

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
NORTHERN DIVISION

SHAWNTA DESHIELDS, et al.

*

Plaintiff,

*

v.

*

Case No.: 02-CV-3694

KENNEDY KRIEGER INSTITUTE, INC.

*

Defendant.

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* * * * *

**REPLY MEMORANDUM IN FURTHER SUPPORT
OF DEFENDANT’S MOTION FOR PROTECTIVE ORDER**

The Defendant, Kennedy Krieger Institute, Inc. (“Kennedy Krieger”) by and through its undersigned counsel, submits the following reply memorandum in support of its Motion for Protective Order and states as follows:

Non-Production vs. Confidentiality

Plaintiffs utterly misunderstand the purpose of Kennedy Krieger’s Motion for Protective Order (“Motion”).¹ Because Plaintiffs neither suffer prejudice by the entry of a confidentiality order nor articulate a reason why they object to use of the documents solely for the purposes of the litigation, this misunderstanding potentially explains why Plaintiffs are objecting at all. Kennedy Krieger is not asking the Court to enter an order *precluding* production of the confidential documents. It has, in fact, already produced not only the TLC documents in its

¹ While Kennedy Krieger does not intend to parse all of the misstatements and improper allegations contained in Plaintiffs’ Response to Kennedy Krieger’s Motion for Protective Order, Kennedy Krieger must clarify two points. One, Kennedy Krieger has not and will not (short of a finding of fact by a jury) agree that the TLC study was “non-therapeutic.” Second, the consent form utilized by the TLC study does not contain a “waiver of confidentiality” as alleged by Plaintiffs. Rather, the TLC trial enrollment consent form states: “The TLC study records are confidential and the names are taken off them and a code number put on as soon as possible. We will protect the records as much as we can under the law. Reports that we publish from this study will be about groups of children, and it will not be possible to tell that your child was in the study.”

possession² but also the TLC Plus³ documents in its possession (including the confidential documents subject to the proposed order). Kennedy Krieger is simply seeking a confidentiality order (which is clearly contemplated by and appended to the Local Rules) preventing *further* dissemination of the confidential documents outside of the course of this litigation.⁴ As stated in the Motion, this request does not seek to prevent the production of documents or limit their use in this litigation and will in no way hinder or prejudice the Plaintiffs' ability to pursue their claims in this case.

Plaintiffs accuse Kennedy Krieger of seeking to "gag" them from access to the documents because the documents were not placed in a "document repository."⁵ In lieu of placing one set of the documents in a location for Plaintiffs to review, Kennedy Krieger went to the time and expense (which was not insignificant) to bates-number and copy the TLC documents for Plaintiffs. Kennedy Krieger then hand-delivered the documents to counsel's office.⁶ It is unclear how Kennedy Krieger's direct production of the documents to Plaintiffs can be construed as anything but exceeding its responsibility to produce TLC documents.

Plaintiffs' Reliance on Burka is Misplaced

Plaintiffs also misunderstand Kennedy Krieger's argument regarding the deliberative process. In its Motion, Kennedy Krieger discussed the deliberative process privilege in an effort

² Kennedy Krieger did not produce documents that related solely to non-party TLC study participants. If a document contained non-party participant information and other TLC information or information related to Plaintiffs, the non-party participant information was redacted but the document was produced. Counsel for Plaintiffs' sought to obtain information about non-party TLC participants in connection with Coles v. Kennedy Krieger Institute, Inc. et al., Circuit Court for Baltimore City, case number 24-C-01-004337. The Honorable Thomas E. Noel issued a Protective Order precluding the discovery of the identities of non-party TLC study participants.

³ TLC Plus was a follow-up study that involved additional blood tests and tests of the child's thinking skills, coordination, and social behavior in school. The TLC Plus participants attended visits at 7 and 7.5 years of age. All participants signed a new consent form in connection with their participation in the TLC Plus study.

⁴ Before filing this Motion, Kennedy Krieger asked Plaintiffs to agree to a stipulated confidentiality order. Because Plaintiffs never responded to the request, Kennedy Krieger was forced to file the subject Motion.

⁵ It is unclear what Plaintiffs seek as Mr. Thalenberg's office is now a "repository" of TLC documents.

⁶ Approximately six banker's boxes of documents were hand-delivered to Mr. Thalenberg's office.

to highlight to the Court that many of the documents Kennedy Krieger produced are “pre-decisional” and “deliberative” in nature and could be withheld by the NIEHS pursuant to 5 U.S.C. 552(b)(5) (“Exemption 5”). It would make little sense to allow a governmental agency to withhold completely documents that reveal the deliberative process on one hand, yet on the other hand, fail to extend at least confidential treatment to the same and similar documents simply because they were in the possession of a research facility that conducts the government’s research pursuant to contract.

Their reliance on Burka v. U.S. Dept. of Health & Human Services, 87 F.3rd 508 (D.D.C. 1996) is wholly misplaced. Once again, Plaintiffs confuse the non-production or withholding of documents (not at issue here) with the production of documents under a confidentiality order (at issue here). Plaintiffs refer to Burka for the proposition that there exists no “absolute privilege” with respect to “research data.” See Memorandum in Support of Plaintiff’s Response to Defendant Kennedy Krieger Institute, Inc.’s Motion for Protective Order, p. 3. It is unclear how this proposition furthers Plaintiffs’ opposition to the Motion as Kennedy Krieger does not assert that an absolute privilege exists with respect to the production of research data.

