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Samuel D. Hodge  
*Temple University*

Maria Zambrano Steinhaus

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# The Ever-Changing Landscape of Informed Consent and Whether the Obligation to Explain a Procedure to the Patient May Be Delegated

Samuel D. Hodge, Jr.\* and Maria Zambrano Steinhaus\*\*

*Informed consent is required for every invasive medical procedure, from getting your ears pierced to having an abortion.*

—Bob McDonnell<sup>1</sup>

Informed consent is an integral part of the shared decision making process and requires a patient be informed of the benefits, risks and alternatives to a medical procedure.<sup>2</sup> This information, which requirement has been codified into the law and practice of every healthcare provider,<sup>3</sup> helps a patient decide whether to proceed with the recommended treatment plan.<sup>4</sup> Informed consent

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\* Samuel D. Hodge, Jr. is a professor at Temple University where he teaches both law and anatomy. He is also a mediator/neutral arbitrator for the Dispute Resolution Institute. Professor Hodge has authored more than 160 articles in medical and legal journals and has written six medical/legal texts. He also enjoys an AV preeminent rating and has been named a top lawyer in Pennsylvania on multiple occasions.

\*\* Maria Zambrano Steinhaus is a graduate of the Beasley School of Law at Temple University. She currently works at a New York personal injury firm and has an Associate's Degree in Paralegal Studies and a Bachelor Degree in Professional Communications.

1. NR Interview, *McDonnell Talks Super Tuesday*, NAT'L REVIEW (Mar. 5, 2012, 5:00 PM), <https://www.nationalreview.com/2012/03/mcdonnell-talks-super-tuesday-interview> [https://perma.cc/8ZCH-SR5E].

2. Definition of Informed Consent, *NCI Dictionary of Cancer Terms*, NAT'L CANCER INST., <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/informed-consent> [https://perma.cc/G924-745W] (last visited Sept. 18, 2018); *Medical Definition of Informed Consent*, MEDICINENET, <https://www.medicinenet.com/script/main/art.asp?articlekey=22414> [https://perma.cc/HPG5-GRL2] (last updated May 13, 2016).

3. *A Practical Guide to Informed Consent, Background: Requirements for Informed Consent*, TEMPLE HEALTH, <https://www.templehealth.org/ICTOOLKIT/html/ictoolkitpage1.html> [https://perma.cc/H939-GSVH] (last visited Sept. 18, 2018).

4. NAT'L CANCER INST., *supra* note 2.

has its foundation in the ethical notion of patient autonomy and fundamental human rights.<sup>5</sup> After all, it is the patient's decision to determine what may be done to his or her body and to ascertain the risks and benefits before undertaking a procedure.<sup>6</sup> On the other hand, a physician's role is to act as a facilitator in the patient's decision making process by providing information about the planned treatment and to answer questions.<sup>7</sup> While the roles of the patient and physician seem clearly defined, a number of barriers present challenges in creating a process that guarantees a patient understands a test or procedure.<sup>8</sup> This includes ineffective communication between the doctor and patient.

The first part of this article will explore the liability of various health care providers who participate in the informed consent process, such as the physician, nurse, physician assistant and hospital. The second section will examine whether the treating physician may delegate the duty to explain the risks and alternatives of a procedure to another. The controversial decision of *Shinal v. Toms*, which mandates that the doctor must have a one-on-one exchange with the patient in order to secure a valid informed consent,<sup>9</sup> will also be explored. This recent ruling has sent shock waves throughout the medical community causing a reexamination of their informed consent policies.<sup>10</sup>

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5. K H Satyanarayana Rao, *Informed Consent: An Ethical Obligation or Legal Compulsion?*, 1 J. Cutaneous & Aesthetic Surgery 33, 33-34 (2008) (discussing the ethical and legal reasons for informed consent and how the level of disclosure is always determined on a case-by-case basis). As for a discussion of a patient's autonomy, the American College of Obstetricians and Gynecologists has noted that as an ethical doctrine, "[i]nformed consent should be looked on as a process rather than a signature on a form. This process includes a mutual sharing of information over time between the clinician and the patient to facilitate the patient's autonomy in the process of making ongoing choices." *Informed Consent*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (Aug. 2009), <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Ethics/Informed-Consent> [<https://perma.cc/R7Q5-UJGJ>].

6. Rao, *supra* note 5, at 33.

7. *Id.*

8. Examples of barriers include the lack of information on the consent form, ineffective doctor-patient communication, and a patient's literacy and cultural issues. *Informed Consent: More Than Getting a Signature*, JOINT COMM'N (Feb. 2016), <https://www.jointcommission.org/issues/article.aspx?Article=5kmqmwV14ugGGireNakQqaCw1iqenpblIjAYdRsubU%3d> [<https://perma.cc/5E7B-WUKL>].

9. 162 A.3d 429, 455 (Pa. 2017).

10. Dan Logsdon, *Why Your Medical Consenting Practices Will Change*, AGILE CONSENT (Sept. 18, 2017), <http://agileconsent.com/consenting-will-change> [<https://perma.cc/L85M-S59A>].

## I. THE HISTORICAL DEVELOPMENT OF INFORMED CONSENT

Informed consent was first introduced to the American public by Justice Cardozo in 1914 when he opined: “Every 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, for which he is liable in damages.”<sup>11</sup> The American Medical Association incorporated this concept into its Code of Medical Ethics by declaring that patients have the right to obtain information and ask questions about proposed services so that they can make appropriate decisions about their care.<sup>12</sup> This ethical mandate is premised upon the idea of utility, or from the advantage that arises from a patient’s active participation in the decision making process regarding their health.<sup>13</sup> This involvement is beneficial because it helps guard against treatment that a person deems harmful and it provides a positive influence on their welfare.<sup>14</sup> Regardless of how one views the purpose for informed consent, the doctrine is firmly established in American jurisprudence but remains a constant source of litigation as the courts struggle over the meaning of these two simple words.<sup>15</sup>

Historically, participation in the medical decision-making process was discouraged because physicians believed that deception was a critical component to the practice of medicine.<sup>16</sup> The disclosure of the possible risks of a procedure was frowned

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11. *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914), *abrogated on other grounds by* *Bing v. Thunig*, 143 N.E.2d 3 (N.Y. 1957). Informed consent in an international setting was initially set forth in the Declaration of Nuremberg in 1947 and ratified by consecutive Declarations of Helsinki from 1964 to 2000. M Kottow, *The Battering of Informed Consent*, 30 J. MED. ETHICS 565, 565 (2004).

12. *AMA Code of Medical Ethics Opinion 2.1.1*, AM. MED. ASS’N (2016), <https://www.ama-assn.org/delivering-care/informed-consent> [<https://perma.cc/5HLK-AD5V>].

13. AM. COLL. OBSTETRICIANS & GYNECOLOGISTS, *supra* note 5.

14. *Id.*

15. A Westlaw search on informed consent on February 28, 2018 revealed over 30,000 appellate court decisions, trial court orders and administrative decisions (on file with the *Arkansas Law Review*).

16. In the 1800’s, most physicians believed that a patient should not be informed about critical conditions to facilitate care. Peter M. Murray, *The History of Informed Consent*, 10 IOWA ORTHOPAEDIC J. 104, 104 (1990).

upon because it might erode patient trust and would be counterproductive to building a relationship of confidence.<sup>17</sup>

The earliest example of a signed consent originated in Turkey more than 500 years ago, but it was not until 1957, that a lawsuit introduced the term “informed consent.”<sup>18</sup> In *Salgo v. Stanford*, the court determined that a healthcare provider who withholds any relevant facts needed to establish the foundation of an intelligent informed consent violates the physician’s obligation to the patient and exposes the doctor to liability.<sup>19</sup> Similarly, a physician may not downplay the risks of an operation to induce the patient’s consent.<sup>20</sup>

Critical dialogue about the meaning of informed consent in the context of medicine, law and ethics first took place in 1972.<sup>21</sup> During that year, three decisions became the foundation for the recognition of the principle as a legal precedent:<sup>22</sup> *Canterbury v. Spence*,<sup>23</sup> *Cobbs v. Grant*,<sup>24</sup> and *Wilkerson v. Vesey*.<sup>25</sup> In fact, the

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17. *Id.*

18. Historians studying the Ottoman Empire discovered a document signed by a patient allowing the surgeon to remove a stone in the patient’s bladder. George Dvorsky, *The First-Known Medical Consent Form Dates Back to 1524*, GIZMODO (Apr. 2, 2015, 1:20 PM), <https://io9.gizmodo.com/the-first-known-medical-consent-form-dates-back-to-1524-1695230695> [<https://perma.cc/E5ZT-A49X>].

19. 317 P.2d 170, 181 (Cal. Dist. Ct. App. 1957). The court also concluded that each patient’s case is different and that “in discussing the element of risk certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent.” *Id.*

20. *Id.*

21. See Tom L. Beauchamp, *Informed Consent: Its History, Meaning, and Present Challenges*, 20 CAMBRIDGE Q. HEALTHCARE ETHICS 515, 516 (2011).

22. *Id.*

23. 464 F.2d 772 (D.C. Cir. 1972), *cert. denied*, 409 U.S. 1064. In this case, a patient sued the doctor for his failure to disclose the risk of paralysis during a laminectomy. *Id.* at 778. The court held that “due care normally demands that the physician warn the patient of any risks to his well-being which contemplated therapy may involve.” *Id.* at 781.

24. 502 P.2d 1 (Cal. 1972). The court noted that the patient was not informed of the possibility of injuries to the spleen during duodenal ulcer repairs. *Id.* at 4. There is a “duty of reasonable disclosure of the available choices with respect to proposed therapy and of the dangers inherently and potentially involved in each.” *Id.* at 10.

25. 295 A.2d 676 (R.I. 1972). The patient sued a radiologist for his failure to inform the patient about the risk of radiation burns. *Id.* at 681. The court held that a “patient is entitled to receive material information upon which he can base an informed consent.” *Id.* at 688.

