 J. A.M.A. 1357, 1362 (1987); *Prevention and Control of Acquired Immunodeficiency Syndrome*, 258 J. A.M.A. 2097, 2100 (1987);

283. Horizontal transmission refers to the spread of HIV between individuals through shared high risk activities. *See supra* note 20 and accompanying text.

284. Vertical transmission refers to the spread of HIV from mother to child through breast feeding, the birthing process, or transplacental transmission. *See supra* note 20 and accompanying text.

285. HANDBOOK OF DECLARATIONS, *supra* note 268, at 11.

286. Some infamous examples include: Annas, *Baby Fae: The "Anything Goes" School of Human Experimentation*, 15 HASTINGS CENTER REP. 15 (1985) (transplant of primate heart into human child); Beecher, *Infectious Hepatitis: Studies of Its Natural History and Prevention*, 258 NEW ENG. J. MED. 407-16 (1958) (hepatitis infected feces were deliberately fed to children aged five to ten in a mental institution); Brandt, *Racism, Research and the Tuskegee Syphilis Study*, 8 HASTINGS CENTER REP 21 (1978) (observing black men who tested positive for syphilis); *See generally*, Barber, *The Ethics of Experimentation with Human Subjects*, 234 SCIENTIFIC AM. 25-31 (1976).

287. Council on Ethical and Judicial Affairs, 1989 Current Opinions, American Medical Association (1990).

advancement of scientific knowledge must always be secondary to primary concern for the individual.

B. Consent, in writing, should be obtained from the subject, or from his legally authorized representative if the subject lacks the capacity to consent, following: (a) a disclosure of the fact that an investigational drug or procedure is to be used, (b) a reasonable explanation of the nature of the procedure to be used and risks to be expected, and (c) an offer to answer any inquiries concerning the drug or procedure.

C. Minors or mentally incompetent persons may be used as subjects only if:

i. The nature of the investigation is such that mentally competent adults would not be suitable subjects.

ii. Consent in writing, is given by a legally authorized representative of the subject under circumstances in which an informed and prudent adult would reasonably be expected to volunteer himself or his child as a subject.

D. No person may be used as a subject against his will.[288]

While some may argue that removing patient identifiers from sample specimens provides adequate safeguards for the subject, the remaining portions of the section on clinical investigation clearly conflict with the conduct embodied in the current neonatal HIV surveillance program. There is no written consent.[289] There is no disclosure of the fact that an investigational procedure is to be performed on the infant.[290] There is no explanation of the procedure.[291] There is no offer to answer questions regarding the procedure.[292] Because subjects are not given notice of the procedure, are involuntarily enrolled in the study, and have no opportunity to refuse the testing, the presumption must be made that these individuals are being used as subjects against their will.[293] When examined in its entirety, the neonatal HIV surveillance project fails to comply with the AMA's Clinical Investigation section of the Principles of Medical Ethics.[294]

C. Epidemiological Ethics

Physicians are not the only individuals involved in medical research. The particular form of medical study questioned herein is carried out by medical scientists who are often epidemiologists.[295]

288. *Id.* at 4, 5.

289. *Id.* at 5. This violates section 2.07(4)B.

290. *Id.* This violates section 2.07(4)B(a).

291. *Id.* This violates section 2.07(4)B(b).

292. *Id.* This violates section 2.07(4)B(c).

293. *Id.* This violates section 2.07(4)D.

294. Council on Ethical and Judicial Affairs, 1989 Current Opinions, American Medical Association (1990).

295. Epidemiologists may be physicians or may be professionals with graduate degrees in the health sciences. Medical association ethical guidelines have limited value to nonphysicians.

A recent conference on the development of international ethical guidelines for epidemiological research and practice addressed the need to adopt standards for those who undertake epidemiologic research.[296] The ethical considerations adopted balance respect of persons,[297] beneficence[298] and justice.[299] The ethical guidelines, to be published at the end of 1991, are expected to be modeled after the Brazilian code. This code, in part, states:

> 1. It is essential for the community to be organized so that it may willingly participate, through its leaders and organization(s), throughout the investigation.
> 2. The community has the right to be fully informed about the nature, objectives, advantages and eventual hazards of the research to be undertaken.
> 3. Nobody may be submitted to an investigation about which he/she has not been previously informed and consented.
> 4. No experimental procedure may be planned in a way to deprive the community of preventive and/or therapeutic measures, either totally or partially.[300]

Poor and minority communities are not willingly involved in HIV serosurveillance studies. Poor and minority community members do not read the medical journals which publish the CDC papers describing the serosurveillance studies. Wealthy and white women also miss reading Public Health Reports. Regardless, mothers are not directly informed about the nature, objectives, advantages and hazards of the HIV serosurveillance. All women are submitted to an investigation about which they have not been directly informed and without their consent. There is also the possibility that the experimental procedure was planned in a way that deprives the community of preventive and therapeutic measures.

