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Prick Testing in Children

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Reducing Variability Among Multiple Operators Using a Single Technique and Device for Skin Prick Testing in Children

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Executive Summary

Capstone Project Title
Reducing Variability Among Multiple Operators Using a Single Technique and Device for Skin Prick Testing in Children

Problem
The variability in performance among skin prick test (SPT) operators who performed the twist technique versus the prick technique was raised within the Pediatric Program at the Study Site. Confidence in the SPT results was threatened, treatment plans were delayed and diets remained restricted.

Purpose
This Doctor of Nursing Practice (DNP) Capstone Project was designed to identify a single device and technique that could be used at the facility to reduce variability, increase reliability, and standardize the skin prick test procedure using a single technique and device within the institution. This inexpensive test has the potential to yield enormous results at a single visit and dictate life saving treatment, which is patient specific.

Research Study Objectives
The PICO (Population, Intervention, Comparison, Outcome) research question asked: (P) Among children ages 1 year through 16 years receiving skin prick testing for diagnosis and treatment of their allergic disease, (I) does the Quintip device puncture technique or Duotip device twist technique (C) when compared to the Duotip prick technique (O) decrease variability and increase reproducibility of results when conducted by multiple operators? The Capstone Project successfully identified a single technique and device to be used by multiple operators to provide high quality, reliable, and valid allergy skin testing results for at-risk patients.

Research Methods and Procedures
This DNP Capstone Project was a prospective, double-blind clinical trial using a convenience sample in which pediatric research participants underwent SPT in a single session, with a single operator using the Duotip twist and Quintip puncture techniques as compared to the Duotip prick/lift technique.

Study Results
Comparing results between the three techniques and two devices, the Quintip twist method was most sensitive (97%) as compared to the punch technique (86%) and prick/lift technique (89%). Only 2.8% of those tested using the twist technique produced false negative responses to histamine as compared to 14% (Quintip punch) and 11.1% (Duotip prick/lift).

Implications for Practice and Future Research
As new SPT technique and devices are introduced, ongoing research will be necessary to evaluate variability and respoducibility among operators, to ensure improvements in diagnosis and treatment food, drug and environmental allergies can be achieved.

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Very Respectfully,

Elizabeth

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Reducing Variability Among Multiple Operators Using a Single Technique and Device for Skin Prick Testing in Children

The United States Department of Health and Human Services- National Center for Health Statistics (2013) reported a significant increase in the prevalence of food allergies in children under the age of 18 years living in the United States during 2009-2011 as compared to 1997-2009. Skin prick testing has been used as a diagnostic tool since first described in the literature in 1873 when Dr. Charles H. Blackley scratched the skin on the forearm with a lancet and wet lint saturated in grass pollen to diagnose chronic allergic rhinitis when a whealing response occurred at the site (Krau and McInnis, 2010). This inexpensive, minimally invasive test can be conducted in an outpatient office setting and is highly dependable when performed correctly (Cox et al., 2008). However, if not performed correctly false positive and false negative results can occur and treatment plans may have life threatening consequences. The purpose of this research study aimed to identify the single skin prick test technique and device that allowed for the greatest reproducibility and decreased variability among multiple operators performing skin prick test procedure in the pediatric population at the study site.

Problem Recognition and Definition

Background and Significance of Problem

At the study site, medical providers evaluate and treat pediatric patients with a variety of allergic, rheumatologic and immunologic disorders of childhood including pediatric asthma, exercise-induced asthma, hives, allergies, food allergy, stinging insect allergy, anaphylaxis, atopic dermatitis, immunodeficiency, recurrent infection, chronic cough, vocal cord dysfunction, and illnesses which may complicate chronic allergic disease such as gastroesophageal and laryngopharyngeal reflux (NJH, 2013). The study site brings together a team of America's best

and highly skilled pediatric physician specialists, nurses, dietitians, psychosocial clinicians, and ancillary team members. The comprehensive team approach is designed to provide accurate diagnosis, develop individualized treatment plans, and deliver in-depth education to address the specific needs and goals of each patient.

A common diagnostic procedure performed during the initial evaluation and on-going follow-up care is the skin prick test. This test involves placing allergen solutions on the skin and then pricked using a disposable device. The results of the SPT provide valuable information used to confirm diagnoses and develop treatment plans (Cox et al., 2008). According to Cox (2008), the SPT remains the preferred diagnostic technique for allergy because results are quickly available, allows for evaluation of multiple allergens at a single office visit, and has a good correlation to in vitro (serum IgE) testing. Visually, the SPT can provide a graphic representation of the sensitivity for the allergen as compared to the saline and histamine controls. In addition, less common allergens, such as local fruits and vegetables or certain brand name medications, can be specifically tested using the SPT technique when no specific IgE antibody serum measurements are available (Heinzerling et al., 2013).