*Canterbury* decision established a more patient-oriented disclosure:<sup>26</sup>

[T]he patient's right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is the information material to the decision. Thus, the test for determining whether a particular peril must be divulged is its materiality to the patient's decision: all risks potentially affecting the decision must be unmasked. And, to safeguard the patient's interest in achieving his own determination on treatment, the law must itself set the standard for adequate disclosure.<sup>27</sup>

These judicial pronouncements prompted the American Medical Association to acknowledge informed consent as "a basic social policy" required to allow patients to formulate their own decisions even if the physician disagrees with that process.<sup>28</sup>

Initially, the lack of informed consent was considered an encroachment of a person's body integrity and constituted a battery.<sup>29</sup> The courts were of the opinion that operations or procedures undertaken without obtaining a patient's approval constituted an intentional, unwarranted touching.<sup>30</sup> Over the years, the failure to obtain the patient's consent has shifted in a number of jurisdictions to a negligence claim,<sup>31</sup> partially as the result of the court's desire not to find a well-intentioned physician liable for battery.<sup>32</sup>

Surgeons must deal with informed consent on a routine basis and the American College of Surgeons has noted that the principle

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26. Encyclopedia of Bioethics, *Informed Consent: I. History of Informed Consent*, ENCYCLOPEDIA.COM (2004), <https://www.encyclopedia.com/science/encyclopedias-almanacs-transcripts-and-maps/informed-consent-i-history-informed-consent> [<https://perma.cc/FFR7-HZE4>].

27. See *Canterbury*, 464 F.2d at 786-87.

28. Encyclopedia of Bioethics, *supra* note 26.

29. Erin Sheley, *Rethinking Injury: The Case of Informed Consent*, 2015 BYU L. REV. 63, 68 (2015).

30. *Id.* at 73.

31. *Id.* at 68.

32. *Id.*

is more than just a legal mandate.<sup>33</sup> It is a benchmark for proper ethical practice that supplements the doctor/patient relationship and has the ability to enhance the person's care and treatment outcomes. Consequently, surgeons are mandated to inform every patient about his or her affliction and strategy for treatment.<sup>34</sup> This information must be explained "fairly, clearly, accurately, and compassionately."<sup>35</sup> Physicians, at a minimum, should discuss:

[1.]The nature of the illness and the natural consequences of no treatment.

[2.]The nature of the proposed operation, including the estimated risks of mortality and morbidity.

[3.]The more commonly known complications, which should be described and discussed. The patient should understand the risks as well as the benefits of the proposed operation. The discussion should include a description of what to expect during the hospitalization and posthospital convalescence.

[4.]Alternative forms of treatment, including nonoperative techniques.

[5.]A discussion of the different types of qualified medical providers who will participate in their operation and their respective roles.<sup>36</sup>

All states have enacted informed consent legislation in one form or another.<sup>37</sup> The specific language of the individual laws has changed over the years and differs from jurisdiction-to-jurisdiction, but the general premise is that of patient knowledge.<sup>38</sup> The requirement is that the doctor must inform the

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33. See *Informed Consent*, AM. COLL. SURGEONS, <https://www.facs.org/education/patient-education/patient-resources/informed-consent> [<https://perma.cc/XSA7-BR9L>] (last visited Sept. 19, 2018).

34. Samuel D. Hodge, Jr. et al., *Must Physicians Disclose an Alcohol or Substance Abuse Problem When Requesting a Patient Sign an Informed Consent Document?*, 91 N.D. L. REV. 309, 317 (2015).

35. *Statements on Principles*, AM. COLL. SURGEONS (Apr. 12, 2016), <https://www.facs.org/about-acs/statements/stonprin#anchor171960> [<https://perma.cc/63S9-ENPS>].

36. *Id.*

37. *A Practical Guide to Informed Consent*, *supra* note 3.

38. *Understanding Informed Consent and Your Rights as a Patient*, FINDLAW, <http://healthcare.findlaw.com/patient-rights/understanding-informed-consent-a-primer.html> [<https://perma.cc/D6Z8-8G4P>] (last visited Sept. 19, 2018).

patient of the important advantages, dangers and alternatives to the proffered service and obtain the patient's authorization to proceed with treatment.<sup>39</sup> There are exceptions for emergencies and legally determined mental incompetency or physical incapacity.<sup>40</sup>

The type and amount of information that must be disclosed is focused on two fundamental values owed by the physician: beneficence, or the obligation "to do good[]," and respect for the person's autonomy.<sup>41</sup> These tenets have resulted in court-imposed elements required for a patient to establish a malpractice claim based on a lack of informed consent:

(1) . . . the person providing the professional treatment failed to . . . inform the patient of reasonably foreseeable risks associated with the treatment, and the alternatives, that a reasonable medical practitioner would have disclosed in the same circumstances, (2) . . . a reasonably prudent patient in the same position would not have undergone the treatment if he or she had been fully informed, and (3) . . . the lack of informed consent is a proximate cause of the injury[.]<sup>42</sup>

There is always a grey area about how many potential risks should be explained and how detailed the discussion should be with the patient. While many jurisdictions apply the standard of what a "reasonable physician" would disclose or what a "reasonable patient" would want to know, this language still leaves room for interpretation.<sup>43</sup> Therefore, it is not surprising that litigation involving informed consent has increased especially since the Internet provides patients with the ability to learn more information about a doctor or to better understand their medical condition. Attorneys have also become much more creative in their attempts to expand physician liability.<sup>44</sup>

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39. *Id.*

40. *Id.*

41. Sheley, *supra* note 29, at 69 (quoting *Foote v. Rajadhyax*, 268 A.D.2d 745, 745 (2000)).

42. *Godel v. Goldstein*, 155 A.D.3d 939, 941-42 (N.Y. App. Div. 2017). As noted in *Matthies v. Mastromonaco*, a healthcare provider is required to reveal that information which will allow a reasonable patient to consider and weigh knowledgeably the alternatives available and the risks associated with each procedure. 733 A.2d 456, 460 (N.J. 1999).

43. *A Practical Guide to Informed Consent*, *supra* note 3.

44. See Hodge et al., *supra* note 34, at 319.

Case law demonstrates that a healthcare provider may no longer assume that it is sufficient to merely disclose the material risks of a procedure. Lawsuits are now physician-specific and may be based on a doctor's failure to disclose that he has been the subject of prior lawsuits or disciplinary action,<sup>45</sup> the failure to reveal important physical or mental health issues involving the physician,<sup>46</sup> the investigational status of a device being employed,<sup>47</sup> a doctor's lack of experience,<sup>48</sup> a physician's alcohol or drug dependency,<sup>49</sup> success rates for a technique or

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45. In *Tsouristakis v. Guerrino*, the court found that a dentist was not obligated to inform a patient that he had been sued by other patients or had been the subject of a disciplinary proceeding. No. 1234/06, 2007 WL 7314864, at \*3 (N.Y. Sup. Ct. May 16, 2007). *See also* *Curran v. Buser*, 711 N.W.2d 562, 570 (Neb. 2006) (holding that a physician did not have to disclose his disciplinary history to patient unless doctors in similar locations and situations would ordinarily disclose their disciplinary history).

46. *See Hawk v. Chattanooga Orthopedic Grp.*, 45 S.W.3d 24, 26-27 (Tenn. Ct. App. 2000). There, the court held that a surgeon's disabling hand condition was relevant to the informed consent claim. *Id.* at 35. In *May v. Cusick*, a surgeon had suffered two prior strokes, which were not disclosed to the patient. No. 99-2520, 2001 WL 436286, at \*1 (Wis. Ct. App. May 1, 2001). The plaintiff alleged that the doctor may have suffered ill effects from the strokes that affected his ability to operate on her. *Id.* The court dismissed the lack of informed consent claim and opined that the plaintiff failed to show any evidence that the past minor strokes presented any risk to her. *Id.* at \*5.

47. *Blazoski v. Cook*, 787 A.2d 910, 921 (N.J. Super. Ct. App. Div. 2002) (holding that a surgeon was not required to inform a patient about the FDA's investigational status of pedicle screws, but suggesting that the jury can consider whether this information would be "material to a prudent patient's decision"); *see also DeNeui v. Wellman*, No. CIV. 07-4172-KES, 2009 WL 4847086, at \*4 (D.S.D. Dec. 9 2009) (holding that the "reasonable person" standard indicate[d] that the issue of materiality of the off-label use of BMP is to be decided by a jury").

48. *Barriocanal v. Gibbs*, 697 A.2d 1169, 1173 (Del. 1997) (holding that a doctor's qualifications were relevant to the issue of informed consent). Courts in Maryland and Wisconsin have issued similar decisions. *See Goldberg v. Boone*, 912 A.2d 698, 717 (Md. 2006); *Johnson v. Kokemoor*, 545 N.W.2d 495, 498 (Wis. 1996). A narrower approach was followed in *Whiteside v. Lukson*, where the court held that a physician's lack of experience in handling a specific procedure was not a material risk that had to be disclosed. 947 P.2d 1263, 1265 (Wash. Ct. App. 1997). In *Howard v. Univ. of Med. & Dentistry of N.J.*, the court established that "misrepresented or exaggerated physician experience would have to significantly increase a risk of a procedure in order for it to affect the judgment of a reasonably prudent patient in an informed consent case." 800 A.2d 73, 85 (N.J. 2002).

49. *Hodge et al.*, *supra* note 34, at 320-21.

procedure,<sup>50</sup> a doctor's HIV positive status,<sup>51</sup> the obligation to reveal that the person is part of a research study<sup>52</sup> as well as the doctor's monetary interest in a technique.<sup>53</sup> Another source of litigation is whether the informed consent form must be a signed written document.<sup>54</sup>

## II. WHO HAS THE DUTY TO OBTAIN A PATIENT'S INFORMED CONSENT?

Two of the latest disputes involving informed consent deal with which healthcare provider must explain a procedure to the patient and whether a physician may delegate that duty to a nurse, physician assistant, or hospital employee.

### A. LIABILITY OF A HOSPITAL

#### 1. *Respondent Superior, Ostensible Agency and Corporate Negligence.*

Medical procedures are regularly performed in a hospital. Therefore, medical institutions are often sued for failing to obtain

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50. In *Wlosinski v. Cohn*, the court determined that a doctor's success rate in performing kidney transplants did not constitute a risk that had to be disclosed to a patient. 713 N.W.2d 16, 21-22 (Mich. Ct. App. 2005). See also *Arato v. Avedon*, 858 P.2d 598, 606-07 (Cal. 1993) (noting that the court could not determine as a matter of law that a cancer patient's statistical life expectancy information before treatment is material to an informed consent).