Epidemiologists participating in the neonatal HIV serosurveillance studies depart from the standards established in the proposed code for epidemiological research. Ethically, a screening program designed to detect an infectious disease must be accompanied by notification, counseling, confidentiality safeguards, and medical services.

D. Other

British medical journals have been debating the propriety of

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296. *Ethics and Epidemiology: XXVth CIOMS Conference*, 66 WEEKLY EPIDEMIOLOGICAL RECORD 17 (1991).

297. Defined as "the right to be informed and the right of expression." *Id.*

298. Defined as "the requirement that benefits outweigh cost or harm." *Id.*

299. Defined as "the obligation to protect the weak and to ensure equity." *Id.*

300. World Health Organization, *Ethics and Epidemiology: XXVth CIOMS Conference*, 66 WEEKLY EPIDEMIOLOGICAL REC. 17, 19 (1991).

using children in medical studies for over two decades.[301] English physicians[302] and lawyers[303] believed that ethical guidelines prohibited blood sampling of infants for purely research purposes, while American professionals suggested that children could be used in clinical investigations where there was no direct benefit intended for the child and omitted mentioning consent.[304] English editors expected informed parental consent and special scrutiny of studies involving children,[305] while the editor of a prominent American medical journal rejected the International Code of Medical Ethics as impractical and extremist.[306]

The British Medical Research Council's ethical guidelines formed the basis of the debate concerning the ethics of experiments on infants. The Council's statement on professional responsibility in clinical research emphasized the need for explicit informed consent to be given to test subjects.[307]

According to the Department of Health, "it is not legitimate to do experiments in children which are not in the interests of that particular child."[308] Scholars echoed this philosophy in a 1978 sym-

301. *Treatment-Research-Experiment?* 42 ARCHIVES DISEASE CHILDHOOD 109 (1967).

302. Pratt, *Research on Infants*, 1 LANCET 699 (1977); Dodge & Evans, *Research on Infants*, 1 LANCET 852 (1977).

303. *Valid Parental Consent*, 1 LANCET 1346 (1977) ("individual lawyers had stated that no parent can give consent which is valid in law for any experiment to be made on their child which is not demonstrably in the child's interest; such an experiment would constitute an assault on the child"]. *Cf.*, Skegg, English Law Relating to Experimentation on Children, 2 LANCET 754, 755 (1977) (suggesting a reasonable parent test and actual parental consent would allow participation).

304. Curran & Beecher, *Experimentation in Children: A Reexamination of Legal Ethical Principles*, 210 J. A.M.A. 77, 83 (1969).

305. *The Ethics of Research Involving Children as Controls*, 48 ARCHIVES DISEASE CHILDHOOD 751, 752 (1973).

306. The editor of the New England Journal of Medicine stated that "the World Medical Association's declaration is neither observed nor practical. Nor, since it represents an extremist position, is it really moral." Ingelfinger, *Ethics of Experiments on Children*, 288 NEW ENG. J. MED. 791, 792 (1973). These comments followed criticism of the journal's publication of the Willowbrook studies. Willowbrook was a residential institution for mentally impaired individuals. These studies, among other things, involved feeding children feces infected with Hepatitis B to better understand the disease.

307. Statement by Medical Research Council, *Responsibility in Investigations on Human Subjects*, BRITISH MED. J. 178-80 (July 18, 1964). The Council stated:

> It should be clearly understood that the possibility or probability that a particular investigation will be of benefit to humanity or posterity would afford no deference in the event of legal proceedings. The individual has rights that the law protects and nobody can infringe those rights for the public good. In investigations of this type it is therefore always necessary to ensure that the true consent of the subject is explicitly obtained.

Id. at 179.

