

# Holly Fernandez Lynch

## List of Publications by Year in descending order

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Version: 2024-02-01

156  
papers

1,392  
citations

471509

17  
h-index

414414

32  
g-index

173  
all docs

173  
docs citations

173  
times ranked

1717  
citing authors

#	ARTICLE	IF	CITATIONS
1	How Do Accredited Organizations Evaluate the Quality and Effectiveness of Their Human Research Protection Programs?. <i>AJOB Empirical Bioethics</i> , 2023, 14, 23-37.	1.6	4
2	“We measure what we can measure”: Struggles in defining and evaluating institutional review board quality. <i>Social Science and Medicine</i> , 2022, 292, 114614.	3.8	12
3	Allocation of Opportunities to Participate in Clinical Trials during the Covid-19 Pandemic and Other Public Health Emergencies. <i>Hastings Center Report</i> , 2022, 52, 51-58.	1.0	1
4	Institutional Review Board Use of Outside Experts: A National Survey. <i>AJOB Empirical Bioethics</i> , 2022, 13, 251-262.	1.6	8
5	Aspiring to Reasonableness in Accelerated Approval: Anticipating and Avoiding the Next Aducanumab. <i>Drugs and Aging</i> , 2022, 39, 389-400.	2.7	7
6	Emergency Approvals for COVID-19: Evolving Impact on Obligations to Patients in Clinical Care and Research. <i>Annals of Internal Medicine</i> , 2021, 174, 256-257.	3.9	2
7	Reopening schools safely in the face of COVID-19: Can cluster randomized trials help?. <i>Clinical Trials</i> , 2021, 18, 371-376.	1.6	5
8	The limits of acceptable political influence over the FDA. <i>Nature Medicine</i> , 2021, 27, 188-190.	30.7	7
9	Ethical Inclusion of Health Care Workers in Covid-19 Research. <i>Ethics &amp; Human Research</i> , 2021, 43, 19-27.	0.9	3
10	An ethics framework for consolidating and prioritizing COVID-19 clinical trials. <i>Clinical Trials</i> , 2021, 18, 226-233.	1.6	13
11	Promoting Ethical Payment in Human Infection Challenge Studies. <i>American Journal of Bioethics</i> , 2021, 21, 11-31.	0.9	25
12	Waivers and Alterations of Research Informed Consent During the COVID-19 Pandemic. <i>Annals of Internal Medicine</i> , 2021, 174, 415-416.	3.9	10
13	Plumbing the Depths of Ethical Payment for Research Participation. <i>American Journal of Bioethics</i> , 2021, 21, W8-W11.	0.9	0
14	A snapshot of U.S. IRB review of COVID-19 research in the early pandemic. <i>Journal of Clinical and Translational Science</i> , 2021, 5, e205.	0.6	7
15	Helpful Lessons and Cautionary Tales: How Should COVID-19 Drug Development and Access Inform Approaches to Non-Pandemic Diseases?. <i>American Journal of Bioethics</i> , 2021, 21, 4-19.	0.9	20
16	FDA Drug Approval and the Ethics of Desperation. <i>JAMA Internal Medicine</i> , 2021, 181, 1555.	5.1	18
17	Challenges in confirming drug effectiveness after early approval. <i>Science</i> , 2021, 374, 1205-1207.	12.6	11
18	Paying Clinical Trial Participants: Legal Risks and Mitigation Strategies. <i>Journal of Clinical Oncology</i> , 2020, 38, 532-537.	1.6	7

