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An Evaluation of Current Policy Guidelines for the Best Practices of Robotic Surgery Training

By

Zachary Geffert

A Thesis Submitted in Partial Fulfillment of the Requirements for the Degree of

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AN EVALUATION OF CURRENT POLICY GUIDELINES FOR THE BEST PRACTICES OF ROBOTIC SURGERY TRAINING

A thesis proposal submitted to the
Public Policy Program at
Rochester Institute of Technology
in partial fulfillment of 0521-703

By **ZACHARY GEFFERT**

under the faculty guidance of

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Abstract

Robotic surgery is a young and new technology, becoming widely used only within the past twenty years. Robotic surgery is categorized as minimally invasive and has immense patient benefits, including shorter hospital stays, reduction of human errors, increased precision, and faster recovery time. A recent study looked “at more than 10,000 incident reports from the FDA spanning from 2000 to 2013…found [finding] that robots were involved in 144 patient deaths and 1,391 patient injuries” (Wagstaff, 2015, pp. 2). Wagstaff (2015) also notes that very little information regarding cause of death was provided by the incident reports, which brings forth the need for proper regulation and evaluation of surgical training. For this to happen, the effectiveness of modern robotic surgery practices has to be carefully assessed. This research focused on assessing effectiveness by attempting to determine the best practices for robotic surgery training, specifically aiming to determine what components would make up a good hospital/institution policy. By understanding the components that should make up a hospital/institution policy and ensuring they meet expert guidelines, the need for a universal robotic surgery training guideline could be assessed. This study analyzed the policies provided by three major institutions in New York State that use robotic surgery. This included Upstate University Hospital (Syracuse, NY), Roswell Park (Buffalo, NY), and Stony Brook University Medical Center (Stony Brook, NY). The three hospitals policies were compared against each other as well as to expert opinions from peer reviewed journal articles on robotic surgery policies. It was concluded that adverse event reporting needs to improve in order to allow for improvement in the area of robotic surgical training and credentialing. Additionally, two of the three institutions analyzed were found to have very similar guidelines and meet all expert credentialing criteria.

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Introduction

The technology of robotic surgery has only been prevalent for the past twenty years which makes it an interesting topic to research and discuss. The first documented use of a robot-assisted surgical procedure was in 1985 (Samadi, n.d). Despite the fact the first documented surgical procedure was in 1985, the idea of robotics had been around for much longer. Back in ancient China around 1023-957 BC, a mechanical engineer known as Yan Shi presented King Mu of Zhou with a life-size, human-shaped mechanical figure (Yates et al., 2011, pp.1). Following this through the centuries, different mathematicians and engineers expanded on this idea of robotics. Perhaps the most known of these innovators is the “genius Italian sculptor, painter, architect, engineer, anatomist and mathematician, Leonardo Da Vinci circa 1495” (Yates et al., 2011, pp.1). He is how the daVinci surgical robotic system got its name.

Well after Da Vinci’s time came the Industrial Revolution where robotic advancement began to spark and complex mechanics and electricity began to be discovered. Telepresence robotic arms were developed in the 1950s by NASA and were originally used in hazardous environments like in space or moving hazardous materials (Yates et al., 2011, pp.2). These robotic arms are what we see and distinguish a surgical robot by today. In the 1980s, the development of microelectronics, computing, video electronics and display technology thrived. The world’s first surgical robot was developed in 1983 by Arthrobot and the first robot-assisted surgical procedure came soon after in 1985 (Yates et al., 2011, pp.2). In the year 2000, the daVinci Surgery System became the first robotic surgery system to be approved by the FDA (Samadi, n.d., pp. 2). Since then, Intuitive has manufactured more than 5,500 daVinci robots globally (Crew, 2020, pp. 2). Though the daVinci robot started as a research device, given its high number of devices around the world today, it is clear that enough hospitals utilize it to raise concern and begin some examination of this area.

The medical community has welcomed robotic surgery because of its promise to be minimally invasive, which can benefit the patients immensely. These benefits may include shorter hospital stays, reduction of human errors, increased precision, and faster recovery time. The drawbacks of any traditional surgery include human error, longer procedure times, and longer recovery times. On the other hand, robotic surgery has its flaws. Recently, researchers looked "at more than 10,000 incident reports from the FDA spanning from 2000 to 2013…found [finding] that robots were involved in 144 patient deaths and 1,391 patient injuries" (Wagstaff, 2015, pp. 2). Wagstaff (2015) also notes that very little information regarding cause of death was provided, which leaves the cause open to human error, problems with the robot, or the inherent risks associated with the surgery.

Although this lack of information combined with the rapid advancement of technology potentially leads us down a scary path, robotic surgery has come a long way and will only get better. Today it is "possible to perform a surgical procedure without directly visualizing or touching the organ being operated on" (Mack, 2001, p. 5). Researchers are focusing on developing techniques that allow for more complex tasks to be completed using minimally invasive techniques. With all of these promises comes the need for proper regulation and evaluation of surgical training. The effectiveness of modern robotic surgery practices needs to be carefully assessed. To assess effectiveness, this thesis research will determine what practices work best for robotic surgery training. To be more specific, it will identify components that would make up a good hospital or institutions policy. These recommendations would provide support for a universal robotic surgery training policy.

Literature Review

In this literature review, I will be looking at research conducted on the effectiveness of modern robotic surgery practices. Across specialties, robotic surgery has claimed to offer greater advantages over conventional open surgery. However, many articles often debate the best approach to surgery – open vs. robotic. Clinical advantages of robotic surgery include "stabilization of instruments within the surgical field, mechanical advantages over traditional laparoscopy, improved ergonomics for the operating system, and superior visualization including three-dimensional imaging of the operative field" (Herron and Marohn, 2007, pp. 15). These authors also argue that robotic surgery has limitations including, "lack of haptics (force feedback), large size of the devices, instrument limitations (both size and variety), inflexibility of certain energy devices, and problems with multiquadrant surgery" (Herron and Marohn, 2007, pp. 17). While we can see there are many benefits and uses for robotic, it certainly has its drawbacks. The practicality of using robotic over open surgery is a topic that can easily be debated, calling for more research in the area to be done, which seems to be a common theme in the literature.

This literature review aims to verify the leading causes of adverse events in robotic surgery. It will also look at various factors that may go into creating a successful robotic surgery program. It touches upon safety factors that lead to successful robotic surgery programs, the evidence in a learning curve being present in robotic surgery, costs and benefits associated with robotic surgery, harmful events in robotic surgery history, and research that clearly defines factors that contribute to a successful robotic surgery program.

Robotic surgery is categorized as "minimally invasive surgery" (Robotic Surgery Center, n.d.). Minimally invasive surgery involves miniaturized surgical instruments that fit through a series of 1/4” incisions instead of larger incisions required for a typical surgery (Robotic Surgery Center, n.d.). These miniature surgical instruments are mounted on separate robotic arms, which allows the surgeon to have maximum range of motion and precision. The surgeon sits at a console across the room looking through a 3D stereoscopic high definition monitor. Another robotic arm holding a magnified high definition 3D camera provides the image. The surgeon can literally see inside the patient while being able to control all the robotic arms. The arms are controlled by “master controls” in which the surgeon places each of his/her hands (Robotic Surgery Center, n.d.). The robot mimics every movement made with master controls precisely at the other side of the operating room. Overall, the surgeon has extraordinary control in a minimally invasive environment. The most common robotic surgery system out there today is the daVinci system[1]. Because robotic surgery is minimally invasive there are many benefits for the patients, but with any new technology, come risks and unintended consequences.

Current research in the area of robotic surgery is limited due to the length of time surgical robots have been approved by the FDA. “In 2000, the daVinci Surgery System broke new ground by becoming the first robotic surgery system approved by the FDA for general laparoscopic surgery” (Samadi, n.d., pp. 2). Today, many institutions and hospitals have taken advantage of this robotic technology. The main issue with finding research and articles related to mistakes, complications, or injuries is that institutions or hospitals are hesitant to publicize any problems or complications that occur with robotic surgery. In turn, we are only informed of the benefits and positive effects that robotic surgery has to offer. The other issue with the limited

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[1] Intuitive launched the da Vinci Surgical System in 1999. It became the first robotic assisted surgical systems cleared by the FDA for general laparoscopic surgery in 2000. With the surgeon fully in control, it featured a fully immersive experience, enhanced visualization, dexterity, precision and ergonomic comfort. For many surgeons, da Vinci was-and remains- a game changer in the delivery of minimally invasive care.
URL: https://www.intuitive.com/en-us/about-us/company

literature that does exist is they do not go into detail on roots of the incident. Therefore, the readers are left with a number of occurrences, with no indication of the cause, which does not allow for specific improvements to be made.

According to Dr. Martin A. Makary, Chief of Islet Transplant Surgery and Professor of Surgery at the Johns Hopkins University School of Medicine, '"standardized reporting is needed for all adverse events related to robotic devices"' (Yates, 2013, pp. 9). Dr. Makary conducted a study looking at robotic surgery complication reporting, finding that among nearly 1 million robotic surgeries, performed since 2000, only 245 complications were reported to the FDA saying that '"The number reported is very low for any complex technology used over a million times"' (Yates, 2013, pp. 3). The FDA only collects data from device related errors, which means surgeon error may be unreported, additionally with the potential unreported device errors. '"Doctors and patients can't properly evaluate safety when we have a haphazard system of collecting data that is not independent and not transparent"' (Yates, 2013, pp. 3). Dr. Makary brings many concerns to light that may have been in the shadows. We cannot know the success of robotic surgery procedures without a standardized reporting system for all adverse events. With this data, the source(s) of the complications, be it surgical training or other, factors can be identified and corrected accordingly.

Overall, while the literature discussed several aspects of robotic surgery, very few analyzed the reasons for adverse events from an empirical viewpoint. There were, however, a number of indirect explanations for adverse events, as well as suggestion for improvements. There are a number of factors that could create complications during robotic surgery. The reviewed articles had a few different conclusions. Three articles noted that safety is a leading factor in the success of robotic surgery. The top safety precautions include properly trained surgeons being matched with appropriate surgical cases and the thorough credentialing of robotic surgeons. Three articles (Amodeo et al., 2009; Herron & Marohn, 2007; Kaul et al., 2006) simply stated that there is a learning curve associated with robotic surgery. There was not much detail included on training processes, but the significant characteristics associated with the learning curve were the unfamiliarity with robotic controls and the lack of haptic feedback. In addition, two articles (Lanfranco et al., 2004; Patel, 2006) mentioned that many hospitals and institutions are using robotic surgery technology. Concern was expressed with the lack of guidelines for the use of robots in surgery as well as the need for a consensus on credentialing guidelines. Further, three articles (Alemzadeh et al., 2016; Cooper et al., 2015; Yates, 2013) noted the harmful effects associated with robotic surgery, but not what specifically caused them. Based on all of these findings, there is a need for more research to understand what is leading to adverse events caused by robotic surgery. In the next section, more findings are presented with the limits and benefits of robotic surgery, the reported mistakes and causes, and robotic surgery program recommendations.

A summary of the nine articles reviewed is presented in Table 1 below. Three articles focused on examining adverse events in robotic surgery, including the potential for underreporting of adverse robotic surgery events. Two articles looked at current robotic surgery training practices and what a successful robotic surgery program should be comprised of. Two articles provided a current perspective on robotic surgery which included analyzing the history, current applications, and future outlook of robotic surgery. One article specifically looked at the learning curve associated with robotic surgery in relation to traditional open surgery. The last article looked at principles of ethics related to robotic surgery.

Table 1. Overview/Summary of Articles Reviewed

Study	Research Question/ Objective	Type of Surgery	Method
Alemzadeh et al., 2016	What are the causes of adverse events and impact on patients in robotic surgery	Various – most urologic and gynecologic	Used data from MAUDE database between 2000-2013. Found # of events per procedure and common device malfunctions.
Amodeo et al., 2009	How can we effectively train robotic prostatectomy as part of mainstream surgical training, while keeping cost in mind	Prostatectomy (Urology)	Reviewed existing articles related to laparoscopic vs. robotic training and the learning curve associated.
Cooper et al., 2015	To evaluate device-related robotic surgery complications reported to the FDA	Various	Searched FDA MAUDE database, LexisNexus, and PACER to identify robotic surgery complications between 2000-2012.
Herron and Marohn, 2007	4 Questions: training/credentialing, clinical applications of robots in surgery, risk of surgery and cost-benefit analysis, and research	Various	20 international institutions convened in NYC in June 2006.
Kaul et al., 2006	What contributes to the learning curve associated with robotic surgery compared to laparoscopic	General	Reviewed existing articles to provide the current gold standard for assessing skill training.
Lanfranco et al., 2004	To review the history, development, and current applications of robotic surgery	General	Review of the literature using Medline.
Larson et al., 2013	Discuss principles of ethics for nonmaleficence	General	Reviewed existing articles to provide 5 principles of ethics related to robotic surgery.
Patel, 2006	What elements are essential to the establishment of a successful robotic surgery program	General	Reviewed existing articles to provide recommendations for a successful robotic surgery program.
Yates, 2013	Are robotic surgery complications underreported	General	A review of research done by Cooper et al., 2015; included interviews with authors

Supplemental information not included in table: MAUDE – Manufacturer and User Facility Device Experience. PACER – Public Access to Court Electronic Records.

The majority of the reviewed literature on patient safety suggested that safety was a leading factor in contributing to the success of robotic surgery. They suggest that when proper pre-surgery planning procedures (includes, but not limited to: adequate prep time, potential for rehearsal, surgical team briefing) are followed, the more successful robotic surgeries will be. One article (Larson et al., 2004) found there to be five principles of ethics for nonmaleficence for robotic surgery, which are:

1. *Credentialing may be underpowered, and mentorship should not be limited to initial credentialing.*
2. *Robotic surgery should be coupled with knowledge of laparoscopic physiology, access, and management of minimally invasive complications.*
3. *Case selection should be appropriate for the robotic skill level of the surgeon*
4. *When needed for safety reasons, conversion from robotic assisted to laparoscopy or laparotomy should be encouraged by the organization and be acceptable to the surgeon, patient, and operating room team.*
5. *Industry representatives can be present to ensure that the equipment is functional, but they are not trained or credentialed to influence medical or surgical decisions.*

(Larson et al., 2004)

The key takeaways from this article are that there are some overlap between robotic and normal laparoscopic surgery, but it is necessary to have separate credentialing and proctoring requirements for robotics. The authors are also concerned with the fact that there is potential that certain obvious ethical principles may be easily overlooked or ignored to rush to implement robotic surgery into regular use.

As previously mentioned, multiple articles looked at harmful events in robotic surgery. One (Alemzadeh, et al, 2016) used FDA data from the past fourteen years. It was found that for surgical specialties where "robots are extensively used, such as urology or gynecology, had the lowest number of injuries, deaths, and conversions per procedure [switching back to normal open surgery mid procedure]" (Alemzadeh, et al, 2016, p. 1). On the other hand, complex procedures, like cardiothoracic or head/neck, had the highest number of injuries, deaths, and conversions per procedure. The authors noted that the data they collected on harmful events in robotic surgery shows that a non-negligible number of technical difficulties and complications are still being experienced during robotic procedures. They also note that the adoption of advanced techniques in operation of robotic systems may reduce preventable incidents in the future. This hints at a need for stricter guidelines for robotic surgeries in the future because of unnecessary failures.

As seen in Table 2 below, all of the reviewed articles discuss issues with robotic surgery in some regards. Identified causes included 1) device malfunction, 2) human error and 3) device limitations. Three articles (Alemzadeh et al., 2016; Cooper et al., 2015; Yates, 2013) show finite numbers for reported events including deaths and injuries, but no indication of the cause of the event. Out of those three, two made suggestions on potential causes of error which fell under device malfunction as well as human error. Five articles reference device malfunction as a potential cause for mistakes. Three articles mentioned specific device limitations that may have caused mistakes. Seven out of the nine articles mentioned a source of human error as a potential cause of mistakes, which raises concerns with current robotic surgery training practices.

Table 2. Issues with Robotic Surgery

Study	Reported Mistakes	Causes of Mistakes		
		Device Malfunction	**Device Limitations**	**Human Error**
Alemzadeh et al., 2016	Noted death/injury amounts specific to specialties and specific surgery. 144 deaths, 1,391 injuries, 8,061 device malfunctions.	Noted most common device malfunctions.	N/A	Suggested potential causes for catastrophic events.
Amodeo et al., 2009	All for laparoscopic radical prostatectomy. Team training noted as critical.	N/A	N/A	Learning curve associated with naïve surgeons: 80-100 cases. 8-12 cases to transfer to robotic. Proficient surgeons 40-60 cases.
Cooper et al., 2015	245 events reported: 71 deaths and 174 nonfatal injuries. Large issue with delay of reporting.	"True incidence of complications with robotic-assisted laparoscopic surgery must be known to ensure safe innovation."	N/A	"True incidence of complications with robotic-assisted laparoscopic surgery must be known to ensure safe innovation."
Herron and Marohn, 2007	Noted that here are no studies suggesting that robotic procedures have complication rates that differ for the better or the worse.	N/A	Theoretically - lack of haptic feedback and quality of data connection between robot and console.	Substantial learning curve.
Kaul et al., 2006	N/A – looked at how robotic surgical technique is learned.	N/A	N/A	Problems may arise with the transition – including remote surgical control, stereoscopic vision, and lack of haptic feedback.
Lanfranco et al., 2004	Studies indicate robotic surgery is feasible.	N/A	Data was concerned with costs and benefits of robotics versus conventional techniques.	N/A
Larson et al., 2013	N/A – noted most important ethical principles.	Conversion to laparoscopic should be encouraged; industry reps. only responsible for equipment functionality.	Robotic surgery should be coupled with laparoscopic.	Credentialing may be underpowered; case selection based on surgeon skill.
Patel, 2006	N/A – noted key elements to implement a robotic surgery program.	Clear goals from the start; a sound financial plan; identification of applicable specialties; motivated robotic surgical team.	N/A	N/A
Yates, 2013	Among ~1 million robotic surgeries performed since 2000, only 245 complications were reported to the FDA. Number is very low for such a complex technology.	Issue with deciding if complication device error or user error. (i.e. there is no haptic feedback, so if a surgeon pushed too hard and cut into a vessel).	N/A	Issue with deciding if complication device error or user error. (i.e. there is no haptic feedback, so if a surgeon pushed too hard and cut into a vessel).

Articles related to safety specifically mentioned a learning curve associated with robotic surgery. There are many similarities (according to Kaul, et al.) in procedural steps and actions between regular open surgery and robotic surgery, but there are other factors that involve a need for a transition period (Kaul, et al., 2006). These factors may include remote surgical control, stereoscopic vison, and lack of haptic feedback. The authors mentioned that the successful learning of robotic skills, accurate assessment of proficiency in robotics, and structured training for active surgeons and residents are the most important improvements that are needed. Another article points out that "the amount of time and energy necessary to develop and maintain such advanced laparoscopic skills is not insignificant" and that the learning curve associated with robotic surgery is very much present (Amodeo, et al., 2009, pp. 1). The authors suggest the greater expense and consumption of operating room resources like space and availability of skilled technical staff (surgeons, nurses, techs, etc.), complete elimination of physical feedback, and limited options for locations to minimally enter the body are all significant disadvantages of robotic surgery. They conclude that the field of robotic surgery is growing, and as it does, educational programs in this area need to be further developed keeping the factors mentioned in mind.

Other articles show that several medical centers/institutions currently use surgical robots and publish data on their use. This data is important to understand the growing popularity of robotic surgery because "Between 2007 and 2011… the number of procedures involving the robot increased by more than 400% in the United States" (Yates, 2013, pp. 4). The main stipulation with robotic surgery at the moment is the costs and benefits compared to conventional open surgery techniques (Lanfranco, et al., 2004). If the benefits outweigh the costs or vice versa is the question these researchers are currently trying to address. This article was written in 2004, which is when robotic surgery was in its infancy. They concluded that robotic surgery has already proven itself to be of great value, but it investigates if it is more beneficial to use robotic over traditional open surgery. The biggest takeaway is that there is a need for more prospective randomized trials evaluating efficacy and safety to be conducted in order to determine the true benefits or costs associated with robotic surgery.

Herron et al. came to a conclusion on robotic surgery and stated that the "guidelines for the use of robots in surgery were lacking and the surgical community would benefit from a consensus statement on robotic surgery including guidelines for training and credentialing" (Herron et al., 2007). This conclusion is reflected during a conference (SAGES-MIRA Robotics Consensus Conference at Mount Sinai Medical Center in NYC on 2-3 June 2006) comprised of 20 international institutions who set out to answer four key questions:

1. *How should training for robotic surgery be accomplished/what is the appropriate process?*
2. *What are the appropriate clinical applications for robotic surgery?*
3. *What are the physical risks of robotic surgery to the patient/what are financial costs involved in robotic surgery and are they justified?*
4. *What are the important unanswered questions in robotic surgery/what direction should future research on robotic surgery take?*

(Herron et al., 2007)

They concluded that technical training and utilizing the robot for specific operations are the two most important aspects. This article then goes into specific detail on recommendations for proper robotic surgeon training and credentialing. It suggests that more work needs to be done in this area to build a uniform training system. As far as appropriate clinical applications, this article found that a wide range of surgical disciplines are taking steps to either move certain procedures to robotic or already have procedures being done robotically. These authors go into detail on many types of risks (capital cost, equipment maintenance, operating room time, general benefits, ergonomics, to name a few) in order to answer question three above. They concluded that robotic surgery comes with a number of surgical and institutional risks, as does any normal surgery, but adds mechanical risk on top of that. Finally, the authors make suggestions for future research directions including improving mobility of existing technology, researching the addition of haptic feedback, and the use of simulation to provide a pre-surgery rehearsal with patient specific information. The two groups that attended the conference were the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the Minimally Invasive Robotic Association (MIRA). They are two significant stakeholder organizations concerning about the future outlook of robotic surgery from many angles.

Perhaps the most important research article (Patel, 2006) is the one that explicitly stated elements that are key in the design of a successful robotic surgery program. Once an institution or hospital has a robotic device, a surgical team must be created which includes necessary personnel: the surgeons, nursing staff, physician assistants, resident/fellows, program coordinator, marketing, and a financial analysis team (Patel, 2006). All are essential in their own ways to the success of the program. Patel concluded that in order to safely and effectively establish a program, a comprehensive pre-emptive plan for installation of the program must be put into place. The success is directly related to the infrastructure of the program. Essential pieces include the creation of a sound financial plan, early identification of applicable specialties, and a motivated surgical team.

Throughout this literature review, a number of potential factors influencing the effectiveness of robotic surgery are identified that need further discussion. The goal of this review is to determine if we know where these issues in robotic surgery are coming from. One of the goals is to explore the human side of robotic surgery. Did the known learning curve associated with robotic surgery affect surgeons' outcomes? Are certain ethical considerations made? Ultimately, it is found that robotic surgery is still in its infancy and more research is needed for further development. This following section begins by addressing the limitations associated with this literature review. This includes the limited research available, limited adverse data, and no universal robotic surgery training guideline. Next, the discussion section includes implications for research, policy, and practice. It is noted that at this point, more research is necessary, and it is difficult to develop an effective policy to put into practice due to lack of research and information. Final conclusions derived from this literature review are followed.

There are few limitations to this literature. The largest and most relevant was the fact that there is very limited research available on robotic surgery, as it is a relatively new technology. Articles that report on adverse events associated with robotic surgery leave out the detailed explanations for the events. Hospitals and institutions using robotic surgery devices do not publicly release this information. The final limitation of this review is that there is no universal guideline for robotic surgery training, which means there is no standard audited measures to keep all hospitals and institutions in check with each other.