308. Pratt, *Research on Infants*, 1 LANCET 1052 (1977).

posium at the National Institutes of Health.[309]

For unknown reasons, medical professionals set aside the special protection given to infants and performed seroprevalence surveys.[310] The Faculty of Community Medicine relegated the ethical concerns to a "quibble".[311] Even the British Medical Association exalted involuntary testing over voluntary testing.[312] Only the Royal College of Midwives lambasted the proposal, stating: "Pregnant women are a captive audience when attending antenatal clinics, and to use them in a new monitoring and surveillance exercise for AIDS is morally wrong."[313] At least superficially, our current neonatal HIV surveillance and the English studies fail to measure up to the Council's standard because both avoid parental consent and parental notice.[314]

Canada thoughtfully analyzed individual rights and medical ethics prior to initiating anonymous unlinked seroprevalence studies.[315] The governmental group recommended using serosurveillance accompanied by public notice of the research and by involvement of community and special interest groups.[316] Notably absent in the Canadian guidelines is the option for individuals to refuse to participate in the testing.

The World Health Organization reviewed serosurveillance and found that these studies serve a useful purpose by clarifying the epidemiological pattern of HIV infection.[317] This body of professionals concerned with global health concluded that serosurveys could be performed with "either informed consent and counseling and ensure confidentiality or they may be anonymous (no record of name or other specific identifiers)."[318]

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309. Nat'l Inst. Health, Pub. No. 80-1858, Issues in Research with Human Subjects 122, 123 (1980).

310. Peckham, Tedder, Briggs, Ades, Hjelm, Wilcox, Parra-Mejia & O'Connor, *Prevalence of Maternal HIV Infection Based on Unlinked Anonymous Testing of Newborn Babies*, 335 LANCET 516, 518 (1990).

311. *Testing for HIV Infection*, 7 LANCET 1293 (1988) ("we're convinced that the ethical worry which concerns some doctors is a quibble . ").

312. *BMA View on HIV Prevalence Screening*, 2 LANCET 582 (1988) ("would prefer prevalence screening by involuntary unnamed testing to voluntary unnamed testing, because any form of screening with consent is liable to bias.").

313. *Testing for HIV Infection*, 7 LANCET 1293 (1988).

314. Of note, the English are considering copying our system. Peckham, *supra* note 310, at 518.

315. *See* Federal Centre for AIDS Working Group on Anonymous Unlinked HIV Seroprevalence, *Guidelines on Ethical and Legal Considerations in Anonymous Unlinked HIV Seroprevalence Research*, 143 CAN. MED. A. J. 625 (1990).

316. *Id.* at 627.

317. WORLD HEALTH ORGANIZATION, SPECIAL PROGRAMME ON AIDS: SCREENING AND TESTING IN AIDS PREVENTION AND CONTROL PROGRAMMES, (WHO/SPA/GLO/87.2) (Jan. 1988) (copies can be obtained from the Special Programmes on AIDS, WHO, Avenue Appia, CH-1211 Geneva 27, Switzerland).

318. *Id.*

In 1983, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research examined ethical and legal issues in medical studies.[319] This esteemed group of individuals delineated a principle of respect due to "people in health care situations."[320] This respect contains two essential components:

> The first two of these obligations are probably the most familiar. They are commonly phrased as the principle of self-determination: "that individuals should be treated as autonomous agents, and . . that persons with diminished autonomy are entitled to protection." To differentiate this aspect of respect for persons from the other, the Commission makes special reference to the self-determination principle-although the rationale for honoring self-determination also supports other aspects of the principle of respect for persons.[321]

Surreptitiously removing infant blood specimens without notice or consent of parents demonstrates a clear lack of respect for self-determination and takes full advantage of the diminished autonomy of newborn infants.

2. *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*

Ethical guidelines are also contained in the Uniform Requirements For Manuscripts Biomedical Journals.[322] The relevant section states:

> Ethics: When reporting experiments on human subjects, indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) or with the Helsinki Declaration of 1975, as revised in 1983.[323]

The inclusion of a statement concerning ethical standards in reports on studies involving humans exists in the description of manuscript requirements because of the recognized need to protect persons from their unwilling participation in such studies.

In addition, some of the prestigious medical journals contain other instructions to authors which expressly include documenta-

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319. PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SUMMING UP: ETHICAL AND LEGAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH 17 (March 1983).

320. *Id.* at 68.

321. *Id.* (quoting NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, U.S. DEP'T OF HEALTH, EDUC. & WELFARE, THE BELMONT REP. 4 (1978)).

322. International Committee of Medical Journal Editors, *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, N.Y. STATE J. MED. 456 (Aug. 1988).

