Solicited, Not Secondary:

The Common Rule Exemption, the Seam Between Two Regimes, and Research on Adults in Psychiatric Crisis

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Abstract

The Common Rule exempts secondary research uses of identifiable private information, and places non-identifiable information outside the definition of human subjects research altogether. Both provisions were written for the reuse of material that came into existence for some other reason: clinical records, registries, banked specimens, completed studies. Neither was written for material assembled by asking people to hand it over so that researchers could have it.

This Article argues that solicited collection is not secondary research, and that treating it as such produces a jurisdictional gap rather than a substantive one. The Common Rule attaches to investigators at institutions holding an assurance. The Privacy Rule attaches to covered entities. A private organization that solicits sensitive records from individuals and supplies them to universities is neither, so the conduct that would receive the most scrutiny if an investigator performed it receives none when a non-covered party performs it first. The receiving institution's inquiry begins at receipt and turns on identifiability, never on provenance. No body with authority ever sees the collection.

The population this reaches hardest is the one Congress and the Department have declined to cover for forty-eight years. Subparts exist for pregnant women, prisoners, and children. No subpart exists for adults whose decisional capacity is uncertain or impaired, though a federal commission recommended one in 1978, successive bioethics bodies repeated the request, the Department solicited public comment on it in 2007, and the 2018 revision added nothing. The Article offers an account of that pattern, examines a published study whose methods section states the mechanism in the researchers' own words, and proposes an amendment to 45 C.F.R. § 46.104(d)(4) that reaches solicited collection while leaving registry, archival, and clinical reuse untouched.

Keywords: human subjects research; Common Rule; secondary research exemption; solicited collection; intermediary shield; decisional capacity; Subpart E; institutional review board; HIPAA covered entity; psychiatric crisis; research provenance; informed consent.

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Contents

I. Introduction

Federal human subjects protection is built around a place. The National Research Act of 1974 created the commission that produced the Belmont Report,[1] and the regulatory scheme that followed placed its review requirement at the point where an institution holding a federal assurance touches a person. That placement answered the abuses that produced it, every one of which happened inside an institution, performed by that institution's own investigators, on a population the institution already held.

Fifty years later the placement has a consequence its drafters did not face. Where the regulated boundary is drawn around the institution, collection can be performed outside it and delivered inward. At the receiving end the analysis turns on a single question: is the information identifiable.[2] If it is not, the activity is not human subjects research and no board reviews anything. If it is, one of the secondary research exemptions may apply.[3] Under either route, the conduct of the party that assembled the material is not an element of any determination the institution makes.

This Article is about the second of those routes and the assumption buried in it. The exemption for secondary research uses of identifiable private information was written for reuse: clinical records generated in the course of care, registries built for surveillance, specimens banked from completed trials, datasets produced by one study and useful to another.[4] In each case the material came into existence for a reason unrelated to the research now proposed, and the exemption's logic is that re-contacting the source would impose burden without adding protection.

That logic does not describe material that was assembled by asking people to provide it so that researchers could have it. When a party solicits sensitive records from individuals, for the

1. National Research Act, Pub. L. No. 93-348, 88 Stat. 342 (1974).

2. 45 C.F.R. § 46.102(e)(1) (2018).

3. 45 C.F.R. § 46.104(d)(4) (2018).

4. *See* Holly Fernandez Lynch, Barbara E. Bierer & I. Glenn Cohen, *Confronting Biospecimen Exceptionalism in Proposed Revisions to the Common Rule*, 46 Hastings Ctr. Rep. 4, 4–5 (2016).

stated purpose of research, and transfers them to a university, nothing was reused. Something was collected. The Article's central claim is that solicited collection is not secondary research within the meaning of the exemption, that the current text nonetheless covers it, and that the covering is an accident of drafting rather than a policy choice anyone defended.

Part II sets out the architecture and locates the seam. The Common Rule attaches to investigators.[5] The Privacy Rule attaches to covered entities.[6] A private organization soliciting conversation records from a support community is neither, and the two sectoral regimes do not touch at the point where it operates.

Part III addresses the population. Subparts exist for pregnant women and neonates, for prisoners, and for children.[7] None exists for adults whose decisional capacity is uncertain or impaired, and the absence has been the subject of formal recommendation since 1978.[8] Part III.C offers an account of why those three and not this one, and the account is not that anyone thought this population was safe.

Part IV shows the exemption operating, using a published study whose methods section describes the mechanism in the researchers' own words. Part V shows that two state appellate courts have already articulated the substance of the rule the Department declines to write, and why that body of law cannot reach the arrangement at issue. Part VI develops the doctrinal argument that solicited collection falls outside the exemption's purpose, and answers the objections. Part VII proposes regulatory text and identifies the levers available without rulemaking, which matters because the rulemaking process has declined the adjacent request for four decades.