Based on all of the findings in this literature, it is clear that there is a need for more research regarding robotic surgery. To be more specific, research needs to be conducted on the specific causes of adverse events in robotic surgery. These causes need to be investigated more systematically in order to improve robotic surgery as a whole. Without more research, it is difficult to advance and improve robotic surgery training. The causes for complications are likely already identified by individual institutions/hospitals conducting robotic surgery, but they need to be better reported in a standardized way. The idea of proactive vs. reactive relates quite well to robotic surgery. An adverse event data analysis should be done sooner rather than later because of the rapid evolution of robotic surgery. We should be proactive now before something catastrophic happens and we need to be reactive about the situation. The need for further research leads directly to this thesis topic, which focuses on determining what the best practices are for robotic surgery training. In other words, what components would be best needed for a robotic surgery training policy. This research may lead to further study to attempt to determine if there is a need for a universal robotic surgery training guideline.

It is important to note that no public research articles on robotic surgery are explicitly stating specific reasons behind the adverse events. This directly calls for more research and data collection in the area of robotic surgery. A standardized reporting system (Stone, 2002) is needed for all adverse events related to robotic devices. The book talked about how a lot of policies happen to be written in such a way that they're open to interpretation from different people. We do not know how different robotic surgery training is among different institutions. Training policies are just in writing, so it is unknown what happens in practice. Without reporting of all adverse events, it is hard to say what the root cause of training problems is. The goal of this literature review is to determine the leading cause of adverse events in robotic surgery. The goal partially accomplished this. Some causes are device malfunction, human error, and device limitations. The direct cause was not identified because there is no data on the cause of adverse events, aside from device malfunction related events. Overall, more research needs to be geared towards robotic surgery, specifically the training process, in an effort to reduce complication rates and improve robotic surgery as a whole.

Research Questions

The literature review concluded that no publicly available research articles based around robotic surgery explicitly state reasons behind reported adverse events. This lack of reporting brings forward a need for more research on robotic surgery. The end of the literature review introduced two main questions that I plan on addressing for my thesis research.

1. *What practices work best for robotic surgery training? i.e. what components would make up a good hospital/institution policy? Are hospitals addressing what the experts think is needed?*
2. *Is there a need for a universal robotic surgery training guideline?*

Best practices are studied to determine if standardization is needed. In this case, standardized training is necessary because there is no public policy or regulation specific to robotic surgery training. This thesis research will seek to identify components that would compose a good policy based on the causes of potential issues of robotic surgery practiced identified by the literature review. The identification of these causes was important as they work to minimize concerns over robotic surgery. Robotic surgery deals firsthand with human lives and any concern raised by the public does not help the perception of robotic surgery.

Methods

Fifteen major hospitals/institutions in New York State that utilize robotic surgery were contacted to determine if access could be granted to their robotic surgery policies, training procedures, or relevant documentation. Four hospitals were completely unresponsive to contact by phone and email. Six hospitals were open to talk, but eventually unresponsive to any further contact. Two hospitals were very helpful, but ultimately could not provide any documentation, as they wanted to keep the information internal only. The 3 remaining hospitals (Upstate University Hospital in Syracuse, NY, Roswell Park in Buffalo, NY, and Stony Brook University Medical Hospital in Stony Brook, NY) were able to provide sufficient documentation. The documentation provided by the three hospitals was interpreted and made into a clearer table format. The three hospitals policies were compared against each other as well as to expert opinions from peer reviewed journal articles on robotic surgery policies. Firstly, this allowed for conclusions to be made on how the different institutions compare to each other, and secondly if the existing policies are sufficient.

I would have liked to obtain more than three hospital policies, but I began my thesis research right around the time the COVID-19 pandemic began. For this reason, it is understandable why the responsiveness from hospitals and institutions was limited. Hospitals across the world had to drastically shift their priorities to focus on patients with COVID-19 and combating the disease as efficiently and effectively as possible.

Findings

Upstate University Hospital

The table below, Table 3, summarizes the exact criteria required by Upstate University Hospital to attain robotic privileges at their hospital. It includes 4 credentialing privilege pathways based on the surgeon's history with robotic surgery. These include (1) surgeons with no previous experience or that have not performed cases in the last 12 months, (2) surgeons who have previous experience, (3) surgeons who have had previous robotic privileges, and (4) surgeons who want to re-privilege. The complete document can be found in Appendix A.

Table 3. Robotic Criteria at Upstate University Hospital

	4 Credentialing Privilege Pathways			
Criteria	**(1) Not previously experienced or have not performed cases in last 12 months on the robotic platform.**	**(2) Surgeons with prior training or experience on the robotic platform.**	**(3) Surgeons with prior privileges with the robotic platform who have had previous experience at other hospitals.**	**(4) Re-privileging.**
Training Modules	Prior to three proctored cases, completion of daVinci training modules as well as approval by daVinci instructor.	N/A	N/A	N/A
Competency	Robotic proctor will sign off on the competency of the surgeon to proceed with independent use of the robot.	A letter of recommendation from the Chair of the training program (from a residency or fellowship) should be submitted to the Robotic Committee indicating proficiency with the robotic platform.	Documentation demonstrating privileges at other hospitals will be reviewed by the Robotic Committee prior to performing any cases.	Surgeon should provide the Robotic Committee case logs demonstrating performance of at least 20 robotic assisted cases in the most recent two-year period. If surgeon fails to provide this evidence, they will be required to repeat the credentialing process as outlined in (1).

Criteria	4 Credentialing Privilege Pathways			
Preliminary Approval/ Case Review	Once competency form is complete, a provisional privilege is given to the surgeon to proceed with scheduling the next 7 cases.	After the letter is received and approved by the Robotic Committee the surgeon will be given provisional privileges to perform 10 cases with review of peri-operative and post-operative outcomes.	After the documentation is received and reviewed by the Robotic Committee, the surgeon will be given provisional privileges to perform 10 cases with review of peri-operative and post-operative outcomes.	N/A
Committee Review/ Privileging	At the conclusion of 10 cases (3 proctored, 7 independent) intra- and peri- operative outcomes will be reviewed by the Robotic Committee, a formal recommendation will be given to the credentialing committee if the surgeon should be given robotic privileges to continue robotic cases without review or require more cases to be reviewed.	After the 10 cases, and upon approval of the Robotic Committee, a formal recommendation will be given to the credentialing committee if the surgeon should be given robotic privileges to continue robotic cases without review or require more cases to be reviewed.	After the 10 cases, and upon approval of the Robotic Committee, a formal recommendation will be given to the credentialing committee if the surgeon should be given robotic privileges to continue robotic cases without review or require more cases to be reviewed.	The coordinator will send the request for case logs and forward to the Robotic Committee and a formal recommendation will be made to Credentials to continue robotic privileges, to require more cases be reviewed, or to not continue robotic privileges.

As previously mentioned, and seen in Table 3, the credentialing privileges are broken into four pathways. These pathways cover all the variations possible for a surgeon to obtain robotic surgery privileges. The first pathway (1) is for surgeons who do not have previous robotic experience or have not performed cases in the past 12 months. They must complete the daVinci training modules and be approved by a daVinci instructor. A robotic proctor will then sign off on the competency of the surgeon to allow them to move forward to complete 10 cases. Of these 10 cases, 3 are proctored, the remaining 7 are independent. These few preliminary steps are what differ between the first pathway and the rest. The first three pathways have the same final steps, which include: the completion of 10 independent cases, followed by a review of the outcomes of each case, and upon Robotic Committee approval, a formal recommendation will be made to the credentialing committee if the surgeon can continue robotic cases without review or require more cases to be reviewed.

Pathway two (2), which is for surgeons with prior training or experience on the robotic platform, requires a letter of recommendation from the chair of the training program to be submitted to the Robotic Committee to be reviewed. Upon approval, the same final steps just mentioned will be taken.

Pathway (3), which is for surgeons with prior robotic privileges, requires documentation demonstrating robotic ability to be reviewed by the Robotic Committee. Upon approval, the same final steps as the first three pathways will be taken.

The fourth pathway (4), which is re-privileging, requires the surgeon to provide 20 case logs demonstrating robotic ability in the most recent two-year period. This pathway has multiple possible outcomes. If the surgeon fails to provide the documentation, they will have to repeat the credentialing process. The Robotic Committee can also decide to allow the surgeon to continue with robotic privileges, require more cases to be reviewed, or not allow the surgeon to continue with robotic privileges.

The Upstate University Hospital documentation also notes procedure for becoming a robotic proctor at the hospital. “A surgeon may serve as a proctor after having performed at least forty (40) robotic assisted cases previously and approved by the Robotic Committee.” (Medical Staff Services, 2017) Surgeons of this caliber need to be the best in order to be teaching the next generations of surgeons, not to mention robotic surgeons.

Roswell Park

The table below, Table 4, is a summary of the criteria required by Roswell Park to successfully pass their Applied Technology Laboratory for Advanced Surgery (ATLAS) robotic surgery training program at their hospital. It includes 3 main training areas: laparoscopic, robot assisted, and surgical robot, all broken down into supplemental tasks. The entire manual can be referenced in Appendix B.

Table 4. Applied Technology Laboratory for Advanced Surgery (ATLAS) Training Program at Roswell Park

Training Areas	Details
Laparoscopic	• Basic Curriculum Checklist ○ 1 Section ▪ 4 Tasks • Repeat 5x each • Intermediate Curriculum Checklist ○ 3 Sections ▪ 8 Tasks • Repeat 3x each
Robot Assisted	• RoSS® Curriculum Checklist ○ 4 Sections ▪ 15 Tasks • 4 Levels each • RoSS® HoST Checklist ○ 3 Sections (Procedures) ▪ 20 Tasks
Surgical Robot	• Intermediate Curriculum Checklist ○ 3 Sections ▪ 6 Tasks • Repeat 3x each

The first area of training is laparoscopic, which involves small incisions and trocars through which the instruments can be inserted. The single basic section of laparoscopic involves utilizing both hands which includes 4 basic tasks like Loops and Wire and Post and Sleeve. The 3 intermediate sections involve utilizing both hands, using a suture pad, and using an inanimate model which includes tasks like Peg Transfer and Running Suture, Start and End Knot. Moving into the Robot Assisted area, we see 4 RoSS® Curriculum sections including Orientation, Motor

Skills, Basic Surgical Skills, and Intermediate Surgical Skills. Here there are tasks like Camera Control, Ball Drop, Needle Remove, and Vessel Dissection. The next piece of the Robot Assisted area is the RoSS® HoST checklist which includes 3 sections, which is actually 3 common robotic procedures that the surgeons need to complete. The 3 procedures are a Prostatectomy (prostate removal), Hysterectomy (uterus removal), and a Cystectomy (bladder removal). The tasks for this are rather steps for each procedure. The final training area is the Surgical Robot which includes similar tasks to the intermediate laparoscopic curriculum, this time performing them with the surgical robot. Two example tasks are threading using both hands and using a suture pad to perform interrupted surgical knots. All tasks are scored individually in terms of a proficiency rating for each task to ensure surgeons are proficient at all tasks. Each task has a unique grading system value or pass/fail criteria to be evaluated by the trainer.

Stony Brook University Medical Center

The table below, Table 5, summarizes the exact criteria required by Stony Brook University Medical Center to attain robotic privileges at their hospital. It includes 4 credentialing privilege categories based on the surgeon’s history with robotic surgery. These include (1) independently practicing surgeon with <10 robotic surgery cases in the past year and does not meet criteria for robotic surgery training during residency or fellowship, (2) independently practicing surgeon with <10 robotic surgery cases in the past year and meets criteria for training in robotic surgery during residency or fellowship, (3) independently practicing surgeon with >10 and <50 robotic surgery cases in the past year, and (4) independently practicing surgeon with >50 robotic surgery cases in the past year. The complete document can be found in Appendix C.

Table 5. Criteria for Privileges in Robotic Surgery at Stony Brook University Medical Center

Criteria	**Category 1** **Independently practicing surgeon with <10 robotic surgery cases in the past year and does not meet criteria for robotic surgery training during residency or fellowship.**	**Category 2** **Independently practicing surgeon with <10 robotic surgery cases in the past year and meets criteria for training in robotic surgery during residency or fellowship (minimum 30 cases as primary surgeon and training completed within past 18 months)**	**Category 3** **Independently practicing surgeon with >10 and <50 robotic surgery cases in the past year.**	**Category 4** **Independently practicing surgeon with >50 robotic surgery cases in the past year.**
Board Certified/Qualified	Required	Required	Required	Required
References – Robotic Experience	Not applicable	From Program Director	From Chief of Service	From Chief of Service
Robotic Training Course	Required	Required	Required	Required
Observation of Robotic Cases	3 cases within 3 months	Not required	Not required	Not required
Currently privileged to perform the procedure using conventional techniques	Required	Required	Required	Required
Robotic Cases (minimum #)	Not applicable	30 as resident/fellow	>10 and <50 in the past year as practitioner	>50 cases in past year as practitioner
Review of conventional cases for each procedure for which robotic privileges are requested	5 most recently performed cases	5 most recently performed cases	5 most recently performed cases	5 most recently performed cases
Proctoring (minimum #)	5	3	2	0
Review of robotic cases performed independently	First 5 sequential cases	First 5 sequential cases	First 5 sequential cases	First 5 sequential cases
Minimum robotic cases per year performed at SBUH	5	5	5	5
Satisfactory QA Review	Required	Required	Required	Required

As previously mentioned, and seen in Table 5, the credentialing privileges are broken into four categories. These categories cover all the variations of experience possible for a surgeon to obtain robotic surgery privileges. The four categories have several similarities which consist of: the surgeon must be board certified/qualified, complete a robotic surgery training course approved by the Stony Brook University Hospital (SBUH) Director of Robotic Surgery (DRS), must be privileged to perform requested procedure using conventional techniques, must have the five most recently performed conventional cases for each procedure for which robotic surgery privileges are requested reviewed, must have the first five sequential independently performed robotic cases reviewed, perform a minimum of five robotic cases per year at SBUH, and must have a satisfactory Quality Assurance (QA) Review. All of the above-mentioned criteria are what must be met by the surgeon in all four Categories. The differences between the Categories will be outlined below.

The first, Category 1, is for surgeons with <10 robotic surgery cases in the past year and that do not meet criteria for robotic surgery training during residency or fellowship. As far as training and privilege requirements, the surgeon must observe 3 relevant cases approved by the DRS within 3 months. The surgeon must be proctored for 5 robotic surgery cases and upon completion, the proctor shall determine if the practitioner requires additional proctoring or may perform robotic surgery independently. The proctor will base the decision on the operative performance rating form (shown in Appendix C). The practitioner must score a 5 in every category in which they are evaluated. Following this, a decision to recommend robotic privileging is made by the proctor to the DRS who will then make a recommendation to the department credentials committee.

The second, Category 2, is for independently practicing surgeons with <10 robotic surgery cases in the past year and meets criteria for training in robotic surgery during residency or fellowship. The residency/fellowship criteria include a minimum of 30 cases as primary surgeon and training completed within past 18 months. As far as training and privilege requirements, the surgeon must have a reference from their previous program director outlining robotic experience. For case experience, the surgeon must have a minimum of 30 robotic cases as a resident or fellow. The surgeon must be proctored for 3 robotic surgery cases and upon completion, the proctor shall determine if the practitioner requires additional proctoring or may perform robotic surgery independently. The proctor will use the same performance rating form mentioned for Category 1. Following this the same decision process will proceed and a recommendation will be made to the DRS and credentials committee.

The third, Category 3, is for independently practicing surgeons with >10 and <50 robotic surgery cases in the past year. As far as training and privilege requirements, the surgeon must have a reference from their previous chief of service outlining robotic experience. For case experience, the surgeon must have between 10 and 50 robotic surgery cases in the past year as the practitioner. The surgeon must be proctored for 2 robotic surgery cases and upon completion, the proctor shall determine if the practitioner requires additional proctoring or may perform robotic surgery independently. Similarly, the proctor will use the performance rating form mentioned for Category 1. Following this the same decision process will proceed and a recommendation will be made to the DRS and credentials committee.

The fourth and final, Category 4, is for independently practicing surgeon with >50 robotic surgery cases in the past year. As far as training and privilege requirements, the surgeon must have a reference from their previous chief of service outlining robotic experience. For case experience, the surgeon must have more than 50 robotic surgery cases in the past year as the practitioner. Following this the same decision process will proceed and a recommendation will be made to the DRS and credentials committee.

The Stony Brook University Medical Center documentation has additional information for reference in Appendix C regarding supplemental material to Table 5, documentation descriptions, and the performance rating form mentioned in each Category.

Discussion and Conclusions

Summary of Results

The three pieces of documentation provided to me, can be categorized as two different types of documents. The first type, from Upstate University Hospital and Stony Brook University Medical Center, was a well-defined set of requirements for granting robotic surgery privileges. The second type, from Roswell Park, was a training program conducted at the hospital. The differences between types made comparison and analysis rather difficult. Though, the similarity between Upstate and Stony Brook allowed them to be compared against each other. The first research question, what components should make up a good robotic surgery policy, was able to be answered by expert opinions. The second, should there be a universal robotic surgery training policy, proved more difficult to answer given the data provided. The three documents were compared to expert opinions explaining the minimum requirements for granting robotic surgery privileges at hospitals and institutions.

Limitations

This study had a number of limitations. The first and most critical limitation was the amount of data acquired. Having only 3 hospitals to compare may not be significant enough to make noteworthy conclusions. However, during a pandemic, one can expect that hospitals in New York have been overwhelmed and simply do not have the time to respond to my requests.

Another limitation of this study was the location where data was collected. This study was limited to New York State, which only accounts for a small percentage of hospitals/institutions nationwide or even worldwide that utilize robotic surgery. However, for a thesis, it did not make sense at the start to expand the number of sites to hospitals outside of the state. Additionally, medical licensing is done by state and it made the most sense to stay within a specific state, rather than expanding the search. It is likely that an expanded search across different states would come with inherent comparison problems because different states will not have the same licensing requirements for their surgeons. And again, no one imagined the impact of the COVID-19 pandemic when this research was begun.

There is also a limitation specific to each piece of documentation collected. The three pieces of documentation were vastly different. The first, very clearly laid out what was required of the surgeon in any situation to be given robotic surgery privileges at that hospital. The second, was more of a training program with no indication that this was the only requirement a surgeon would need to complete to gain robotic surgery privileges. This hospital noted that this was all that they could provide to me. The third did clearly explain the requirements for a surgeon with various experience to obtain robotic surgery privileges but was found on the hospital's website with no indication if there were other requirements. There was no communication with anyone at the third hospital. Additionally, the difference made the pieces of documentation quite tough to compare to each other.

Discussion

Research Question 1

The concern to develop a stronger uniform training system was brought forward in the literature review. Experts from 20 international institutions came to a consensus on robotic surgery, stating that the "guidelines for the use of robots in surgery were lacking and the surgical community would benefit from a consensus statement on robotic surgery including guidelines for training and credentialing" (Herron et al., 2007). These experts define specific details to successfully implement their recommendations for proper robotic surgeon training and credentialing. A full writeup by the experts of the minimum requirements for granting robotic surgery privileges can be found in Appendix D and a summary is found in Table 6 below.

Table 6. Summary of Minimum Requirements for Granting Privileges (Herron et al., 2007)

Components	**Details**
A. Formal Specialty Training	Must include satisfactory completion of an accredited surgical residency program.
B. Formal Training in Residency and/or Fellowship Programs	For surgeons who successfully completed a residency and/or fellowship program that incorporated a structured curriculum in minimal access procedures and therapeutic robotic devices and their use. • Should include the science and techniques of access to the body cavity and area of surgery. • Includes adequate clinical experience. • The applicant's program director, and if desired other faculty members, should supply the appropriate documentation of training and clinical experience.
C. No Formal Residency Training in Therapeutic Robotic Surgery	For those surgeons without residency and/or fellowship training which included structured experience in therapeutic robotic procedures, or without documented prior experience in these areas. • Should be defined by the institution and should include a structured program. • The curriculum should include didactic education on the specific technology and an educational program for the specialty specific approach to the organ systems. • If the access is an intracavitary procedure, then that experience and education should be a prerequisite to the training. • Necessary hands-on training, which includes experience with the device in a dry lab environment as well as a specialty-specific model which may include animate, cadaveric and/or virtual reality and simulation modeling. • Observation of live case(s) should be considered mandatory. • Other teaching aids may include video review and interactive computer programs.
D. Practical Experience	1. Applicant's Experience – Documented experience that includes an appropriate volume of cases with satisfactory outcomes, equivalent to the procedure in question in terms of complexity. The chief of service should determine the appropriateness of this experience. 2. Initial clinical experience on the specific procedure must be undertaken under the review of an expert and may include assisting. An adequate number of cases to allow proficient completion of the procedure should be performed with this expert review.

	3. Preceptor or proctor – The specific role and qualifications of the expert must be determined by the institution. Criteria of competency for each procedure should be established in advance and should include evaluation of: familiarity with instrumentation and equipment, competence in their use, appropriateness of patient selection, clarity of dissection, safety, and successful completion of the procedure. The criteria should be established by the chief of service in conjunction with the specific specialty chief where appropriate.
E. Formal Assessment of Competency	When available, validated measures of competency should be used to further document the applicant's abilities. May include: • Knowledge, medical decision making, and/or technical skill assessments. ○ May include certificates of completion of training or validated assessment tools for competency or proficiency in a specific procedure, or set of similar procedures.

Part A is mandatory, and must be accompanied by either part B, or C and at least one component of D.

The experts determined that there are 4 minimum requirements for the granting of robotic surgery privileges. The first (A) is that formal specialty training is a mandatory requirement for robotic privileges. This includes satisfactory completion of an accredited surgical residency program with subsequent certification by the applicable specialty board. In laymen terms, this means the surgeons must attend and successfully complete a residency in a specialty area following graduation from medical school.

The next requirement for granting privileges has 2 options (B or C). Component B is for surgeons who completed a residency program that incorporated a structured curriculum in minimal access procedures and therapeutic robotic devices and their use. This residency program also needs to include the science and the techniques of access to the body cavity and area of surgery. The program director needs to supply appropriate documentation of training and clinical experience to the institution granting robotic privileges. Component C is for surgeons who completed a residency program that didn't include a structured curriculum in therapeutic robotic procedures, or without documented prior experience in these areas. Surgeons in this category are required to participate in a structured training curriculum for these areas. It should be defined by the institution and include didactic education on the specific technology and an educational program for the specialty specific approach to the organ systems. The experts note a few other teaching tools that would be useful in creating a structured training curriculum like this.

The third requirement (D) relates to practical experience and has 3 options. At a minimum the surgeon must complete one of these. The first is the surgeon having documented experience that includes an appropriate volume of cases with satisfactory outcomes, equivalent to the procedure in question in terms of complexity. The chief of service should determine the appropriateness of this experience. The second is initial clinical experience on the specific procedure must be undertaken under the review of an expert and it may include assisting. An adequate number of cases to allow proficient completion of the procedure should be performed with this expert review. The third is the surgeon as a preceptor or proctor. The specific role and qualifications of the expert should be determined by the evaluating institution. The surgeon's competency for each procedure should be determined in advance and include an evaluation of familiarity with instrumentation and equipment, competence in their use, appropriateness of patient selection, clarity of dissection, safety, and successful completion of the procedure. The chief of service in conjunction with the specific specialty chief should determine said criteria.

The final requirement (E) is a formal assessment of competency. Validated measures of competency should be used to further document the applicant's abilities which may include knowledge, medical decision making, and/or technical skill assessments. This assessment may also include certificates of completion of training or validated assessment tools for competency or proficiency in a specific procedure or set of similar procedures.

As previously mentioned, the three documents were compared to expert opinions explaining the minimum requirements for granting robotic surgery privileges at hospitals and institutions. Table 7, below, summarizes the evaluation of the three hospitals policies compared to the expert requirements defined in Table 6.