51. In *Faya v Almaraz*, the court held that a doctor who is HIV positive may have breached his legal duty in failing to disclose this information before performing invasive surgery. 620 A.2d 327, 339 (Md. 1993). But see *K.A.C. v. Benson*, 527 N.W.2d 553, 561 (Minn. 1995); *Brzoska v. Olson*, 668 A.2d 1355, 1363-64 (Del. 1995) (holding that a doctor did not have to disclose an HIV status).

52. *Grimes v. Kennedy Krieger Inst.*, 782 A.2d 807 (Md. 2001). The court held that when it comes to research studies, "[a] human subject is entitled to all material information." *Id.* at 844 (emphasis original).

53. In *Moore v. Regents of Univ. of Cal.*, the court opined that "a reasonable patient would want to know whether a physician has an economic interest that might affect the physician's professional judgment. . . . '[A] sick patient deserves to be free of any reasonable suspicion that his doctor's judgment is influenced by a profit motive.'" 793 P.2d 479, 483 (Cal. 1990) (quoting *Magan Med. Clinic v. Cal. State Bd. Med. Examiners*, 249 Cal. App. 2d 124, 132 (1967)).

54. Some courts have held that patient's informed consent does not have to be in writing. See, e.g., *Cooper v. United States*, 903 F. Supp. 953, 957 (D.S.C. 1995); *Maerklein v. Smith*, 266 P.2d 1095, 1099 (Colo. 1954); *Yahn v. Folse*, 639 So. 2d 261, 265 (La. Ct. App. 1993); *Patterson v. Van Wiel*, 570 P.2d 931, 934 (N.M. Ct. App. 1977).

or insure that a patient has executed the informed consent document. Many medical facilities in the twenty-first century have created multimedia platforms that walk the patient and physician through a procedure.<sup>55</sup> These platforms also document the patient's agreement or refusal to proceed and incorporate the informed consent form into the patient's medical chart.<sup>56</sup> While physicians universally remain responsible for defects in the process, hospitals have escaped liability in most cases.<sup>57</sup> This history, however, has not stopped counsel from suing hospitals on three theories: respondent superior, ostensible agency and corporate negligence.<sup>58</sup>

In *Davis v. Hoffman*, the plaintiff suffered from a fibroid uterus and had a pre-surgical interview with the surgeon's nurse.<sup>59</sup> The patient maintained that she specifically told the doctor and nurse that she refused to have a hysterectomy.<sup>60</sup> During the operation, it became necessary to undertake such operation but no one awakened the patient to obtain her consent.<sup>61</sup> Suit was instituted against the hospital, surgeon and nurse for a battery.<sup>62</sup> The plaintiff maintained that the hospital was liable for the actions of the doctor and nurse under the theories of respondent-superior, ostensible agency and corporate negligence.<sup>63</sup> The hospital

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55. Robert Gatter, *The Mysterious Survival of the Policy Against Informed Consent Liability for Hospitals*, 81 NOTRE DAME L. REV. 1203, 1204 (2006).

56. *Id.*

57. *Id.* at 1205; *see also* *Davis v. Hoffman*, 972 F. Supp. 308, 311-12 (E.D. Pa. 1997) (holding that hospitals have no duty to obtain informed consent from the patient). One author, however, has suggested that hospitals may one day incur liability for the failure of a doctor, who works primarily at the facility, to obtain a patient's informed consent. Shelley S. Fraser, *Hospital Liability: Drawing A Fine Line With Informed Consent in Today's Evolving Health Care Arena*, 1 IND. HEALTH L. REV. 253, 253 (2004). This is based on the fact that medical facilities exert some degree of control over the informed consent process as the result of policies and procedures, the supplying of forms, accreditation standards and by employing physicians to perform tasks that require informed consent. *Id.*

58. Gatter, *supra* note 55, at 1218-19, 1251; *see also* *Davis*, 972 F. Supp. at 312. Since 1967, courts all over the country have held that medical institutions do not have a duty to inform a patient about the specifics of a procedure or treatment alternatives, or to investigate whether the physician has secured the patient's informed consent because informed consent is the responsibility of the physician. Gatter, *supra* note 55, at 1216.

59. 972 F. Supp. at 311.

60. *Id.*

61. *Id.*

62. *Id.*

63. *Id.*

moved for dismissal which was granted.<sup>64</sup> The court noted that Pennsylvania imposes an obligation upon the surgeon to secure the patient's informed consent.<sup>65</sup> This requirement is limited to the doctor and a hospital has no such obligation, even if one of the institution's doctors performs the procedure with hospital personnel.<sup>66</sup> An exception occurs if the hospital voluntarily assumes the duty to obtain the release.<sup>67</sup> In that case, the hospital must not act negligently.<sup>68</sup>

Ostensible agency is a valid and recognizable theory by which a healthcare provider may incur liability if the hospital holds out the negligent physician as one of its employees.<sup>69</sup> However, in *Davis v. Hoffman*, the plaintiff could not establish ostensible agency because, by her own assertions in the complaint, she entered into a doctor-patient relationship with the defendant doctor directly and the hospital did not refer her to the surgeon.<sup>70</sup> As for the claim of corporate negligence, the court noted that to prove such claim, the plaintiff must demonstrate the hospital's "failure to uphold the proper standard of care owed to patient."<sup>71</sup> Such count is predicated under the doctrine that a hospital must: "1) 'use reasonable care in the maintenance of safe and adequate facilities;' 2) 'select and retain only competent physicians;' 3) 'oversee all persons who practice medicine within its walls;' and 4) 'formulate, adopt and enforce adequate rules and policies to ensure quality care.'"<sup>72</sup> Nevertheless, the court pointed out that a hospital may not be liable for corporate negligence for the failure to obtain an informed consent.<sup>73</sup>

The Supreme Court of Nebraska also agreed that a hospital does not have an independent duty to warn a patient about the

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64. *Davis*, 972 F. Supp. at 311.

65. *Id.* (citing *Friter v. Iolab Corp.*, A.2d 1111, 1113 (Pa. Super. Ct. 1992)).

66. *Id.* at 312 (citing *Friter*, A.2d at 1113).

67. *Id.*

68. *Id.*

69. *Capan v. Divine Providence Hosp.*, 430 A.2d 647, 649 (Pa. Super. Ct. 1980) (holding that ostensible agency is established if the patient looks at the institution rather than the individual doctor for care and if the hospital "holds-out" the doctor as its employee).

70. *Davis v. Hoffman*, 972 F. Supp. 308, 313 (E.D. Pa. 1997).

71. *Id.* (quoting *Thompson v. Nason Hosp.*, 591 A.2d 703, 707 (Pa. 1991)).

72. *Id.* (quoting *Thompson*, 591 A.2d at 707).

73. *Id.*

risks and advantages of a procedure.<sup>74</sup> In *Giese v. Stice*, the court opined that the majority of jurisdictions that have considered the question have declined to impose liability upon a hospital to obtain a patient's informed consent.<sup>75</sup> This court concluded that only the treating doctor has the "education, expertise, skill, and training" needed to treat a patient and ascertain what a person needs to know in order to provide a proper informed consent.<sup>76</sup>

## 2. Procedure Performed By A Hospital Employee

A distinguishable result is achieved if the hospital's employees are performing the procedure and they fail to inform

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74. *Giese v. Stice*, 567 N.W.2d 156, 164 (Neb. 1997). The courts have declined to impose a duty upon the hospital to obtain the informed consent document unless they "specifically assumed the duty" or the physician was an agent of the hospital." *Robertson v. Iuliano*, No. RDB-10-1319, 2012 WL 6138441, at \*3, (D. Md. 2012) (quoting *Valles v. Albert, Einstein Med. Ctr.*, 758 A.2d 1238, 1243 (Pa. Super. Ct. 2000)). The court in *Robertson* found that the doctor has exclusive control in the manner in which he/she obtains the informed consent and dismissed the case against the doctor's employer. *Id.* at \*5.

75. *Giese*, 567 N.W.2d at 162 (citing *Kelly v. Methodist Hosp.*, 664 A.2d 148, 151 (Pa. Super. Ct. 1995)).

76. *Id.* at 163; *see also* *Krane v. Saint Anthony Hosp. Sys.*, 738 P.2d 75, 77 (Colo. App. 1987) (holding a hospital does not have an obligation to inform the patient of the nature of the procedure to be employed and the risks involved, so the hospital has no requirement to secure an informed consent comparable to that which the surgeon is required to obtain); *Petriello v. Kalman*, 576 A.2d 474, 479 (Conn. 1990) (holding a hospital has no duty to obtain a patient's informed consent to a surgery to be performed by a surgeon who is not an employee of the hospital); *Pickle v. Curns*, 435 N.E.2d 877, 880-81 (Ill. App. Ct. 1982) (holding a hospital has no requirement to notify a patient about the risks of surgery); *Lincoln v. Gupta*, 370 N.W.2d 312, 318 (Mich. Ct. App. 1985) (holding that a doctor has the exclusive obligation to notify a patient about the risks related to a medical procedure); *Baltzell v. Baptist Med. Ctr.*, 718 S.W.2d 140, 142 (Mo. Ct. App. 1986) (holding a hospital has no requirement to tell a patient about the chances of an infection from surgery); *Johnson v. Sears, Roebuck & Co.*, 832 P.2d 797, 799 (N.M. Ct. App. 1992) (holding a hospital has no duty to obtain informed consent when a non-employee orders a procedure, but the hospital employees perform the procedure); *Schloendorff v. Soc'y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914), *abrogated on other grounds by* *Bing v. Thunig*, 143 N.E.2d 3, 3 (N.Y. 1957) (holding that a hospital which did not retain the surgeon had no obligation to acquire a patient's informed consent for the planned surgery); *Kershaw v. Reichert*, 445 N.W.2d 16, 17-18 (N.D. 1989) (holding that a hospital generally has no duty to obtain a patient's informed consent); *Goss v. Okla. Blood Inst.*, 856 P.2d 998, 1007 (Okla. Civ. App. 1990) (holding that a hospital has no requirement to notify a patient of the relevant risks of the surgery nor must the facility tell the patient about alternative procedures); *Ritter v. Delaney*, 790 S.W.2d 29, 32 (Tex. Ct. App. 1990) (holding that a hospital has no obligation to obtain a patient's informed consent simply because the doctor had told a nurse to obtain the patient's informed consent).