The Article does not argue that the researchers in Part IV violated any rule. The argument is that they complied with one, and that compliance is the problem.

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5. 45 C.F.R. § 46.102(e)(1) (2018).

6. 45 C.F.R. § 160.103 (2013) (defining covered entity as a health plan, health care clearinghouse, or health care provider transmitting health information electronically in connection with a covered transaction).

7. 45 C.F.R. §§ 46.201–.207 (subpart B), 46.301–.306 (subpart C), 46.401–.409 (subpart D).

8. *See infra* Part III.B.

II. The Architecture and the Seam

A. The Common Rule Attaches to Investigators

A human subject is a living individual about whom an investigator conducting research either obtains information through intervention or interaction with the individual and then uses, studies, or analyzes it, or obtains, uses, studies, analyzes, or generates identifiable private information.[9] Identifiable private information is private information for which the subject's identity is or may readily be ascertained by the investigator or is associated with the information.[10] Intervention includes physical procedures and manipulations of the subject's environment performed for research purposes; interaction includes communication or interpersonal contact between investigator and subject.[11]

Two features of the definition control everything that follows.

First, it attaches to the investigator and asks what the investigator did. The conduct of a third party who assembled the material before the investigator saw it is not an element. This is not an oversight; the regulation governs institutions and their agents, and a rule cannot readily reach a party over whom the promulgating authority has no hold.[12]

Second, where the material reaching the investigator is not identifiable, the second prong is not satisfied and the first was never engaged, because there was no intervention or interaction. The activity is not human subjects research at all. No board reviews it, no consent standard applies, and no record of the collection is created anywhere in the institution.

9. 45 C.F.R. § 46.102(e)(1)(i)–(ii) (2018).

10. 45 C.F.R. § 46.102(e)(5) (2018).

11. 45 C.F.R. § 46.102(e)(2)–(e)(3) (2018).

12. The Common Rule applies to research conducted or supported by a federal department or agency, and institutions extend it by assurance. 45 C.F.R. § 46.101(a) (2018). An institution's assurance does not reach a party with which it has no relationship other than a data transfer.

B. The Privacy Rule Attaches to Covered Entities

The Privacy Rule reaches protected health information held or transmitted by covered entities, defined as health plans, health care clearinghouses, and health care providers that transmit health information electronically in connection with covered transactions.[13] It does not apply to de-identified health information at all.[14]

The boundary has been stated plainly in the research literature: health information not held by a covered entity may be used and disclosed without regard to the Privacy Rule.[15] The comparison with the European regime makes the design choice visible. The General Data Protection Regulation attaches to anyone processing personal data within its territorial scope; the Privacy Rule attaches to a defined class of entities.[16] One regulates an activity. The other regulates a category of institution.

C. The Seam

An organization that solicits conversation records from people describing a mental health crisis is not a health plan, not a clearinghouse, and not a provider transmitting claims. It holds no federal assurance and receives no federal research support. It sits outside both regimes at once.

This is not a loophole in the sense of a drafting error exploited against the drafters' intent. It is the ordinary and predictable result of two sectoral rules meeting at a party neither describes. The Common Rule governs what institutions do with people. The Privacy Rule governs what a defined set of health entities do with records. A private collector standing between a person in crisis and a university is doing something neither statute was written to see.

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13. 45 C.F.R. § 160.103 (2013).

14. 45 C.F.R. § 164.502(d)(2) (2013); *see also* Nicolas Terry, *Developments in Genetic and Epigenetic Data Protection in Behavioral and Mental Health Spaces*, 33 Behav. Sci. & L. 653, 657–58 (2015) (noting that the Privacy Rule reaches only protected health information held by covered entities and does not protect de-identified information).

15. Tonya White, Elisabet Blok & Vince D. Calhoun, *Data Sharing and Privacy Issues in Neuroimaging Research: Opportunities, Obstacles, Challenges, and Monsters Under the Bed*, 43 Hum. Brain Mapping 278, 283 (2020).

16. *Id.*

The consequence is asymmetric in a way worth naming. Identical conduct receives maximum scrutiny when an investigator performs it and none when a non-covered party performs it first and hands over the result. An investigator who approached a person in acute psychiatric distress, obtained their conversation records, and analyzed them would be conducting human subjects research on the face of the definition, requiring a protocol, board review, and documented informed consent. The same records, gathered by a party outside the perimeter and delivered as a file, reach the same investigator through a door that asks only whether the names have been removed.

III. The Population Congress Never Covered

A. Three Subparts

In 1991 the Department added special protections for three populations: pregnant women, human fetuses, and neonates; prisoners; and children.[17] Each addressed a population whose capacity to refuse was constrained by the circumstances of its holding, and each responded to documented abuse.