Table 7. Summary of Expert Requirements Versus Hospital Policy

Expert Requirements	**Upstate University Hospital**	**Roswell Park**	**Stony Brook University Medical Center**
A	✓	✓	✓
B	✓ *		✓ *
C	✓ *		✓ *
D	✓		✓
E	✓		✓

✓ *** Hospital needs to clarify if surgeons residency/fellowship programs incorporate a structured curriculum.**

When looking at the criteria provided by Upstate University Hospital, there are many requirements that match the ones from the experts. While it isn't explicitly stated, it's fair to assume the surgeons who are employed by the hospital went through a residency program following medical school. This requirement is known nationwide. What is not fair to assume is that residency program incorporated a structured curriculum in minimal access procedures and therapeutic robotic devices and their use. This is something the hospital should require of the surgeons, according to the experts. An alternative, provided by the experts, was if the surgeons did not complete a residency program with such structure, the hospital should be responsible for putting the surgeons through an alternative structured training program.

Another requirement that matches that of the experts is the surgeon proving their experience through the completion of proctored and/or individual cases. The number of cases was determined by Upstate and varies based on past experience. This section was absolutely well defined by the hospital and meets the expert's criteria. The final expert requirement is a formal assessment of competency. This requirement is adequately met by the hospital as well, since it includes a formal review by their Robotic Committee, followed by a recommendation to the credentialing committee. All in all, the documentation provided by Upstate University hospital meets the expert's criteria. The only area lacking was the specifics of the surgeon's residency programs, which is a simple adjustment to be made by the hospital's admissions/hiring requirements.

When interpreting the criteria provided by Roswell Park, most of the requirements provided by experts are not met. As mentioned in the limitations, this is largely due to the type of documentation provided. A program training manual was provided rather than precise credentialing requirements. This does not mean that Roswell Park does not have a credentialling document, it just indicates that I can only analyze the documentation I was given. I am hopeful that Roswell Park has a credentialling document, but if they do not, that raises many concerns. If surgeons applying to be robotic surgeons do not have a strict credentialing document to follow and complete, they cannot be held accountable. The lack of a credentialing document would also allow differences in training and skill between robotic surgeons. This could lead to patient complications, lower surgeon skill expectations, and hurt the reputation of robotic surgery down the road, all because of improper credentialing documentation.

Like Upstate, it is not explicitly stated that the surgeons completed a residency program, but this is required in this field. What this hospital can improve on is the requiring the surgeons to complete a residency program that incorporated a structured curriculum in minimal access procedures and therapeutic robotic devices and their use. If the surgeons did not do so, the hospital should be responsible for putting the surgeons through an alternative structured training program that meets the requirements. The training documentation provided by Roswell Park may qualify as equivalent to such a program, I am not qualified to say. This documentation doesn't meet the practical experience requirement either. Again, the document is simply a training program and has no reason to mention what the surgeons need to do following the program, but the hospital must have a document specifying so. According to the experts, completing a simple training program is not sufficient enough. Practical experience including performing cases with satisfactory outcomes is required. Finally, there is no mention of a formal assessment of competency, likely again because it is a training document. Roswell Park does not meet the requirements provided by the experts for granting robotic surgery privileges. If more documentation could be provided, this analysis may have a difference outcome, but currently, this is not a sufficient training program.

When looking at the criteria provided my Stony Brook University Medical Center, there are many requirements that match the ones from the experts. Again, while it isn't explicitly stated in the criteria provided, it's fair to assume the surgeons who are employed by the hospital went through a residency program following medical school because it is required nationally. However, it cannot be assumed that the residency program incorporated a structured curriculum in minimal access procedures and therapeutic robotic devices and their use. According to the experts, this is something a hospital should require of their surgeons looking to obtain privileges in robotic surgery. The experts offer an alternative for surgeons who did not complete a residency program with such a structure. This alternative requires the hospital to be responsible for putting the surgeons through a well-defined structured training program.

The other crucial requirement that matched that of the experts is the surgeon demonstrating their experience through the observation of cases, completion of proctored cases, and/or individual cases. The required number of cases in each respect was determined by Stony Brook and varies based on past experience. These requirements were detailed in depth in the supporting documentation provided and exceed the expert’s criteria. The final expert requirement consists of a formal assessment of competency. Stony Brook met this requirement as they included a review of the surgeons five most recently performed cases, a review of their first five sequential independently performed robotic cases, and a satisfactory QA review. In sum, the documentation provided by Stony Brook University Medical Center meets the expert’s criteria. This documentation, like Upstate, lacked definition of the surgeon’s residency programs and can simply be improved by adjusting the hospital’s hiring requirements.

The first research question, what components should make up a good robotic surgery policy, was answered by expert opinions above, in detail. A brief summary of the components is written below for review. The experts determined that there are 4 minimum requirements for the granting of robotic surgery privileges. The first (A) is that formal specialty training is a mandatory requirement for robotic privileges. This includes satisfactory completion of an accredited surgical residency program with subsequent certification by the applicable specialty board. The next requirement for granting privileges has 2 options (B or C). Component B is for surgeons who completed a residency program that incorporated a structured curriculum in minimal access procedures and therapeutic robotic devices and their use. Component C is for surgeons who completed a residency program that did not include a structured curriculum in therapeutic robotic procedures, or without documented prior experience in these areas.

The third requirement (D) relates to practical experience and has 3 options. At a minimum the surgeon must complete one of these. The first is the surgeon having documented experience. The second is initial clinical experience on the specific procedure must be undertaken under the review of an expert and it may include assisting. The third is the surgeon as a preceptor or proctor. The specific role and qualifications of the expert must be determined by the evaluating institution with the chief of service in conjunction with the specific specialty chief determining said criteria. The final requirement (E) is a formal assessment of competency. Validated measures of competency should be used to further document the applicant's abilities which may include knowledge, medical decision making, and/or technical skill assessments.

It is clear that the experts thoroughly deliberated what components should be in a successful robotic surgery policy and the results are intuitive and made analysis simple. As we saw in the analysis comparing each hospital to expert guidelines, Upstate and Stony Brook address all of what the experts think is needed for granting robotic surgery privileges. Roswell Park did not meet all expert criteria, they only met one of five. We can see that there are hospitals out there that are addressing what experts think is needed in in a hospital/institution policy, but there are also hospitals that are not.

Research Question 2

The second research question, should there be a universal robotic surgery training policy, proved more difficult to answer given the data provided. Given that only three institutions in New York State were examined, the data was limited. However, it was clear that two of the three institutions had acceptable robotic surgery privilege policies. The third, was only able to provide limited documentation, and is likely the reason that institution's guidelines did not meet all of the expert requirements. The two institutions that did meet expert requirements had many similarities in their documentation. The parallel documentation indicates hope for a universal policy. This fact, that two institutions in the same state already have close requirements for robotic surgery privileging, is quite significant.

If the analysis were to be expanded, it is likely that more similarities would be found among other institutions, statewide, and even nationwide. Hospitals and institutions must look to each other when developing policies for any new area in development. Consultation in an area of such importance like the field like medicine is undoubtedly necessary. A universal policy would eliminate the existence of the many uncertainties present. Since a large difference was found between only 3 hospitals in New York State, the differences between the thousands of hospitals with robotic surgery across the United States could be countless. Based on the limited data, it is reasonable to say there is a need for a universal robotic surgery policy.

Implications for Research

Based on the findings in the literature review as well as the findings in the follow-up research, it is clear that more research needs to be done in this area. The literature review found that research needs to be conducted on the specific causes of adverse events in robotic surgery. To improve robotic surgery as a whole, the causes need to be investigated. Research in this area is key to advancing and improving robotic surgery training. It was noted that the causes for complications are likely already known by institutions or hospitals practicing robotic surgery, improvement lies with increasing the reporting. The literature review made these conclusions and opened the door for the follow up research presented here. This research found that there is a program out there that meets experts' opinions and there are others that do not. This means there needs to be an increase in collaboration between hospitals/institutions. The research aspects would come with conducting another expert consensus. The one described was held in 2006, which was nearly 14 years ago. A lot has changed in the field of robotic surgery since then. It is possible that more requirements need to be added to the credentialing process and some may not be as important today. All this is not possible without further research in this area. Considering this study only looked at 3 institutions and the requirements were vastly different, an increase in research is necessary.

Policy Recommendations

Policy recommendations are difficult to be made based on the limited data provided in this research. Making a useful and beneficial recommendation comes with significant research backing. This study only focused on three institutions that utilized robotic surgery and the results were quite different. A few recommendations are explained below.

Recommendation #1

One area that needs to explored is simply reaching out to more institutions. A large barrier was not being able to receive information for a variety of reasons. In order to have robotic surgeons of the same caliber, robotic surgery credentialing needs to be compared to expert opinions. This lack of guidelines has raised concerns by scholars in the literature review and is an area where focus needs to be. The greater the number of hospitals and institutions involved, the greater the outcome for the greater good will be.

This extension to more institutions would allow for better data sharing as well as the ability to make more significant decisions. Based on the data that was available, individual hospitals should not be allowed to do as they please. There is a need for states to have a universal policy to keep them in check with other hospitals and institutions in that state. A policy at the state level would allow the state to comply with its own states regulations rather than New York having to comply with California regulations, for example. This policy at a state level could also be a steppingstone for a larger national policy. The more states with a robotic surgery policy, the easier a national universal policy could be in the future.

Recommendation #2

It was clear that the documents provided by each institution were different. One type of document was specific to credentialing requirements and the other to training guidelines. Upstate

University Hospital and Stony Brook University Medical Center provided credentialing requirements and had nearly identical requirements evident in Table 3 and Table 5. Both had four Pathways/Categories for surgeons with varying experience. In each of the Pathways/Categories at both hospitals, the surgeon is required to complete robotic training and must be proctored for a defined number of cases as well as perform individual cases. Each of the proctored and individual cases are reviewed independently. Surgeons with previous experience are required to provided references and/or letters of recommendation from prior institutions. Finally, assuming all requirements are met, both hospitals require a satisfactory completion of a committee review. It is clear that Upstate and Stony Brook's polices are incredibly similar. The similarities explained above indicate that two different institutions independently came up with analogous guidelines. This gives certainty to the fact that institutions have thorough robotic policies that are parallel with other institutions. These similarities also demonstrate why both hospitals easily met all expert criteria for robotic credentialing privileges.

On the other hand, Roswell Park provided training guidelines for their surgeons. Both of these document types are necessary and should exist at all hospitals. The fact that each hospital only had one piece is troublesome. While the documents are different, they are related. Both are useful as there needs to be a policy on how to credential and a curriculum for them to credential with. The two credentialing documents provided were consistent with the expectation of the experts. This consistency provides a positive outlook for the future.

Recommendation #3

With the increasing amount of robotic surgeries, reducing complications should be a top priority. Robotic surgery complication rate traces back to surgeon ability, which is directly linked to robotic surgery training and proper credentialing. Without collaboration on robotic surgery policy, there will be no reduction in complications. This again, calls the need for some universal policy. A universal robotic surgery training policy would have to start at the state level. It would initially be too difficult to cross state lines because each state has their own set of licensing requirements. A universal policy at the state level would be a huge undertaking and would be the first step in the right direction to establishing uniformity between robotic surgery training. Once a policy is established by states individually, it would be possible to move to develop a national universal policy. The development of such a policy would allow for institutions across the states and nation to work collaboratively to develop a policy that could someday be implemented anywhere.

The recommendation to have a universal policy would allow more hospitals and institutions to add robotic surgery with ease and in a timely fashion. New programs would have detailed guidance from their state and potentially nation on how to setup and maintain a successful robotic surgery program at their institution. This opportunity of a universal policy may also bring forward new funding opportunities to get hospitals and institutions to meet expert guidelines. Funding would also help to develop robotic surgery programs at existing institutions, where it may not have been possible before. The possibilities are endless. A universal robotic surgery policy would reduce the uncertainty between institutions and spark more conversations in the robotic surgery world.

Conclusions

This thesis looked at current robotic surgery privilege credentialing policies in place at major hospitals/institutions in New York State. Robotic surgery is a technology that has only been around for 20 years, which means the training and credentialing processes are even younger. Robotic surgery surely has reasons behind its praise and usefulness in this day in age, but with benefits, drawbacks always follow.

It was found that there is not a standard reporting system for all adverse events related to robotic devices. This, in turn, does not allow for improvement in the area of surgical training since the causes for adverse events are not explicitly reported. This huge limitation brought forward the main research question: what should a good robotic surgery training policy in a hospital be comprised of?

Expert guidelines were compared to policies in place at three major hospitals. It was found that two successfully met expert guidelines and had only small improvements to be made in the future. The other, based around the documentation provided, did not meet expert guidelines. This documentation was strictly a training program and did not state other regulations the hospital had in place. The two types of documentation were vastly different, therefore not logical to compare to each other. These findings did however show that there is are two institutions that have guidelines very similar to each other and that of an expert's opinion in this area. This shows promise that more programs exist out there that meet high expert expectations.

Future work would first include to reach out again to the New York State hospitals/institutions that practice robotic surgery. As mentioned in the limitations, I would have liked to have more documentation from other hospitals/institutions. If I were to continue this research, having three or four more pieces of documentation would allow for the solidification of the results. While we saw similarities between two hospitals and differences with the third, it would be the most beneficial to have more to compare to and add to the validity. If unsuccessful in finding more documentation within New York State, the search can be expanded to hospitals/institutions in the United States. This is a notably more difficult task, as there may be thousands of institutions that practice robotic surgery. There is also the potential limitation of different licensing requirements across states, as pointe out in the limitations as well. Therefore, there would need to be a limiting factor of some kind. A large positive for expanding the search would be the potential for a lot more data. Other institutions may be more open to sharing information and policies.

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Appendix A – (Upstate University Hospital, 2017)

UPSTATE
UNIVERSITY HOSPITAL

Medical Staff Services
Robotic Criteria

Initial privileging

A. Credentialing for robotic privileges at Upstate for surgeons not previously experienced or have not performed cases in the last 12 months with the robotic platform:
   1. Prior to three proctored cases, completion of daVinci training modules as well as approval by daVinci instructor must be performed by the surgeon (proctored by a robotic credentialed proctor).
   2. Once robotic proctor finds surgeon to be competent with the use of a robotic platform, he or she signs off on the competency of the surgeon to proceed with independent use of the robot (competency form already exists and available to robotic proctors at the end of the case).
   3. Once a competency form is completed by the certified proctor, a provisional privilege is given to the surgeon to proceed with scheduling the next 7 cases.
   4. At the conclusion of 10 cases (7 independent cases plus 3 previously proctored cases), intra- operative and peri-operative outcomes will be reviewed by the Robotic Committee. A formal recommendation will be given to the credentialing committee if the surgeon should be given robotic privileges to proceed with further scheduling of robotic cases without further review or require more cases to be reviewed by the committee.

B. Credentialing for robotic privileges at Upstate for surgeons with prior training or experience on the robotic platform:
   1. Instead of proctored cases, a letter of recommendation from the Chair of the training program (either a residency or fellowship) should be submitted to the Robotic Committee indicating proficiency with the robotic platform.
   2. After the letter of recommendation is received and approved by the Robotic Committee, the surgeon will be given provisional privileges to perform 10 cases with review of peri-operative and post-operative outcomes.
   3. At the conclusion of 10 cases, and upon approval of the Robotic Committee, a formal recommendation will be given to the credentialing committee if the surgeon should be given robotic privileges to proceed with further scheduling of robotic cases without further review or require more cases to be reviewed by the committee.

C. Credentialing for robotic privileges at Upstate for surgeons with prior privileges with the robotic platform who have had previous experience at other hospitals:
   1. Documentation demonstrating privileges at other hospitals will be reviewed by the Robotic Committee prior to performing any cases.
   2. After the documentation is received and reviewed by the Robotic Committee, the surgeon will be given provisional privileges to perform 10 cases with review of peri-operative and post-operative outcomes.
   3. At the conclusion of 10 cases, and upon approval of the Robotic Committee, a formal recommendation will be given to the credentialing committee if the surgeon should be given robotic privileges to proceed with further scheduling of robotic cases without further review or require more cases to be reviewed by the committee.

D. Re-privileging:
   1. Surgeon should provide to the Robotic Committee case logs demonstrating performance of at least 20 robotic assisted cases in the most recent two-year period. Should the surgeon fail to provide this

evidence, surgeon will be required to repeat the credentialing process as outlined in initial privileging above.

a. The coordinator will send the request for case logs and forward to the Robotic Committee upon receipt (Dr. Bratslavsky is the Chair), and a formal recommendation will be made to Credentials to continue robotic privileges, to require more cases to be reviewed, or to not continue robotic privileges. If the recommendation is for anything other than continuation of privileges, the Director, MSS should be notified and will discuss the recommendation with the Chair (Dr. Bratslavsky) prior to the Credentials meeting.

***When submitting the Robotic Committee Procedure Tracking Form, all cases must be consecutive.*

Proctorship Eligibility

A surgeon may serve as a proctor after having performed at least forty(40) robotic assisted cases previously and approved by the Robotic Committee

PA's

A. Take online daVinci assistant course and submit certificate to Robotic Committee for approval; or, personal proctoring by a certified robotic PA or surgeon.

B. Three (3) proctored cases with either a certified robotic PA or surgeon with robotic privileges.

C. Assist with seven (7) additional consecutive cases to total ten (10) consecutive cases; submit details to Robotic Committee (include any complications).

D. Robotic Committee will review for approval.

Use of Robotic Assisted System for Thoracic Procedures:

Initial privileging:

- Physician must hold privileges in or demonstrate training and experience in general thoracoscopic and laparoscopic procedures
- Physician must have training and experience in the particular system being used
- Completion of at least 12 robotic assisted procedures in the past 12 months

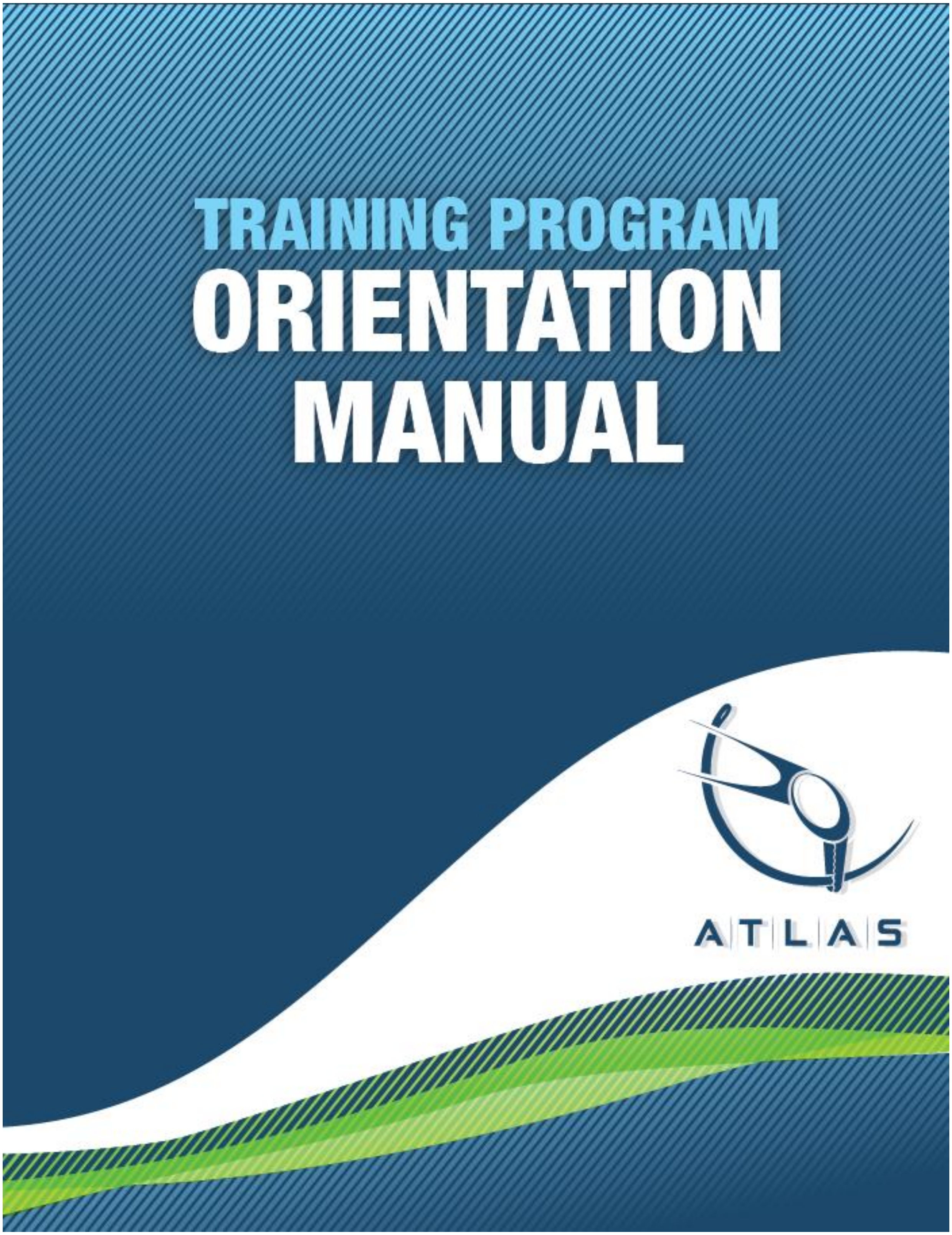
Re-privileging:

- Completion of at least 12 procedures within the past 24 months

Originating Department: Medical Staff Services
Approved by: Robotics Committee, Credentials Committee

Last Credentials Review Date: 02/2017

Appendix B – (Roswell Park, 2017)



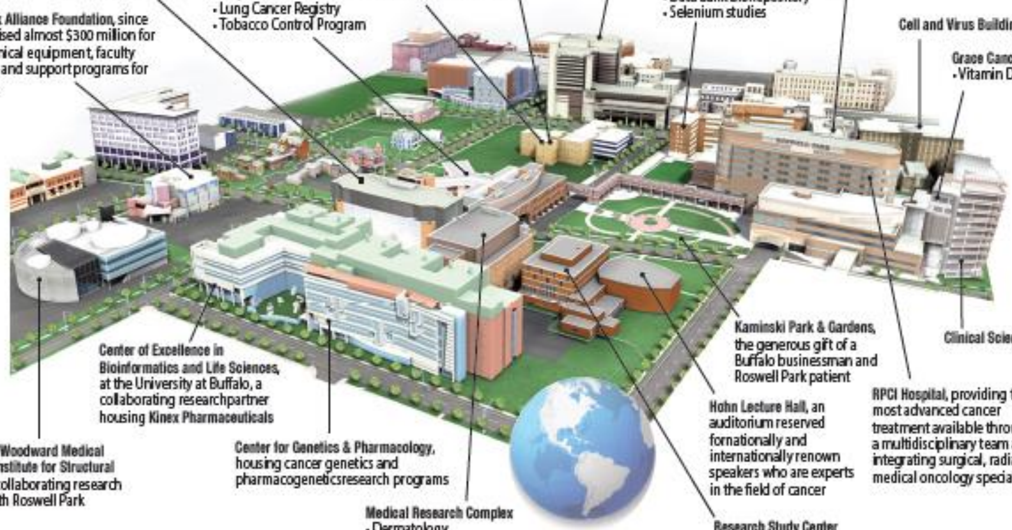
TRAINING PROGRAM
ORIENTATION
MANUAL

ATLAS

ROSWELL PARK
CANCER INSTITUTE

Elm & Carlton Streets
Buffalo, NY 14263
716-845-2300
www.roswellpark.org
E-mail: askrpci@roswellpark.org

- **Arrive at Roswell Park Institute to begin training at 8:00am on your first day.**
- **Proceed into the Main Hospital building to the front desk.**
- **Use the phone at the front desk to call ext. 8227 or if you prefer, your personal phone to call or (716) 845-8227.**



Roswell Park Alliance Foundation, since 1991, has raised almost $300 million for research, clinical equipment, faculty recruitment and support programs for patient care

Cancer Cell Center
- Photodynamic Therapy
- Immunology
- Prevention Vaccines

Carlton House
- Outreach
- Epidemiology
- Disparities
- Lung Cancer Registry
- Tobacco Control Program