323. *Id.* at 457.

tion of informed consent.[324] A journal which has published the results of nonconsensual seroprevalence surveys specifically require that articles "state formally that an appropriate institutional review board approved the project and/or that informed consent was obtained from the subjects after the nature of the procedure(s) had been explained."[325] The use of "and/or" is abhorred[326] in constructing meaningful guidelines.

"And/or" allows for two very different interpretations. One interpretation is that:

> a review board's approval and informed consent is required, or
> informed consent alone suffices for meeting the requirements.

The alternative reading is that :

> a review board approval alone is required (without informed consent), or
> informed consent alone suffices for meeting the requirements.

Since several journals published studies without patient consent,[327] it appears that these journals adopted the "review board alone" interpretation. A committee eliminated the need for obtaining the patient's informed consent. This ad hoc erasure of individual autonomy is not surprising, given the precedent of publishing the Tuskegee syphilis study results for forty years without criticism.[328]

IV. CONCLUSION

Several studies amply described the primary epidemiology of

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324. *Instructions for Authors*, 261 J. A.M.A. 3253 (1990).

325. *Id.*

326. 1A SUTHERLAND STATUTORY CONSTRUCTION 21.41 (N. Singer 4th ed. 1985) ("[t]he phrase "and/or" should never be used").

327. For example, The Journal of the American Medical Association published: Marwick, *HIV Antibody Prevalence Data Derived From Study of Massachusetts Infants*, 258 J. A.M.A. 171 (1987); Landesman, Minkoff, Holman, McCalla & Sijin, *Serosurvey of Human Immunodeficiency Virus Infection in Parturients: Implications for Human Immunodeficiency Virus Testing Programs of Pregnant Women*, 258 J. A.M.A. 2701, 2701-03 (1987). The New England Journal of Medicine published: Donegan, Edelin & Craven, *HIV Seroprevalence Rate at the Boston City Hospital*, 319 NEW ENG. J. MED. 653 (1988); Hoff, Berardi, Weiblen, Mahoney-Trout, Mitchell & Grady, *Seroprevalence of Human Immunodeficiency Virus Among Childbearing Women: Estimation by Testing Samples of Blood from Newborns*, 318 NEW ENG. J. MED. 525, 525-30 (1988); Krasinski, Borkowsky, Bebenroth & Moore, *Failure of Voluntary Testing for Human Immunodeficiency Virus to Identify Infected Parturient Women in a High-Risk Population*, 318 NEW ENG. J. MED. 185 (1988); Minkoff, Holman, Beller, Delke, Fishbone & Landsman, *Routinely Offered Prenatal HIV Testing*, 319 NEW ENG. J. MED. 1018 (1988).

328. Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*, 8 HASTINGS CENTER REP. 21, 27 (1978).

HIV disease years ago.[329] Therefore, on medical, economic, legal, and moral grounds, one must question the utility of continuing a national serosurveillance program.

In any infectious disease, intervention is most effective when initiated at the earliest possible moment. There is no infectious agent — bacterial, viral, fungal, rickettsial, or otherwise — with which delayed therapy results in an improved outcome. In fact, starting therapy late can yield a fatal outcome even when the proper medications are employed. Thus, the present policy of testing for an infectious disease and not initiating treatment makes little sense from a medical perspective.

A well designed screening program anticipates detection of infected persons[330] and contains a management plan. The management plan may be a referral to comprehensive services already available in the community through another institution or the establishment of direct treatment to those detected. Direct treatment services for HIV-infected mothers and their newborns should include routine ambulatory care,[331] inpatient services, hospice care, psychological support services, sociological support services,[332] drug treatment services and reproductive health counseling. What exists now is a national system of involuntary secret testing independent of legal authority and bereft of patient services. Valuable health care dollars and manpower are being wasted by repeatedly analyzing the demographics of HIV infection in reproductively active women. Therefore, the study is flawed from an economic and public health perspective.