There is no subpart for adults whose decisional capacity is uncertain or impaired. Research involving that population is governed only by the general instruction in Subpart A that boards include additional safeguards for subjects vulnerable to coercion or undue influence.[18]

B. Forty-Eight Years of Asking

The absence was identified at the outset. The National Commission published a report in 1978 recommending that the regulations cover persons then described as mentally infirm, and the Department did not adopt it.[19] Contemporary analysis records that the proposed regulations for

17. 45 C.F.R. §§ 46.201–.207, 46.301–.306, 46.401–.409.

18. 45 C.F.R. § 46.111(b) (2018).

19. *See* Carrie Hoyt et al., *An Analysis of Institutional Review Board Policies for Enrollment of Adults with Impaired or Uncertain Decision-Making Capacity* (2025) (recounting the 1978 recommendation and the Department's non-adoption).

mentally disabled persons were abandoned against strong opposition, leaving the population governed by the general provision alone.[20]

Successive bodies repeated the request. In December 1998 the National Bioethics Advisory Commission published *Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity*, issuing twenty-one recommendations to boards, investigators, and federal regulators.[21] A Department working group analyzed the report and proposed action. The National Human Research Protections Advisory Committee added recommendations before being replaced by the Secretary's Advisory Committee on Human Research Protections, which formed a subcommittee on the inclusion of individuals with impaired decision making and reported in 2009.

In September 2007 the Department published a request for information and comments asking whether existing protections were adequate for adults with impaired decision-making capacity.[22] The solicitation is itself the admission: twenty-nine years after being told the gap existed, the Department was asking the public whether it did.

In 2013 Stacey Tovino argued in the Houston Law Review for a new Subpart E governing research involving adults with impaired decision-making capacity, and worked through the drafting problem.[23]

The Common Rule was then comprehensively revised, with a final rule in 2017 and general compliance from January 21, 2019.[24] The revision restructured the exemptions, introduced limited review, created broad consent for secondary use, and renumbered the definitions. It did not add the subpart.

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20. *See* Robert D. Truog et al., *Protecting Subjects with Decisional Impairment in Research: The Need for a Multifaceted Approach*, 167 Am. J. Respiratory & Critical Care Med. 1 (2003).

21. Nat'l Bioethics Advisory Comm'n, Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity (1998).

22. Request for Information and Comments on Research That Involves Adult Individuals with Impaired Decision-Making Capacity, 72 Fed. Reg. 50,966 (Sept. 5, 2007).

23. Stacey A. Tovino, *A "Common" Proposal*, 50 Hous. L. Rev. 787 (2013).

24. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149 (Jan. 19, 2017); *see also* 83 Fed. Reg. 2885 (Jan. 22, 2018) (interim final rule delaying the effective date); 83 Fed. Reg. 28,497 (June 19, 2018) (final rule setting general compliance at January 21, 2019).

C. Why Those Three

The standard account of the three subparts is that each population is vulnerable. That account is true and it does not explain the pattern, because the population left out is at least as vulnerable as the three included, and everyone involved said so at the time.

A better account is available and it is uncomfortable. Each covered population had an organized constituency able to speak in its own name from outside the institution holding it. Prisoners had litigation and a civil rights movement. Children had parents. Pregnant women had a political coalition. Adults whose decisional capacity is in question had, and largely still have, no equivalent, and the very condition that makes them vulnerable is the condition that makes an organized constituency hardest to build.

The consequence is measurable. A cross-sectional study of the human subjects policies of ninety-four top-funded American research institutions found that 41.5 percent maintained policies requiring exclusion of people with uncertain or impaired decision-making capacity unless inclusion is scientifically justified, while 5.3 percent required inclusion unless exclusion is justified.[25] In the absence of a rule, institutions converged on avoidance. That is the opposite of protection: the population is neither safeguarded when enrolled nor reliably included in the research that concerns it.

The scholarly literature on digital mental health states the underlying dynamic more directly. Writing on algorithmic surveillance in mental health applications, Idil Abdillahi observes that people living with mental health conditions are not trusted with information about themselves while their most sensitive information is sought from them, and calls the result expectation without explanation, a formula for exploitation and disenfranchisement.[26]

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25. Hoyt et al., *supra* note 21.

26. Idil Abdillahi, *Algorithmic Surveillance in the Era of the Mental Health Appsphere*, 73 Am. J. Cmty. Psych. 17, 22–23 (2024).

IV. The Exemption at Work

A. What the Provision Was Written For

Section 46.104(d)(4) exempts secondary research uses of identifiable private information where at least one of several conditions is met, including that the information is publicly available, or that the investigator records it so that identity cannot readily be ascertained, does not contact the subjects, and will not re-identify them.[27]

The provision descends from a settled position on reuse. Under the pre-2018 scheme and the revision alike, de-identified data fell outside the threshold definition, secondary research with identified data was exempt where the investigator did not record it identifiably, and waivers of consent for secondary research were routinely granted.[28] The 2015 proposed rule attempted a more restrictive regime and drew sustained criticism from both directions; one assessment concluded that the status quo and the proposal were both critically flawed.[29] The final rule left de-identified data outside the definition entirely.