Cleveland Bio Labs, a relocated biotech company, forming a strategic partnership with the Institute todevelop cancer and radio-protectant drug candidates

Panacella & Buffalo BioLabs

Clinical Translational Research Center houses **AndroBioSys**, a Roswell Park spin-off biotech company, improving prostate cancer treatment

Basic Science Building
- Data Bank BioRepository
- Selenium studies

DoubleTree Club Hotel, a full-servicehotel for patients and their families

Cell and Virus Building

Grace Cancer Drug Center
- Vitamin D research

Center of Excellence in Bioinformatics and Life Sciences, at the University at Buffalo, a collaborating researchpartner housing **Kinex Pharmaceuticals**

Hauptman-Woodward Medical Research Institute for Structural Biology, a collaborating research partner with Roswell Park

Center for Genetics & Pharmacology, housing cancer genetics and pharmacogeneticsresearch programs

Medical Research Complex
- Dermatology
- Nanotechnology

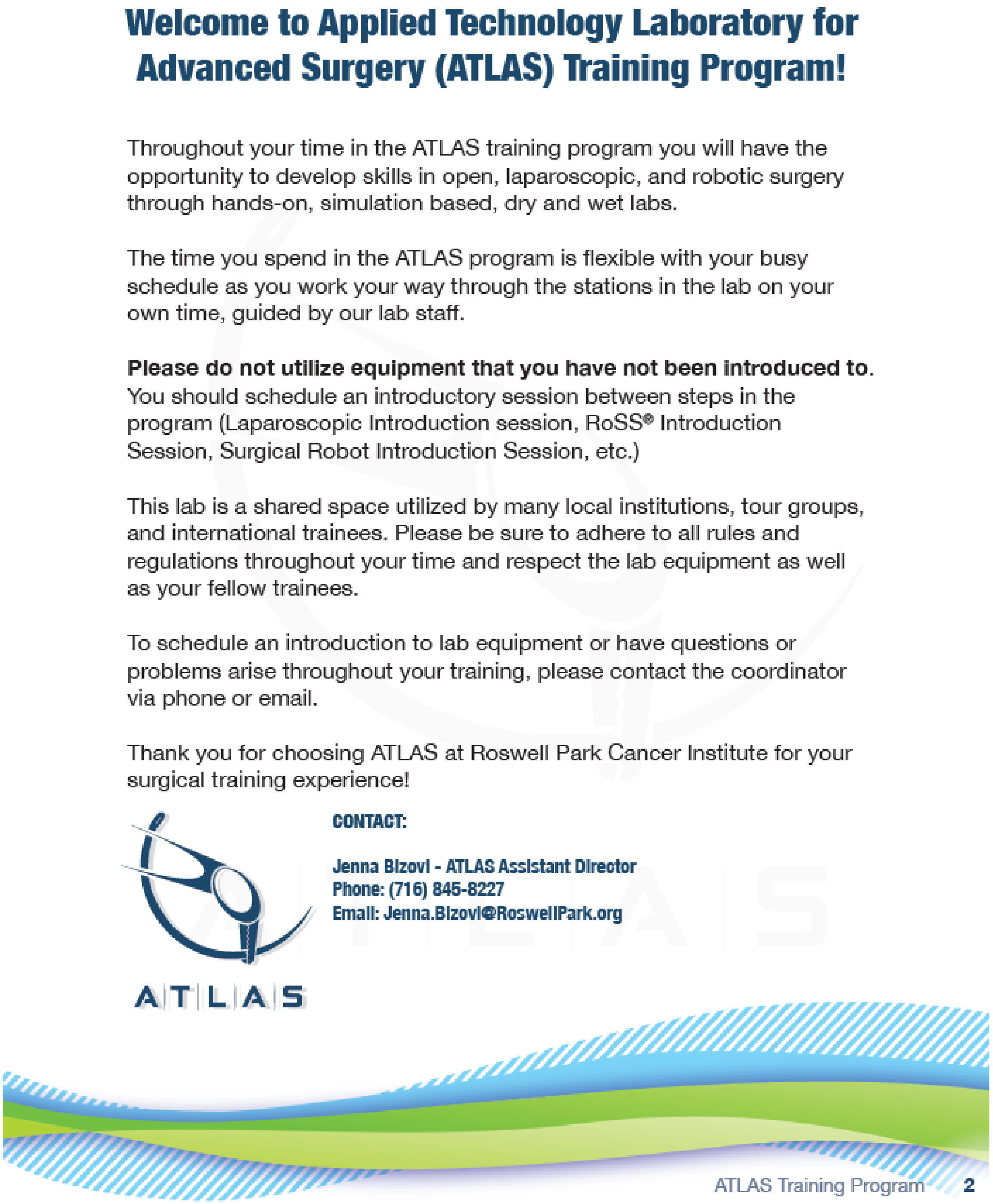
Kaminski Park & Gardens, the generous gift of a Buffalo businessman and Roswell Park patient

Hohn Lecture Hall, an auditorium reserved fornationally and internationally renown speakers who are experts in the field of cancer

Research Study Center
- Graduate Programs
- Yroswell

Clinical Sciences Center

RPCI Hospital, providing the most advanced cancer treatment available through a multidisciplinary team approach integrating surgical, radiation and medical oncology specialists



Welcome to Applied Technology Laboratory for Advanced Surgery (ATLAS) Training Program!

Throughout your time in the ATLAS training program you will have the opportunity to develop skills in open, laparoscopic, and robotic surgery through hands-on, simulation based, dry and wet labs.

The time you spend in the ATLAS program is flexible with your busy schedule as you work your way through the stations in the lab on your own time, guided by our lab staff.

Please do not utilize equipment that you have not been introduced to. You should schedule an introductory session between steps in the program (Laparoscopic Introduction session, RoSS® Introduction Session, Surgical Robot Introduction Session, etc.)

This lab is a shared space utilized by many local institutions, tour groups, and international trainees. Please be sure to adhere to all rules and regulations throughout your time and respect the lab equipment as well as your fellow trainees.

To schedule an introduction to lab equipment or have questions or problems arise throughout your training, please contact the coordinator via phone or email.

Thank you for choosing ATLAS at Roswell Park Cancer Institute for your surgical training experience!

CONTACT:

Jenna Bizovi - ATLAS Assistant Director
Phone: (716) 845-8227
Email: Jenna.Bizovi@RoswellPark.org

ATLAS

CAMPUS NAVIGATION

Throughout your training here at Roswell Park Cancer Institute's Robotic Training Center, properly navigating throughout the various buildings in a timely manner will allow you to maximize your learning opportunity. Please use these directions as a guide when asked to meet in a specific room throughout the hospital. If you have any additional questions, please call the lab phone at extension (845) *8227.

Due to the inclement weather Buffalo faces in the winter, these directions will allow you to remain inside the buildings. If you are unable to move through some part of the building, please pick up the blue phone and inform public safety that you are a robotics trainee headed for training.

ATLAS Training Laboratory and Offices

- Proceed into the lobby of the Main Hospital at Roswell Park Cancer Institute
- Take a right towards the lobby seating area when you are in front of Dunkin' Donuts
- Walk all the way to the end of the carpeted waiting area
- Proceed through the double doors
- Enter into the Clinical Sciences Center building and take your first left down the ramp
- Use your badge to pass through the door into the Grace Cancer Drug Center (GCDC). Turn left, then a quick right until you reach elevators.
- Take the elevators up to the 4th floor (G460)
- Lab entry for ATLAS will be the second door on your left or through the double doors around the corner

ATLAS

Directions to the Operating Room (OR)

- Proceed into the lobby of the Main Hospital at Roswell Park Cancer Institute
- Enter any of the 4 elevators on the ground floor to the 3rd floor (Just past the Dunkin' Donuts)
- As you exit the elevator, make a left
- Enter the 2nd door on the left
- As you exit the 2nd door, make a right and then a quick left
- Take the hallway around the corner and the scrubs station is on the right and changing rooms are on the left
- The Robots are located in room 4 and room 8

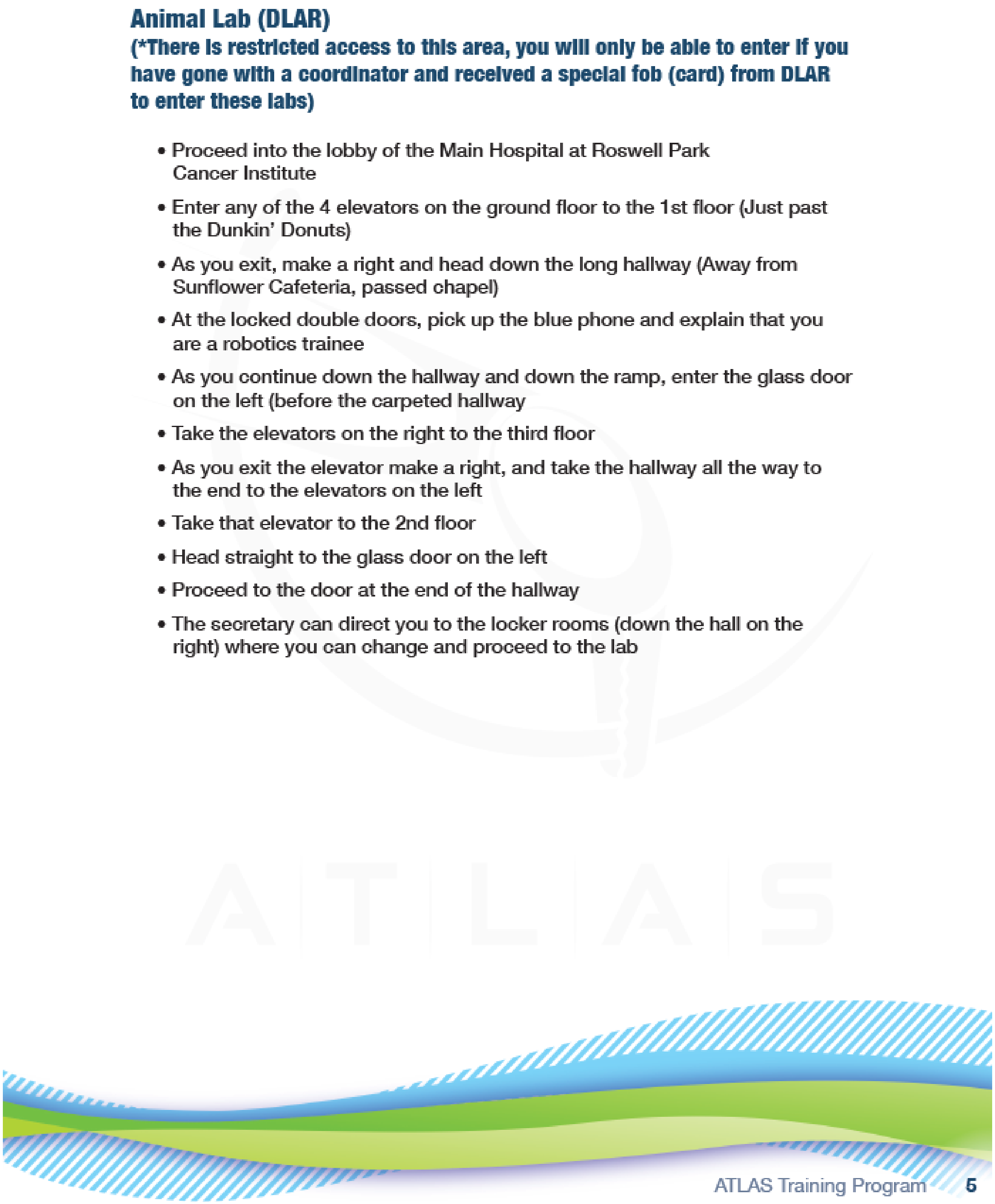
Sunflower Cafeteria

(*Open for breakfast, lunch, and dinner on weekdays, excluding holidays)

- Proceed into the lobby of the Main Hospital at Roswell Park Cancer Institute
- Enter any of the 4 elevators on the ground floor to the 1st floor (Just past the Dunkin' Donuts)
- As you exit the elevator, make a left
- The Sunflower Cafeteria will be on your left
- Sunflower Café takes credit (Master/Visa) as well as cash

Urology Offices (*Will need a badge for access)

- Proceed into the lobby of the Main Hospital at Roswell Park Cancer Institute
- Turn right and start walking past the seating area towards the double door leading into the Clinical Science Center building (may also be accessed through a separate entrance on Carlton street, to the right of the main hospital building entrance).
- Continue through the hallway into the Clinical Science Center building.
- Walk towards the elevators on the right and take an elevator to the 8th floor. You will need to swipe your badge in the levator for access.
- Take the double doors to your left



Animal Lab (DLAR)

(*There is restricted access to this area, you will only be able to enter if you have gone with a coordinator and received a special fob (card) from DLAR to enter these labs)

- Proceed into the lobby of the Main Hospital at Roswell Park Cancer Institute
- Enter any of the 4 elevators on the ground floor to the 1st floor (Just past the Dunkin' Donuts)
- As you exit, make a right and head down the long hallway (Away from Sunflower Cafeteria, passed chapel)
- At the locked double doors, pick up the blue phone and explain that you are a robotics trainee
- As you continue down the hallway and down the ramp, enter the glass door on the left (before the carpeted hallway
- Take the elevators on the right to the third floor
- As you exit the elevator make a right, and take the hallway all the way to the end to the elevators on the left
- Take that elevator to the 2nd floor
- Head straight to the glass door on the left
- Proceed to the door at the end of the hallway
- The secretary can direct you to the locker rooms (down the hall on the right) where you can change and proceed to the lab

RESOURCES FOR YOUR STAY

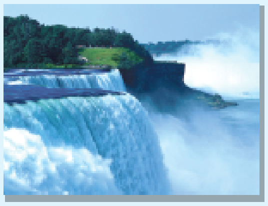
Explore & Enjoy Buffalo

The training program runs from Monday-Friday 8am-4pm weekly, excluding institutionally recognized holidays. During the weekends and after completion of independent curriculum, there are many local attractions in Buffalo that can be explored.

Our Suggestions

The Anchor Bar

The birth place of the ‘Buffalo wing’, the original anchor bar is located within walking distance of Roswell.

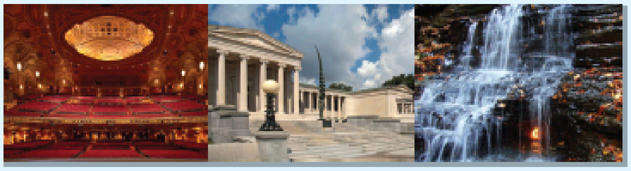


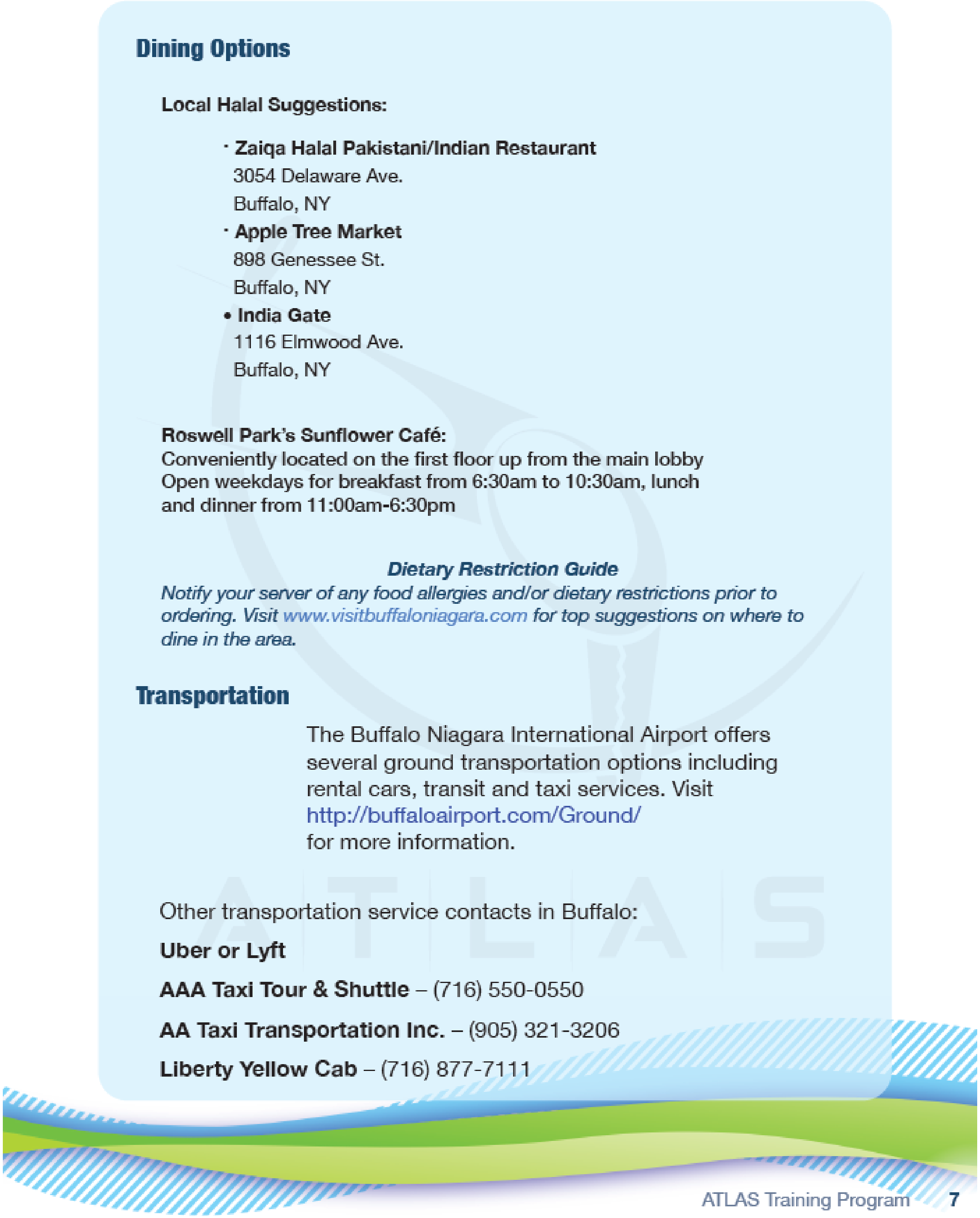
Niagara Falls

This powerful trio of waterfalls sports the highest flow rate of any waterfall in the world, and can be easily reached by shuttle or car.

Other

The city has theaters, famous architecture, art galleries, botanical gardens, shopping in the Elmwood Village and more. Visit www.visitbuffaloniagara.com for up-to-date information and suggestions on where to eat and what to do!





Dining Options

Local Halal Suggestions:

- **Zaiqa Halal Pakistani/Indian Restaurant**
  3054 Delaware Ave.
  Buffalo, NY
- **Apple Tree Market**
  898 Genessee St.
  Buffalo, NY
- **India Gate**
  1116 Elmwood Ave.
  Buffalo, NY

Roswell Park's Sunflower Café:
Conveniently located on the first floor up from the main lobby
Open weekdays for breakfast from 6:30am to 10:30am, lunch
and dinner from 11:00am-6:30pm

Dietary Restriction Guide

Notify your server of any food allergies and/or dietary restrictions prior to ordering. Visit www.visitbuffaloniagara.com for top suggestions on where to dine in the area.

Transportation

The Buffalo Niagara International Airport offers several ground transportation options including rental cars, transit and taxi services. Visit http://buffaloairport.com/Ground/ for more information.

Other transportation service contacts in Buffalo:

Uber or Lyft

AAA Taxi Tour & Shuttle – (716) 550-0550

AA Taxi Transportation Inc. – (905) 321-3206

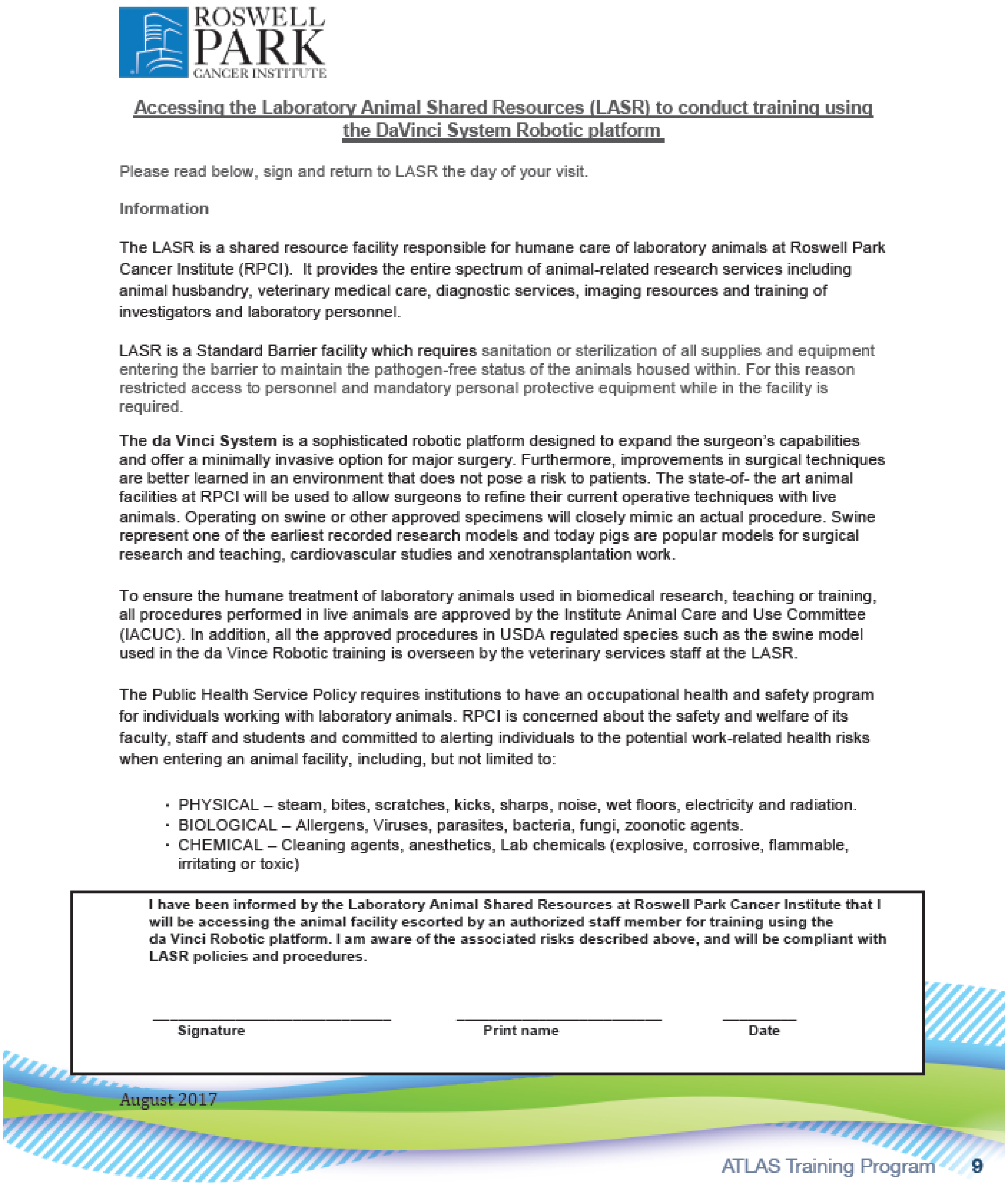
Liberty Yellow Cab – (716) 877-7111

TRAINING SCHEDULES

ONE WEEK

	Monday	Tuesday	Wednesday	Thursday	Friday
8:00-8:30am	General Orientation	OR Observation/ Simulator	Simulator	DaVinci®	Wet Lab
8:30-9:00am					
9:00-9:30am					
9:30-10:00am					
10:00-10:30am					
10:30-11:00pm	OR Observation/ Simulator				
11:00-11:30am					
11:30-12:00pm					
12:00-12:30pm	*Lunch*	*Lunch*	*Lunch*	*Lunch*	*Lunch*
12:30-1:00pm					
1:00-1:30pm	OR Observation/ Simulator	OR Observation/ Simulator	Simulator	DaVinci®	Wet Lab
1:30-2:00pm					
2:00-2:30pm					
2:30-3:00pm					
3:00-3:30pm					
3:30-4:00pm					
4:00-4:30pm					
4:30-5:00pm	*Independent study, digital textbook, Complete RoSS*				Certificated and Goodbyes
5:00-5:30pm					
5:30-6:00pm					

ATLAS Training Program 8



ROSWELL
PARK
CANCER INSTITUTE

Accessing the Laboratory Animal Shared Resources (LASR) to conduct training using the DaVinci System Robotic platform

Please read below, sign and return to LASR the day of your visit.