The United States Joint Council of Allergy, Asthma and Immunology (2013) and the European Academy of Allergy and Clinical Immunology (2013) highly recommend percutaneous SPT as the primary tool for diagnosing allergic disease. Skin prick testing is a key test in identifying allergens causing allergic symptoms, prescribing immunotherapy treatment, and defining avoidance diets. As a result, physicians and health care providers must be confident in the SPT results as they construct their medical diagnoses and treatment recommendations. False positive findings may occur if the operator presses the SPT device too hard against the skin, causing erythema from technique versus true allergic response to antigen (Carr, W. et al.,

2005). On the other hand, the operator may not press the SPT device hard enough against the skin so the antigen cannot penetrate the epidermis, leading to a false negative finding. Patients may end up being exposed to allergens that they are highly allergic to and subsequently have life threatening reactions when allergens are unknowingly introduced.

New SPT devices continue to be developed including multihead devices, which allow for application of several antigens simultaneously; however, these have been difficult to use in the pediatric population at the study site. Children have a tendency to move unpredictably during the procedure and multihead devices can cause variation in penetration of allergens across the placement region on the back (Carr, 2005). Locally, the preferred single head tool is the Duotip device using the prick-lift technique and the twist technique. However, for this DNP Capstone Research Project, the researcher also used the single head Quintip device employing the punch technique to assess reproducibility and variability among multiple operators.

In Fall 2013, the health care team at the study site noted increased variability of SPT results among multiple operators. Before permitted to conduct the SPT procedure at the facility, Certified Nursing Assistants and Registered Nurses had to successfully pass a written test and demonstrate performance competency using their technique choice and read/record results with 100% accuracy. When concern about the SPT was raised at the facility, data was collected including the technique each operator used, the number of previous tests performed, and the date initial SPT education and training were completed. Results revealed the operators were trained and deemed competent on one SPT technique but now were using another technique. Placement of allergens on skin varied between operators and reading of results varied up to three minutes-from 15 to18 minutes (Esterl, 2013). Immediate actions to increase the reliability and reduce variability of results included repeat education and training for all operators before further SPT

was permitted, significantly limiting the number of operators performing the SPT procedures, and restricting the technique to the twist technique using the Duotip device.

This DNP Capstone Research Project aided in identifying the single technique and device needed to further limit variability and increase reliability of the SPT results when conducted on children by multiple operators at the study site. According to the Allergy Diagnostic Practice Parameter (Bernstein, 2008), "The reliability of prick/puncture tests depends on the skill of the tester, the test instrument, color of the skin, skin reactivity on the day of the test, potency, and stability of the reagents"(p 56). Health care providers must be confident in the results of the SPT to assist in the diagnoses of food, environmental and drug allergies and develop a trustworthy treatment plans for pediatric patients seen at the facility.

Statement of the Research Problem

Increased variability in SPT results was noted by the medical providers at the facility when multiple operators conducted the SPT using the twist and prick techniques. Confidence in the SPT results was threatened, treatment plans were delayed and diets remained restricted. The goal of this DNP Capstone Research Project was to identify a single technique and device to standardize the SPT procedure, reduce multiple operator variability and improve reproducibility among the pediatric patients seen at the study site.

Statement of the Research Study Purpose and Aims

The purpose of this research study was to compare the variability of Skin Prick Test (SPT) results of the Duotip twist and Quintip puncture techniques as compared to the Duotip prick/lift technique when carried out on the backs of the pediatric participants by multiple operators. Specifically, this Doctor of Nursing Practice (DNP) Capstone Research Project was intended to evaluate reliability and variability of the SPT techniques and devices used by

multiple operators in order to identify the superior single technique and device to be use by all operators at the study site. With these results, physicians will be able to make accurate diagnoses and treatment care plans for their highly allergic pediatric patients.

Aims related to SPT techniques and devices included:

1. To determine the variability of each SPT technique and device using multiple operators.
2. To determine the reliability of results using multiple operators and different SPT techniques and devices.
3. To determine the single SPT technique and device to be used by all operators in the study site

Literature Review/ Selection Process/ Summary

The focus of the systematic literature review was to assess the use of single-head SPT devices and variability of results when performed by multiple operators in the pediatric population. Six electronic databases searched included: PubMed, ClinicalTrials.Gov, CINAHL, National Center for Biotechnology Information, Cochrane Database of Systematic Reviews (CDSR) and Database of Abstracts for Review of Effectiveness (DARE). Initial searches were restricted to English language articles published between 2002-2013. However, dates were expanded to 1980-2013 to increase the number of research studies and reports used to confirm previously published research on the SPT techniques and devices, regardless of the age of participant. Searches included research conducted in the United States and throughout Europe as long as it met all other criteria.