The justification for all of this is reuse-specific. Material already exists, generated for care or surveillance or an earlier study; re-contacting every source would impose real burden and, for large historical datasets, would be impossible; and the marginal protection gained is small because the collection itself was governed at the time it occurred.

That last clause is the load-bearing one, and it is doing silent work. The exemption presumes that the collection happened somewhere governed.

B. The Intermediary Shield

Interpose a third party between the person and the investigator and the presumption fails without any provision noticing.

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27. 45 C.F.R. § 46.104(d)(4)(i)–(ii) (2018).
28. Lynch, Bierer & Cohen, *supra* note 4, at 4.
29. Mark A. Hall & Nancy M. P. King, *Conscience, Courage, and "Consent,"* 46 Hastings Ctr. Rep. 30, 30 (2016).

Recruitment is performed by an entity holding no assurance. Consent, if obtained, is obtained by that entity under terms it drafted for itself. De-identification, if performed, is performed by that entity and represented to the researchers rather than verified by them. The investigator's own conduct begins at receipt, and every determination the institution makes is about the file rather than about how the file came to exist.

The general form of this problem is named in the research ethics literature. Friesen and colleagues trace the review board to a world in which health research was federally funded, performed inside academic institutions, and dependent on data obtainable only in clinical settings, and then state the consequence: research has moved outside those contexts, is performed by for-profit device, pharmaceutical, and internet companies that often circumvent ethics oversight requirements, and where the data is de-identified or publicly available it is treated as exempt regardless of the risks present.[30]

The argument here is narrower than that observation and does not repeat it. Friesen and colleagues describe companies that generate data incidentally through their own operations and later make it available. This Article addresses material solicited from individuals, for the stated purpose of research, by an entity that exists to solicit it. Incidental data and solicited data arrive at the same exempt door. Only one of them was gathered by asking a person in crisis to hand it over.

C. The Supply Side Is a Market

The supply side is neither hypothetical nor confined to research. A study published by the Duke Sanford Cyber Policy Program approached thirty-seven data brokers about bulk mental health data; twenty-six responded and eleven were willing and able to sell what was requested, at prices ranging from a few hundred dollars for aggregated record counts to flat fees and subscriptions in the tens of thousands, with some records carrying names and addresses.[31] One finding bears

30. Phoebe Friesen et al., *Governing AI-Driven Health Research: Are IRBs Up to the Task?*, 43 Ethics & Hum. Rsch. 35, 37 (2021).

31. Joanne Kim, Data Brokers and the Sale of Americans' Mental Health Data (Duke Sanford Cyber Pol'y Program 2023).

directly on the provenance question: every broker asked what the data would be used for, and none of them verified the answer.[32]

Purchase is an ordinary procurement act inside a research institution. Nothing in the procurement pathway asks how the material was obtained, because the regulatory question at the institution is about identifiability rather than about provenance.

D. A Worked Example

The mechanism appears in the published record, stated by researchers who plainly did not regard themselves as describing a regulatory position.

A team led by researchers at Stanford University published a study in 2026 analyzing chat logs from individuals who experienced delusional episodes during extended interaction with large language model systems, accepted to the ACM Conference on Fairness, Accountability, and Transparency.[33] The methods section states that the team received chat logs via an outside organization, describes that organization as a nonprofit community for people with lived experience, and states that with individuals' consent the organization removed identifiers from the logs before the research team reviewed them, with no demographic data transferred. Twelve of the study's nineteen participants were sourced this way.

Read as a regulatory matter, that passage does four things. It identifies the collector as a party outside the institution. It attributes consent to that party. It attributes de-identification to that party. And it reports both as facts rather than as representations the authors received and did not audit.

Nothing in the Common Rule required them to audit either one. That is the point. A methods section is not a compliance document, and the authors were writing for readers who wanted to know what the data was, not for a regulator asking where it came from. The scheme asked the institution whether the information was identifiable. The institution answered. The

32. Gary Enos, *Duke Public Policy Report Suggests Federal Law Restricting Data Brokers*, 33 Mental Health Wkly. 1, 3 (2023).

33. Jared Moore et al., *Characterizing Delusional Spirals Through Human-LLM Chat Logs*, in Proceedings of the 2026 ACM Conference on Fairness, Accountability, and Transparency (2026).

question of what the people in those logs were told, by whom, and in what condition, was never put to anyone with the standing to insist on an answer.

The population supplying the material makes the omission consequential rather than technical. These were people describing psychiatric crises. They are members of the class that has had no dedicated protection since the first recommendation in 1978, reached through a channel that no subpart would govern even if one existed.