Information

The LASR is a shared resource facility responsible for humane care of laboratory animals at Roswell Park Cancer Institute (RPCI). It provides the entire spectrum of animal-related research services including animal husbandry, veterinary medical care, diagnostic services, imaging resources and training of investigators and laboratory personnel.

LASR is a Standard Barrier facility which requires sanitation or sterilization of all supplies and equipment entering the barrier to maintain the pathogen-free status of the animals housed within. For this reason restricted access to personnel and mandatory personal protective equipment while in the facility is required.

The **da Vinci System** is a sophisticated robotic platform designed to expand the surgeon's capabilities and offer a minimally invasive option for major surgery. Furthermore, improvements in surgical techniques are better learned in an environment that does not pose a risk to patients. The state-of- the art animal facilities at RPCI will be used to allow surgeons to refine their current operative techniques with live animals. Operating on swine or other approved specimens will closely mimic an actual procedure. Swine represent one of the earliest recorded research models and today pigs are popular models for surgical research and teaching, cardiovascular studies and xenotransplantation work.

To ensure the humane treatment of laboratory animals used in biomedical research, teaching or training, all procedures performed in live animals are approved by the Institute Animal Care and Use Committee (IACUC). In addition, all the approved procedures in USDA regulated species such as the swine model used in the da Vince Robotic training is overseen by the veterinary services staff at the LASR.

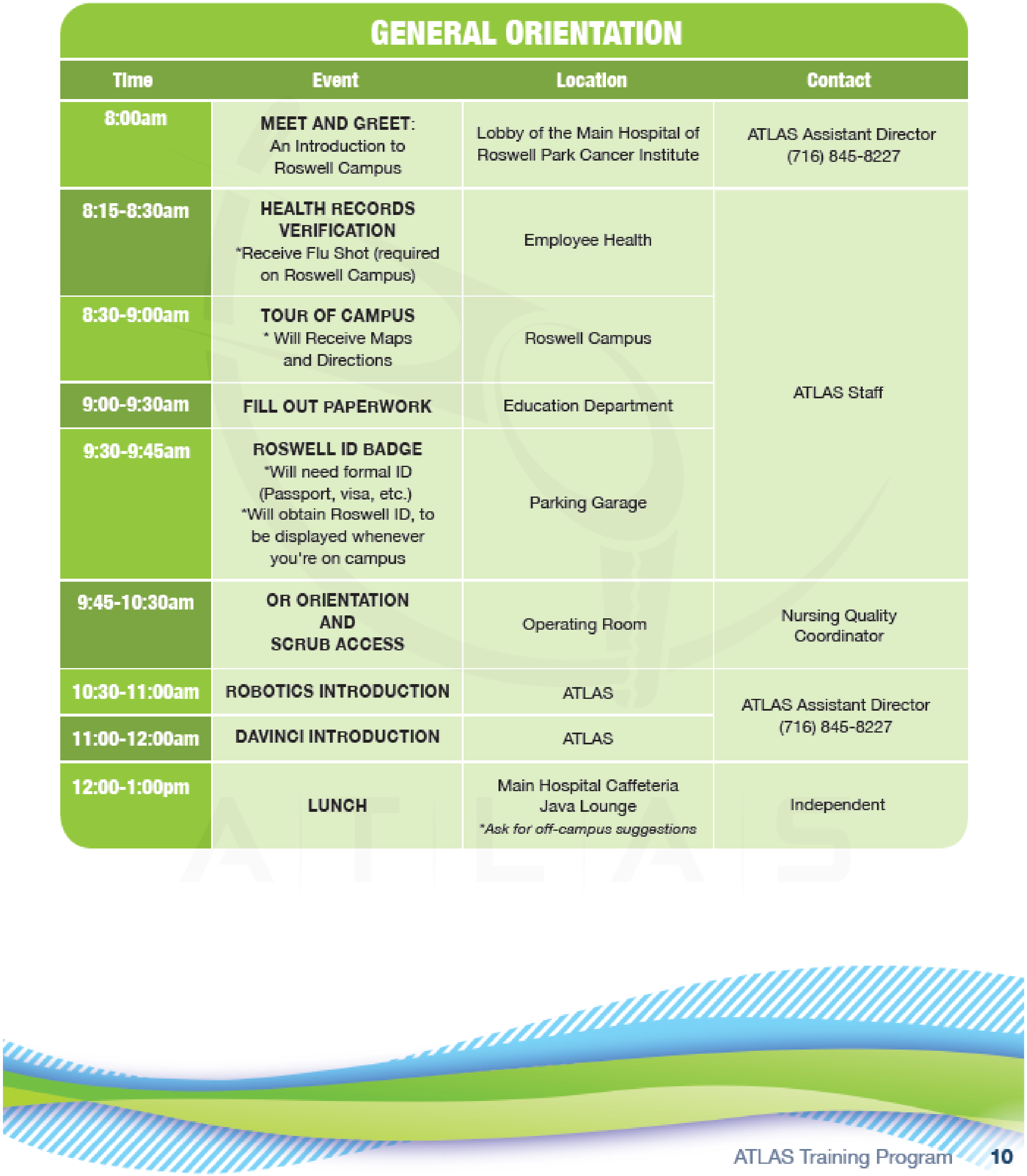
The Public Health Service Policy requires institutions to have an occupational health and safety program for individuals working with laboratory animals. RPCI is concerned about the safety and welfare of its faculty, staff and students and committed to alerting individuals to the potential work-related health risks when entering an animal facility, including, but not limited to:

- PHYSICAL – steam, bites, scratches, kicks, sharps, noise, wet floors, electricity and radiation.
- BIOLOGICAL – Allergens, Viruses, parasites, bacteria, fungi, zoonotic agents.
- CHEMICAL – Cleaning agents, anesthetics, Lab chemicals (explosive, corrosive, flammable, irritating or toxic)

I have been informed by the Laboratory Animal Shared Resources at Roswell Park Cancer Institute that I will be accessing the animal facility escorted by an authorized staff member for training using the da Vinci Robotic platform. I am aware of the associated risks described above, and will be compliant with LASR policies and procedures.

______________________________	__________________________	_________
Signature	**Print name**	**Date**

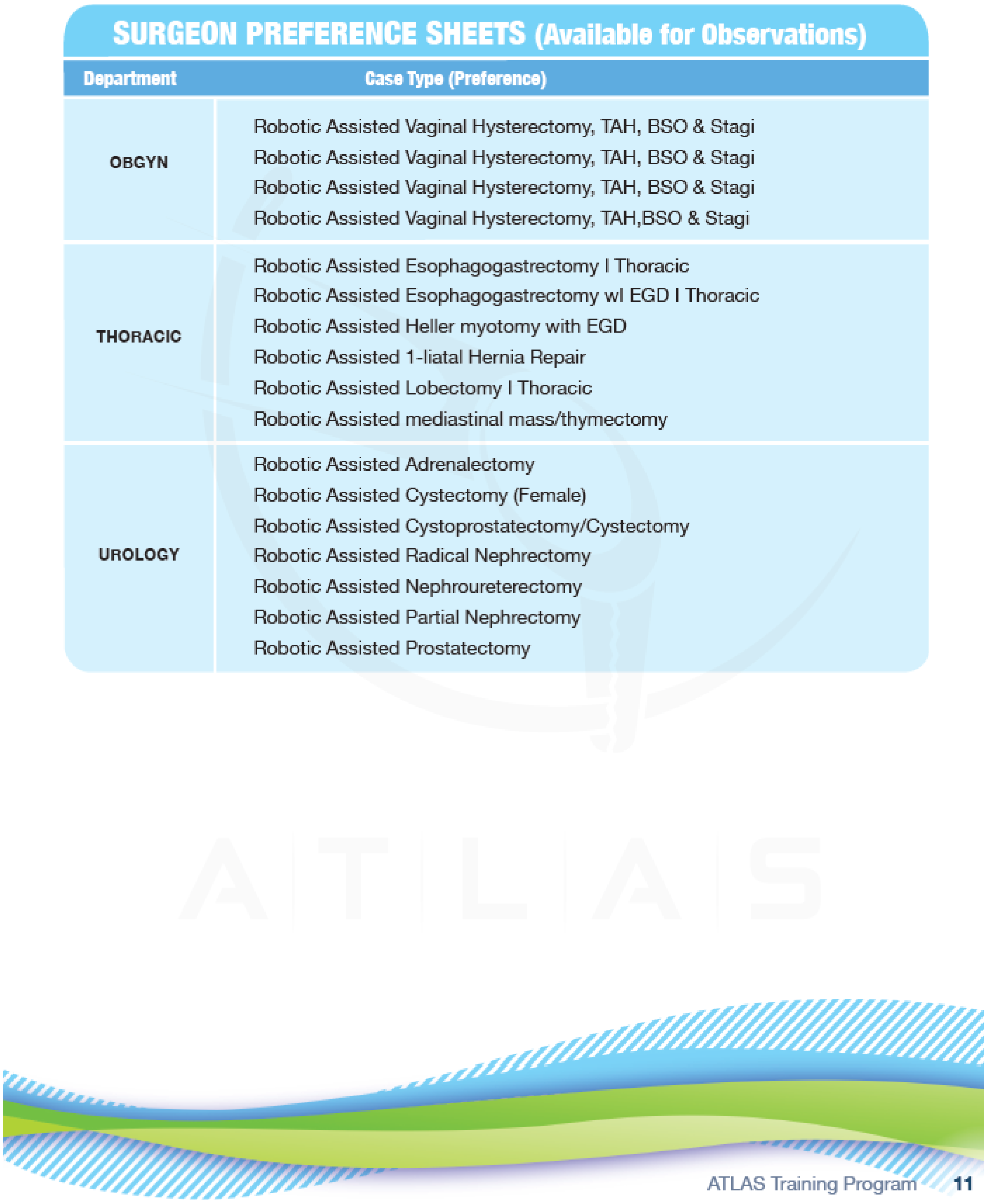
August 2017



GENERAL ORIENTATION

Time	Event	Location	Contact
8:00am	**MEET AND GREET:** An Introduction to Roswell Campus	Lobby of the Main Hospital of Roswell Park Cancer Institute	ATLAS Assistant Director (716) 845-8227
8:15-8:30am	**HEALTH RECORDS VERIFICATION** *Receive Flu Shot (required on Roswell Campus)	Employee Health	ATLAS Staff
8:30-9:00am	**TOUR OF CAMPUS** * Will Receive Maps and Directions	Roswell Campus	
9:00-9:30am	**FILL OUT PAPERWORK**	Education Department	
9:30-9:45am	**ROSWELL ID BADGE** *Will need formal ID (Passport, visa, etc.) *Will obtain Roswell ID, to be displayed whenever you're on campus	Parking Garage	
9:45-10:30am	**OR ORIENTATION AND SCRUB ACCESS**	Operating Room	Nursing Quality Coordinator
10:30-11:00am	**ROBOTICS INTRODUCTION**	ATLAS	ATLAS Assistant Director (716) 845-8227
11:00-12:00am	**DAVINCI INTRODUCTION**	ATLAS	
12:00-1:00pm	**LUNCH**	Main Hospital Caffeteria Java Lounge *Ask for off-campus suggestions*	Independent

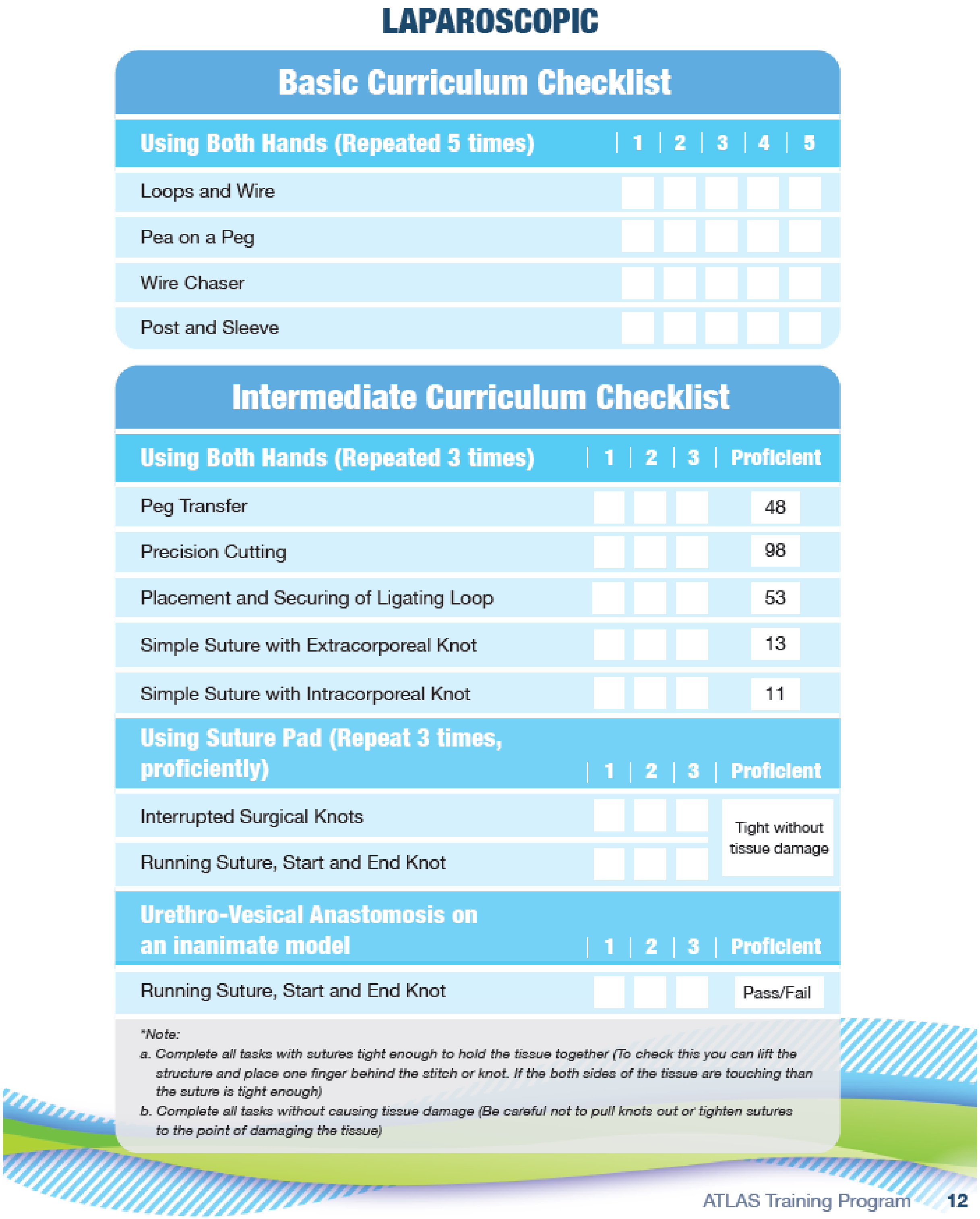
ATLAS Training Program 10



SURGEON PREFERENCE SHEETS (Available for Observations)

Department	Case Type (Preference)
OBGYN	Robotic Assisted Vaginal Hysterectomy, TAH, BSO & Stagi
	Robotic Assisted Vaginal Hysterectomy, TAH, BSO & Stagi
	Robotic Assisted Vaginal Hysterectomy, TAH, BSO & Stagi
	Robotic Assisted Vaginal Hysterectomy, TAH,BSO & Stagi
THORACIC	Robotic Assisted Esophagogastrectomy I Thoracic
	Robotic Assisted Esophagogastrectomy wl EGD I Thoracic
	Robotic Assisted Heller myotomy with EGD
	Robotic Assisted 1-liatal Hernia Repair
	Robotic Assisted Lobectomy I Thoracic
	Robotic Assisted mediastinal mass/thymectomy
UROLOGY	Robotic Assisted Adrenalectomy
	Robotic Assisted Cystectomy (Female)
	Robotic Assisted Cystoprostatectomy/Cystectomy
	Robotic Assisted Radical Nephrectomy
	Robotic Assisted Nephroureterectomy
	Robotic Assisted Partial Nephrectomy
	Robotic Assisted Prostatectomy

ATLAS



LAPAROSCOPIC

Basic Curriculum Checklist

Using Both Hands (Repeated 5 times)	1	2	3	4	5
Loops and Wire	☐	☐	☐	☐	☐
Pea on a Peg	☐	☐	☐	☐	☐
Wire Chaser	☐	☐	☐	☐	☐
Post and Sleeve	☐	☐	☐	☐	☐

Intermediate Curriculum Checklist

Using Both Hands (Repeated 3 times)	1	2	3	Proficient
Peg Transfer	☐	☐	☐	48
Precision Cutting	☐	☐	☐	98
Placement and Securing of Ligating Loop	☐	☐	☐	53
Simple Suture with Extracorporeal Knot	☐	☐	☐	13
Simple Suture with Intracorporeal Knot	☐	☐	☐	11
Using Suture Pad (Repeat 3 times, proficiently)	**1**	**2**	**3**	**Proficient**
Interrupted Surgical Knots	☐	☐	☐	Tight without tissue damage
Running Suture, Start and End Knot	☐	☐	☐	
Urethro-Vesical Anastomosis on an inanimate model	**1**	**2**	**3**	**Proficient**
Running Suture, Start and End Knot	☐	☐	☐	Pass/Fail

**Note:*

a. Complete all tasks with sutures tight enough to hold the tissue together (To check this you can lift the structure and place one finger behind the stitch or knot. If the both sides of the tissue are touching than the suture is tight enough)

b. Complete all tasks without causing tissue damage (Be careful not to pull knots out or tighten sutures to the point of damaging the tissue)

ATLAS Training Program 12

ROBOT-ASSISTED

RoSS® Curriculum Checklist

Orientation	**Levels**	**1**	**2**	**3**	**4**
Instrument Control		☐	☐	☐	☐
Camera Control		☐	☐	☐	☐
Coordinated Tool Control		☐	☐	☐	☐
4th Arm Control		☐	☐	☐	☐
Motor Skills		**1**	**2**	**3**	**4**
Ball Drop		☐	☐	☐	☐
Ball Placement		☐	☐	☐	☐
Spatial Control I		☐	☐	☐	☐
Spatial Control II		☐	☐	☐	☐
Basic Surgical Skills		**1**	**2**	**3**	**4**
Needle Handling and Exchange		☐	☐	☐	☐
Needle Remove		☐	☐	☐	☐
Basic Electrocautery		☐	☐	☐	☐
Tissue Cutting		☐	☐	☐	☐
Intermediate Surgical Skills		**1**	**2**	**3**	**4**
4th Arm Tissue Retraction		☐	☐	☐	☐
Blunt Tissue Dissection		☐	☐	☐	☐
Vessel Dissection		☐	☐	☐	☐

ATLAS Training Program 13

ROBOT-ASSISTED

RoSS® HoST Checklist

Prostatectomy

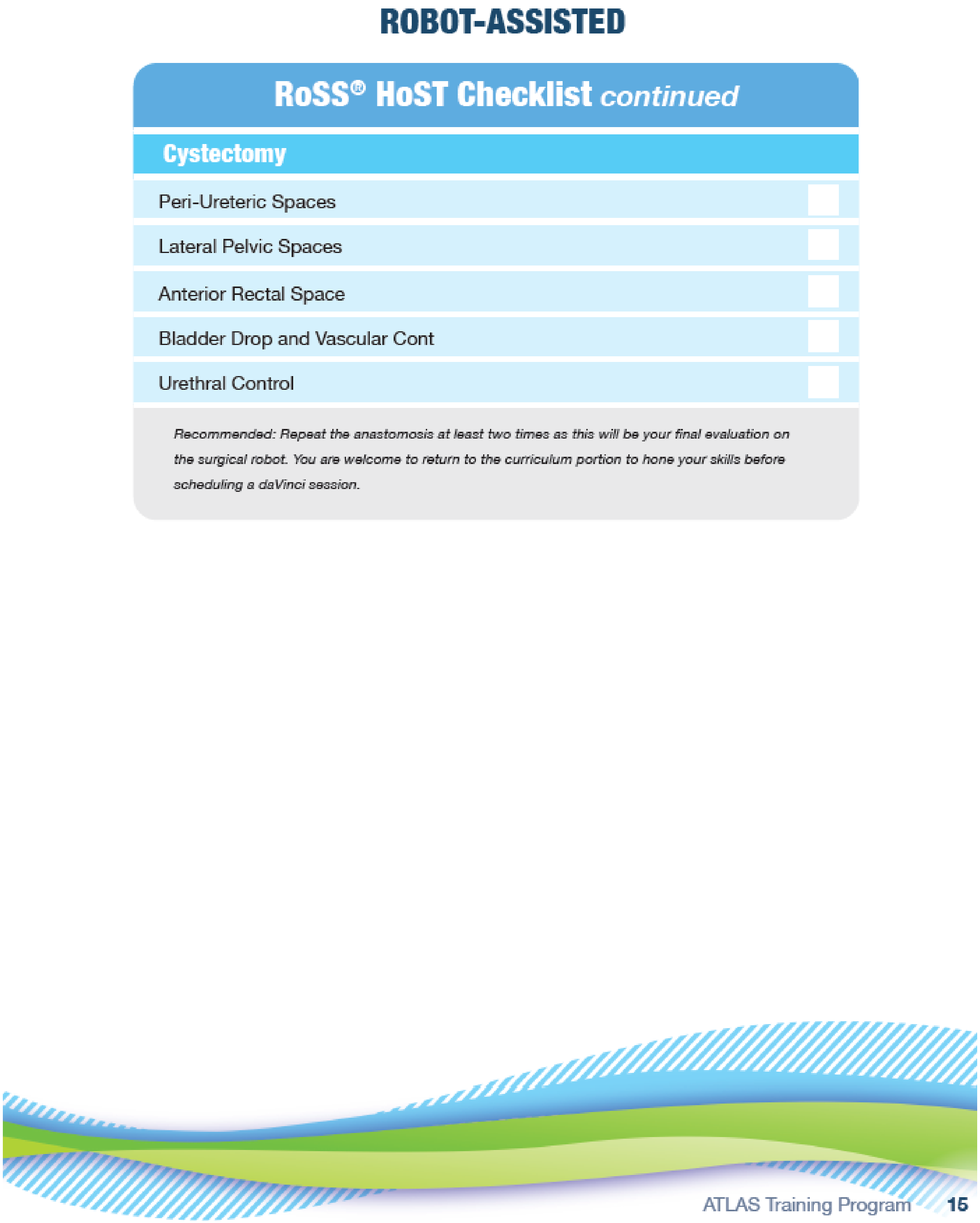
- Bladder Drop ☐
- Apical Space ☐
- Bladder Neck ☐
- BV Dissection ☐
- Veil ☐
- DVC Incision ☐
- DVC Suture ☐
- Anastomosis ☐

Hysterectomy

- Dissection of Vascular Pedical A ☐
- Dissection of Vascular Pedical B ☐
- Bladder Flap A ☐
- Colpotomy A ☐
- Colpotomy B ☐
- Vaginal Reconstruction A ☐
- Vaginal Reconstruction B ☐