the patient of the known risks.<sup>77</sup> In *Keel v. St. Elizabeth Medical Center*, a patient's personal physician ordered a dye enhanced CT scan to be performed at the medical center.<sup>78</sup> The plaintiff was not provided with any information about the risks of the procedure and subsequently developed thrombophlebitis at the injection location.<sup>79</sup> The court found the hospital liable under an informed consent theory since its employees administered the test and failed to explain the risks of the procedure.<sup>80</sup> It noted that "a juror might reasonably infer . . . that St. Elizabeth's utter silence as to risks amounted to an assurance that there were none, whereas . . . St. Elizabeth itself, as the health care provider performing the treatment, recognized the substantial possibility of complications[.]"<sup>81</sup>

### 3. Clinical Investigations

A hospital may be found liable for failing to obtain an informed consent if the medical institution is participating in a clinical investigation,<sup>82</sup> in which case the hospital is required to ensure that informed consent is obtained from any patient participating in the study.<sup>83</sup> In *Friter v. Lolab Corp.*, the patient was the recipient of an intraocular lens that was implanted at Wills Eye Hospital.<sup>84</sup> The hospital was an approved institution for conducting experimental studies and was bound by FDA rules that required the informed consent of any patient participating in experimental treatment.<sup>85</sup> The patient was never told prior to his eye surgery that he was participating in an experimental program.<sup>86</sup> Subsequently, he developed numerous complications and sued the hospital for failing to obtain his informed consent.<sup>87</sup> The court noted that historically only the physician performing

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77. See *Keel v. St. Elizabeth Med. Ctr.*, 842 S.W.2d 860, 862 (Ky. 1992) (finding the hospital had a duty due to the statutory definition of "health care providers").

78. *Id.* at 860-61.

79. *Id.* at 861.

80. *Id.* at 862.

81. *Id.*

82. See *Friter v. Iolab Corp.*, 607 A.2d 1111, 1116 (Pa. Super. Ct. 1992).

83. *Id.* at 1113.

84. *Id.* at 1111.

85. *Id.*

86. *Id.* at 1111-12.

87. *Friter*, 607 A.2d at 1112.

the operation is required to obtain a patient's informed consent and that it could not find any Pennsylvania case imposing an independent duty on a non-physician to secure a patient's informed consent.<sup>88</sup> However, the hospital, as a participant in a clinical study under the auspices of the FDA, has an affirmative obligation to protect the right of individuals and that informed consent notifies the person of the risks associated with an investigational study.<sup>89</sup>

#### *4. Duty of a Hospital and Physician as Joint Health Care Providers*

Another argument is that a hospital and physician have a "joint duty" to obtain the patient's informed consent as "health care providers" as that term is defined in the informed consent statutes.<sup>90</sup> This position was rejected in *Alexander v. Gosner*<sup>91</sup> and *Howell v. Spokane & Inland Empire Blood Bank*.<sup>92</sup> Under Washington law, "health care providers' are subject to suit for breach of the duty to secure an informed consent by a patient."<sup>93</sup> While conceding that the statute encompasses a hospital within the definition of "health care providers," the court refused to extend an equal informed consent requirement to every entity that falls within the definition.<sup>94</sup> A hospital does not possess specific knowledge regarding a patient and its employees are only aware of the general risk relevant to all patients.<sup>95</sup> The information

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88. *Id.* at 1113.

89. *Id.* at 1113-14. A similar result in finding a hospital liable occurred in *Jones v. Philadelphia College of Osteopathic Medicine*, 813 F. Supp. 1125, 1130-31 (E.D. Pa. 1993). In this case, the hospital, on its own volition, prepared a consent form that contained the name and logo of the medical college and hospital. *Id.* at 1131. Under the circumstances, the court determined that a hospital has no duty to secure informed consent, but once it voluntarily assumes that duty, a plaintiff may have a valid cause of action based on the consent form. *Id.* at 1130-32.

90. *Giese v. Stice*, 567 N.W.2d 156, 164 (Neb. 1997) (The plaintiff argued that there was a joint duty between the hospital and physician because the informed consent statute uses the term "health care providers"; however, the court rejected this argument.)

91. *Id.* (citing *Alexander v. Gosner*, 711 P.2d 347 (Wash. Ct. App. 1985)).

92. *Id.* (citing *Howell v. Spokane & Inland Empire Blood Bank*, 785 P.2d 815 (Wash. 1990)).

93. *Howell v. Spokane & Inland Empire Blood Bank*, 785 P.2d 815, 822 (Wash. 1990) (citing WASH. REV. CODE ANN. § 7.7.050 (current version at WASH REV. CODE ANN. § 7.7.050 (West 2011))).

94. *Giese*, 567 N.W.2d at 164.

95. *Howell*, 785 P.2d at 822-23.

pertaining to the risks of a specific service or procedure are better left to the patient's physician.<sup>96</sup> Except in a very unusual circumstance, the hospital's staff is not required to obtain an informed consent from the patient.<sup>97</sup>

### *5. Hospital Supplies the Informed Consent Document*

A number of hospitals supply the informed consent forms used by physicians to secure the patient's authorization.<sup>98</sup> This has triggered lawsuits that assert, albeit unsuccessfully, that the hospital assumes the duty to obtain the patient's consent when it provides the forms to the patient.<sup>99</sup> For instance, in *Robertson v. Iuliano*, the plaintiff underwent back surgery and claimed that he was never informed that the procedure carried the risk of infection and that he would have refused the surgery if he had been made aware of this problem.<sup>100</sup> The facts showed that the hospital routinely supplied the informed consent forms as a precautionary measure to the physicians on its premises.<sup>101</sup> The court ruled that the hospital's supplying of these forms did not impose an independent duty upon the facility to ensure the patient's consent was obtained.<sup>102</sup> The court rationalized that the duty to inform the person of the risks of the procedure rests exclusively with the doctor because "unlike the physician, the patient is untrained in medical science, and therefore depends completely on the trust and skill of his physician for the information on which he makes his decision."<sup>103</sup>

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96. *Id.* at 823.

97. *Id.*

98. *See* *Robertson v. Iuliano*, No. RDB-10-1319, 2012 WL 6138441, at \*4 (D. Md. Dec. 10, 2012) (holding a hospital did not assume a duty by supplying consent forms).

99. *Id.* at \*4-5.

100. *Id.* at \*1.

101. *Id.* at \*4.

102. *Id.*

103. *Robertson*, 2012 WL 6138441, at \*2 (quoting *Sard v. Hardy*, 379 A.2d 1014, 1020 (Md. 1977)) (quotation marks omitted).

## B. LIABILITY OF THE DOCTOR'S STAFF

## 1. Nurse

Nurses possess superior medical skill and knowledge; therefore, they must use the degree of care that a reasonable nurse practitioner would employ under the circumstances.<sup>104</sup> However, this type of health care professional does not have a duty to obtain a patient's informed consent.<sup>105</sup> The nurse's primary task is to assist the physician.<sup>106</sup> More than one-half of the states have considered this issue and have concluded that nurses do not have an independent duty to secure the consent form.<sup>107</sup>

In *Wells v. Storey*, the court declined to create a duty requiring a nurse to obtain a patient's informed consent.<sup>108</sup> The physician is the only one uniquely qualified through education and training to determine the information necessary to share with the patient.<sup>109</sup> Likewise, in *Foflygen v. Zemel*, the court noted that

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104. In *Berdyck v. Shinde*, the court noted that nurses could be held liable if they breach their duty of care by failing to inform the doctor about a patient's condition. 613 N.E.2d 1014, 1024 (Ohio 1993).

105. See *Davis v. Hoffman*, 972 F. Supp. 308, 314 (E.D. Pa. 1997) (holding that "Pennsylvania law generally imposes no duty on persons other than surgeons to obtain informed consent before performing surgery. Thus, courts have not imposed the duty on nurses.").

106. *Id.* (citing *Jones v. Philadelphia Coll. of Osteopathic Med.*, 813 F. Supp. 1125, 1130 (E.D. Pa. 1993)).

107. *Wells v. Storey*, 792 So. 2d 1034, 1038 (Ala. 1999) (citations omitted).

108. *Id.* at 1039.

109. *Id.* at 1038-39 (quoting *Johnson v. Sears, Roebuck & Co.*, 832 P.2d 797, 799 (N.M. Ct. App. 1992)); see also *Krane v. Saint Anthony Hosp. Sys.*, 738 P.2d 75, 77 (Colo. App. 1987) (holding that since the hospital does not know the patient's history or details of the surgery, it is the surgeon who must obtain the informed consent); *Petriello v. Kalman*, 576 A.2d 474, 479 (Conn. 1990) (The court held that although the hospital drafted the consent form and had rules to make sure the surgeon obtained it before surgery, the rules did not authorize the operating room nurse "to countermand the judgment of the attending physician as to whether the patient had given an informed consent."); *Valcin v. Pub. Health Tr. of Dade Cty.*, 473 So. 2d 1297, 1307 (Fla. Dist. Ct. App. 1984), *rev'd in part on other grounds*, 507 So. 2d 596 (Fla. 1987); *Parr v. Palmyra Park Hosp.*, 228 S.E.2d 596, 598 (Ga. Ct. App. 1976); *Winters v. Podzamsky*, 621 N.E.2d 72, 75-76 (Ill. App. Ct. 1993); *Auler v. Van Natta*, 686 N.E.2d 172, 174-75 (Ind. Ct. App. 1997) (quoting *Giese v. Stice*, 567 N.W.2d 156, 163 (Neb. 1997)); *Pauscher v. Iowa Methodist Med. Ctr.*, 408 N.W.2d 355, 362 (Iowa 1987); *Kelley v. Kitahama*, 675 So. 2d 1181, 1182-83 (La. Ct. App. 1996); *Lincoln v. Gupta*, 370 N.W.2d 312, 318 (Mich. Ct. App. 1985); *Ackerman v. Lerwick*, 676 S.W.2d 318, 320-21 (Mo. Ct. App. 1984); *Giese v. Stice*, 567 N.W.2d 156, 163 (Neb. 1997); *Baird v. Am. Med. Optics*, 693 A.2d 904, 907 (N.J. Super. Ct. App. Div. 1997); *Johnson v. Sears, Roebuck & Co.*, 832 P.2d 797, 799 (N.M. Ct. App. 1992); *Nisenholtz v. Mount Sinai Hosp.*, 483

a nurse is not a joint-tortfeasor.<sup>110</sup> The patient underwent a stomach stapling procedure which resulted in multiple complications.<sup>111</sup> Two of the defendants, a nurse and a physician who performed the plaintiff's pre-surgery physical examination, moved to have the claims against them dismissed.<sup>112</sup> The plaintiff countered that they were joint tortfeasors who acted in concert with the other defendants in failing to obtain the patient's informed consent.<sup>113</sup> The court held that only the physician who performs the operation has a duty to secure the informed consent of the patient.<sup>114</sup> Therefore, neither the nurse nor the physician who conducted the physical examination could be liable as joint tortfeasors with the surgeon.<sup>115</sup>