E. Two Accounts of the Transfer

The organization the methods section describes is The Human Line Project, named in the paper itself, which solicits conversation records and personal accounts from people who describe crises connected to chatbot use. At a recorded public session in Montreal, available in full, its founder was asked about the study and gave an account of the transfer that the published methods contradict.[34] He stated that the study did not go through the organization for the transcripts, that the researchers asked people in the community directly, and that the researchers compensated those people directly. Later in the same session, answering a different question, he described the study as one in which the organization analyzes transcripts and reported figures from it. The methods section, quoted above, states that the team received the logs via the organization and that the organization performed the de-identification.

The Article does not need to determine which account is accurate, because each account is, on its own, a legal conclusion, and the two conclusions condemn the same structure from opposite directions.

If the published methods are accurate, the exemption operated exactly as this Part describes. Consent was obtained by a party under no assurance, de-identification was performed by that party and represented rather than verified, and the institution's regulatory analysis began at receipt. If the founder's account is accurate, the researchers approached individuals in a

34. Presentation and Question Period with Etienne Brisson, The Human Line Project, Montreal AI Safety, Ethics and Governance Event Series (2026) (recording available at https://archive.org/details/brisson-human-line-project-montreal-ai-safety-2026_202608).

crisis community, enrolled them, and paid them, which is interaction with living individuals under 45 C.F.R. § 46.102(e)(1)(i) on the face of the definition. That is not secondary research at all. No exemption for existing data reaches it, and it would have required a protocol, review, and informed consent obtained by the investigators from each person, in a population in acute psychiatric distress, with compensation operating as an inducement.

The dilemma is the exhibit. A published methods section and the organization it names give incompatible accounts of how material from people in psychiatric crisis reached a federally funded research team, and nothing in the regulatory structure requires either account to be reconciled with the other. There is no actor in the system with both the duty and the standing to ask which one is true. Under the amendment this Article proposes, the question would have been answered before the exemption issued, because the institution would hold documentation of the collection instrument and the terms presented at solicitation, and the two accounts could not both survive contact with that file.

V. The Standard the Regulations Decline to Write

The absence described in Part III is often treated as though the content of the missing rule were unknown. It is not. Two state appellate courts have articulated the substance of it, in litigation, on records made by actual subjects, and their reasoning converges on the propositions a Subpart E would codify.

A. Surrogate Consent Cannot Reach Nontherapeutic Research

In *T.D. v. New York State Office of Mental Health*, the First Department invalidated state regulations governing human subject research on patients in facilities operated or licensed by the Office of Mental Health.[35] The court held that the Commissioner lacked authority to promulgate

35. *T.D. v. N.Y. State Office of Mental Health*, 228 A.D.2d 95 (N.Y. App. Div. 1996).

them, that authority residing exclusively with the Commissioner of Health under article 24-A of the Public Health Law.[36]

The court did not stop at the authority question, because it recognized that the defendants intended to continue the research whatever became of the regulations. On the common law it held that surrogate consent for participation in greater than minimal risk nontherapeutic research is impermissible where there is no evidence of the patient's personal intent and the research offers the subject no benefit.[37] On due process it held that provisions for determining a potential subject's capacity fail where they do not provide adequate notice to the patient that capacity is being evaluated and supply no mechanism for patient-requested review of a determination of incapacity.[38]

The statutory declaration the court applied is worth stating in its own terms. New York Public Health Law § 2440 provides that safeguarding the rights and welfare of individual human subjects is a matter of vital state concern, and that every human being has the right to be protected against the possible conduct of medical or psychological research upon his or her body without voluntary informed consent.[39]

B. Researchers Owe Subjects a Duty of Care

Maryland reached the parallel conclusions in *Grimes v. Kennedy Krieger Institute*, and the Court of Special Appeals restated them in *White v. Kennedy Krieger Institute*.[40] Three holdings from *Grimes* carry here.

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36. *Id.* at 106.

37. *Id.* (rejecting the argument that surrogate decision-making short of withholding life-sustaining treatment is permissible, and reasoning that because participation in greater than minimal risk studies exposes subjects to possible harmful and even fatal side effects, "similar substantive and procedural safeguards should be provided to these potential research subjects as are provided to patients in life-sustaining treatment settings"). On parental and guardian consent the court reached the same result for minors, *id.* at 123–24, holding that a parent or guardian may not consent to a child's submission to painful or potentially life-threatening research procedures holding no prospect of benefit for the child.

38. *T.D.*, 228 A.D.2d at 114–15. The court relied on *Rivers v. Katz*, 67 N.Y.2d 485, 496 (1986), for the proposition that a determination of capacity "is uniquely a judicial, not a medical function."