Continued on next page →

ATLAS Training Program **14**



ROBOT-ASSISTED

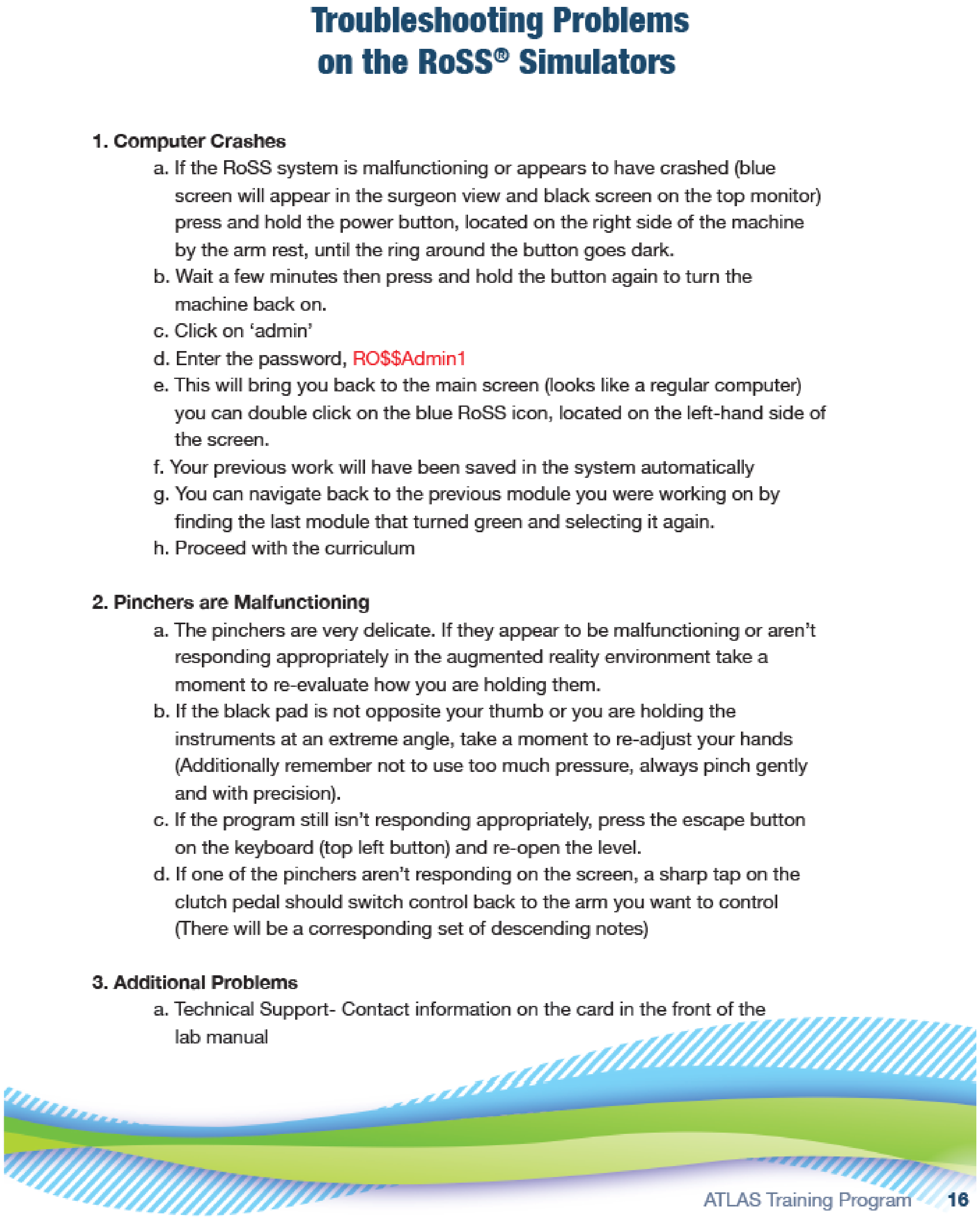
RoSS® HoST Checklist *continued*

Cystectomy

- Peri-Ureteric Spaces ☐
- Lateral Pelvic Spaces ☐
- Anterior Rectal Space ☐
- Bladder Drop and Vascular Cont ☐
- Urethral Control ☐

Recommended: Repeat the anastomosis at least two times as this will be your final evaluation on the surgical robot. You are welcome to return to the curriculum portion to hone your skills before scheduling a daVinci session.

ATLAS Training Program **15**



Troubleshooting Problems on the RoSS® Simulators

1. Computer Crashes

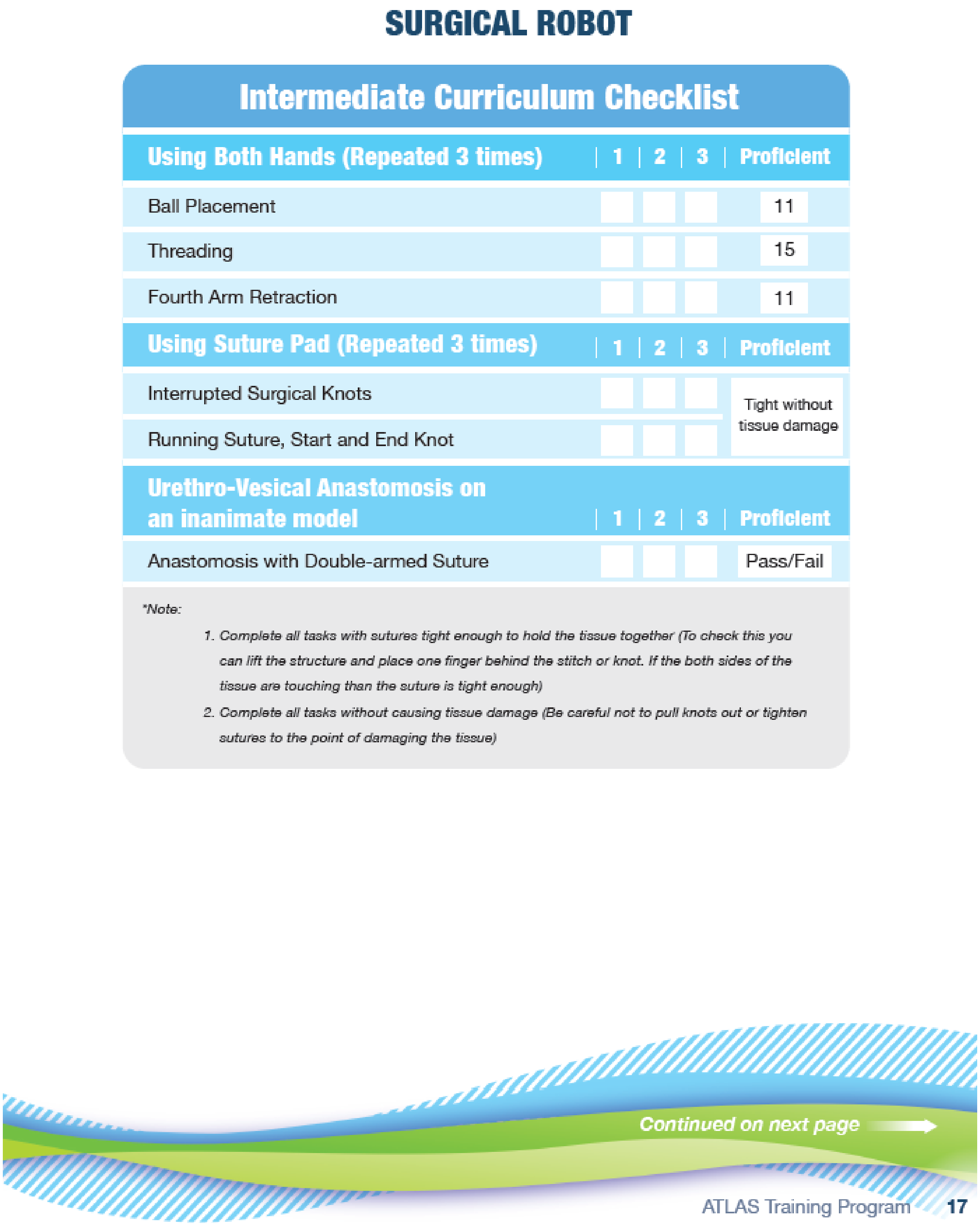
- a. If the RoSS system is malfunctioning or appears to have crashed (blue screen will appear in the surgeon view and black screen on the top monitor) press and hold the power button, located on the right side of the machine by the arm rest, until the ring around the button goes dark.
- b. Wait a few minutes then press and hold the button again to turn the machine back on.
- c. Click on ‘admin’
- d. Enter the password, RO$$Admin1
- e. This will bring you back to the main screen (looks like a regular computer) you can double click on the blue RoSS icon, located on the left-hand side of the screen.
- f. Your previous work will have been saved in the system automatically
- g. You can navigate back to the previous module you were working on by finding the last module that turned green and selecting it again.
- h. Proceed with the curriculum

2. Pinchers are Malfunctioning

- a. The pinchers are very delicate. If they appear to be malfunctioning or aren’t responding appropriately in the augmented reality environment take a moment to re-evaluate how you are holding them.
- b. If the black pad is not opposite your thumb or you are holding the instruments at an extreme angle, take a moment to re-adjust your hands (Additionally remember not to use too much pressure, always pinch gently and with precision).
- c. If the program still isn’t responding appropriately, press the escape button on the keyboard (top left button) and re-open the level.
- d. If one of the pinchers aren’t responding on the screen, a sharp tap on the clutch pedal should switch control back to the arm you want to control (There will be a corresponding set of descending notes)

3. Additional Problems

- a. Technical Support- Contact information on the card in the front of the lab manual



SURGICAL ROBOT

Intermediate Curriculum Checklist

Using Both Hands (Repeated 3 times)	**1**	**2**	**3**	**Proficient**
Ball Placement	☐	☐	☐	11
Threading	☐	☐	☐	15
Fourth Arm Retraction	☐	☐	☐	11
Using Suture Pad (Repeated 3 times)	**1**	**2**	**3**	**Proficient**
Interrupted Surgical Knots	☐	☐	☐	Tight without tissue damage
Running Suture, Start and End Knot	☐	☐	☐	
Urethro-Vesical Anastomosis on an inanimate model	**1**	**2**	**3**	**Proficient**
Anastomosis with Double-armed Suture	☐	☐	☐	Pass/Fail

**Note:*

1. *Complete all tasks with sutures tight enough to hold the tissue together (To check this you can lift the structure and place one finger behind the stitch or knot. If the both sides of the tissue are touching than the suture is tight enough)*
2. *Complete all tasks without causing tissue damage (Be careful not to pull knots out or tighten sutures to the point of damaging the tissue)*

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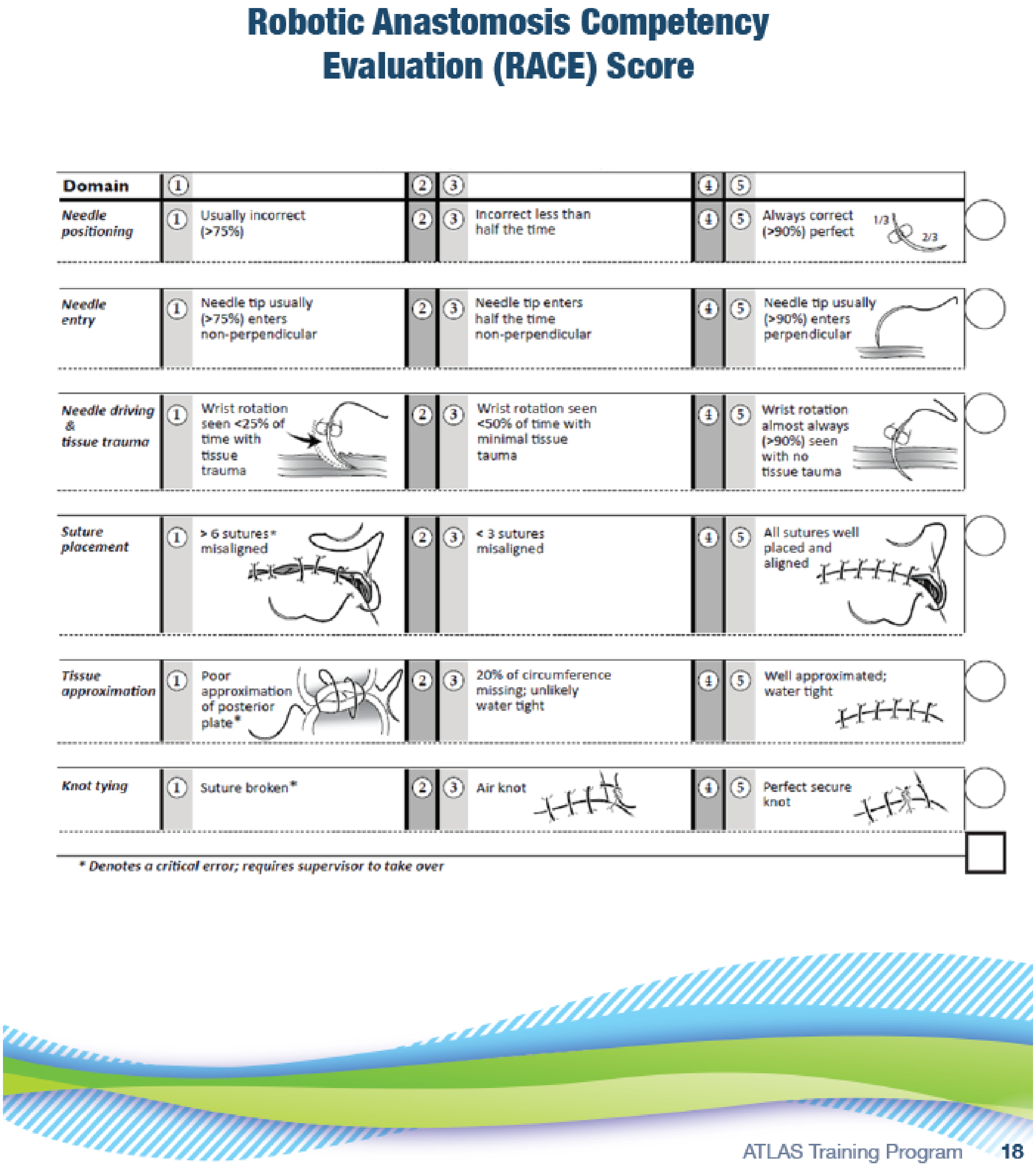
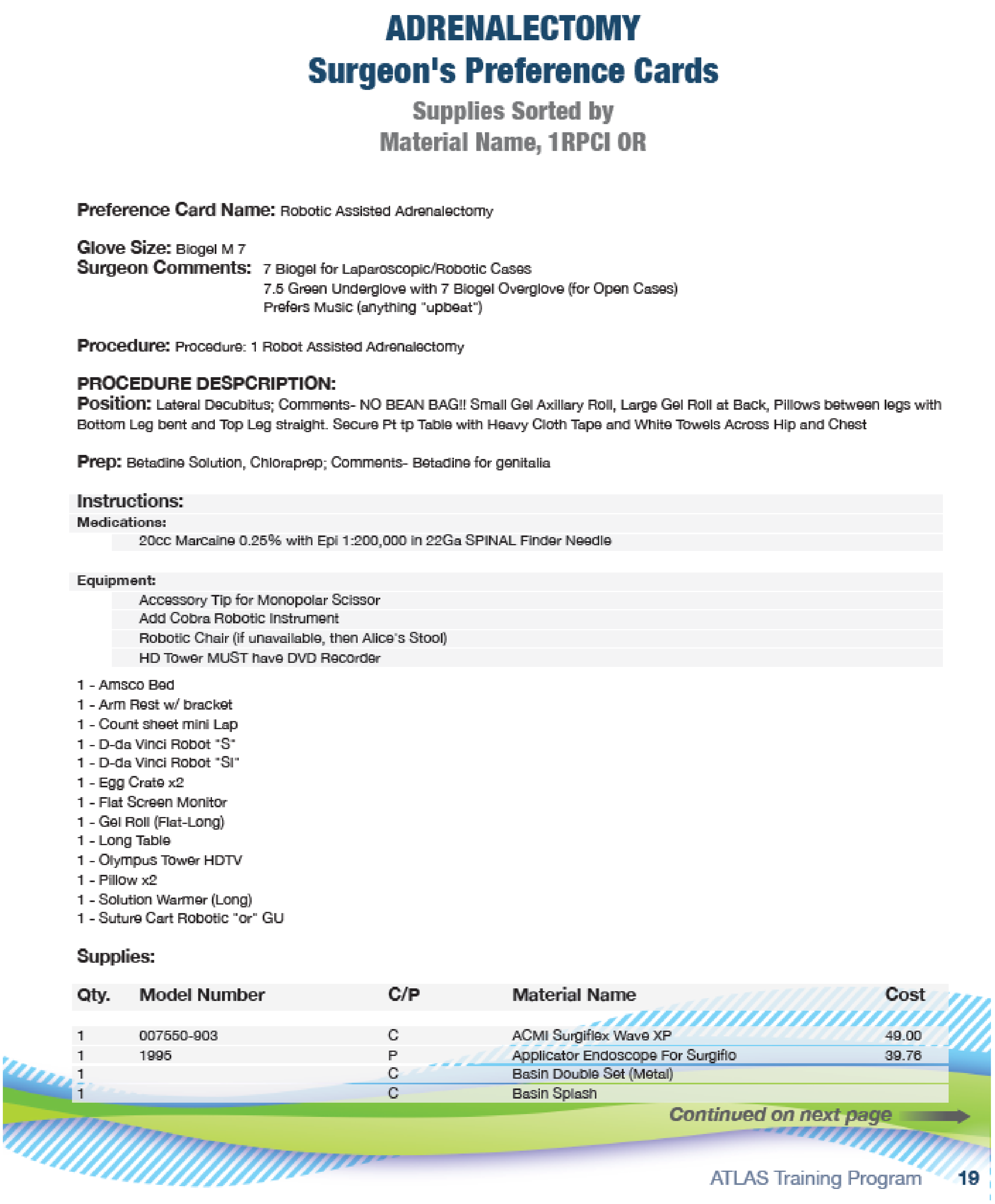


Robotic Anastomosis Competency Evaluation (RACE) Score

Domain	①		②	③		④	⑤		
Needle positioning	①	Usually incorrect (>75%)	②	③	Incorrect less than half the time	④	⑤	Always correct (>90%) perfect	○
Needle entry	①	Needle tip usually (>75%) enters non-perpendicular	②	③	Needle tip enters half the time non-perpendicular	④	⑤	Needle tip usually (>90%) enters perpendicular	○
Needle driving & tissue trauma	①	Wrist rotation seen <25% of time with tissue trauma	②	③	Wrist rotation seen <50% of time with minimal tissue tauma	④	⑤	Wrist rotation almost always (>90%) seen with no tissue tauma	○
Suture placement	①	> 6 sutures* misaligned	②	③	< 3 sutures misaligned	④	⑤	All sutures well placed and aligned	○
Tissue approximation	①	Poor approximation of posterior plate*	②	③	20% of circumference missing; unlikely water tight	④	⑤	Well approximated; water tight	○
Knot tying	①	Suture broken*	②	③	Air knot	④	⑤	Perfect secure knot	○
									☐

** Denotes a critical error; requires supervisor to take over*



ADRENALECTOMY
Surgeon's Preference Cards
Supplies Sorted by
Material Name, 1RPCI OR

Preference Card Name: Robotic Assisted Adrenalectomy

Glove Size: Biogel M 7
Surgeon Comments: 7 Biogel for Laparoscopic/Robotic Cases
7.5 Green Underglove with 7 Biogel Overglove (for Open Cases)
Prefers Music (anything "upbeat")

Procedure: Procedure: 1 Robot Assisted Adrenalectomy

PROCEDURE DESPCRIPTION:
Position: Lateral Decubitus; Comments- NO BEAN BAG!! Small Gel Axillary Roll, Large Gel Roll at Back, Pillows between legs with Bottom Leg bent and Top Leg straight. Secure Pt tp Table with Heavy Cloth Tape and White Towels Across Hip and Chest

Prep: Betadine Solution, Chloraprep; Comments- Betadine for genitalia

Instructions:

Medications:
- 20cc Marcaine 0.25% with Epi 1:200,000 in 22Ga SPINAL Finder Needle

Equipment:
- Accessory Tip for Monopolar Scissor
- Add Cobra Robotic Instrument
- Robotic Chair (if unavailable, then Alice's Stool)
- HD Tower MUST have DVD Recorder

1 - Amsco Bed
1 - Arm Rest w/ bracket
1 - Count sheet mini Lap
1 - D-da Vinci Robot "S"
1 - D-da Vinci Robot "SI"
1 - Egg Crate x2
1 - Flat Screen Monitor
1 - Gel Roll (Flat-Long)
1 - Long Table
1 - Olympus Tower HDTV
1 - Pillow x2
1 - Solution Warmer (Long)
1 - Suture Cart Robotic "or" GU

Supplies:

Qty.	Model Number	C/P	Material Name	Cost
1	007550-903	C	ACMI Surgiflex Wave XP	49.00
1	1995	P	Applicator Endoscope For Surgiflo	39.76
1		C	Basin Double Set (Metal)	
1		C	Basin Splash	

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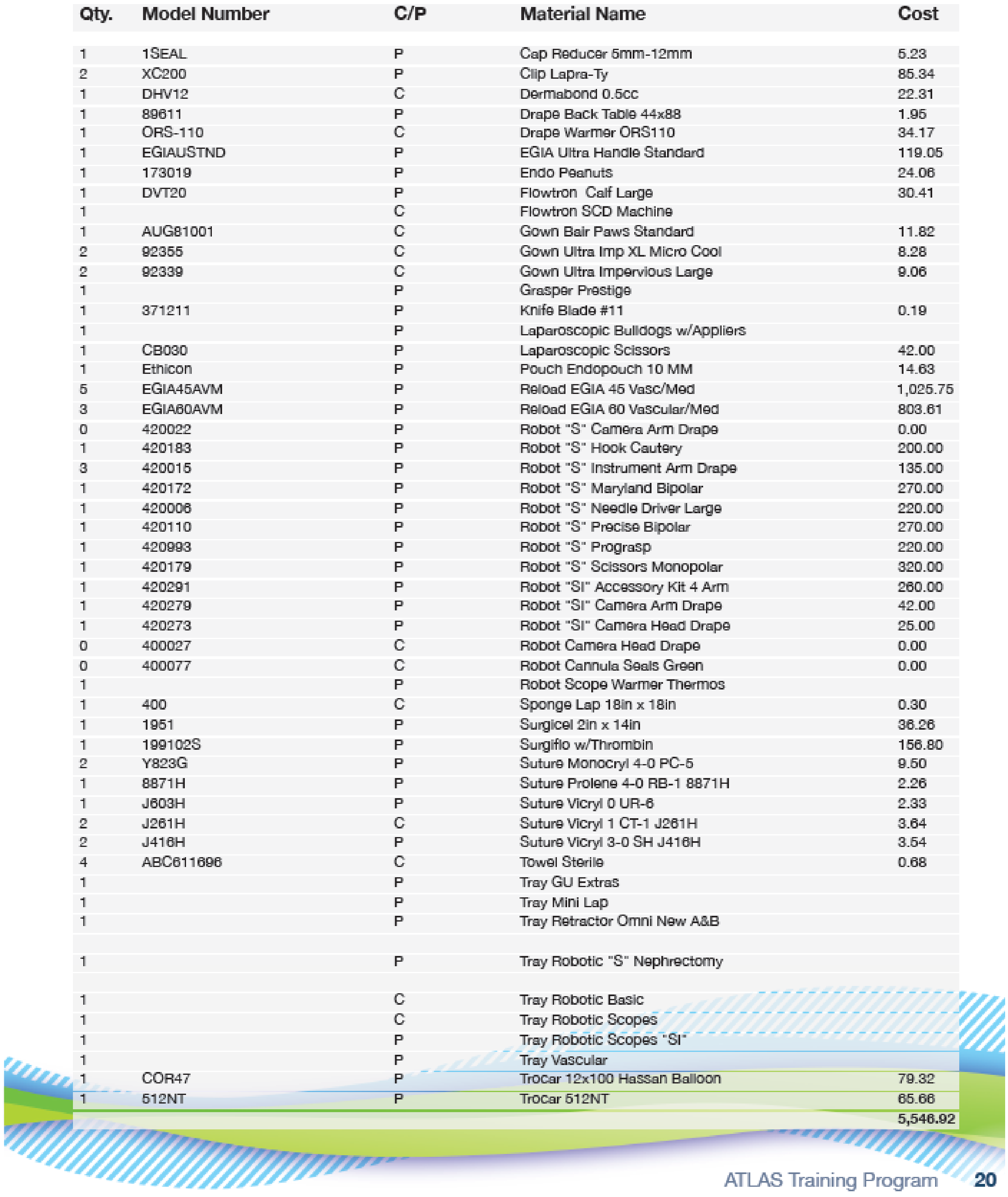