Does a hospital assume a duty to obtain a patient's informed consent when a physician orders a nurse, an employee of the hospital, to secure the patient's informed consent? This question was answered in *Ritter v. Delaney*.<sup>116</sup> The plaintiff underwent a procedure to increase the blood flow to her brain which resulted in severe complications.<sup>117</sup> The plaintiff argued that the hospital was liable because it became an agent of the surgeon when the doctor asked the hospital's nurse to obtain the signed informed consent form.<sup>118</sup> The court concluded that the acts of the nurse did not create a duty on the hospital to obtain informed consent.<sup>119</sup>

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N.Y.S.2d 568, 572 (N.Y. Sup. Ct. 1984); *Cox v. Haworth*, 283 S.W.2d 392, 395-96 (N.C. Ct. App. 1981); *Kershaw v. Reichert*, 445 N.W.2d 16, 17-18 (N.D. 1989) (quoting *Krane v. Saint Anthony Hosp. Sys.*, 738 P.2d 75, 77 (Colo. App. 1987)); *Goss v. Okla. Blood Inst.*, 856 P.2d 998, 1007 (Okla. Civ. App. 1990); *Kelly v. Methodist Hosp.*, 664 A.2d 148, 150-51 (Pa. Super. Ct. 1995); *Boney v. Mother Frances Hosp.*, 880 S.W.2d 140, 142-43 (Tex. App. 1994); *Howell v. Spokane & Inland Empire Blood Bank*, 785 P.2d 815, 822-23 (Wash. 1990); *Cross v. Trapp*, 294 S.W.2d 446, 459 (W. Va. 1982); *Mathias v. St. Catherine's Hosp.*, 569 N.W.2d 330, 333-34 (Wis. Ct. App. 1997).

110. 615 A.2d 1345, 1353 (Pa. Super. Ct. 1992), *overruled by* *Shinal v. Toms*, 162 A.3d 429, 455 (Pa. 2017) (overruling *Foflygen* to the extent it permitted a physician to fulfill duty of informed consent through an intermediary).

111. *Id.* at 1348. The plaintiff alleged the operation caused her to suffer from, among other things, a pulmonary embolism, respiratory problems, phlebitis of the arm, stroke, and a carotid artery occlusion. *Id.*

112. *Id.* at 1351.

113. *Id.* at 1352.

114. *Id.* at 1353.

115. *Foflygen*, 615 A.2d at 1353.

116. 790 S.W.2d 29 (Tex. Ct. App. 1990).

117. *Id.* at 30.

118. *Id.* at 31-32.

119. *Id.* at 32.

The court also stated that the obligation to secure the patient's consent belongs to the surgeon, and asking the nurse to obtain the patient's signature does not make the nurse the doctor's agent.<sup>120</sup>

On the other hand, if a nurse assumes the obligation of informing a patient about the risks of a procedure and that explanation falls short of the prudent nurse standard of care, liability will attach under the laws of negligence.<sup>121</sup> Likewise, a nurse who fails to report an inconsistency between the patient's understanding of the procedure and a test or operation being performed may be exposed to civil liability.<sup>122</sup> For instance, in *Urban v. Spohn Hospital*, a patient complained to a hospital nurse that she did not desire or consent to a hemorrhoidectomy and the nurse failed to report that fact to the specialist or to someone in a managerial status.<sup>123</sup> The court determined that this type of omission can result in liability against the nurse or hospital.<sup>124</sup>

## 2. Physician Assistants

A physician assistant ("PA") is licensed to examine, diagnose and treat patients, and to prescribe medication.<sup>125</sup> The PA augments the delivery of high quality health care and their education and training allows for their treatment of patients with significant autonomy.<sup>126</sup> This includes the ability to treat minor trauma by suturing, splinting and casting.<sup>127</sup> They also author progress notes, advise patients, and order therapy.<sup>128</sup>

Physician assistants have become involved in obtaining a patient's informed consent. As the American Academy of

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120. *Id.*

121. *Davis v. Hoffman*, 972 F. Supp. 308, 313 (E.D. Pa. 1997); *see also* *Titchnell v. United States*, 681 F.2d 165, 170 (3d Cir. 1982); *Baur v. Mesta Machine Co.*, 176 A.2d 684, 688 (Pa. 1962); *Navarro v. George*, 615 A.2d 890, 892 (Pa. 1992).

122. Russell G. Thornton, *Informed Consent*, BAYLOR UNIV. MED. CENTER (April 13, 2000), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1312305> [<https://perma.cc/K8E9-YB29>].

123. 869 S.W.2d 450, 452 (Tex. App. 1993).

124. *Id.* at 453.

125. *Physician Assistant*, EXPLOREHEALTHCAREERS.ORG, <https://explorehealthcareers.org/career/medicine/physician-assistant> [<https://perma.cc/ZNN4-8QBC>] (last visited Sept. 22, 2018).

126. *Id.*

127. *Physician Assistant*, MAYO CLINIC, <http://www.mayo.edu/mayo-clinic-school-of-health-sciences/careers/physician-assistant> [<https://perma.cc/U33Z-ZGR7>] (last visited Sept. 22, 2018).

128. *Id.*

Physician Assistants' Guidelines for Ethical Conduct indicates, a PA may be part of the informed consent process as long as the information provided "is comprehensible to a competent patient . . . ."<sup>129</sup> Does this undertaking expose the physician assistant to liability for a defective informed consent? Some courts have refused to extend such liability since the physician remains the person performing the surgery or procedure.<sup>130</sup>

In *Baker v. Williams*, the plaintiff sustained a work related injury and was treated by an orthopedic surgeon who recommended spinal surgery.<sup>131</sup> The doctor was assisted in his practice by the defendant, a physician assistant.<sup>132</sup> The plaintiff signed a consent form which did not mention the possible use of hardware.<sup>133</sup> On the day of surgery, the PA was instructed to secure a new consent form which mentioned the need for instrumentation.<sup>134</sup> The surgery was done in the nature of a fusion using a BAK cage.<sup>135</sup> Two weeks post-surgery, the plaintiff developed complications, suffered a stroke and the fusion failed.<sup>136</sup> Suit was filed against the doctor and PA.<sup>137</sup> The claim against the PA was premised on the failure to obtain the patient's informed consent.<sup>138</sup> That assertion, however, was dismissed by way of summary judgment.<sup>139</sup>

On appeal, the court examined the duties of a physician assistant as set forth by statute which noted that the PA may perform medical services within the scope of his/her education, training and experience, which are delegated by the supervising doctor.<sup>140</sup> However, the listed duties do not include securing of a

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129. Rose Clifford, *Who Can Obtain a Patient's Consent? Answer Elusive*, THE MEDICAL-LEGAL NEWS (Sept. 1, 2008), <http://www.medical-legalnews.com/who-can-obtain-a-patients-consent-answer-elusive> [https://perma.cc/M6JX-8WLS] (internal quotation marks omitted).

130. *Bradley v. Sugarbaker*, 809 F.3d 8, 20-22 (1st Cir. 2015) (holding that the legal responsibility for the physician assistant's action falls on the supervising doctor).

131. 825 So. 2d 563, 565 (La. Ct. App. 2002).

132. *Id.*

133. *Id.*

134. *Id.*

135. *Id.*

136. *Baker*, 825 So. 2d at 565.

137. *Id.*

138. *Id.*

139. *Id.* at 566.

140. *Id.* at 570.

patient's informed consent.<sup>141</sup> That reasonability under the statute remains with the physician.<sup>142</sup> The PA is merely acting as the agent of the surgeon, who as principal, is responsible for the conduct of the agent.<sup>143</sup> Therefore, the dismissal of the claim against the physician assistant was, proper.<sup>144</sup>

However, when the PA is the person performing the procedure, the PA may be exposed to liability if he does not obtain proper informed consent. *Zarata v. Buitriago* involves a medical malpractice and lack of informed consent claim against a PA as the result of the assistant's administration of a cortisone injection in the patient's hand.<sup>145</sup> The plaintiff developed a staph infection which the plaintiff asserts was never explained as a risk of the procedure.<sup>146</sup> The claim was dismissed because the physician assistant had properly informed the patient about the proposed injection and viable alternatives.<sup>147</sup> The PA also showed that a reasonably prudent person in the plaintiff's position would still have undergone the procedure performed by the assistant despite the known risks.<sup>148</sup>

### III. INFORMED CONSENT AS A NON-DELEGABLE DUTY

Pennsylvania has become the battle ground for one of the latest disputes involving informed consent<sup>149</sup> – whether the physician must personally explain the procedure to the patient or whether the task can be delegated to another person? This question has caught the attention of health care providers around the country.

Case law clearly demonstrates that the treating physician has the affirmative duty to obtain a patient's consent to a procedure or test.<sup>150</sup> This obligation is not the independent responsibility of

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141. *Baker*, 825 So. 2d at 570.

142. *Id.*

143. *Id.* at 571.

144. *Id.*

145. 107 A.D.3d 977, 977-78 (N.Y. App. Div. 2013).

146. *Id.* at 978.

147. *Id.* at 979-80.

148. *Id.*

149. *See generally* *Bulman v. Meyers*, 467 A.2d 1353 (Pa. Super. 1983), *overruled by* *Shinal v. Toms*, 162 A.3d 429 (Pa. 2017).