39. N.Y. Pub. Health Law § 2440 (McKinney).

40. *White v. Kennedy Krieger Inst., Inc.*, 110 A.3d 724 (Md. Ct. Spec. App. 2015); *Grimes v. Kennedy Krieger Inst., Inc.*, 366 Md. 29, 782 A.2d 807 (2001).

First, a parent, appropriate relative, or other applicable surrogate cannot consent to the participation of a child or other person under legal disability in nontherapeutic research or studies in which there is any risk of injury or damage to the health of the subject.[41]

Second, informed consent agreements in nontherapeutic research projects can, as a matter of law, constitute special relationships giving rise to duties, breach of which will support a negligence action, and such relationships are normally created between researchers and the human subjects they use.[42]

Third, and this is the proposition that does the most work in the present argument, governmental regulations can create duties on the part of researchers toward human subjects out of which special relationships can arise.[43]

The duty itself was put to a Maryland jury in terms that state it plainly: scientific researchers and research entities owe a duty of care to participants in scientific research studies, requiring protection of participants from unreasonable harm and complete and prompt disclosure of hazards existing during the study.[44]

C. Why This Does Not Solve the Problem

Three limits keep this body of law from reaching the arrangement in Part IV, and the third is the one that matters most.

The duties are state law and they vary. *T.D.* is New York. *Grimes* and *White* are Maryland. A federal district court applying North Carolina law found that the state's informed consent statute reached health care providers and health care treatment and therefore did not

41. *Grimes*, 366 Md. at 113–14, as quoted in *White*, 110 A.3d 724. The holding is limited to nontherapeutic research carrying an articulable risk beyond the minimal risk inherent in any endeavor, and does not reach therapeutic research.

42. *Grimes*, 366 Md. at 113–14.

43. *Grimes*, 366 Md. at 113–14 ("[G]overnmental regulations can create duties on the part of researchers towards human subjects out of which 'special relationships' can arise.").

44. *White*, 110 A.3d 724 (reciting the instruction given at trial: "scientific researchers and research entities owe a duty of care to participants in scientific research studies," requiring "the protection of the study participants from unreasonable harm" and complete and prompt disclosure of "potential hazards existing during the study").

directly apply to nontherapeutic experimentation at all.[45] A subject's protection turns on where the study happened.

The duties attach to researchers, not to collectors. Every proposition above runs against a party conducting the research. None reaches a private organization that assembles material and hands it over, because that organization is not a researcher and has no relationship with any subject that these cases describe. The pattern extends up the chain as well as sideways: courts have declined to extend the treating physician's fiduciary duties to supervisors, sponsors, and other entities profiting from research, reasoning that parties who are not physicians and hold no fiduciary relationship with the subject can be liable, if at all, only through secondary liability for the physician's own acts.[46]

And the duties run in tort, after harm, on a record made by a plaintiff. That is the wrong instrument for a consent failure that produces no physical injury, no identifiable damages, and no plaintiff who knows what happened to their file. The person whose records were transferred learns of it, if at all, when the paper appears. Even in fully governed settings, what a subject retains after handing material over is thin: consent forms characterize the transfer as a gift, disclaim the participant's ownership of anything derived from it, and, as litigated in *Washington University v. Catalona*, say nothing at all about the participant's ability to withdraw the material or direct it elsewhere.[47]

The last point deserves its own statement, because it turns the missing subpart from an omission into an active subtraction. *Grimes* held that governmental regulations can generate the duty from which a special relationship arises. Where no regulation governs research with adults of uncertain capacity, there is no regulatory source from which such a duty can be built, and a

45. *Whitlock v. Duke Univ.*, 637 F. Supp. 1463, 1470–71 (M.D.N.C. 1986).

46. *Suthers v. Amgen, Inc.*, 372 F. Supp. 2d 416 (S.D.N.Y. 2005) (discussing *Moore v. Regents of the University of California* and the limits of duty beyond the treating physician). If a trial sponsor standing at the center of a study can sit outside the duty, an organization that merely assembled the material sits farther outside it.

47. *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006), *aff'd*, 490 F.3d 667 (8th Cir. 2007) (noting that the informed consent forms at issue characterized samples as donated gifts, disclaimed participant ownership of resulting products, and did not address withdrawal of samples or transfer to another institution). If that is the residue of control in a governed collection, the residue in an ungoverned one is whatever the collector's own terms provide.

plaintiff in that position must construct the duty from general principles that other subjects can take from a subpart. The absence does not merely leave the population unprotected by regulation. It leaves them with less common law than the populations that were covered.

VI. Solicited Collection Is Not Secondary Research

A. The Distinction

The distinction this Article proposes is between two categories that the current text treats identically.

Incidental material came into existence for a reason unrelated to the research now proposed. A clinical record was made to treat a patient. A registry was built for surveillance. A dataset was produced by an earlier study with its own protocol and its own consent. In each case a governed collection already occurred, and the exemption's premise holds.