Qty.	Model Number	C/P	Material Name	Cost
1	1SEAL	P	Cap Reducer 5mm-12mm	5.23
2	XC200	P	Clip Lapra-Ty	85.34
1	DHV12	C	Dermabond 0.5cc	22.31
1	89611	P	Drape Back Table 44x88	1.95
1	ORS-110	C	Drape Warmer ORS110	34.17
1	EGIAUSTND	P	EGIA Ultra Handle Standard	119.05
1	173019	P	Endo Peanuts	24.06
1	DVT20	P	Flowtron Calf Large	30.41
1		C	Flowtron SCD Machine	
1	AUG81001	C	Gown Bair Paws Standard	11.82
2	92355	C	Gown Ultra Imp XL Micro Cool	8.28
2	92339	C	Gown Ultra Impervious Large	9.06
1		P	Grasper Prestige	
1	371211	P	Knife Blade #11	0.19
1		P	Laparoscopic Bulldogs w/Appliers	
1	CB030	P	Laparoscopic Scissors	42.00
1	Ethicon	P	Pouch Endopouch 10 MM	14.63
5	EGIA45AVM	P	Reload EGIA 45 Vasc/Med	1,025.75
3	EGIA60AVM	P	Reload EGIA 60 Vascular/Med	803.61
0	420022	P	Robot "S" Camera Arm Drape	0.00
1	420183	P	Robot "S" Hook Cautery	200.00
3	420015	P	Robot "S" Instrument Arm Drape	135.00
1	420172	P	Robot "S" Maryland Bipolar	270.00
1	420006	P	Robot "S" Needle Driver Large	220.00
1	420110	P	Robot "S" Precise Bipolar	270.00
1	420993	P	Robot "S" Prograsp	220.00
1	420179	P	Robot "S" Scissors Monopolar	320.00
1	420291	P	Robot "SI" Accessory Kit 4 Arm	260.00
1	420279	P	Robot "SI" Camera Arm Drape	42.00
1	420273	P	Robot "SI" Camera Head Drape	25.00
0	400027	C	Robot Camera Head Drape	0.00
0	400077	C	Robot Cannula Seals Green	0.00
1		P	Robot Scope Warmer Thermos	
1	400	C	Sponge Lap 18in x 18in	0.30
1	1951	P	Surgicel 2in x 14in	36.26
1	199102S	P	Surgiflo w/Thrombin	156.80
2	Y823G	P	Suture Monocryl 4-0 PC-5	9.50
1	8871H	P	Suture Prolene 4-0 RB-1 8871H	2.26
1	J603H	P	Suture Vicryl 0 UR-6	2.33
2	J261H	C	Suture Vicryl 1 CT-1 J261H	3.64
2	J416H	P	Suture Vicryl 3-0 SH J416H	3.54
4	ABC611696	C	Towel Sterile	0.68
1		P	Tray GU Extras	
1		P	Tray Mini Lap	
1		P	Tray Retractor Omni New A&B	
1		P	Tray Robotic "S" Nephrectomy	
1		C	Tray Robotic Basic	
1		C	Tray Robotic Scopes	
1		P	Tray Robotic Scopes "SI"	
1		P	Tray Vascular	
1	COR47	P	Trocar 12x100 Hassan Balloon	79.32
1	512NT	P	Trocar 512NT	65.66
				5,546.92

CYSTOPROSTATECTOMY
Surgeon's Preference Cards

Supplies Sorted by
Material Name, 1RPCI OR

Preference Card Name: Robotic Assisted Cystoprostatectomy/Cystectomy

Glove Size: Biogel Opti-Fit 8
Surgeon Comments: Extra large gown
Procedure 1: Robotic Assisted Cystectomy
Procedure 2: Robotic Assisted Cystoprostatectomy

PROCEDURE DESPCRIPTION:
Procedure card created for Combined Robotic/Open procedure where prostate is done by Robot and opened to do cystectomy and Ileo-conduit
Position: Aid- Egg Crate, Position- Lithotomy ,Position- Yellow-Fin Strrups ; Comments- Yellow Fin Stirrups. Have enough length on draw sheet to tuck arms at side. Lay patient's arms along sides, place padded arm through to protect arms and tuck arms next to the side snuggly. Place Kerlix in patient's two gel strips, place Criss Cross over patient's chest and tape with 4" tape. Finish by criss-crossign two narrow black safety belts over the gel pads. Anesthesia will then place patient in Trendelenburg and determine that patient is secure in position.

Prep: Chloraprep; Comments- Female patients- Please use Betadine Solution for vaginal prep.

Drapes: U-Bar III; Comments- Have drape for lower body when patient is placed supine. Under buttock drape for female patients

Instructions:

Medications:
- 0.25% Marcaine with Epi 20cc for end of procedure
- Mineral Oil for stents

Equipment:
- Headlight and Xenon Light Source for outside room
- Please have a long Russian Forceps available & open on table

Special Instructions:
- MAKE SURE CANNULA MOUNT IS ETH
- BERCHTOLD TABLE MANDATORY
- Bovie Settings: 70/50/50
- Complete Robotic Cystectomy Timesheet
- Keep Plastic ruler from marker for bowel measurement/open 2nd urimeter for urostomy bag
- M/L endoclips, Endoretractor, and 10mm JP drain
- Open 10mm Endopouch for retrieval of lymph nodes; label one left and the other right
- Please have 5ml Evicel, Flexible tip 45cm (3909) & Evicel Pump in Room, Dr. Guru will usually use this after Lymph Node dissection
- Please have mini laps & 3x6 cottonoids on table
- OPEN SUTURE CUT NEEDLE DRIVER & CADIERE & 18 FOLEY SILICONE CATHETER TO IRRIGATE BOWEL

Female Patients:
- Under buttocks drape
- Uterine Malpulator- Apple- GYN cart
- Vaginal packing with x-ray detectable strip
- **Sutures:** Intracorporeal Ileoconduit sutures
- ALL SUTURECUT 5" except for anastomosis suture (4")

Continued on next page

1 Silk tie full length on a Keith needle
0 Silk CT-1 (7")
4-0 Vicryl RB-1 (J304H) dyed anastomotic stitch
4-0 Vicryl SH-1 (J218H) undyed XL anastomotic stitch
3-0 Chromic to secure stent
3-0 V-LOC CV-23 for DVC
3-0 Silk SH to approximate bowel edges
0 Silk CT-1 to close mesentery defect
2-0 Vicryl SH stoma creation
1 Vicryl CT-1 closure
3-0 Vicryl SH fprp subcutaneous closure
#1 PDS Looped for closure
Vicryl 4-0 FS-2 Skin closure
Ethilon 3-0 cutter for drain

Trocars:

(2) 10/12 mm Ethicon 512NT
(1) 5mm Trocar XCEL
(1) 15mm Trocar XCEL

Staplers:

ENDO GIA UNIVERSAL ROTICULATOR 45-2.5 have 6-8 refills, 60 blue X 6 available

Neobladder:

3-0 PDS-RB-1
4-0 PDS-RB-1
2-0 Silk- SH
Free up bladder with staples (NVB)
Pull out trocar, open abdomen, 60 purple staples, undock robot, use plastic yankauer suction tip as guide to open loop of bowel for bladder. Sew neobladder and redock to sew anastomosis. Suprapbic tube- Silicone 20 Fr. Foley.
1 da Vinci Robot

Equipment:

1 Berchtold bed
1 D-da Vinci Robot "S"
1 D-da Vinci Robot "SI"
1 Extra Skin Graft Table X2
1 Long Table
1 Narrow long thin blue gel pads X2
1 Pink gel armpads X2
1 Yellow Fin Stirrups w/brackets

Supplies:

Qty.	Model Number	C/P	Material Name	Cost
1	007550-903	P	ACMI Surgiflex Wave XP	49.00
1	50021	C	Adapter Ureteral Catheter	3.58
1	861100	P	Bag Urine Collection w/ Valve (Latex)	4.06
1		C	Basin Douible Set (metal)	
1		C	Basin Splash	
1	2550H24	C	Catheter Hematuria 24 Fr x 30cc	22.95
1	260725	C	Chloraprep 26cc w/Tint	3.92
2	544240	C	Clip Hemolok Large	34.28
1	544230	C	Clip Hemolok M/L	55.00

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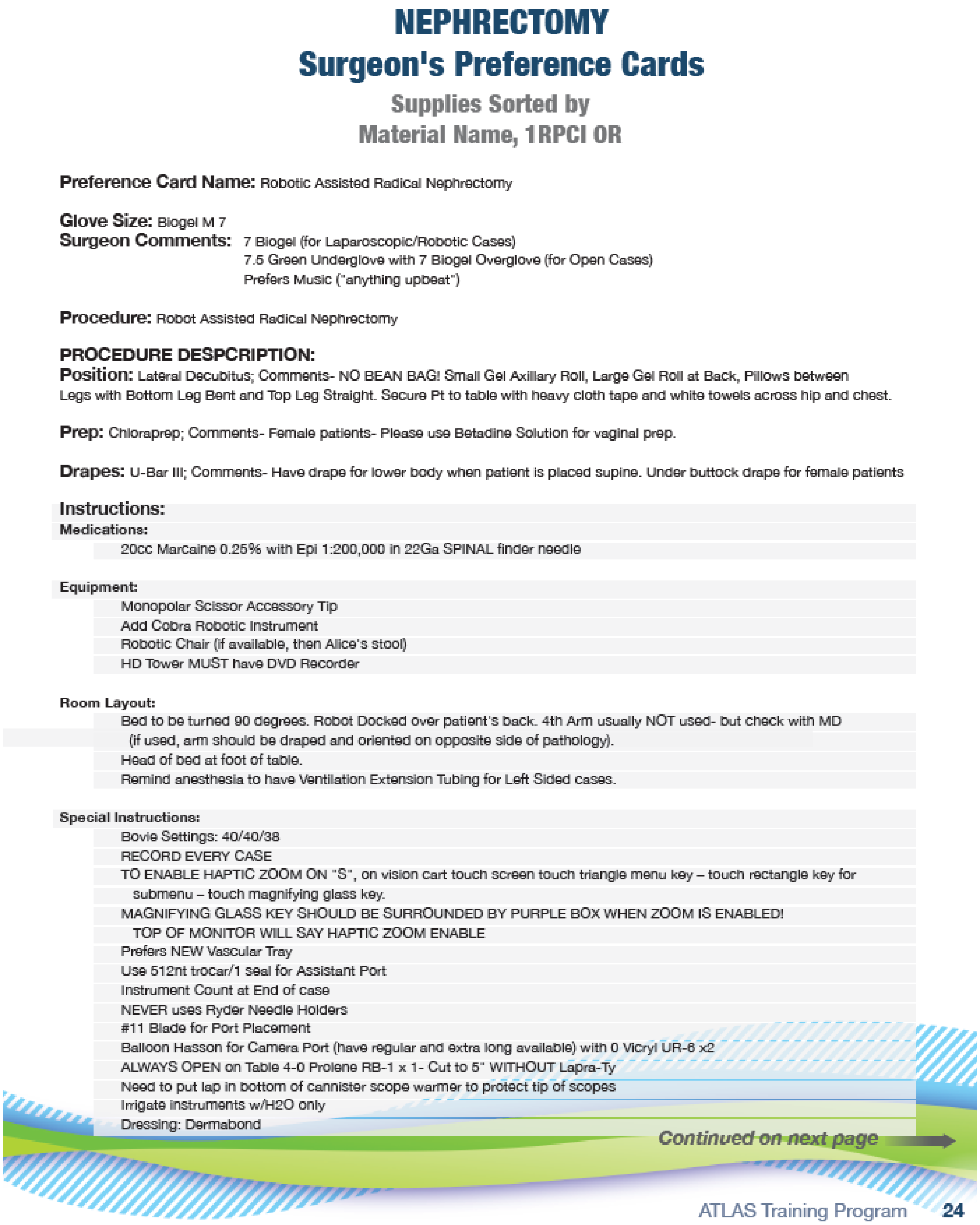
Qty.	Model Number	C/P	Material Name	Cost
1	420006	P	Robot "S" Needle Driver Large	220.00
1	420110	P	Robot "S" Precise Bipolar	270.00
1	420993	P	Robot "S" Prograsp	220.00
1	420179	P	Robot "S" Scissors Monopolar	320.00
1	420291	P	Robot "SI" Accessory Kit 4 Arm	260.00
1	420279	P	Robot "SI" Camera Arm Drape	42.00
1	420273	P	Robot "SI" Camera Head Drape	25.00
0	400027	C	Robot Camera Head Drape	0.00
0	400077	C	Robot Cannula Seals Green	0.00
1		P	Robot Scope Warmer Thermos	
1	400180-05	P	Robot Tip Cover Accessory	20.00
1	MLI-CDS981362	C	Robotic Procedure Pack	875.21
1	2B0304	C	Solution IV Water 1000cc	1.02
2	2F7114	C	Solution Water Bottle 1000	1.78
1	400	C	Sponge Lap 18in x 18in	0.30
1	1951	P	Surgicel 2in x 14in	38.26
1	199102S	P	Surgiflo w/Thrombin	156.80
2	Y823G	P	Suture Monocryl 4-0 PC-5	9.50
1	8871H	P	Suture Prolene 4-0 RB-1 8871H	2.26
1	J603H	P	Suture Vicryl 0 UR-6	2.33
2	J261H	C	Suture Vicryl 1 CT-1 J261H	3.64
2	J416H	P	Suture Vicryl 3-0 SH J416H	3.54
4	ABC611696	C	Towel Sterile	0.68
1		P	Tray GU Extras	
1		P	Tray Mini Lap	
1		P	Tray Retractor Omni New A&B	
1		P	Tray Robotic "S" Nephrectomy	
1		C	Tray Robotic Basic	
1		C	Tray Robotic Scopes	
1		P	Tray Robotic Scopes "SI"	
1		P	Tray Vascular	
1	COR47	P	Trocar 12x100 Hassan Balloon	79.32
1	512NT	P	Trocar 512NT	65.66
				5,546.92



NEPHRECTOMY
Surgeon's Preference Cards
Supplies Sorted by
Material Name, 1RPCI OR

Preference Card Name: Robotic Assisted Radical Nephrectomy

Glove Size: Biogel M 7
Surgeon Comments: 7 Biogel (for Laparoscopic/Robotic Cases)
7.5 Green Underglove with 7 Biogel Overglove (for Open Cases)
Prefers Music ("anything upbeat")

Procedure: Robot Assisted Radical Nephrectomy

PROCEDURE DESPCRIPTION:
Position: Lateral Decubitus; Comments- NO BEAN BAG! Small Gel Axillary Roll, Large Gel Roll at Back, Pillows between Legs with Bottom Leg Bent and Top Leg Straight. Secure Pt to table with heavy cloth tape and white towels across hip and chest.

Prep: Chloraprep; Comments- Female patients- Please use Betadine Solution for vaginal prep.

Drapes: U-Bar III; Comments- Have drape for lower body when patient is placed supine. Under buttock drape for female patients

Instructions:

Medications:
- 20cc Marcaine 0.25% with Epi 1:200,000 in 22Ga SPINAL finder needle

Equipment:
- Monopolar Scissor Accessory Tip
- Add Cobra Robotic Instrument
- Robotic Chair (if available, then Alice's stool)
- HD Tower MUST have DVD Recorder

Room Layout:
- Bed to be turned 90 degrees. Robot Docked over patient's back. 4th Arm usually NOT used- but check with MD (if used, arm should be draped and oriented on opposite side of pathology).
- Head of bed at foot of table.
- Remind anesthesia to have Ventilation Extension Tubing for Left Sided cases.

Special Instructions:
- Bovie Settings: 40/40/38
- RECORD EVERY CASE
- TO ENABLE HAPTIC ZOOM ON "S", on vision cart touch screen touch triangle menu key – touch rectangle key for submenu – touch magnifying glass key.
- MAGNIFYING GLASS KEY SHOULD BE SURROUNDED BY PURPLE BOX WHEN ZOOM IS ENABLED! TOP OF MONITOR WILL SAY HAPTIC ZOOM ENABLE
- Prefers NEW Vascular Tray
- Use 512nt trocar/1 seal for Assistant Port
- Instrument Count at End of case
- NEVER uses Ryder Needle Holders
- #11 Blade for Port Placement
- Balloon Hasson for Camera Port (have regular and extra long available) with 0 Vicryl UR-6 x2
- ALWAYS OPEN on Table 4-0 Prolene RB-1 x 1- Cut to 5" WITHOUT Lapra-Ty
- Need to put lap in bottom of cannister scope warmer to protect tip of scopes
- Irrigate instruments w/H2O only
- Dressing: Dermabond

Continued on next page

ATLAS Training Program 24

- 1 Amsco Bed
- 1 Arm Rest w/Bracket
- 1 Count Sheet Mini Lap
- 1 D-da Vinci Robot "S"
- 1 D-da Vinci Robot "SI"
- 1 Egg Crate x2
- 1 Extra Skin Graft Table x2
- 1 Flat Screen Monitor
- 1 Gel Roll (Flat-Long)
- 1 Gel Roll (Half-Moon)
- 1 Long Table
- 1 Olympus Tower HDTV
- 1 Pillow x 2
- 1 Solution Warmer (Long)
- 1 Suture Cart Robotic "or" GU

Supplies:

Qty.	Model Number	C/P	Material Name	Cost
1	007550-903	C	ACMI Surgiflex Wave XP	49.00
1		C	Basin Double Set (Metal)	
1		C	Basin Splash	
1	1SEAL	P	Cap Reducer 5mm-12mm	5.23
1	XC200	P	Clip Lapra-Ty	42.67
1	DHV12	C	Dermabond 0.5cc	22.31
1	89611	P	Drape Back Table 44x88	1.95
1	ORS-110	C	Drape Warmer ORS110	34.17
1	EGIAUSTND	P	EGIA Ultra Handle Standard	119.05
1	ECATCH15	P	Endo Catch II 15mm (Pouch)	116.00
3	173019	P	Endo Peanuts	72.18
1	176657	P	Endoclip II Applier 10mm	88.28
1	DVT20	P	Flowtron Calf Large	30.41
1		C	Flowtron SCD Machine	
1	AUG81001	C	Gown Bair Paws Standard	11.82
1		P	Grasper Prestige	
1	371211	P	Knife Blade #11	0.19
1		P	Laparoscopic Bulldogs w/Appliers	
1	CB030	P	Laparoscopic Scissors	42.00
5	EGIA45AVM	P	Reload EGIA 45 Vasc/Med	1,025.75
3	EGIA60AVM	P	Reload EGIA 60 Vascular/Med	803.61
1	420256	P	Robot "S" Accessory Kit 3 Arm	174.00
1	420022	P	Robot "S" Camera Arm Drape	29.50
3	420015	P	Robot "S" Instrument Arm Drape	135.00
1	420172	P	Robot "S" Maryland Bipolar	270.00
1	420006	P	Robot "S" Needle Driver Large	220.00
1	420179	P	Robot "S" Scissors Monopolar	320.00
1	420291	P	Robot "SI" Accessory Kit 4 Arm	260.00
1	420279	P	Robot "SI" Camera Arm Drape	42.00
1	420273	P	Robot "SI" Camera Head Drape	25.00
1	400027	C	Robot Camera Head Drape	25.00
3	400077	C	Robot Cannula Seals Green	45.00
1		P	Robot Scope Warmer Thermos	
1	400180-05	P	Robot Tip Cover Accessory	20.00
1	MLI-CDS981362	C	Robotic Procedure Pack	875.21
1	2B0304	C	Solution IV Water 1000cc	1.02

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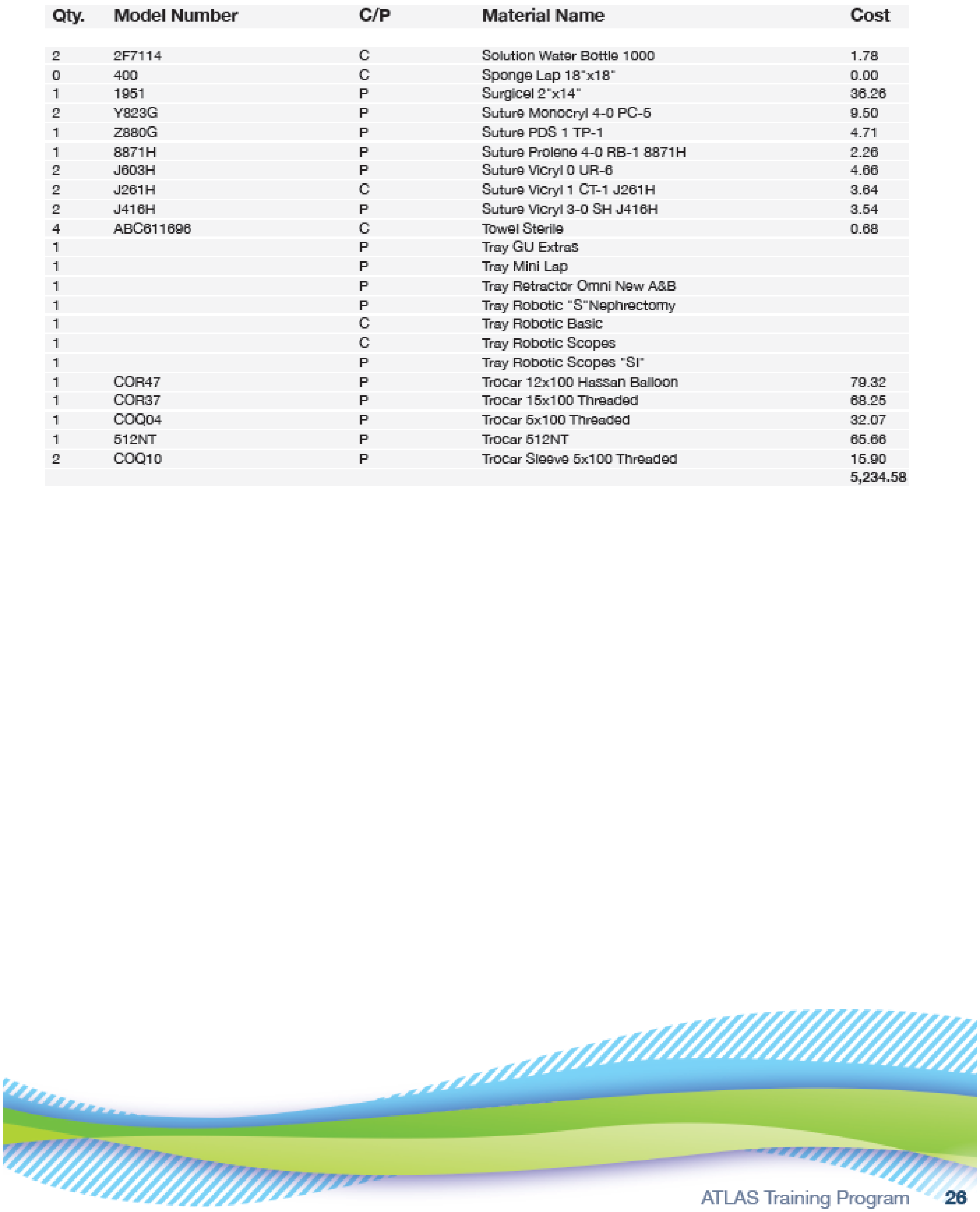

Qty.	Model Number	C/P	Material Name	Cost
2	2F7114	C	Solution Water Bottle 1000	1.78
0	400	C	Sponge Lap 18"x18"	0.00
1	1951	P	Surgicel 2"x14"	36.26
2	Y823G	P	Suture Monocryl 4-0 PC-5	9.50
1	Z880G	P	Suture PDS 1 TP-1	4.71
1	8871H	P	Suture Prolene 4-0 RB-1 8871H	2.26
2	J603H	P	Suture Vicryl 0 UR-6	4.66
2	J261H	C	Suture Vicryl 1 CT-1 J261H	3.64
2	J416H	P	Suture Vicryl 3-0 SH J416H	3.54
4	ABC611696	C	Towel Sterile	0.68
1		P	Tray GU Extras	
1		P	Tray Mini Lap	
1		P	Tray Retractor Omni New A&B	
1		P	Tray Robotic "S"Nephrectomy	
1		C	Tray Robotic Basic	
1		C	Tray Robotic Scopes	
1		P	Tray Robotic Scopes "SI"	
1	COR47	P	Trocar 12x100 Hassan Balloon	79.32
1	COR37	P	Trocar 15x100 Threaded	68.25
1	COQ04	P	Trocar 5x100 Threaded	32.07
1	512NT	P	Trocar 512NT	65.66
2	COQ10	P	Trocar Sleeve 5x100 Threaded	15.90
				5,234.58

PROSTATECTOMY
Surgeon's Preference Cards
Supplies Sorted by Material Name, 1RPCI OR

Preference Card Name: Robotic Assisted Prostatectomy

Glove Size: Biogel Opti-Fit 8
Surgeon Comments: Extra large gown
Procedure: 1 Robotic Assisted Prostatectomy

PROCEDURE DESPCRIPTION:
Position: Lithotomy, Position- Yellow Fin Stiffups Comments-Yellow Fin Stirrups, Trendelenbnerg. Have enough length on draw sheet to tuck arms at side. Lay patient's arms along sides, place pink pad along patient's sides to protect upper arms and tuck arms next to side snugggly. Place Kerlix in patient's hands. PLace gel pads Criss Cross over patient's chest and tape with 4" cloth tape. Finish by criss-corssing two narrow black safety belts over the gel pads. Anesthesia will then place patient in Trendelenberg after marking where the patient's shouldser are and will test to see that patient is seucre in that position.