The terms used in the database searches included: food allergy, immunoglobulin E, SPT, children, operator variability, allergy, sensitization, food allergens, eosinophil esophagitis,

allergies, Type I, diagnostic test asthma, Duotip, Lancet, Quintip, and oral food challenges. The search resulted in 30 reports as follows:

- 1 Cochrane systematic review

The Cochrane systematic review included electronic searches of PubMed, Cochrane Database of Systematic Reviews, Cochrane Database of Abstracts of Review and Effect, and Cochrane Central Register of Controlled Trials. Searches were limited to English language articles indexed between January 1988 and September 2009. A total of 12378 citations were identified and two investigators reviewed 72 citations independently, using the AMSTAR criteria, the quality of the studies using the QUADAS criteria relevant to food allergy, and the quality of the randomized controlled studies using the Jadad criteria (Chafen et al., 2010).

- 13 Well-designed randomized controlled adult trials
- 10 Well-designed controlled adult trials without randomization
- 6 Evidence from systematic reviews of descriptive or qualitative studies

A review of the 30 reports revealed the use of SPT as the primary diagnostic tool for allergy evaluation. However, this review revealed only one study that focused specifically on children (Illi et al., 1998) and one study that included adults and children that compared SPT with another diagnostic tool to identify and treat allergies in patients, but did not address operator variability or reproducibility (Mehl, Niggemann, Keil, Wahn, & Beyer, 2012). Illi et al., (1998) examined the variability of SPT testing performed by four different operators on 28 pediatric subjects ages 6 years to 14 years. Researchers tested 16 children using the multihead device and lancet on the forearm and found the lancet to be superior with operator reproducibility. The remaining children were only tested with one device, 11 children were tested with the multihead device and one child was tested was the lancet. Illi et al., (1998) noted "the skin prick tests

applied by the four fieldworkers resulted in small, by statistically significant differences in their outcomes" (pg. 357, para 1). This was the only study found during the review process that focused specifically on multiple operator variability and reproducibility when performing SPT on the pediatric population.

The remaining studies and reports from this systematic review focused on the adult population, which served to inform this DNP Capstone Research Project. Studies comparing the performance of commonly used SPT devices and techniques to achieve reproducible results revealed significant differences when the SPT was conducted on the forearms and backs of the adult participants (Carr, Martin, Howard, Cox, & Borish, 2005; Corallino, Nico, Kourtis, Filomena Caiaffa, & Macchia, 2007; Masse et al., 2011; Werther et al., 2012; Nelson, Kolehmainen, Lahr, Murphy, & Buchmeier, 2004; Nelson, Rosoniec, McCall, & Ikle, 1993). However, the sample sizes in all of these studies were small, ranging from 12 to 22 adult participants.

Four research studies on adults were completed (Nelson, Knoetzer, & Bucher, 1997; Nelson, Kolehmainen, Lahr, Murphy, & Buchmeier, 2004; Nelson, Lahr, Buchmeier, & McCormick, 1998; Nelson, Rosoniec, McCall, & Ikle, 1993) between 1993 and 2004 and included 53 adult subjects enrolled in three SPT device comparison studies evaluating quality, reproducibility, patient acceptance and one clinical study evaluating the distance between SPT sites and the quality of allergen extracts with 79 adult subjects. These studies reported that the SPT results varied greatly based on the SPT device used to conduct the test as depicted by the size of reactions to the positive (histamine) and negative (glycerol-saline) control solutions. The investigators recommended that operators be competency tested with the SPT devices to establish testing baseline before allowing performance in the clinical setting. Furthermore,

Nelson, Rosoniec, McCall, & Ikle (1993), reported the greater the trauma from the SPT device, the larger the reaction to the histamine or allergan and the greater likelihood of a whealing reaction and less likelihood of a false negative reaction. In addition, single and multihead devices displayed a consistent and significant trend for larger wheals when performed lower on the back and are unlikely to cause a false positive reaction when placed apart at least 2cm from another prick site (Nelson, Knoetzer, & Bucher, 1997).

Carr et al., (2005) enrolled 20 adult subjects (13 subjects completed the study) into a study comparing the performance of four multihead SPT devices and four single-head SPT devices performed by a single operator and found significant differences between the two types of devices ($p<0.008$), with multihead devices demonstrating the greatest variability and more painful as compared to the single head devices. Skin prick test reactions using the multihead devices were larger when tested on the back as compared to the single head devices with larger reactions on the forearm.

In a study of 22 adults comparing the reproducibility and sensitivity of four SPT instruments with the use of a positive control, Masse et al., (2011) calculated interpatient and intrapatient reproducibility between each technique and found the 23G intravenous (IV) needle and metal lancet were superior ($p < 0.01$) when compared to the two Stallerpoint and Stallergenes prick lancet and methods.