Solicited material was assembled by asking individuals to provide it so that researchers could have it. The request is the collection. There was no prior governed event to reuse, because the only event was the asking, and the asking was performed by a party the regulations do not reach.

The field's own foundational document states the governing instinct. The Belmont Report's discussion of the boundary between practice and research closes on a general rule: if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.[48] Solicited collection is an element of research on any reading: it exists for no other purpose. The exempt door contradicts the rule the field recites.

Calling the second category secondary research is a category error that the text does not currently prevent. What follows from the error is not merely a labeling problem: it is that the entire consent inquiry vanishes, because the exemption was written on the assumption that the inquiry already happened somewhere else.

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48. Nat'l Comm'n for the Prot. of Human Subjects of Biomedical & Behavioral Rsch., The Belmont Report (1979), *as quoted in Ancheff v. Hartford Hosp.*, 260 Conn. 785, 799 A.2d 1067 (2002).

B. Text

The phrase is secondary research uses of identifiable private information.[49] Secondary carries content. It denotes a use that follows a primary one, and the ordinary sense of the word presupposes an antecedent use for a different purpose.

Where the sole purpose of the collection was transfer to researchers, there is no antecedent use. The proposed research is the first and only use. A use cannot be secondary to nothing.

The reading is available on the current text and this Article does not claim otherwise. It has not been adopted, because the enumerated conditions in subparagraphs (i) through (iv) do the practical work in institutional determinations and the threshold word rarely receives attention. A determination that runs straight to whether identity can readily be ascertained never reaches the question of what the use is secondary to.

C. Purpose and History

The rulemaking history supports the narrower reading. The 2015 proposed rule and the debate around it concerned biospecimens and data generated in clinical care and prior research, and the arguments on both sides ran in terms of reuse.[50] Neither the proposal, the comments, nor the final rule addressed material solicited from individuals by a non-covered party for the purpose of research supply, because the practice was not on anyone's mind in 2015.

Botkin, writing on secondary use in learning health systems, identifies what the omission costs even where every actor complies. Public trust is lost when people discover a practice they were never told about, and the reaction is not a risk assessment but a question about disclosure: if this is innocent, why did nobody mention it.[51] He proposes notice and an opt-out.

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49. 45 C.F.R. § 46.104(d)(4) (2018).

50. Lynch, Bierer & Cohen, *supra* note 4, at 4–5; Hall & King, *supra* note 18, at 30–32.

51. Jeffrey R. Botkin, *Transparency and Choice in Learning Healthcare Systems*, 2 Learning Health Sys. e10049, at 4 (2017).

A solicited-collection arrangement offers neither, and the person who supplied the material has no node in the chain at which a withdrawal must be honored.

D. Objections

1. The Burden Objection

The strongest objection is that the exemption is load-bearing for legitimate research, and that a provenance requirement would burden registry, archival, and clinical reuse heavily. That objection is correct as to incidental material and is the reason the amendment proposed in Part VI is drawn as narrowly as it is. A rule reaching only material solicited from individuals for the purpose of transfer to researchers leaves every ordinary reuse case exactly where it is.

2. The Line-Drawing Objection

The second objection is that the line will be contested at its edges, and it will. A support community that collects accounts for its own purposes and later shares them presents a harder case than an organization whose intake form states a research purpose on its face. The answer is that a contested edge is not an argument against a line, that the proposed text keys to the stated purpose of the collection rather than to the collector's character, and that the alternative to a contested line is the present arrangement, in which the question is never asked.

3. The Beneficence Objection

The third objection is that research on this population is badly needed and that added friction will produce less of it. The premise is right and the conclusion does not follow. Institutions have already converged on avoidance without any rule requiring it, and 41.5 percent of top-funded institutions exclude this population absent scientific justification.[52] A documentation requirement that makes lawful collection legible is more likely to increase defensible research on this population than to decrease it, because the present alternative is not careful inclusion but a channel nobody inspects.

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52. Hoyt et al., *supra* note 21.

VII. Proposal

A. Regulatory Text

The amendment adds a limiting clause to § 46.104(d)(4):

> This exemption does not apply to information that was solicited from individuals by any person or entity for the purpose of transfer to investigators for research. Where an institution obtains information described in this paragraph, the institution shall obtain and retain the instrument by which the information was solicited and the record of any consent obtained at the time of solicitation, and shall determine whether the information may be used consistent with the terms under which it was provided.

Three features are deliberate. The clause keys to the stated purpose of the collection rather than to the identity or character of the collector, so it does not require the institution to evaluate an outside organization. It imposes a documentation duty rather than a review duty, so the institution obtains two files and reads them. And it reaches any person or entity, so it does not depend on the collector's tax status, jurisdiction, or corporate form.