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19	Right to Try Requests and Oncologistsâ€™ Gatekeeping Obligations. <i>Journal of Clinical Oncology</i> , 2020, 38, 111-114.	1.6	7
20	Academic Advocacy. <i>Academic Medicine</i> , 2020, 95, 44-51.	1.6	6
21	Regulatory flexibility for COVID-19 research. <i>Journal of Law and the Biosciences</i> , 2020, 7, Isaa057.	1.6	18
22	No Easy Answers in Allocating Unapproved COVID-19 Drugs Outside Clinical Trials. <i>American Journal of Bioethics</i> , 2020, 20, W1-W4.	0.9	0
23	Institutional Review Board Quality, Private Equity, and Promoting Ethical Human Subjects Research. <i>Annals of Internal Medicine</i> , 2020, 173, 558-562.	3.9	8
24	The role of community engagement in addressing bystander risks in research: The case of a Zika virus controlled human infection study. <i>Bioethics</i> , 2020, 34, 883-892.	1.4	2
25	Facilitating Both Evidence and Access: Improving FDA's Accelerated Approval and Expanded Access Pathways. <i>Journal of Law, Medicine and Ethics</i> , 2020, 48, 365-372.	0.9	18
26	Ethically Allocating COVID-19 Drugs Via Pre-approval Access and Emergency Use Authorization. <i>American Journal of Bioethics</i> , 2020, 20, 4-17.	0.9	23
27	Evaluating the Quality of Research Ethics Review and Oversight: A Systematic Analysis of Quality Assessment Instruments. <i>AJOB Empirical Bioethics</i> , 2020, 11, 208-222.	1.6	11
28	Ethics of controlled human infection to address COVID-19. <i>Science</i> , 2020, 368, 832-834.	12.6	95
29	Paying Participants in COVID-19 Trials. <i>Journal of Infectious Diseases</i> , 2020, 222, 356-361.	4.0	7
30	The right to withdraw from controlled human infection studies: Justifications and avoidance. <i>Bioethics</i> , 2020, 34, 833-848.	1.4	10
31	Minimal or reasonable? Considering the ethical threshold for research risks to nonconsenting bystanders and implications for nonconsenting participants. <i>Bioethics</i> , 2020, 34, 923-932.	1.4	3
32	Offering Payment in Clinical Research: Enrolling Individuals With or at Risk for Opioid Use Disorder. <i>Journal of Empirical Research on Human Research Ethics</i> , 2020, 15, 163-174.	1.3	1
33	Compensating for research risk: permissible but not obligatory. <i>Journal of Medical Ethics</i> , 2020, 46, 827-828.	1.8	4
34	The European Medicines Agencyâ€™s Approach to Transparency. , 2019, , 210-226.		1
35	Designing development programs for non-traditional antibacterial agents. <i>Nature Communications</i> , 2019, 10, 3416.	12.8	46
36	Nontransparency in Electronic Health Record Systems. , 2019, , 273-285.		0

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37	Smashing into Windows. , 2019, , 17-29.		1
38	The Interplay of Privacy and Transparency in Health Care. , 2019, , 30-43.		0
39	Transparency Trade-offs. , 2019, , 44-57.		0
40	Slightly Hazy. , 2019, , 58-68.		0
41	Transparency versus Informed Consent. , 2019, , 75-87.		0
42	Transparency and Financial Conflicts. , 2019, , 88-102.		0
43	Making Religion Transparent. , 2019, , 103-114.		0
44	Transparency on Prescription Drug Research Expenditures. , 2019, , 121-131.		0
45	Is Pharmaceutical Price Transparency an Effective Means to Reduce High Prices and Wide Variations?. , 2019, , 132-152.		1
46	Solving Surprise Medical Bills. , 2019, , 165-178.		0
47	Increasing the Transparency of FDA Review to Enhance the Innovation Process. , 2019, , 185-195.		0
48	Transparency and Clinical Trial Data Sharing. , 2019, , 196-209.		0
49	Introduction to Part V. , 2019, , 229-232.		0
50	The Role of Transparency in Promoting Healthy Behaviors. , 2019, , 233-243.		0
51	The Role of Transparency in Patient Safety Improvement. , 2019, , 244-259.		0
52	Personal Health Records as a Tool for Transparency in Health Care. , 2019, , 260-272.		0
53	Transparency Challenges in Reproductive Health Care. , 2019, , 286-296.		0
54	Introduction to Part VI. , 2019, , 299-300.		0