Werther et al. (2012) reported in a research study that SPT results carried out by eight operators using four different single-head devices. The researchers concluded that the lancet and Quintip SPT devices using the punch technique had less variability among multiple operators than those using the prick technique with the Greer Pick and Feather Lancet. However, their sample size was small, five subjects in total and conducted with healthy adult volunteers.

Regardless of the SPT device used, studies reported that the SPT caused minimal discomfort, offered a high yield of information, but had significant variability dependent on operator education and training (Carr, Martin, Howard, Cox, & Borish, 2005; Corallino, Nico, Kourtis, Filomena Caiaffa, & Macchia, 2007; Masse et al., 2011; Nelson, Lahr, Buchmeier, & McCormick, 1998; Werther et al., 2012).

In 2008, the American College of Allergy, Asthma and Immunology (ACAAI) and the American Academy of Allergy, Asthma and Immunology (AAAAI) developed a task force charged with developing the Allergy Diagnostic Practice Parameters (Cox et al., 2008). The guidelines offered a comprehensive review of diagnoses, tests, and procedures, and expected results for healthcare professionals caring for patients with allergic diseases for infants, children, and adults. The updated information included SPT technique instructions and suggested proficiency testing and quality assurance techniques for prick and puncture SPT (Cox et al., 2008).

Based on the review of the literature, there was an identified need for research that focused on SPT testing in the pediatric population. Therefore, this DNP Capstone Research Project aimed to contribute to understand of SPT testing in children and improve the quality and outcomes of care for the pediatric population.

Theoretical Foundation for Study

Nursing is an important part of the study site and directed to serve the health care needs of children and their families. A general understanding of theoretical foundation and how theories impact evidence-based practices were essential in the success of this research project.

Change theory. A theory of change provided the framework to move from one point to another to achieve a goal. It differed from other theories by:

- Showed a pathway which time points and associated actions were needed to achieve goals
- Underlying assumptions were required, tested, and measured
- Changed the way of thinking from what was currently being done to what was wanted to be achieved

Kurt Lewin's three-step change theory. Universally, Lewin is known as the founder of modern psychology and pioneered the use of experimentation in testing the change hypothesis (Greathouse, 1997). In 1947, Kurt Lewin introduced the three-step change model. Lewin stressed the importance of not only defining the goals of the change, but also including supportive objectives to achieve during the change process to break the emotional bond noted at the initial starting point. The three-step change model of Lewin's includes:

1. Unfreezing- The step is achieved by directing behavior away from the status quo, promote positive force that will facilitate change through trust and recognition, and actively participate in brainstorming solutions to achieve change (Lewin, 1947).
2. Movement- Create movement by changing the status quo. This can be accomplished by providing new perspective with beneficial solutions, working together towards the new common goal and leadership supporting the change.
3. Freezing- The third step reinforces the new behaviors and values that have been integrated into the community. The driving forces of change and the restraining forces are now stabilized and the combined forces are stronger. New policy and procedures formalize the new process.

Lewin's contribution to the DNP Capstone Research Project. Health care providers at the study site conducted SPT using the Duotip device and prick technique for over 25 years.

Within the department, a single Certified Nursing Assistant conducted a majority of the procedures ordered by the physician specialists for the pediatric patients. Over the last two years, additional staff members were trained using the twist technique. The health care providers expressed concern that results had increased variability when using the twist technique- more specifically a higher incidence of erythema and increased false positive and false negative results. Lack of confidence in results was further accentuated when multiple trained operators conducted the SPT on the highly allergic pediatric patients.

The first step in Lewin's Change Theory was to change the status quo. This DNP Capstone Research Project aimed to set a new goal and identify a single device and technique to standardize the SPT procedure at the facility. This step required unfreezing the current mindset by providing a feasible research opportunity, actively listening to the healthcare providers' concerns, and allowing input for possible device options. Literature reviews and conversations with manufacturers provided a third technique to investigate the Quintip puncture technique.

Movement was the second step in Lewin's Change Theory. This step included implementing the study, enrolling participants and collecting data for analysis. The author worked closely with the healthcare providers, operators, and other support members to discuss daily activities and reassess goals dependent on data collected.

The last step in Lewin's Change Theory was freezing the change once the new goal was attained. Communication of results, training, and educating the healthcare team were mandatory to solidify the new process. Updating the current policies and procedures with the new information reinforced that positive change occurred.

Lewin's Change Theory identified the necessary steps to define the status quo and the steps to achieve a new goal through change in practice through evidence-based research. Change

was easier to accept when team members were involved in every aspect of the change process, objectives were clear, and roles defined. Because the three steps of the Change Theory were followed sequentially with buy in from the team members, positive change occurred.