B. What It Does Not Reach

Clinical records used for research. Public health registries. Specimens and datasets from completed studies. Publicly available information. Administrative data. Anything that came into existence for a reason other than supplying researchers. The amendment does not touch the reuse the exemption was written to permit.

C. The Subpart

The amendment is not a substitute for the subpart. Tovino's argument for a Subpart E governing research with adults whose decisional capacity is impaired remains correct and remains unadopted.[53] Two points about the relationship between them.

A subpart alone would not reach the arrangement in Part IV, because a subpart binds covered institutions and their investigators, and the collection at issue is performed by a party

53. Tovino, *supra* note 25.

that is neither. A rule specifying how investigators must assess capacity before enrolling a subject does not reach a party that is not enrolling subjects and is not an investigator.

The amendment alone is likewise incomplete, because it produces documentation without a standard against which to read it. An institution that obtains a consent instrument still needs a rule telling it what adequate consent looks like when the person signing was in acute distress. That rule is the subpart, and its absence has been the answer to the same question for forty-eight years.

D. Levers That Do Not Require Rulemaking

Burris argued that human subjects protection is best understood as a regulatory space rather than a single instrument, and that the review board is one node among many with capacity to set standards, monitor conduct, and enforce.[54] His inventory includes funders, accreditation bodies, professional organizations, courts, state law, and journals, each holding its own lever, and journals hold one of the sharpest: refusal to review or publish.[55]

Three asks follow, available now.

Journals and conference program committees already require a statement of board approval or exemption. That requirement should extend one step, to a provenance statement in the methods: who collected the material, under what instrument, who obtained consent, and whether the authors verified either or are reporting a representation. The methods passage in Part IV would satisfy the first half and fail the second, and a required statement would put that question to the authors while the paper was being written.

Institutional determination workflows should ask provenance alongside identifiability. An affirmative answer should not bar the research; it should require the institution to obtain the collection instrument before accepting the material.

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54. Scott Burris, *Regulatory Innovation in the Governance of Human Subjects Research: A Cautionary Tale and Some Modest Proposals*, 2 Reg. & Governance 65, 71–73 (2008).

55. *Id.* at 72 tbl.1.

Courts already treat the Common Rule's commitments as legally consequential outside the review setting: a Texas appellate court, resolving a public records dispute, read the federal policy's informed consent requirements, including the required description of confidentiality protections, as bearing on what a university could be compelled to disclose.[56] A regulation whose promises are enforceable against an institution in litigation it did not choose is a regulation whose gaps are equally consequential, and the gap here is that no promise attaches to material that arrived through the exempt door.

The Office for Human Research Protections should issue guidance parallel to its existing guidance on coded private information, stating that the secondary research exemption was written for reuse of material generated for other purposes and does not describe material assembled for research supply by a party outside any assurance.

Guidance for research with this population already exists and is not required by anything. A consensus statement developed through a modified Delphi process with twenty-four experts, including scientists, clinicians, ethicists, legal experts, and people with lived experience, addresses inclusion criteria, elements of consent, data review during a study, and real-time response to elevated risk in digital monitoring studies with people at risk of suicide.[57] Nothing about the arrangement in Part IV would have brought it into play.

VIII. Conclusion

The regulations were written against institutions because institutions were where the harm was. Fifty years on, the institution is the most closely watched part of the chain, and it is watched at the wrong point: at receipt, on a question about names.

The exemption for secondary research carries an unstated premise, which is that a governed collection already happened. Where a party outside the perimeter solicits sensitive

56. *Univ. of Tex. Sys. v. Paxton*, No. 03-13-00329-CV (Tex. App. July 7, 2015) (discussing 45 C.F.R. § 690.116(a)(5) and the Common Rule's confidentiality requirements in a Public Information Act dispute).

57. Matthew K. Nock et al., *Consensus Statement on Ethical and Safety Practices for Conducting Digital Monitoring Studies with People at Risk of Suicide and Related Behaviors*, 3 Psychiatric Rsch. & Clinical Prac. 57 (2020).

records from individuals and supplies them to a university, the premise is false and nothing in the text notices. The consent inquiry does not fail. It never opens.

The population reached this way is the one that has been asked about, and declined, since 1978. It is the only population named in the original recommendation that never received a subpart, and the account offered here for why is that it is the population least able to organize a constituency to demand one, which is a restatement of the condition that made it vulnerable in the first place.

None of this requires bad faith from anyone, which is what makes it durable. A researcher who receives a de-identified dataset and asks no further questions has complied with the rule as written. A board that never sees the transaction cannot review it. An organization that solicits from a crisis community and drafts its own consent terms is doing what no federal rule forbids. The harm is distributed across a set of individually defensible steps, and the person whose worst hours are in the file is the only party to the arrangement who is represented nowhere in it.

Two questions would have reached every case in this Article. Who solicited this, and what were they told. Neither requires a rulemaking to ask.

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