Plaintiffs’ analysis of Burka and application to the present issue is flawed. The two-pronged test cited by Plaintiffs⁷ does not apply to documents protected by the deliberative process privilege. In Burka, the government agency, the National Cancer Institute, did not assert the deliberative process privilege against production. Instead, it withheld the documents requested under FOIA (questionnaires and data tapes relating to a 1990 survey of ninth-grade students) because the

⁷ The lower court in Burka held that the agency “had identified two interests which would trigger protection of the material in discovery: 1) interference with ongoing scientific research, which would occur if the data was released prior to the follow-up surveys, and individuals then modified their behavior or survey answers in response to this information; and 2) harm to “the [COMMIT] researchers’ interest in having their research published in prestigious, peer-reviewed journals.” Burka, 87 F.3d at 513.

documents were “confidential research material.” Burka, 87 F.3d at 513.⁸ The holding in Burka did not expressly address the deliberative process but nevertheless recognized that documents reflecting the deliberative process are properly withheld from production under Exemption 5 of FOIA.

Thus, in the present case, if Plaintiffs sought to obtain directly from the government much of the confidential information already produced by Kennedy Krieger, the NIEHS would be entitled to withhold the documents that reflect the pre-decisional, deliberative process that took place during the development and conduct of the TLC study.

Kennedy Krieger Met its Burden Pursuant to FRCP 26

Kennedy Krieger has met its burden to demonstrate the need for a confidentiality order precluding Plaintiffs from disseminating the confidential documents outside the scope of the litigation. Courts weigh the following factors when deciding to limit discovery by means of a Federal Rule of Civil Procedure (“FRCP”) 26 order: “the requester’s need for the information from this particular source, its relevance to the litigation at hand, the burden of producing the sought-after material; and the harm which disclosure would cause to the party seeking to protect

⁸ The government argued that “confidential research data is a category of information protected in civil discovery proceedings, and that the specific records sought by Burka would be eligible for such protection and may therefore be withheld in the FOIA context, as well.” Id. Because the government did not assert one of the *privileges* enumerated in Exemption 5 (pre-decisional deliberative memoranda; attorney-client communications, or attorney work product), the government had the burden to show that the documents sought would be protected from production during discovery in a civil proceeding. The Court stated:

Translating this two-tiered arrangement into the FOIA context means that merely identifying information as falling within a *privileged* category—deliberative material, attorney/client communications, work product—may be sufficient to withhold the material from a FOIA requester. When dealing with information withheld on the grounds that it may be subject to a protective order, though, something more is required: just as the target of a discovery request must show “good cause” under Rule 26(c) to escape disclosure, the agency claiming exemption from FOIA must identify an interest similar to one which courts have found sufficient to justify the “good cause” standard in discovery proceedings.

Burka, 87 F.3d at 518 (emphasis in original).

the information.” Burka, 87 F.3d at 517 (citations omitted). These factors weigh heavily in favor of issuing a confidentiality order in the present case to limit use of the confidential documents to the scope of this litigation.

The first prong, the requester’s need for the information from this particular source, to the extent that it is applicable, weighs in favor of entering a confidentiality order. Kennedy Krieger has already produced the documents at issue in the Motion. Therefore, the Plaintiffs’ (Shawnta DeShields and Lamont Mitchell) need for discovery of TLC documents is met. It is noteworthy that Plaintiffs failed to provide any reason why they object to use of the documents solely for purposes of the litigation. The second prong, the relevance of the information to the litigation at hand, does not apply because Kennedy Krieger produced the subject documents. Similarly, the burden of producing the sought-after material, though significant, is at this point irrelevant because Kennedy Krieger has already produced the sought-after material. The final prong, the harm that disclosure would cause to the party seeking to protect the information, ultimately compels a confidentiality order in this case.

As set forth more fully in Kennedy Krieger’s Motion, the documents designated as “confidential” should be protected from dissemination *outside of the course of this litigation* for the following reasons: (1) Kennedy Krieger is obligated by contract to maintain the confidentiality of information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution;⁹ (2) many of the documents reflect the deliberative process of the NIEHS and its contractors;¹⁰ and (3) Institutional Review Board documents must be treated as confidential based on legislative intent and sound public

⁹ See Motion, p. 4 (quoting 48 C.F.R. § 352.224-70).

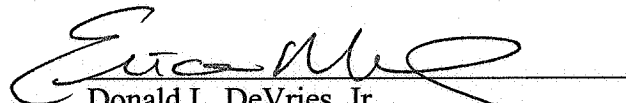
¹⁰ See Motion, pp. 5-10 (stating that the purpose of the deliberative process privilege was established to prevent injury to the quality of agency decisions).

policy.¹¹ In sum, open communication and frank discussion among researchers is paramount to the success of scientific and medical research. If researchers believed that their personal notes, observations, internal communications, and critiques would be subject to *unfettered* disclosure, the chilling effect would hinder the frank and open discussions necessary to conduct valuable and scientifically sound research. See U.S. v. Nixon, 418 U.S. 683, 705 (1974).

CONCLUSION

For the reasons set forth above and in its Motion for Protective Order, Kennedy Krieger respectfully requests that this Court grant its Motion and enter a confidentiality order limiting the use of all confidential documents to the scope of this litigation.

Respectfully submitted,



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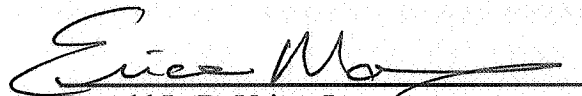
**Attorneys for Kennedy
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¹¹ See Motion, pp. 10-11 (explaining that to ensure that research on human subjects is conducted in the best manner possible, members of the IRB must be free to voice opinions and criticisms with candor, without fear that a comment will later be used in litigation).

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 9th day of September 2003, a copy of the foregoing Reply Memorandum in Support of Defendant's Motion for Protective Order was mailed first-class, postage prepaid, to:

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