Prep: Chloraprep

Drapes: U-Bar III; Comments-U Sheet placed at patient's head; uses sticky towels

Instructions:

Medications:

Marcaine 0.25% with Epi 20 cc for end of procedure

100 ml Sodium Chloride IV for hydrodissection

Special Instructions:

Make sure cannula Mount is ETH

Berchtold OR Table Mandatory

Complete robotic yellow time sheet

(1) lap in bottom of canister scope warmer to protect tip of scopes

Please give 3 V-Loc CV-23 suture. 1 for DVC and 2 for anastomosis

Vicryl 4-0 RB-1 used for bladder repair only

Posterior sling stitch 3-0 Vicryl SH cut to 7 inches

Dr. Guru uses all XCEL Ethicon Trocars on all Cases

Do Not Open Trocars in Robotic Pack

1-daVinci Robot

Supplies:

Qty.	Model Number	C/P	Material Name	Cost
1	007550-903	C/P	ACMI Surgiflex Wave XP	49.00
1		C	Basin Double Set (Metal)	
1		C	Basin Splash	
0	544240	P	Clip Hemolok Large	0.00
0	544230	P	Clip Hemolok M/L	0.00
0	544250	P	Clip Hemolok X-Large	0.00
1	DVT20	C	Flowtron Calf Large	30.41
1		C	Flowtron SCD Machcine	
2	92355	C	Gown Ultra Imp XL Micro Cool	8.28
2	92339	C	Gown Ultra Impervious Large	9.06

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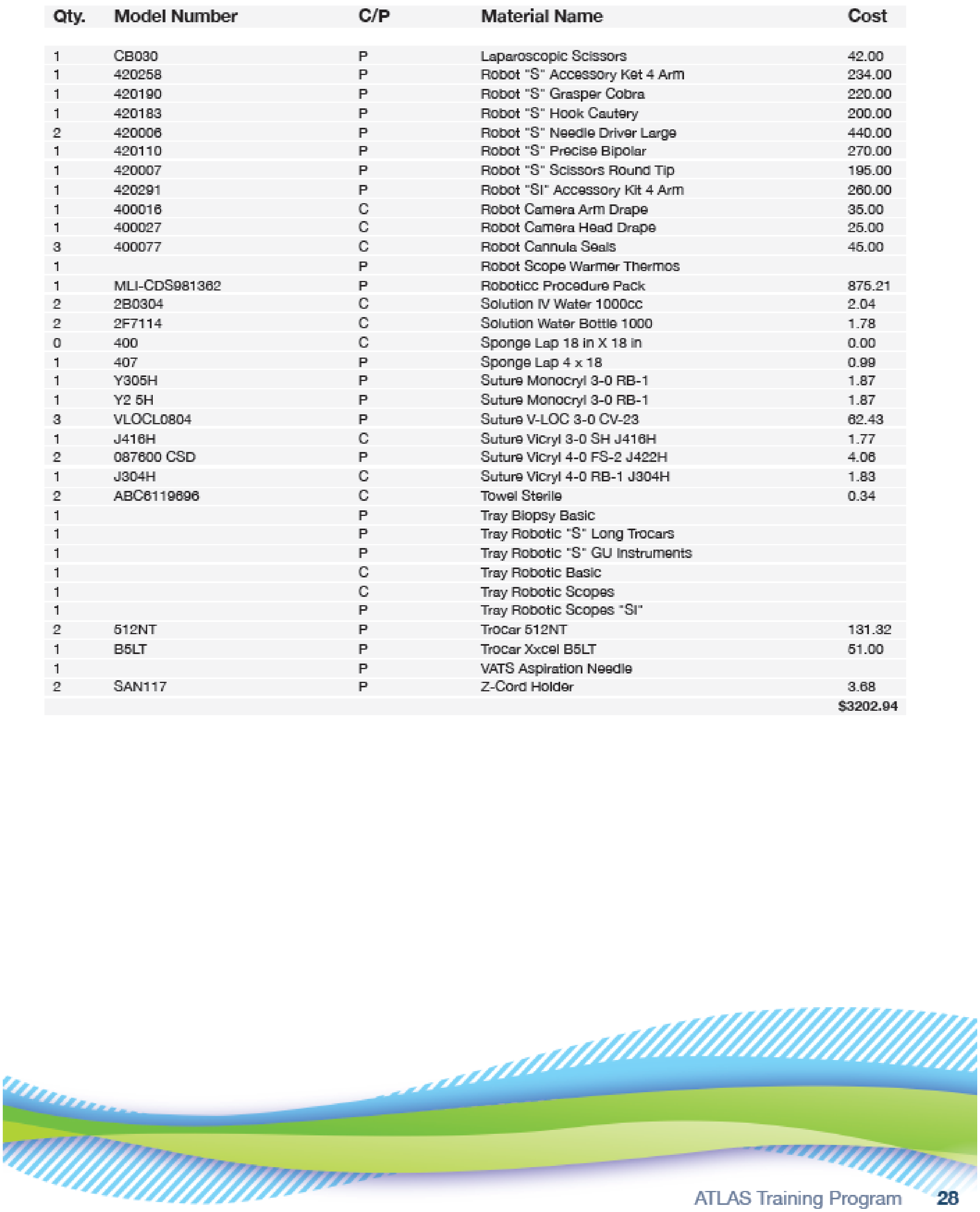
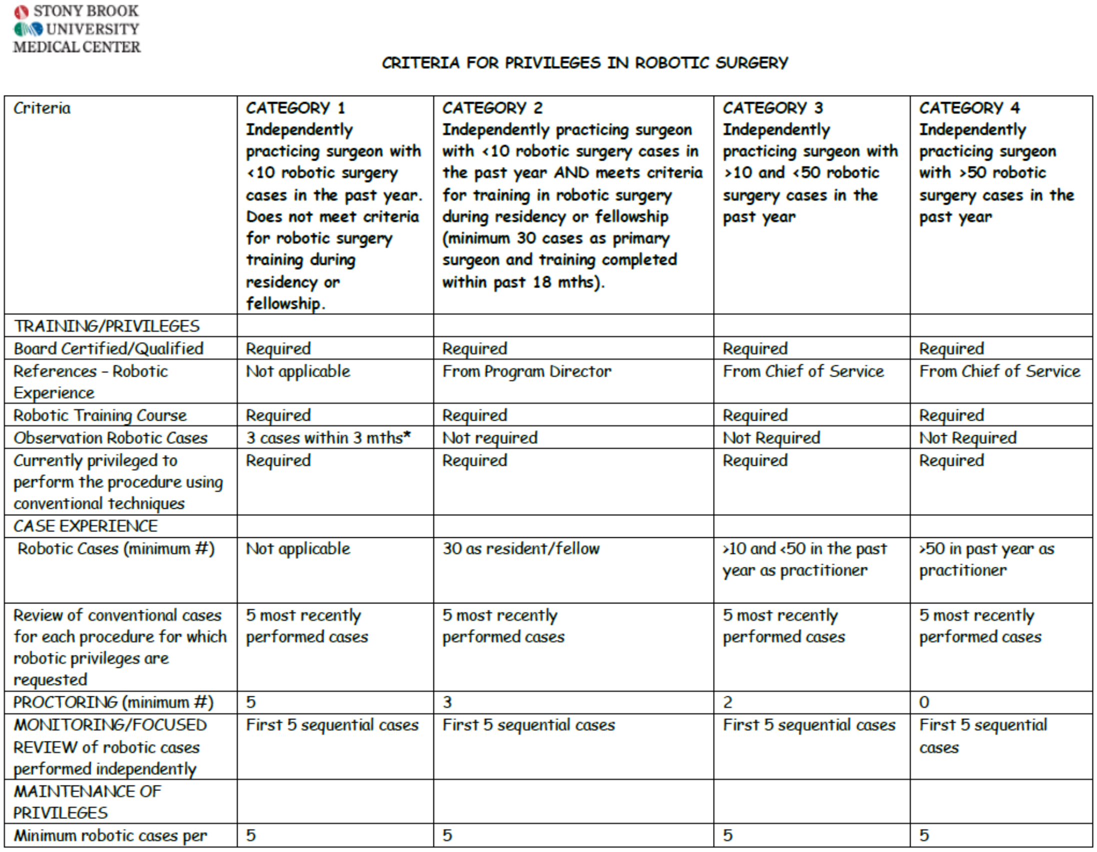


Qty.	Model Number	C/P	Material Name	Cost
1	CB030	P	Laparoscopic Scissors	42.00
1	420258	P	Robot "S" Accessory Ket 4 Arm	234.00
1	420190	P	Robot "S" Grasper Cobra	220.00
1	420183	P	Robot "S" Hook Cautery	200.00
2	420006	P	Robot "S" Needle Driver Large	440.00
1	420110	P	Robot "S" Precise Bipolar	270.00
1	420007	P	Robot "S" Scissors Round Tip	195.00
1	420291	P	Robot "SI" Accessory Kit 4 Arm	260.00
1	400016	C	Robot Camera Arm Drape	35.00
1	400027	C	Robot Camera Head Drape	25.00
3	400077	C	Robot Cannula Seals	45.00
1		P	Robot Scope Warmer Thermos	
1	MLI-CDS981362	P	Roboticc Procedure Pack	875.21
2	2B0304	C	Solution IV Water 1000cc	2.04
2	2F7114	C	Solution Water Bottle 1000	1.78
0	400	C	Sponge Lap 18 in X 18 in	0.00
1	407	P	Sponge Lap 4 x 18	0.99
1	Y305H	P	Suture Monocryl 3-0 RB-1	1.87
1	Y2 5H	P	Suture Monocryl 3-0 RB-1	1.87
3	VLOCL0804	P	Suture V-LOC 3-0 CV-23	62.43
1	J416H	C	Suture Vicryl 3-0 SH J416H	1.77
2	087600 CSD	P	Suture Vicryl 4-0 FS-2 J422H	4.06
1	J304H	C	Suture Vicryl 4-0 RB-1 J304H	1.83
2	ABC6119696	C	Towel Sterile	0.34
1		P	Tray Biopsy Basic	
1		P	Tray Robotic "S" Long Trocars	
1		P	Tray Robotic "S" GU Instruments	
1		C	Tray Robotic Basic	
1		C	Tray Robotic Scopes	
1		P	Tray Robotic Scopes "SI"	
2	512NT	P	Trocar 512NT	131.32
1	B5LT	P	Trocar Xxcel B5LT	51.00
1		P	VATS Aspiration Needle	
2	SAN117	P	Z-Cord Holder	3.68
				$3202.94

ATLAS Training Program 28

Appendix C – (Stony Brook University Medical Center, 2008)



STONY BROOK
UNIVERSITY
MEDICAL CENTER

CRITERIA FOR PRIVILEGES IN ROBOTIC SURGERY

Criteria	**CATEGORY 1** **Independently practicing surgeon with <10 robotic surgery cases in the past year. Does not meet criteria for robotic surgery training during residency or fellowship.**	**CATEGORY 2** **Independently practicing surgeon with <10 robotic surgery cases in the past year AND meets criteria for training in robotic surgery during residency or fellowship (minimum 30 cases as primary surgeon and training completed within past 18 mths).**	**CATEGORY 3** **Independently practicing surgeon with >10 and <50 robotic surgery cases in the past year**	**CATEGORY 4** **Independently practicing surgeon with >50 robotic surgery cases in the past year**
TRAINING/PRIVILEGES				
Board Certified/Qualified	Required	Required	Required	Required
References - Robotic Experience	Not applicable	From Program Director	From Chief of Service	From Chief of Service
Robotic Training Course	Required	Required	Required	Required
Observation Robotic Cases	3 cases within 3 mths*	Not required	Not Required	Not Required
Currently privileged to perform the procedure using conventional techniques	Required	Required	Required	Required
CASE EXPERIENCE				
Robotic Cases (minimum #)	Not applicable	30 as resident/fellow	>10 and <50 in the past year as practitioner	>50 in past year as practitioner
Review of conventional cases for each procedure for which robotic privileges are requested	5 most recently performed cases	5 most recently performed cases	5 most recently performed cases	5 most recently performed cases
PROCTORING (minimum #)	5	3	2	0
MONITORING/FOCUSED REVIEW of robotic cases performed independently	First 5 sequential cases	First 5 sequential cases	First 5 sequential cases	First 5 sequential cases
MAINTENANCE OF PRIVILEGES				
Minimum robotic cases per	5	5	5	5

year performed at SBUH				
Satisfactory QA Review	Required	Required	Required	Required

TRAINING/PRIVILEGES

- *Board Certified/Qualified*
- *Reference(s)-Robotic Experience:* Reference letter must include a statement that the applicant has performed the minimum number of robotic cases as defined above. It must also attest to the current clinical competence of the applicant with respect to robotic surgery
- *Robotic Training Course:* The course must be acceptable to the SBUH Director of Robotic Surgery (DRS)
- *Observation Robotic Cases:* practitioner must observe cases in the appropriate specialty. The observation can be done in any hospital that is acceptable to the DRS.
- *Currently privileged to perform the procedure using conventional techniques:* This applies to every procedure for which the applicant is requesting robotic privileges.

CASE EXPERIENCE

- *Robotic Cases:* In all reported cases, the applicant must have been the primary surgeon
- *Review of 5 most recent conventional cases for each procedure for which robotic privileges are requested:* Review will be conducted by SBUH departmental QA committee. Results to be indicated on Robotic Surgery Privilege Sheet.

PROCTORING

- The proctor must be a physician fully privileged in robotic surgery at SBUH and have satisfactorily completed the QA review of the first 5 consecutive-non proctored cases.
- If such a person is not on the SBUH medical staff in the specialty in question, an outside proctor may be obtained. The outside proctor must be approved by the DRS. Generally accepted standards must be followed in deciding whether a potential proctor is qualified to proctor in the specialty in question.
- At the completion of the required minimum cases, the proctor shall determine if the practitioner requires additional proctoring or may perform robotic surgery independently. The proctor will base the decision on the operative performance rating form (attached). The practitioner must score a 5 in every category in which he/she is evaluated.
- A decision to recommend robotic privileging is made by the proctor to the DRS who then makes a recommendation to the department credentials committee and then through the privilege review process delineated in the SBUH bylaws.

MONITORING/FOCUSED PRACTICE REVIEW

- The SBUH departmental quality assurance committee will conduct a retrospective review of the first consecutive 5 independently performed robotic surgery cases, regardless of outcome.
- The review of each case must be completed before the surgeon may perform the next case independently.
- The dept QA committee shall report any concerns to the DRS as soon as concerns arise.
- In any case, the dept QA committee must send a report to the Director of Robotics Surgery at the conclusion of the 5th case.
- In response to the input from the Departmental QA committee, the director may, at any point, may require further proctoring.

MAINTENANCE OF PRIVILEGES

- *Minimum robotic cases per year performed at SBUH:* This applies only to cases in which the practitioner was the primary surgeon
- *Satisfactory QA review:* Practitioners requesting renewal of privileges who have not met the above requirements or who have adverse procedure outcomes that appear out of proportion to their peers and/or out of proportion to generally accepted complication rates shall be referred to the appropriate Medical Staff QA committee and/or MEC.

ADDITIONAL INFORMATION

The requirements/processes delineated indicate the minimum standard. Each service that privileges in robotic surgery may establish more stringent criteria.

QUALITY ASSURANCE/ONGOING MONITORING. The process and outcome measures used by the existing departmental and hospital QA committees/systems will be used for robotic surgery.

CROSS SERVICES. It is anticipated that the departments of OB/GYN and Surgery will be using robotic surgery in the future.

EMERGENCY PRIVILEGES. In the event that the proctoring surgeon is not privileged in the specialty he is proctoring, he may temporarily take over as primary surgeon if ALL the following circumstances are met:

a. a complication occurs which can be potentially rectified without abandoning the robotic procedure.
b. the surgeon being proctored is unable to resolve the complication in a timely manner
c. the complication is of a type that can be encountered in the proctors own specialty
d. the proctor must feel comfortable in temporarily becoming primary surgeon and attempting to resolve the complication him/herself.
e. The proctor and surgeon of record agree that:
    - the case will be turned back to the surgeon in the appropriate specialty as soon as the complication is resolved.
    - the final decision with regard to, if and when, to abandon robotic surgery shall remain that of the surgeon of record.

The purpose of this provision is solely to protect the interests of the patient by sparing the patient a "open" operation if the complication can still be dealt with robotically.

Per Medical Board March 2008: Administrative privileges are not required because the proctor will NOT provide any direct patient care.

DESCRIPTION OF DOCUMENTATION TO BE SUBMITTED BY THE PRACTITIONER WITH REQUEST FOR PRIVILEGES

This documentation MUST accompany the request

- *Reference(s)-Robotic Experience:* Letter from Program Director (Category 2) or Chief of Service (Category 3,4)

  Letter must include a statement that the applicant has performed the minimum number of robotic cases required as defined in the criteria
  Letter must also include an attestation of the current clinical competence of the applicant with respect to robotic surgery

- *Robotic Training Course:* Copy of certificate from course or letter from course director (Category 1,2,3,4)

- *Observation Robotic Cases:* Submit a statement indicating, the procedure observed, dates of observations, name of primary surgeon, name of institution were procedure was observed (Category 1)

- Operative report and the final outcome: for the last 5 cases performed conventionally for each robotic procedure requested (Category 1,2,3,4).

- *Robotic Cases:* Case log or letter from Chief of Service or Program Director, as indicate above, documenting the number of cases performed (Category 2,3,4) In all reported cases, the applicant must have been the primary surgeon

Operative Performance Rating Form – SURGERY

Practitioner ______________________ Surgery Date __________ Procedure: __________________

Please circle the number corresponding to the practitioner's performance in each area .

Knowledge of Operative Steps

1	**2**	**3**	**4**	**5**
Unfamiliar with steps of the operation. Unable to recall or describe many operative steps		Knows and can explain most of the operative steps but unsure of some		Obvious knowledge of all operative steps: able to give details of steps without hesitation

Instrument Handling

1	**2**	**3**	**4**	**5**
Makes tentative or awkward moves by inappropriate use of instruments		Competent use of instruments but occasionally appears stiff or awkward		Fluid moves with instruments and no awkwardness

Knowledge of Instruments

1	**2**	**3**	**4**	**5**
Frequently asks for wrong instrument or uses inappropriate instrument		Knows names of most instruments and uses appropriate instruments		Obviously familiar with the instruments and their names

Flow of the Operation

1	**2**	**3**	**4**	**5**
Frequently stopped operating and seemed unsure of next move		Demonstrated some forward planning with reasonable progression of procedure		Obviously planned course of operation with effortless flow from one move to next

COMMENTS: ____

____

______________________ Practitioner's Signature

________ Date

______________________ Proctor's Signature

________ Date

Appendix D – (Herron et al., 2007)

Minimum Requirements for Granting Privileges

Part A is mandatory, and must be accompanied by either part B, or C and at least one component of D.

A. Formal Specialty Training

Prerequisite training must include satisfactory completion of an accredited surgical residency program, with subsequent certification by the applicable specialty board or an equivalent as required by the institution.

B. Formal Training in Residency and/or Fellowship Programs

For surgeons who successfully completed a residency and/or fellowship program that incorporated a structured curriculum in minimal access procedures and therapeutic robotic devices and their use. This should also include the science and the techniques of access to the body cavity and area of surgery. This includes adequate clinical experience. The applicant's program director, and if desired other faculty members, should supply the appropriate documentation of training and clinical experience.

C. No Formal Residency Training in Therapeutic Robotic Surgery

For those surgeons without residency and/or fellowship training which included structured experience in therapeutic robotic procedures, or without documented prior experience in these areas, a structured training curriculum is required. The curriculum should be defined by the institution, and should include a structured program. The curriculum should include didactic education on the specific technology and an educational program for the specialty specific approach to the organ systems. If the access is an intracavitary procedure then that experience and education should be a prerequisite to the training. Hands-on training, which includes experience with the device in a dry lab environment as well as a specialty-specific model which may include animate, cadaveric and /or virtual reality and simulation modeling, is necessary. Observation of live case(s) should be considered mandatory as well. Other teaching aids may include video review and interactive computer programs.

D. Practical Experience

1. Applicant's Experience – Documented experience that includes an appropriate volume of cases with satisfactory outcomes, equivalent to the procedure in question in terms of complexity. The chief of service should determine the appropriateness of this experience.

2. Initial clinical experience on the specific procedure must be undertaken under the review of an expert and may include assisting. An adequate number of cases to allow proficient completion of the procedure should be performed with this expert review.

3. Preceptor or proctor. – The specific role and qualifications of the expert must be determined by the institution. Criteria of competency for each procedure should be established in advance, and should include evaluation of: familiarity with instrumentation and equipment, competence in their use, appropriateness of patient selection, clarity of dissection, safety, and successful completion of the procedure. The criteria should be established by the chief of service in conjunction with the specific *specialty chief where appropriate. It is essential that mentoring be provided in an unbiased, confidential, and objective manner.*

E. Formal Assessment of Competency

When available, validated measures of competency should be used to further document the applicant's abilities. These may include knowledge, medical decision making, and/or technical skill assessments. This may include certificates of completion of training or validated assessment tools for competency or proficiency in a specific procedure, or set of similar procedures.