150. *See, e.g., Shinal v. Toms*, 162 A.3d 429, 433, 457 (Pa. 2017).

a nurse, hospital, surgical assistant or referring doctor nor is the duty reduced or eliminated by having another healthcare professional secure the patient's consent.<sup>151</sup> Busy doctors, however, frequently have other staff members explain the proposed procedure to a patient.<sup>152</sup> This is especially true in the era of a team-based approach where multiple professionals participate in the patient's care: "[r]equiring the surgeon to give all of the informed consent all of the time breaks down the team approach."<sup>153</sup>

From a risk management view point, this delegation by physicians is fraught with danger. Agreeing to undergo a medical procedure is a complex process and patients must possess the necessary information to make an informed decision. This frequently includes the need to have an exchange with the physician in order to obtain answers to questions.<sup>154</sup> One other than the treating doctor may not possess the requisite knowledge or may provide incomplete information in response to an inquiry. Absent a direct discussion between the doctor and patient, the physician will remain uncertain as to whether the patient understands the advantages, dangers and likelihood of success of a procedure.<sup>155</sup>

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151. Thornton, *supra* note 122.

152. Mark Crane, *Legal Risks of Delegating Informed Consent to an NP or PA*, MEDSCAPE (Nov. 30, 2017), [https://www.medscape.com/viewarticle/887074\\_2](https://www.medscape.com/viewarticle/887074_2) [<https://perma.cc/6FLL-4DG8>]. In today's era of receiving information in a visual format, it is not surprising that video-based consent improves informed consent comprehension. E.W. Hall, et. al., *Use of Videos Improves Informed Consent Comprehension in Web-Based Surveys Among Internet-Using Men Who Have Sex With Men: A Randomized Controlled Trial*, 19 J. MED. INTERNET RES. 1, 2, 10 (2017). These discussions are also supplemented by medical posters, brochures, physiological models and videos. *Id.* at 2, 11. In fact, it is noted that the use of brochures and video tapes to educate patients are "legally safe" and are advantageous because they will also provide uniformity of content and cover all of the necessary risks and alternatives to a procedure. *Informed Consent Forms and Patient Brochures*, ECT.ORG (July 27, 2006, 10:21 PM), <http://www.ect.org/?p=534> [<https://perma.cc/89NR-D85H>].

153. See Crane, *supra* note 152 (internal quotation marks omitted).

154. *Informed Consent: Are Physicians Putting Themselves at Risk by Delegating*, AXOBLOG (Dec. 21, 2017), <https://axoblog.com/blog/informed-consent-physicians-putting-risk-delegating> [<https://perma.cc/88GQ-5RJ8>].

155. Michael C. Ksiazek, *Can a Doctor Delegate Duty to Obtain Informed Consent to a Staff Member?*, THE NATIONAL LAW REVIEW (July 6, 2017), <https://www.natlawreview.com/article/can-doctor-delegate-duty-to-obtain-informed-consent-to-staff-member> [<https://perma.cc/WX37-AFJF>].

Asking another health care professional to secure the patient's informed consent may not be ideal from a risk management point of view but is it a non-delegable duty owed exclusively by the physician? Based upon a recent Pennsylvania Supreme Court decision, the answer is an emphatic "yes."<sup>156</sup> In fact, some have opined that this ruling "will affect every physician, physician assistant, and nurse practitioner in the US."<sup>157</sup>

### A. HISTORY LEADING UP TO *SHINAL V. TOMS*

Pennsylvania initially considered the question of informed consent being a non-delegable duty in the 1983 case of *Bulman v. Myers*.<sup>158</sup> The plaintiff was admitted to the hospital because of impacted wisdom teeth.<sup>159</sup> Subsequent to having her teeth removed, she developed a loss of taste and sensation in her tongue as well as slurred speech.<sup>160</sup> Bulman sued the oral surgeon claiming that the surgery was done without her informed consent.<sup>161</sup> A defense verdict was returned and the patient appealed claiming that the trial judge failed to charge the jury that a patient cannot formulate a proper informed consent when the risks of the procedure are explained by a nurse and not the surgeon.<sup>162</sup> The plaintiff asserted that only the physician can effectively explain all the necessary information.<sup>163</sup> The court on appeal disagreed and noted that the key factor is the *scope* of the information provided and not the identity of the person making the communication.<sup>164</sup> Other courts have issued similar rulings.<sup>165</sup>

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156. *Shinal v. Toms*, 162 A.3d 429, 433 (Pa. 2017).

157. Logston, *supra* note 10. In fact, the author predicted that "[t]his new ruling will become a precedent ruling in all informed cases and although it started in Pennsylvania, the fall out will affect every physician in every state." *Id.*

158. 467 A.2d 1353-55 (Pa. Super. 1983), *overruled by Shinal v. Toms*, 162 A.3d 429, 433 (Pa. 2017).

159. *Id.* at 1354.

160. *Id.*

161. *Id.*

162. *Id.*

163. *See Bulman*, 467 A.2d at 1355.

164. *Id.*

165. *Foflygen v. Alleghany Gen. Hosp.*, 723 A.2d 705, 710-11 (Pa. Super. 1990), *overruled by Shinal v. Toms*, 162 A.3d 429, 433, 453 (Pa. 2017). This court followed the *Bulman* ruling and dismissed the plaintiff's case holding that the scope of the nurse assistant's disclosure to patient was proper. *Shinal v. Toms*, 162 A.3d 429, 453 (Pa. 2017).

The delegation of informed consent by the physician is also allowed by statute in a number of jurisdictions. For instance, Kentucky provides:

[I]nformed consent . . . shall be considered valid only if a physician or a licensed nurse, physician assistant, or social worker to whom the responsibility has been delegated by the physician has a face-to-face meeting with the patient and both parties are physically located in the same room or are participating in real-time visual telehealth services initiated by the physician or by the patient.<sup>166</sup>

Cases from some states indicate that informed consent is a “non-delegable” duty<sup>167</sup> but a reading of these decisions fails to proclaim that only the doctor may talk to the patient which has resulted in inconsistent holdings.<sup>168</sup> These decisions merely hold that the physician has the ultimate responsibility for obtaining the patient’s informed consent and that the physician remains ultimately responsible for defects in the informed consent process if obtained by someone else.<sup>169</sup>

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166. KY. REV. STAT. ANN. § 311.724 (West 2016).

167. *Boney v. Mother Francis Hosp.*, 880 S.W.2d 140, 143 (Tex. App. 1994) (holding that the duty to obtain informed consent is “imposed solely upon the treating doctor” and that it is non-delegable, and therefore the hospital was not liable); *see also* *Espalin v. Children’s Med. Ctr. of Dallas*, 27 S.W.3d 675, 686 (Tex. App. 2000).

168. *Defranco v. Hamra*, No. 05-97-02173-CV, 200 WL 567220, at \*3 (Tex. App. 2000) (holding that although the physician remains responsible for obtaining informed consent, “the physician shall be considered to have complied with the disclosure requirement as long as the patient receives information about the risks and hazards of the procedure” regardless whether this information was received directly from the surgeon).

169. *Ritter v. Delaney*, 790 S.W.2d 29, 31 (Tex. App. 1990) (holding that even if the hospital nurse obtained the informed consent form from the patient, after being asked by the surgeon, the only one liable for any defects on the consent would be the surgeon). *See also* *Nevaux v. Park Place Hosp., Inc.*, 656 S.W.2d 923, 925 (Tex. App. 1983) (holding that “the duty of securing the patient’s informed consent rests on the doctor treating the patient” and neither the hospital nor the technician owed such a duty to patient); *Kelly v. Methodist Hosp.*, 664 A.2d 148, 151 (Pa. Super. 1995) (holding that only the surgeon had the duty to obtain informed consent). The Veterans Administration has a policy on informed consent that is not limited to a physician providing the necessary information. *Ethical Considerations: Informed Consent Process*, V.A. HEALTH ADMIN. RES. & DEV., [https://www.research.va.gov/programs/pride/resources/Informed\\_Consent\\_Process.pdf](https://www.research.va.gov/programs/pride/resources/Informed_Consent_Process.pdf) [<https://perma.cc/93CY-BH7W>] (last visited Sept. 22, 2018). That policy notes that is not limited to a physician providing the necessary information. That policy states that “a person knowledgeable about the consenting process and the research to be conducted must obtain the informed consent.” *Id.*

*Veith v. O'Brien* is illustrative.<sup>170</sup> The plaintiff was an obese man who underwent bariatric surgery and developed a large abdominal hematoma, pneumonia, infection and abdominal leakage.<sup>171</sup> He underwent additional surgery at which time it was discovered that he had developed a twisted bowel.<sup>172</sup> The plaintiff sued the surgeon and hospital for the failure to obtain his informed consent, and offered as evidence, a booklet the doctor's nurse had given the patient about the surgery.<sup>173</sup> The doctor's nurse testified that it was her responsibility to distribute the booklet by mail before the consult or in person at the time of the visit.<sup>174</sup> Concerning the negligence of this employee, the court reiterated the long standing rule that the physician has the duty to obtain the patient's informed consent.<sup>175</sup> While the doctor's subordinates may have helped him by supplying the booklets to new patients,

nowhere in the record can it be found that he delegated to them his duty to obtain patients' informed consent . . . Even assuming . . . that he had, Dr. O'Brien still would have been liable for failure to obtain [the patient's] informed consent, since "[e]ven an effective delegation does not relieve the delegating party . . . of its duty."<sup>176</sup>

## B. THE *SHINAL V. TOMS* DECISIONS

This litigation arises out of surgery to remove a non-cancerous brain tumor near the plaintiff's pituitary gland.<sup>177</sup> The issue was whether the neurosurgeon obtained the patient's informed consent prior to the operation to remove a recurring lesion.<sup>178</sup> Dr. Toms testified that he informed the patient, Mrs. Shinal, of the risks of the surgery including possible damage to

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170. 739 N.W.2d 15, 32 (S.D. 2007).

171. *Id.* at 18.

172. *Id.* at 19.

173. *Id.* at 18.

174. *Id.* at 32.

175. *Veith*, 739 N.W.2d at 32.

176. *Id.* (quoting E. ALLEN FARNSWORTH, *CONTRACTS* 742 (Aspen Law & Business, 3d ed. 1999)).