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55	ERISA as a Barrier for State Health Care Transparency Efforts. , 2019, , 301-313.		0
56	Transparency and Data Sharing in Clinical Research and Big Pharma. , 2019, , 314-328.		0
57	Promoting IRB Transparency. , 2019, , 329-342.		0
58	Using Disclosure to Regulate PBMs. , 2019, , 343-356.		1
59	Price Transparency. , 2019, , 153-164.		1
60	Filthy Lucre or Fitting Offer? Understanding Worries About Payments to Research Participants. American Journal of Bioethics, 2019, 19, 1-4.	0.9	12
61	Pay-to-Participate Trials and Vulnerabilities in Research Ethics Oversight. JAMA - Journal of the American Medical Association, 2019, 322, 1553.	7.4	6
62	Implementing Regulatory Broad Consent Under the Revised Common Rule: Clarifying Key Points and the Need for Evidence. Journal of Law, Medicine and Ethics, 2019, 47, 213-231.	0.9	14
63	Of Parachutes and Participant Protection: Moving Beyond Quality to Advance Effective Research Ethics Oversight. Journal of Empirical Research on Human Research Ethics, 2019, 14, 190-196.	1.3	27
64	Biospecimens, Research Consent, and Distinguishing Cell Line Research. JAMA Oncology, 2019, 5, 406.	7.1	3
65	Mountains and Molehills When Using Social Media as a Research Support Tool. American Journal of Bioethics, 2019, 19, 64-66.	0.9	4
66	Ethical Review and Methodologic Innovation in Phase 1 Cancer Trialsâ€”Reply. JAMA Pediatrics, 2019, 173, 609.	6.2	0
67	Differential payment to research participants in the same study: an ethical analysis. Journal of Medical Ethics, 2019, 45, 318-322.	1.8	24
68	Making the case for completion bonuses in clinical trials. Clinical Trials, 2019, 16, 176-182.	1.6	11
69	Association Between Financial Incentives and Participant Deception About Study Eligibility. JAMA Network Open, 2019, 2, e187355.	5.9	35
70	Participant Protection in Phase 1 Pediatric Cancer Trials. JAMA Pediatrics, 2019, 173, 8.	6.2	7
71	A Framework for Ethical Payment to Research Participants. New England Journal of Medicine, 2018, 378, 766-771.	27.0	111
72	Mutual Obligations in Research and Withholding Payment From Deceptive Participants. American Journal of Bioethics, 2018, 18, 85-87.	0.9	2

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73	Addressing Financial Barriers to Enrollment in Clinical Trials. <i>JAMA Oncology</i> , 2018, 4, 913.	7.1	16
74	Truth in Advertising: Disclosure of Participant Payment in Research Recruitment Materials. <i>Therapeutic Innovation and Regulatory Science</i> , 2018, 52, 268-274.	1.6	4
75	Federal Right-to-Try Legislation "Threatening the FDA's Public Health Mission. <i>New England Journal of Medicine</i> , 2018, 378, 695-697.	27.0	39
76	On Scarcity and the Value of Clinical Trials. <i>American Journal of Bioethics</i> , 2018, 18, 71-73.	0.9	1
77	Patient-Centered Outcomes Research: Stakeholder Perspectives and Ethical and Regulatory Oversight Issues. <i>IRB: Ethics &amp; Human Research</i> , 2018, 40, 7-17.	0.8	15
78	Protecting clinical trial participants and study integrity in the age of social media. <i>Cancer</i> , 2018, 124, 4610-4617.	4.1	10
79	Oversight of Patient-Centered Outcomes Research: Recommendations From a Delphi Panel. <i>Annals of Internal Medicine</i> , 2018, 169, 559.	3.9	13
80	Promoting Patient Interests in Implementing the Federal Right to Try Act. <i>JAMA - Journal of the American Medical Association</i> , 2018, 320, 869.	7.4	22
81	Informed Consent and the Role of the Treating Physician. <i>New England Journal of Medicine</i> , 2018, 378, 2433-2438.	27.0	20
82	IRB Oversight of Patient-Centered Outcomes Research: A National Survey of IRB Chairpersons. <i>Journal of Empirical Research on Human Research Ethics</i> , 2018, 13, 421-431.	1.3	6
83	Patient-Centered Outcomes Research: Stakeholder Perspectives and Ethical and Regulatory Oversight Issues. <i>IRB: Ethics &amp; Human Research</i> , 2018, 40, 7-17.	0.8	6
84	Using Social Media as a Research Recruitment Tool: Ethical Issues and Recommendations. <i>American Journal of Bioethics</i> , 2017, 17, 3-14.	0.9	306
85	Institutions as an ethical locus of research prioritisation. <i>Journal of Medical Ethics</i> , 2017, 43, 816-818.	1.8	1
86	Nonexceptionalism, Research Risks, and Social Media: Response to Open Peer Commentaries on "Using Social Media as a Research Recruitment Tool: Ethical Issues and Recommendations" <i>American Journal of Bioethics</i> , 2017, 17, W1-W3.	0.9	5
87	Revised "Common Rule" Shapes Protections For Research Participants. <i>Health Affairs</i> , 2017, 36, 784-788.	5.2	17
88	Contraceptive Coverage and the Balance Between Conscience and Access. <i>JAMA - Journal of the American Medical Association</i> , 2017, 318, 2179.	7.4	3
89	A Functional Approach to Assessing Consent for Biospecimen Research. <i>American Journal of Bioethics</i> , 2017, 17, 20-23.	0.9	1
90	When clinical trials compete: prioritising study recruitment. <i>Journal of Medical Ethics</i> , 2017, 43, 803-809.	1.8	37