The current program, in many ways, parallels the shameful

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329. U.S. DEP'T OF HEALTH AND HUMAN SERV., NATIONAL HIV SEROPREVALENCE SURVEYS: SUMMARY OF RESULTS (HIV/CID/9-90/006) (1990); U.S. DEP'T OF HEALTH AND HUMAN SERV., SECRETARY'S WORK GROUP ON PEDIATRIC HIV INFECTION AND DISEASE FINAL REPORT (Nov. 18, 1988); Dondero, *Monitoring the Levels*, *supra* note 1, at 213-20; Centers for Disease Control, *Quarterly Report to the Domestic Policy Council on the Prevalence and Rate of Spread of HIV and AIDS in the United States*, 37 MORBIDITY & MORTALITY WEEKLY REP. 223, 223-26 (1988); Centers for Disease Control, *Quarterly Report to the Domestic Policy Council on the Prevalence and Rate of Spread of HIV and AIDS in the United States*, 37 MORBIDITY & MORTALITY WEEKLY REP. 551, 551-54, 559 (1988); Rogers, Thomas, Starcher, Noa, Bush & Jaffe, *Acquired Immunodeficiency Syndrome in Children: Report of the Centers for Disease Control National Surveillance, 1982-1985*, 79 PEDIATRICS 1008, 1008-14 (1987); Centers for Disease Control, *Human Immunodeficiency Virus Infection in the United States: A Review of Current Knowledge*, 36 MORBIDITY & MORTALITY WEEKLY REP 6, 7 (Supp. 6 1987).

330. If there is no illness to detect, why screen?

331. Ambulatory care refers to ordinary medical care. In addition, HIV-infected persons need periodic immunologic assessment and medical monitoring of prophylaxis and antiviral therapies.

332. These include assistance with housing, income, employment, day care, and so on.

Tuskegee syphilis study.[333] In both the Tuskegee and neonatal studies:

1) seropositives are not treated;
2) treatment is available;[334]
3) infected persons are not counseled or educated regarding the disease, its consequences, and its transmissibility;
4) a federal agency designed the program, yet claimed states are responsible;[335]
5) the studies have only been published in medical journals, and
6) patients are not given enough information to give fully informed, uncoerced consent.

Once again the specters of sexism, racism, eugenics, invasion of privacy, and science without moral control arise. The neonatal serosurveillance details the serostatus of women only. The CDC subgroups the numbers according to demographic variables and this serves to characterize HIV-infected women. Of the women testing positive, over seventy five percent are nonwhite.[336] The demographic display suggests a negative racial connotation towards minority women. For example, the CDC stated:

> Human immunodeficiency virus (HIV) infection disproportionately affects women in racial/ethnic minority groups. Although black [sic] and Hispanic women constitute 19% of all U.S. women, they represent 72% of all U.S. women diagnosed with AIDS. . . . These disproportionate rates largely reflect the occurrence of HIV infection among injecting drug users and their sex partners.[337]

This implies minority women are more likely than white women to be HIV infected and drug users. Like lepers who are unclean, HIV-infected women are similarly perceived as foul.

The eugenic component of the serosurveillance program is not as apparent as the racial overtones. Vertical transmission can only be prevented by interrupting the woman's ability and right to bear children. For sexually active women, this means forced contraceptive control through pharmacologic or surgical methods.[338] One way to accomplish eugenic control is to criminalize the transmission

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333. Brandt, *supra* note 328, at 21.

334. Treatment for syphilis and HIV disease is and has been available. The distinction between the two is that the treatment for syphilis is curative while the treatment for HIV disease is palliative.

335. J. JONES, BAD BLOOD 7 (1981).

336. Gayle, Selik & Chu, *Surveillance for AIDS and HIV Infection Among Black and Hispanic Children and Women of Childbearing Age, 1981-1989*, 39 MORBIDITY & MORTALITY WEEKLY REP. 23, 25 (1990); Centers for Disease Control, *AIDS in Women - United States*, 39 MORBIDITY & MORTALITY WEEKLY REP. 845, 845-46 (1990)[hereinafter *AIDS in Women*].

337. *AIDS in Women, supra* note 336, at 845. The difference in the claim that over seventy five percent are nonwhite reflects the inclusion of Asian, Native American, and other women of color.

338. Surgical methods include forced sterilization and pregnancy termination.

of HIV[339] and then apply the law to vertical transmission.[340] States have already taken the first step.[341]

Three major issues need pubic attention. The first is whether society will accept the involuntary indirect testing of women for HIV. When the CDC concluded "some of the surveys must be blinded, that is anonymous and unlinked to identifiable persons to avoid the uninterpretable impact of self-selection bias,"[342] scientific purity championed over individual rights of autonomy, privacy, and security of the person.

Even if society can accept the involuntary testing of childbearing women for HIV, a second issue is whether society will accept an administrative agency's unilateral decision to test. Our system of checks and balances may be outdated, but exclusive bureaucratic policy determination conflicts with the principles of democracy.