Research Study Objectives

Study Research Question in PICO Format

The PICO (Population, Intervention, Comparison, Outcome) research question that served as the focus of the study was defined in **Table 1.**

Table 1. PICO Question

P	Population of Interest	Among children ages 1 year to 16 years receiving skin prick testing for diagnosis and treatment of their allergic disease,
I	Intervention of Interest	does the Quintip device puncture technique or Duotip device twist technique
C	Comparison of Interest	compare to the Duotip prick technique
O	Outcome of Interest	decrease variability and increase reproducibility of results when conducted by multiple operators?

Study Hypotheses

The following hypotheses were tested in this study:

1. Each of the three SPT techniques- Quintip device puncture technique, Duotip device twist technique, and the Duotip prick technique- produce a positive wheal $\geq$ 3mm to the positive control of histamine on the back of the pediatric research participant.
2. Variability in SPT results was greatest using the Duotip prick technique among multiple operators.
3. Variability in SPT results was the least using the Quintip device puncture technique, regardless of operator change.

4. The Quintip puncture technique was highly reproducible as compared to the Duotip prick and twist techniques.

Definitions of Study Variables

1. Quintip Device- Manufactured by Hollister-Stier Laboratories in Spokane, Washington and previously reported by the research of Carr et al., (2005) to have low variability in results and high sensitivity and specificity.
2. Duotip Device- Manufactured by Lincoln Diagnostics in Decatur, Illinois and previous research conducted by Corder, W., Hogan, M., and Wilson, N. (1996) revealed that the bifurcated needle of the Duotip-Test device using the prick/lift technique had significantly smaller histamine wheal and erythema responses than Duotip-Test twist techniques ($P < .05$). The Duotip twist technique produced significantly larger wheals (mean 1.1 mm, $P < .001$) to saline than the prick/lift technique.
3. Concomitant Medications- normal therapeutic doses may suppress SPT results and alter variability.
4. Allergen Extract- can contain proteins that can induce allergic symptoms with exposure. The end product is a complex mixture of the diluents or solvents, additives, preservatives, and other components of the raw material that survive the manufacturing process. The extract must be used before the expiration date or variation in expected SPT results can occur.
5. Storage of Extracts- should be stored at 4° C to reduce the rate of potency. Extracts beyond the expiration date should to be discarded. Expired extracts could lead to a variation in SPT results.
6. Distance of Placement on Body Surface- between two SPT should be $\geq$ 3 cm to avoid

false positive reactions due to direct contamination of a nearby test or secondary to an axon reflex (Nelson, H.S., 1997).

7. Dermatographism- is a skin condition also known as skin writing that causes the skin to redden when lightly scratched and develop a raised wheal similar to hives.
8. False Positive Result- Operator presses the instrument too hard against the skin, causing erythema from technique versus true allergic response to antigen, causing a false positive SPT result (Carr, W. et al., 2005).
9. False Negative Result- Operator may not press the SPT instrument hard enough against the skin so the antigen cannot penetrate the epidermis, resulting in a false negative SPT result.
10. Skin Prick Test Sites Marking- Sites should be marked with washable blue markers to identify placement of solutions and pricks should be made immediately adjacent to the marks to avoid confusion between solutions.

Research Methods and Procedures

Description of Research Design

This Doctor of Nursing Capstone Research Project was a prospective, double-blind clinical trial using a convenience sample in which pediatric research participants underwent SPT in a single session, with a single operator using the Duotip twist and Quintip puncture techniques as compared to the Duotip prick/lift technique. Each device was tested on the back and included two histamine solutions (10 mg/mL; Hollister-Stier, Spokane, Wash) and two glycerol-saline solutions (Hollister-Stier), in a vertical column and spaced at least 3 cm apart.

To maintain objectivity, the operator who performed the SPT on the back, was blinded to the contents of the test solutions of histamine or saline (Carr et al., 2005). An additional operator,

who was not present in the room during solution placement and SPT procedure, recorded the results at 15 minutes post procedure. This operator was blinded to the device used at each test site, as well as the specific solution tested on the back of each pediatric research participant.

All SPT were performed using histamine solutions (10 mg/mL; Hollister-Stier, Spokane, Washington) as the positive solution and glycerol-saline solutions (Hollister-Stier) as the negative control to compare variability of the SPT size.

Identification of the Population and Sample Selection

All patients followed at the study site, who met the entry criteria, were offered enrollment into this study. It was estimated that 50 patients were seen weekly, requiring the SPT procedure as a part of their clinical treatment activities. Of the known patients, approximately 20 eligible patients were identified each week.

The small population of 600 children was seen at the facility during the study enrollment period. A total sample size of 68 pediatric research participants was enrolled into this study. Each participant received 12 SPT on his or her back body surface, which were used to determine variability and reproducibility of the three techniques. Research participant served as his or her own control and were tested using a blinded tray filled with two histamine and two saline solutions for each technique and device used by a single trained operator.