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91	Brain Death Rejected. , 2017, , 293-305.		1
92	Religious Outliers. , 2017, , 173-186.		2
93	A Common Law Duty to Disclose Conscience-Based Limitations on Medical Practice. , 2017, , 187-197.		3
94	Religion and Reproductive Technology. , 2017, , 360-371.		2
95	Paying Research Participants: The Outsized Influence of "Undue Influence". IRB: Ethics & Human Research, 2017, 39, 1-9.	0.8	18
96	Paying Research Participants: Regulatory Uncertainty, Conceptual Confusion, and a Path Forward. Yale Journal of Health Policy, Law, and Ethics, 2017, 17, 61-141.	1.5	42
97	Reaping the Bounty of Publicly Available Clinical Trial Consent Forms. IRB: Ethics & Human Research, 2017, 39, 10-15.	0.8	4
98	Incorporating ethical principles into clinical research protocols: a tool for protocol writers and ethics committees. Journal of Medical Ethics, 2016, 42, 229-234.	1.8	9
99	Streamlining Review by Accepting Equivalence. American Journal of Bioethics, 2014, 14, 11-13.	0.9	4
100	Discrimination at the Doctor's Office. New England Journal of Medicine, 2013, 368, 1668-1670.	27.0	12
101	The rights and wrongs of intentional exposure research: contextualising the Guatemala STD inoculation study. Journal of Medical Ethics, 2012, 38, 513-515.	1.8	14
102	Give them what they want? The permissibility of pediatric placebo-controlled trials under the best pharmaceuticals for children act. Health System Leader, 2007, 16, 79-138, table of contents.	0.4	2
103	Not Your Father's Religious Exemptions: The Contraceptive- Coverage Litigation and the Rights of Others. , 0, , 60-74.		0
104	Unpacking the Relationship Between Conscience and Access. , 0, , 242-258.		0
105	Accommodating Miracles: Medical Futility and Religious Free Exercise. , 0, , 306-318.		0
106	RELIGION AND REPRODUCTIVE HEALTH CARE: INTRODUCTION. , 0, , 345-347.		0
107	Contracting Religion. , 0, , 113-124.		0
108	Introduction: Law, Religion, and Health in the United States. , 0, , 1-18.		0

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109	LAW, RELIGION, AND HEALTH CARE INSTITUTIONS: INTRODUCTION. , 0, , 87-89.		0
110	Mission Integrity Matters: Balancing Catholic Health Care Values and Public Mandates. , 0, , 125-138.		0
111	Bosses in the Bedroom: Religious Employers and the Future of Employer- Sponsored Health Care. , 0, , 154-168.		0
112	PROFESSIONAL RESPONSIBILITIES, RELIGION, AND HEALTH CARE: INTRODUCTION. , 0, , 169-172.		0
113	Religious Convictions About Homosexuality and the Training of Counseling Professionals: How Should We Treat Religious- Based Opposition to Counseling About Same- Sex Relationships?. , 0, , 263-275.		0
114	Religion and the Unborn Under the First Amendment. , 0, , 372-382.		0
115	Race, Religion, and Masculinity: The HIV Double Bind. , 0, , 387-398.		0
116	Religious Liberty, Health Care, and the Culture Wars. , 0, , 21-33.		0
117	Religious Exemptions to the Individual Mandate: Health Care Sharing Ministries and the Affordable Care Act. , 0, , 143-153.		0
118	How Much May Religious Accommodations Burden Others?. , 0, , 215-229.		3
119	A Corporation's Exercise of Religion: A Practitioner's Experience. , 0, , 90-102.		0
120	“œA Patchwork Array of Theocratic Fiefdoms?â€•RFRA Claims Against the ACA's Contraception Mandate as Examples of the New Feudalism. , 0, , 230-241.		0
121	The HHS Mandate Litigation and Religious Health Care Providers. , 0, , 47-59.		0
122	Recent Applications of the Supreme Court's Hands- Off Approach to Religious Doctrine: From Hosanna- Tabor and Holt to Hobby Lobby and Zubik. , 0, , 75-86.		0
123	A CASE STUDY “œ“ RELIGIOUS BELIEFS AND THE HEALTH OF THE LGBT COMMUNITY: INTRODUCTION. , 0, , 259-262.		0
124	When Religion Pollutes: How Should Law Respond When Religious Practice Threatens Public Health?. , 0, , 411-422.		0
125	From Smith to Hobby Lobby : The Transformation of the Religious Freedom Restoration Act. , 0, , 34-46.		0
126	The Natural Person as the Limiting Principle for Conscience: Can a Corporation Have a Conscience If It Doesn't Have an Intellect and Will?. , 0, , 103-112.		0