177. *Shinal v. Toms*, 122 A.3d 1066, 1069 (Pa. Super. 2015), *rev'd*, 162 A.3d 429, 433 (Pa. 2017).

178. *Id.*

the nearby carotid arteries and optic nerve.<sup>179</sup> The doctor presented two options; a less aggressive approach which carried a reduced survival rate since the tumor could grow back, or the more aggressive surgery that had a better prognosis.<sup>180</sup> However, Mrs. Shinal denied having any recollection of this conversation including being informed of the risks of mortality or complications.<sup>181</sup>

A short time later, the Mrs. Shinal spoke to the the surgeon's physician assistant by telephone and discussed the date of the operation, the scarring that surgery would cause, and whether radiation therapy would be needed.<sup>182</sup> Mrs. Shinal followed up this call with a face-to-face meeting with the PA at which time she executed the informed consent form which set forth the risks of the surgery such as "pain, scarring, . . . heart attack, stroke, injury and death" and stated that the patient understood its contents, had the opportunity to ask questions, and was satisfied with the answers.<sup>183</sup>

During the operation, the physician allegedly punctured Mrs. Shinal's carotid artery and she suffered a brain bleed, stroke, and partial blindness.<sup>184</sup> Mrs. Shinal and her husband filed suit against the neurosurgeon and hospital for the failure to obtain the patient's knowledgeable informed consent under the Medical Care Availability and Reduction of Error (MCARE) Act.<sup>185</sup> The MCARE Act states in part:

**(a) Duty of physicians . . .** a physician owes a duty to a patient to obtain the informed consent of the patient . . . prior to conducting the following procedures: (1) Performing surgery . . . .

**(b) Description of the procedure.**—Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a

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179. *Id.* at 1070.

180. *Id.*

181. *Id.*

182. *Shinal*, 122 A.3d at 1070.

183. *Id.* at 1072-73. *See also* Bill Shields & Tom Hoffman, *The Dangers of Delegation*, ACR BULLETIN, <https://acrbulletin.org/165-jan18/1455-dangers-of-delegation> [<https://perma.cc/DZE7-7X2U>] (last visited Sept. 22, 2018).

184. Shields & Hoffman, *supra* note 183.

185. *Shinal*, 122 A.3d at 1066. *See also* MCARE Act, 40 PA. STAT. AND CONS. STAT. ANN. § 1303.504(a)-(b) (West 2002).

reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and alternatives that a physician acting in accordance with accepted medical standards of medical practice would provide.<sup>186</sup>

Before trial, the court granted summary judgment in favor of the hospital concluding that “the duty to obtain informed consent was personal to Dr. Toms.”<sup>187</sup> Upon the conclusion of the trial, the judge charged the jury that they were permitted to consider the information provided by the defendant’s qualified staff as part of the informed consent process.<sup>188</sup> The jury returned with a defense verdict and the plaintiffs appealed claiming that this charge was erroneous and prejudicial.<sup>189</sup>

The intermediate appellate court upheld the verdict and noted that the validity of the patient’s consent is premised upon the scope of the information provided and not the identity of the person communicating the information.<sup>190</sup> That determination is consistent with prior case law since the “the primary interest of Pennsylvania jurisprudence in regard to informed consent is that of having the patient informed of all the material facts from which he can make an intelligent choice as to his course of treatment[.]”<sup>191</sup> This court rejected the plaintiffs’ argument that the cases used by the trial court to support the jury instruction were pre-MCARE act, and therefore, preempted.<sup>192</sup>

The Pennsylvania Supreme Court reversed this determination in a divided opinion by holding that the physician has a non-delegable duty to inform the patient of the risks and alternatives of a procedure.<sup>193</sup> This can only be accomplished by

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186. 40 PA. STAT. AND CONS. STAT. ANN. § 1303.504(a)-(b) (West 2002) (emphasis in original).

187. *Shinal*, 122 A.3d at 1070 (citing *Valles v. Albert Einstein Med. Ctr.*, 805 A.2d 1232, 1239 (Pa. 2002)).

188. *Id.* at 1073.

189. *Id.* at 1079.

190. *Id.* (citing *Foflygen v. Allegheny Gen. Hosp.*, 723 A.2d 705, 711 (Pa. Super. Ct. 1999)).

191. *Id.* (quoting *Bulman v. Myers*, 467 A.2d 1353, 1355 (Pa. Super. Ct. 1983)).

192. *Shinal*, 122 A.3d at 1079 (the Plaintiffs argued that *Bulman* and *Foflygen* were different because they involved nurses and not a physician’s assistant).

193. *Shinal v. Toms*, 162 A.3d 429, 453 (Pa. 2017) (overruling *Shinal v. Toms*, 122 A.3d 1066 (Pa. Super. Ct. 2015)). The importance of the informed issued is demonstrated by

the physician through a direct discussion with the patient which may not be delegated to another staff member.<sup>194</sup>

One of the issues on appeal was whether the trial court “misapplied the existing common law and the MCARE Act” by instructing, and then clarifying, to the jury that information given by *any* qualified person employed by Dr. Toms was to be taken into consideration to determine whether the plaintiff received proper informed consent.<sup>195</sup> In its analysis, the Court noted that informed consent is about protecting the “patient’s bodily integrity and autonomy” in deciding whether to allow a medical procedure.<sup>196</sup> Also, “[w]ithout the meeting of the minds” the patient would not completely understand what is being done to his or her body which violates the requirement of consent.<sup>197</sup>

The Court pointed out that the superior courts in *Bulman* and *Foflygen* erred in deciding that it is the scope of the information received that matters, regardless of whether the doctor or a member of the staff relayed it to the patient, because the Pennsylvania Supreme Court had previously held that this duty is non-delegable.<sup>198</sup> The Court analogized its reasoning with the general rule that a hospital has no duty to obtain a patient’s informed consent, or even ensure that the physician obtains informed consent from the patient because the duty belongs solely to the physician.<sup>199</sup> This is based on the fact that if the physician is not the one speaking with the patient directly, then they cannot be sure that the patient understands the procedure, risks and options.<sup>200</sup> Further, if the patient is to trust the physician’s knowledge, training and expertise, it is up to the physician to

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the submission of Amicus Curiae briefs by the Hospital and Health Systems Association of Pennsylvania, the American Medical Association, the Pennsylvania Medical Society and the Pennsylvania Association of Justice. *Id.* at 432.

194. *Id.* at 453.

195. *Id.* at 451.

196. *Id.* at 452.

197. *Shinal*, 162 A.3d at 452.

198. *Id.* at 453 (citing *Valles v. Albert Einstein Med. Ctr.*, 805 A.2d 1232, 1239 (Pa. 2002)). The attorneys for Dr. Toms admitted in supreme court brief that “it remains the doctor’s duty to obtain informed consent, but the doctor is not required to supply all of the information himself; it is the information conveyed not the person conveying it, that is at issue.” Brief for Appellee Steven A. Toms, M.D. at 51, *Shinal v. Toms*, 162 A.3d 429 (2016) (No. 31 MAP 2016).

199. *Shinal*, 162 A.3d at 453.

200. *Id.*

“cultivate a relationship with the patient” so that the physician understands the patient’s expectations.<sup>201</sup>

To allow a doctor to delegate to a member of the staff the delivery of critical information undermines the patient’s autonomy and the physician-patient relationship.<sup>202</sup> The Court also held that according to the plain language of the MCARE Act, the duty to obtain informed consent is with the physician.<sup>203</sup> Specifically, the MCARE Act focuses on the duty of the physician and not just whether the patient receives the information.<sup>204</sup> Last, the Court mentioned that even Dr. Toms testified that he does not delegate the obligation to obtain informed consent because he believes that informed consent is “a real compact between the surgeon and the patient that he or she trusts me with their life[,] and I need to know they understand that this is serious, bad things could happen.”<sup>205</sup>

The dissenting justices opined that the majority “makes a leap in logic” by concluding that the language of the MCARE Act precludes the physician from receiving help from qualified staff members in order to fulfill the doctor’s duty to obtain informed consent.<sup>206</sup> While this is a non-delegable duty, the MCARE Act does not expressly require that only physicians can provide the information to the patient.<sup>207</sup> Instead, the statute merely requires that the patient receive the applicable information.<sup>208</sup> “To hold otherwise improperly injects the judiciary into the day-to-day tasks of physicians such as Dr. Toms and fails to acknowledge the reality of the practice of medicine.”<sup>209</sup>

The *Shinal* court has given patients an unprecedented degree of protection<sup>210</sup> and several attorneys noted that the decision would “sow confusion in the medical industry and lead to an

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201. *Id.* at 453-54.

202. *Id.* at 454.

203. *Id.*

204. *Shinal*, 162 A.3d at 454. *See also* MCARE Act, 40 PA. STAT. AND CONS. STAT. ANN. § 1303.504(a)-(b) (West 2002).

205. *Shinal*, 162 A.3d at 455.

206. *Id.* at 457.

207. *Id.* at 458.

208. *Id.*

209. *Id.*

210. GERALD A. MCHUGH & JOSEPH Z. TRAUB, *A Summary of Pennsylvania’s Current Standard as to Informed Consent*, 3 WEST’S PA. PRAC., TORTS: LAW AND ADVOCACY § 8.3 (Supp. 2017).

uptick in legal disputes.”<sup>211</sup> Some engaged in clinical trials have been confused by the ruling and are approaching the opinion from a risk-based perspective. Many are taking a “wait-and-see” approach and are enlisting the assistances of legal experts as they figure out how to reorganize to comply with the new legal mandate.<sup>212</sup>

Needless to say, attorneys for claimants are fully supportive of the ruling. Michael F. Barrett, Esq., a leading malpractice lawyer, felt that the Court’s prohibition against a physician’s delegation of responsibility for informing a patient of the risks and alternatives of a procedure to a non-physician, such as a physician assistant or nurse, is appropriate, sensible, reasonable and fair.<sup>213</sup> Clifford A. Rieders, Esquire, another plaintiff’s malpractice attorney, fully supports the *Shinal* decision, noting that anyone who has worked with physicians fully understands the importance of a physician providing informed consent, explaining risks and alternatives to a patient, and being personally present to answer questions.<sup>214</sup>

As one might imagine, however, the decision has caused quite a stir as healthcare providers scramble to comply with this new mandate. As Michael L. Brooks, a neuro-radiologist at a suburban Philadelphia Hospital and attorney finds that the ruling has disrupted things throughout the hospital.<sup>215</sup> While no other published opinion has yet to cite the decision in an attempt to prevent doctors from asking others to inform their patients of the risks and alternatives to a procedure, a number of medical organizations have warned their members about the decision. In fact, the American Medical Association published an article while

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211. Max Mitchell, *In Wake of Informed Consent Ruling, Med Mal Lawyers Raising Questions*, THE LEGAL INTELLIGENCER (Aug. 4, 2018, 7:49 PM), <https://www.law.com/thelegalintelligencer/almID/1202794800155/In-Wake-of-Informed-Consent-Ruling-Med-Mal-Lawyers-Raising-Questions> [<https://perma.cc/2CZ2-TDLM>].