Power analysis to determine sample size. A sample size of 68 pediatric research participants was calculated to achieve a 95% power or sensitivity to detect differences in standard deviation between the two devices and three techniques (Faino, 2013).
Parameters that went into calculation included:

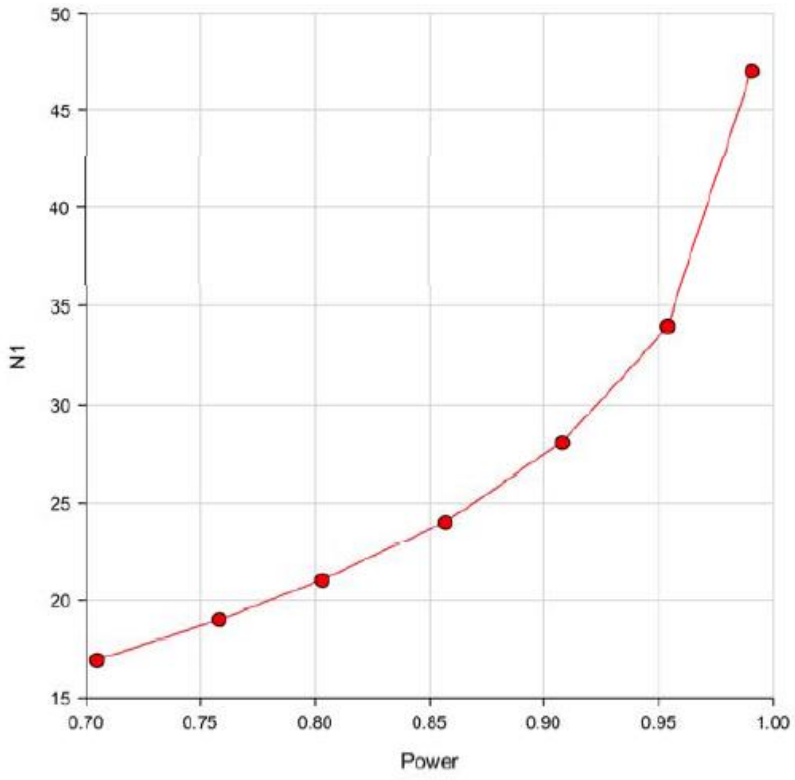
- Alpha= 0.05
- Standard Deviation (Quintip, back)= 0.95

- Standard Deviation (Greer Pick, back) = 1.81 (Values from Werther et al., 2012)

Note: Greer Pick is a surrogate to Duotip twist

N1 verses Power S1 = 1.8100, S2 = 0.9500, Alpha = 0.05, N2 = N1, 2-sided F Test

Table 2. Power Analysis of Variances



Power analysis of variances. Numeric: Results when H0: S1 = S2 verses Ha: S1 ≠ S2

Power	N1	N2	S1	S2	Alpha	Beta
0.990636	47	47	1.8100	0.9500	0.050000	0.009364
0.953888	**34**	**34**	**1.8100**	**0.9500**	**0.050000**	**0.046112**
0.907893	28	28	1.8100	0.9500	0.050000	0.092107
0.856790	24	24	1.8100	0.9500	0.050000	0.143210
0.803054	21	21	1.8100	0.9500	0.050000	0.196946
0.758083	19	19	1.8100	0.9500	0.050000	0.241917
0.704637	17	17	1.8100	0.9500	0.050000	0.295363

*This test was assuming independence between the groups and was likely an overestimation of the total number of patients needed. Thus additional participants were not needed to cover for unusable data (Faino, 2013).

Population/sampling parameters. All current and newly diagnosed patients (based on medical history and/or community physicians referral information) with suspected food, drug or environmental allergies, were offered enrollment into this DNP Capstone Research Project.

The Inclusion Criteria:

1. Children with suspected food, drug, or environmental allergies - ages 1 to 16 years old
2. Both genders, all races and ethnic groups
3. English speaking only
4. Medications, included but not limited to antihistamines, withheld for appropriate time period as per hospital protocol

The Exclusion Criteria:

1. Inability to comply with SPT procedure
2. Failure of a family/patient to sign the informed consent document or the HIPAA medical record release form

Recruitment plan. In order to maximize recruitment of participants with suspected food, drug, or environmental allergies, two recruitment strategies were used:

1. Current and future Clinical Site Patients - The principal investigator discussed the study design, benefits and possible risks with the family. Printed information about the study and the consent form were given to the family. The IRB-approved consent form included the purpose of the trial, the responsible parties and investigator, potential benefits, risks of participation, the right to refuse to be in the study, the right to withdraw from the study under no penalty, contact numbers and information about the responsibility for injury and payment for medical care. If the family consented to participant in the study, written

informed consent was obtained from the parents or guardians and case report forms were completed.