If society can accept involuntary testing solely instigated by an administrative agency, the final issue is whether an administrative agency whose central role is preserving public health fulfills that mission by withholding HIV test results from those individuals who are involuntarily tested.

It is undisputed that there is a growing problem of HIV disease in families. Clearly, the rate of HIV infection in many geographical areas exceeds the rates of other diseases for which states screen families. Screening childbearing women should be discussed, performed voluntarily,[343] or legislatively authorized. And, of course, HIV seropositive individuals must receive the test results, must receive counseling and must receive needed medical and social services.

339. Closen & Isaacman, *Criminally Pregnant*, 76 A.B.A. J. 76 (Dec. 1990).

340. *See generally* Isaacman, *Are We Outlawing Motherhood for HIV-Infected Women?*, 22 LOY. U. CHI. L.J. 479 (1991).

341. Intergovernmental Health Policy Project, *AIDS/HIV in Women: State Legislative Initiatives*, 3 INTERGOVERNMENTAL AIDS REP. 3 (Oct. 1990) ("Twenty-two states have made it a felony or misdemeanor to knowingly expose or transmit HIV infection Women in Idaho with AIDS, AIDS-related condition or HIV who knowingly transfer breast milk can be found guilty of a felony.").

342. Dondero, *supra* note 1, at 215.

343. Here, voluntary refers to fully informed specific consent with the right of refusal.

APPENDIX

NEONATAL SCREENING TESTS FOR BIOTINIDASE, CONGENITAL ADRENAL HYPERPLASIA, GALACTOSEMIA, HYPOTHYROIDISM, PHENYLKETONURIA AND SICKLE CELL

STATE OF ILLINOIS
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF LABORATORIES
2121 WEST TAYLOR STREET
CHICAGO, ILLINOIS 60612

DO NOT WRITE IN THIS SPACE

HOSPITAL: _____ CITY: _____

BABY'S NAME: _____ (LAST, FIRST) MOTHER'S NAME: _____ (LAST, FIRST)

DATE OF BIRTH: ___ (MONTH, DAY, YEAR) SEX M ☐ F ☐ HOSP CHART NO: _____

TWIN? YES ☐ NO ☐ PREMATURE? YES ☐ NO ☐ WEIGHT? _____ GM or ____ LB ____ OZ

DATE OF SPECIMEN: ___ (MONTH, DAY, YEAR) AGE IN HOURS AT TIME OF SPECIMEN? _____ RESUBMITTED SPECIMEN? YES ☐ NO ☐

PUBLIC AID NO: _____ ALL TESTS NORMAL UNLESS BOX CHECKED ☐

PEDIATRICIAN: _____

ADDRESS: _____

CITY/STATE: _____

TELEPHONE: ( ) —

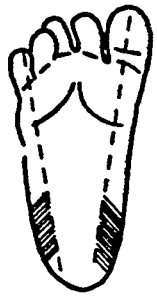
0 1 6 6 7 0 9 9

SEE DIRECTIONS ON REVERSE SIDE

8610

Store specimen cards in a cool dry place.
Do not handle filter paper portion. Skin oils will prevent saturation.
Please fill out form completely.

SAMPLE COLLECTION



COLLECT SAMPLE FROM SHADED AREA

1. Sterilize and dry skin. Puncture heel with sterile lancet.
2. Allow large blood droplet to form.
3. Touch filter paper to blood and allow to soak through completely in each circle. Total saturation of the circles must be evident when the paper is viewed on both sides.

DO NOT APPLY BLOOD TO BOTH SIDES

4. Use of capillary tubes is not recommended because they tend to roughen the filter paper and cause overabsorption.
5. ALLOW BLOOD SPOTS TO AIR DRY THOROUGHLY FOR THREE HOURS AT ROOM TEMPERATURE. KEEP AWAY FROM DIRECT SUNLIGHT AND HEAT. NEVER SUPERIMPOSE ONE WET FILTER PAPER ON ANOTHER BEFORE THOROUGH DRYING.
6. Mail filter paper cards promptly to address on front of form.

NOTE: SPECIMENS MAY BE UNSATISFACTORY IF:

All circles not completely filled.
Circle oversaturated.
Not allowed to dry thoroughly.
Contaminated with foreign substance.

01667099 01667099

SATURATE ALL CIRCLES WITH BABY'S BLOOD