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127	Conscientious Objection, Complicity, and Accommodation. , 0, , 203-214.		0
128	Reclaiming Biopolitics: Religion and Psychiatry in the Sexual Orientation Change Therapy Cases and the Establishment Clause Defense. , 0, , 276-288.		1
129	Putting the Insanity Defense on Trial: Understanding Criminality in the Context of Religion and Mental Illness. , 0, , 319-331.		0
130	Religion as a Controlling Interference in Medical Decision Making by Minors. , 0, , 332-344.		0
131	Regulating Reasons: Governmental Regulation of Private Deliberation in Reproductive Decision Making. , 0, , 348-359.		0
132	RELIGION, LAW, AND PUBLIC HEALTH: INTRODUCTION. , 0, , 383-386.		0
133	The Intersection of Law, Religion, and Infectious Disease in the Handling and Disposition of Human Remains. , 0, , 399-410.		0
134	Big Data and Individual Autonomy in a Crowd. , 0, , 19-29.		1
135	Big Data's Epistemology and Its Implications for Precision Medicine and Privacy. , 0, , 30-41.		2
136	Correlation versus Causation in Health-Related Big Data Analysis. , 0, , 42-55.		3
137	Big Data and Regulatory Arbitrage in Healthcare. , 0, , 56-68.		2
138	The Future of Pharmacovigilance. , 0, , 73-84.		1
139	Big Data's New Discrimination Threats. , 0, , 85-97.		4
140	Who's Left Out of Big Data?. , 0, , 98-111.		3
141	Potential Roadblocks in Healthcare Big Data Collection. , 0, , 112-124.		0
142	Avoiding Overregulation in the Medical Internet of Things. , 0, , 129-141.		4
143	Data Policy for Internet of Things Healthcare Devices. , 0, , 142-156.		0
144	Thought-Leader Perspectives on Risks in Precision Medicine Research. , 0, , 161-174.		2

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145	From Individual to Group Privacy in Biomedical Big Data. , 0 , 175-192.		0
146	Big Data and Informed Consent. , 0 , 193-204.		0
147	Is There a Duty to Share Healthcare Data?. , 0 , 209-222.		13
148	Societal Lapses in Protecting Individual Privacy, the Common Rule, and Big Data Health Research. , 0 , 223-236.		0
149	The Common Rule and Research with Data, Big and Small. , 0 , 237-250.		1
150	Big Data, HIPAA, and the Common Rule. , 0 , 251-264.		2
151	Data Sharing that Enables Postapproval Drug and Device Research and Protects Patient Privacy. , 0 , 269-282.		0
152	Big Data and Human Medical Judgment. , 0 , 283-294.		1
153	Medical Malpractice and Black-Box Medicine. , 0 , 295-306.		18
154	Big Data and Intellectual Property Rights in the Health and Life Sciences. , 0 , 311-323.		9
155	The Pathologies of Data-Generating Patents. , 0 , 324-336.		1
156	Ethical Payment to Participants in Human Infection Challenge Studies, with a Focus on SARS-CoV-2: Report and Recommendations. SSRN Electronic Journal, 0 , .	0.4	4