2. Advertising Strategy for Voluntary Enrollment- To increase the sample size, several steps were taken to add to the recruitment of study participants. A periodic IRB-approved announcement of the objectives of the DNP Capstone Research Project was made on the Pediatric Department Bulletin Board with a request for referral of patients. In addition, the principal investigator posted IRB approved notices on the Pediatric Clinic and Pediatric Care Unit bulletin boards to announce the new study and provided contact information for interested families or patients.

Study enrollment. During the six-month duration of this study, the plan was to enroll **68** patients at the study site. The ethnicity and racial categories of the participants are outlined in **Table 3**.

Table 3. **Planned Enrollment Table.**

Ethnic Categories	**Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	6	7	**13**
Not Hispanic or Latino	27	28	**55**
Ethnic Categories: Total of All Participants	**33**	**35**	**68**
Racial Categories			
American Indian/Alaska Native	1	1	**2**
Asian	1	1	**2**
Native Hawaiian or Other Pacific Islander	0	0	**0**
Black or African American	3	4	**7**
White	28	29	
Racial Categories: Total of All Participants	**33**	**35**	**68**

Setting Description

Participants were recruited from patients evaluated, referred, and followed at the study site in Denver, Colorado. The principal investigator identified the parent(s) or guardian(s) during Pediatric Clinic visits or during inpatient, day patient admissions, or triage visits within the Pediatric Care Unit. The principal investigator discussed the study design, benefits and possible risks with the family. Printed information about the study and a copy of the consent form were given to the family.

Stakeholders and Project Team

Mentor. Dr. Erwin Gelfand, Chairman Department of Pediatrics, provided mentorship and guidance to the author and principal investigator of this DNP Capstone Research Project. Dr. Gelfand is internationally recognized as reporting of his research endeavors, publications and leadership positions posted on the facility website (http://www.nationaljewish.org/about/people-search, 2013).

Capstone Chair. Dr. Diane Ernst, Associate Professor at Regis University, provided education and guidance throughout this DNP Capstone Research Project. Dr. Ernst's clinical expertise and certification are centered on community and public health outcomes. Her research activities include nursing-sensitive outcomes research, health promotion and illness prevention in older adults, and research within the community/public health settings.

Medical Director at the study site. Dr. Pia Hauk, Medical Director Department of Pediatrics, provided medical assistance as necessary if an adverse event occurred. Dr. Hauk oversees all clinical activities within the Department of Pediatrics including the areas of the Pediatric Clinic, Triage, and Pediatric Care Unit.

Additional advisory team members. To complete the DNP Capstone Research Project, active collaboration occurred with Anna Faino, Biostatistician at the facility. Following the departure of Ms. Faino from the institution, Dr. Ronina Covar, Associate Professor in the Division of Pediatric Allergy and Clinical Immunology and Director of The Cohen Family Asthma Institute, Head of Pediatric Clinical Pharmacology, and Biostatistician assisted in the statistical validation and analysis of the study. Pediatric Physician Specialists from the facility, whom raised the initial concerns regarding concern of operator variability, were available during the enrollment period. Ms. Kelly Buller, RN and SPT preceptor, and Ms. Suseth Figueroa, expert SPT operator, were regularly consulted regarding SPT technique, education, and training.

The facility's mission, vision, and organizational structure supported the educational endeavor and provided the necessary physical and financial support to complete the project. Dr. Erwin Gelfand and other members of the advisory team are experts in their field and provided necessary guidance to the overall success of the project.

Community partnerships. In order for this project to be successful, community efforts from different teams were developed. For example, the DNP Capstone Research Project involved two separate device manufacturers and the Institutional Review Boards at Regis University and the study site. The two Institutional Review Boards worked together to ensure the safety of research participants and allowed medical research to proceed in an ethical manner without either intentional or unintentional abuses of power or errors

Interdisciplinary collaboration. Conducting research to identify a single SPT device and technique required interdisciplinary collaboration. Adult and pediatric health care teams relied on accurate results to define initial diagnoses and ongoing treatment plans for allergic patients. Support staff and SPT operators were able to identify appropriate patients for the

project. The principal investigator collaborated fully with the attending physicians to approach potential patients for participation. At the conclusion of the study, results were shared with all departments and policy and procedure were amended to reflect the superior device and technique. Communication was extensive with all health care team members at the table for discussion of results.

Protection of Human Rights Procedures

Institutional review boards. The research protocol, consent, assent, and other regulatory documents were reviewed and approved by the facility's Institutional Review Board and Regis University Institutional Review Board. All pediatric research participants enrolled into the study voluntarily agreed to participate and gave written informed consent by parent or legal guardian and assent from child research participant.

Regis University institutional review board. verified and approved all research activities involving human research. The board met monthly to verify exempt studies, determine and review expedited studies, and conduct formal meetings for studies requiring full review. Even though this study involved a vulnerable population, the research was minimal risk and qualified for expedited review. Two designated Regis University IRB members reviewed the regulatory packet and granted approval.