212. Darshan Kulkarni et al., *How Does Shinal v. Toms Affect Informed Consent in Pennsylvania Trials*, APPLIED CLINICAL TRIALS (Dec. 1, 2017), <http://www.appliedclinicaltrials.com/how-does-shinal-v-toms-affect-informed-consent-pennsylvania-clinical-trials> [<https://perma.cc/4F3V-LG6M>].

213. Interview with Michael F. Barrett, Senior Partner, Saltz Mongeluzzi Barrett & Bendesky (Mar. 22, 2018).

214. Interview with Clifford Reiders, Partner, Rieders, Travis, Humphrey, Waters & Dohrmann (Mar. 27, 2018).

215. Interview with Michael L. Brooks, Doctor, Mercy Fitzgerald Hospital (Mar. 21, 2018).

the case was pending alerting physicians that the matter “could have major implications on how physicians obtain informed consent prior to surgery.”<sup>216</sup> Another journal opined that the impact of the decision is already being felt in clinical trials where informed consent mandates are even more stringent than in clinical medicine.<sup>217</sup> It was predicated that requiring researchers to meet with their patients will slow down even more an already time-consuming informed consent process.<sup>218</sup>

Dr. Alexander R. Vaccaro, Professor and Chair of the Department of Orthopedic Surgery at Thomas Jefferson Hospital, is of the opinion that the physician must have a discussion with a patient regarding the risks and benefits of any surgical procedure but the information should never be discounted even if it didn't come directly from the mouth of the physician provider.<sup>219</sup>

Richard P. Kidwell, Senior Associate Counsel and Vice President of Risk Management at the University of Pittsburgh Medical Center, believes that the court's ruling highlights the important role informed consent plays in patient safety, and that it must consist of a discussion in which the physician clearly states the risks of the procedure, expected benefits, and available alternatives, including the option of not undergoing the treatment.<sup>220</sup> He does not believe, however, that the decision will gain large traction outside of Pennsylvania because of the specific way the informed consent statute is drafted in the Commonwealth.<sup>221</sup> Counsel also does not consider the opinion to be overly draconian and believes that it is limited to surgical procedures and not to such things as endoscopic examinations,

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216. Troy Parks, *Medical Liability Suit Seeks Change to Informed Consent for Surgery*, AMA WIRE (Aug. 19, 2016), <https://wire.ama-assn.org/practice-management/medical-liability-suit-seeks-change-informed-consent-surgery> [<https://perma.cc/H529-C5K7>].

217. Darhan Kulkarni & Erin Grant, *What Impact Will the Shinal Case Have on Informed Consent in Clinical Research*, 13 J. CLINICAL RES. & BEST PRACS. 1, 3 (Sept. 2017), [https://www.firstclinical.com/journal/2017/1709\\_Shinal.pdf](https://www.firstclinical.com/journal/2017/1709_Shinal.pdf) [<https://perma.cc/94NZ-9H3J>].

218. *Id.*

219. Interview with Alexander R. Vaccaro, Professor & Chairman, Department of Orthopedic Surgery at Thomas Jefferson University Hospital, in Philadelphia. (Mar. 23, 2018).

220. Telephone Interview with Richard P. Kidwell, Senior Associate Counsel & Vice President of Risk Management, University of Pittsburgh Medical Center (Mar. 21, 2018).

221. *Id.*

radiation used for diagnostic purposes, spinal taps and catheterizations.<sup>222</sup> Mr. Kidwell goes on to note that “fellows and residents may obtain informed consent for blood transfusions and residents can obtain consent for procedures that their departments determine they are qualified to perform on their own.”<sup>223</sup>

The *Shinal* decision did prompt the University of Pittsburgh Medical Center to change its *Policy and Procedure Manual* on informed consent.<sup>224</sup> That new policy provides in Section III:

1. Except as noted below, **Attending Physicians Are Responsible For Obtaining Informed Consent.** The attending physician overseeing the patient’s care is responsible for and must obtain informed consent for all procedures that require informed consent. The attending shall sign the consent form after the consent discussion occurs. Residents or fellows may only obtain informed consent for blood or blood products or for procedures their departments have deemed them qualified to perform.

2. **Advanced Practice Providers or Medical Students May Not Obtain Informed Consent** for the enumerated items in II A. Advanced practice providers may obtain consent for and perform procedures for which they are credentialed to so.

3. **Nurses May Not Obtain Informed Consent.**

**NOTE: Residents, fellows, advanced practice providers, medical students and nurses may assist the attending physician with the informed consent process by serving as a witness or by presenting the patient with the informed consent form.**<sup>225</sup>

Interestingly, while Ohio has not adopted the *Shinal* ruling, it already prohibits a nurse from obtaining a patient’s informed consent and limits them to acting as a witness and signing the consent document.<sup>226</sup> However, a resident is allowed to secure the form unless the physician is not competent to perform the

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222. *Id.*

223. *Id.*

224. *Patient Informed Consent*, Policy HS-RI1302, UPMC Policy and Procedure Manual (Oct. 5, 2017) (on file with the *Arkansas Law Review*).

225. *Id.* at 3 (emphasis in original).

226. *Joint Commission Update*, CIN. C. MED., [http://med2.uc.edu/libraries/gme\\_forms/joint\\_commission\\_upd\\_1.sflb.ashx](http://med2.uc.edu/libraries/gme_forms/joint_commission_upd_1.sflb.ashx) [https://perma.cc/9FUR-NLVU] (last visited Sept. 25, 2018).

procedure in question in which case the attending doctor remains liable to guarantee that the patient receives the necessary information.<sup>227</sup> Also, the resident can only intercede in those procedures in which he or she is competent to answer the patient's questions.<sup>228</sup>

Informed consent, however, is a two-way street. Patients must listen to what the doctor is explaining and ask questions if they do not understand, or if they desire more comprehensive information.<sup>229</sup> Unfortunately, many individuals do not comprehend the explanation provided and have already made up their minds to have the procedure performed. Research pertaining to surgery has revealed: “[A]dequate overall understanding of the information provided and of the risks associated with surgery was shown” to be a paltry 29%.<sup>230</sup> This lack of understanding is a reflection of the patient's education, literacy and language proficiency, as well as the doctor's skill in adequately explaining the procedure and risks.<sup>231</sup> The logic behind informed consent is certainly a logical and ethical mandate, but in view of these statistics and problems, should the identity of the person who talks to the patient be such a critical issue? It would seem that the patient's receipt of the appropriate information in an understandable format is a much more desirable goal. Nevertheless, if the doctor does delegate the duty, he remains liable if the staff does not do a competent job.

#### IV. CONCLUSION

Informed consent is deeply rooted in the ethical concept of patient autonomy and fundamental human rights. First introduced to the American public in 1914, informed consent has undergone a metamorphosis over the years as health care providers and the

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227. *Id.*

228. *Id.*

229. *Understanding Informed Consent and Your Rights as a Patient*, FINDLAW, <http://healthcare.findlaw.com/patient-rights/understanding-informed-consent-a-primer.html> [<https://perma.cc/49FB-FX7R>] (last visited Sept. 25, 2018).

230. Mathew Falagas et al., *Informed Consent: How Much and What Do Patients Understand?* 198 AM. J. SURGERY 420, 420 (2009).

231. Anne Sherlock & Sonya Brownie, *Patients' Recollection and Understanding of Informed Consent: A Literature Review*, WILEY ONLINE LIBRARY (Feb. 24, 2014), <https://onlinelibrary.wiley.com/doi/full/10.1111/ans.12555> [<https://perma.cc/H59V-UDW7>].

courts struggle over the meaning of the phrase and how much information should be shared with the patient. Everyone agrees that the patient must be told about the nature of the illness and the reasonable risks and alternatives associated with the treatment. This information must also be explained in a clear, accurate, and compassionate manner.

However, these clear and noble mandates have become blurred as lawsuits are continually filed to expand the type of information that should be provided. Claims for lack of informed consent have become physician-specific and are focused on such things as a doctor's failure to disclose that he or she has been the subject of prior lawsuits or disciplinary action, a physician's alcohol or drug dependency and whether the doctor has a monetary interest in a technique.

Two recent challenges deal with the liability of the various health care providers who participate in the informed consent process and whether the treating physician may delegate the duty to explain the risks and alternatives of a procedure to another.<sup>232</sup> This push to expand liability has resulted in the split decision of *Shinal v. Toms*, which now mandates that the physician have a one-on-one exchange with the patient in order to secure a valid informed consent.<sup>233</sup>

Informed consent, however, is a two-way street and little attention is paid to the fact that a number of patients fail to listen to or grasp what the healthcare professional is explaining or to ask questions if they do not understand that explanation. The fact is that many have already decided to have the procedure and do not properly weigh the possibility that something can go wrong until it happens to them. When it is discovered that the physician did nothing wrong and the outcome is an associated risk of the operation, lack of informed consent becomes the focus of liability.

*Shinal v. Toms* has now provided the patient with an unprecedented degree of protection by mandating that only the physician may discuss the risks and alternatives of a procedure with the individual.<sup>234</sup> In view of the fact that most patients have

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232. *Bulman v. Myers*, 467 A.2d 1353 (Pa. Super. 1983); *Veith v. O'Brien*, 739 N.W. 2d 15 (S.D. 2007).

233. *Shinal v. Toms*, 162 A.3d 429, 453.

234. *Id.* at 455.

already decided to undergo the procedure or surgery, does it really matter which health care professional explains the dangers of an operation as long as the patient receives the appropriate information in a clear, accurate, and compassionate manner?