Facility's institutional review board. was consulted during the development of the DNP Capstone Research Project and determined that the protocol met the requirements for expedited review.

As described on the facility's website (2013), "Expedited review is an option when the research activity will expose participants to no more than minimal risk and when the proposed study falls into a category described in the federal regulations. Because the risks of

participating in the research are no more than minimal, the regulations allow the study to be reviewed by the IRB Chairperson or an experienced IRB member".

Procedure for requesting an expedited review of a new protocol. Author and principal investigator applied for expedited review and completed the appropriate submission requirements found on their website There were no submission deadlines for expedited review. Once the regulatory packet was logged into the system, a Primary Reviewer was assigned to the protocol and communicated directly with the principal investigator or IRB contact person. Once all stipulations had been adequately addressed, the protocol was approved and the principal investigator was notified. An expedited review required two to three weeks, but it is dependent upon the availability of the Primary Reviewer.

Informed consent plan. All potential participants were identified by the principal investigator and those meeting the inclusion/exclusion criteria were given the opportunity to participate. Parents/guardians/ participants were given the consent/assent forms to review and ask questions about the study. Parents/guardians/participants were asked to summarize in their own words what participation in this research study involved and that they are comfortable with the risks and benefits of participating in the research study. Any additional questions they had were answered prior to signing the consent/assent. Once the consent/assent form was signed, a copy was provided to the parent/guardian/participant. All participants were consented by the Principal Investigator who had appropriate training regarding human participant protection and HIPAA compliance, as established by the local institutional regulatory requirements. Only English speaking participants were able to participate in the study.

Special consent/assent plan. Spanish only speaking population were excluded from

this study. Children 7 years of age and greater were asked to sign assent after the protocol was explained by the principal investigator.

Incentives or rewards offered for participation. Patients, parents or guardians did not receive reimbursement for their participation in this research study. Patients were not charged for their participation in this study.

Potential risks to participants. There were minimal physical and psychological risks from being in this study. Brief minimal localized site pain was associated with the SPT procedure and resolved immediately without treatment once the prick was completed. No additional treatment was necessary to resolve pain.

Alternative treatments considered. Patients could have elected to not participate in the study and receive SPT as a part of their routine clinical care.

Plan to protect participants/mitigate risks. The study anticipated no excessive risks to the patients, except the possible pain associated with the SPT. Once the procedure was completed and in the 15-minute wait period, a small fan was directed to the back area to minimize any discomfort if requested.

Criteria for removal from study. Participants were seen one time immediately following enrollment into the study. The participants' parents or guardians could request that the patient be removed from the study at any time. In addition, the investigator could withdraw a participant from the study if she determined that it was in the participant's best interests. Withdrawal from the study would not impact the study participant's future medical care.

Potential health benefits to participants. The pediatric research participants did not directly benefit from participation in this research, but in the future, other children needing to

undergo the SPT procedure may benefit from new information that may lead to better medical care.

Importance of the knowledge gained from this research. was to better understand of the SPT technique and devices used, and lead to improvements in diagnoses and treatments for food, drug and environmental allergies. This study was designed to identify a single device and technique that could be used at the facility to reduce variability, increase reliability, and standardize the procedure using a single technique and device within the institution.

Description of the Study Intervention/ Protocol

This prospective, double-blind research study offered comparison in the performance of the Duotip twist and Quintip puncture techniques as compared to the Duotip prick/lift technique. The purpose of this study was to determine the best SPT technique and device that could be used efficiently and effectively to identify and treat severe allergies to drugs, foods and environmental allergens. This inexpensive test has the potential to yield enormous results at a single visit and dictate lifesaving treatment, which is patient specific.

This DNP Clinical Research Project was performed under Good Clinical Practice guidelines (FDA, 2013), which enforced tight rules on ethical aspects for human research. Good Clinical Practice guidelines aim to ensure that studies are scientifically valid, necessary procedure and tests are safely performed, and all research activities are accurately documented. In addition, the Good Clinical Practice Guidelines provide information about subject protection, roles and responsibilities of the research team and participants, and study oversight (FDA, 2013). Four Certified Nursing Assistants and two Registered Nurses involved in this DNP Clinical Research Project completed their CITI training and other regulatory requirements as required by the local Institutional Review Board. Medical liaisons from Lincoln Diagnostics, Inc. and

Hollister Stier, manufacturers of the devices, provided educational training sessions on the Quintip punch technique and the Duotip twist technique before first subject was enrolled into the study. Operators performed all SPT on the pediatric research participants, and another trained SPT operator immediately read all of the results at a specific time interval and documented the results in the SPT test form.

Research intervention. Each subject underwent 12 SPT during a single session with a single operator using the Duotip twist and Quintip puncture techniques as compared to the Duotip prick/lift technique. Each technique and device were tested on the back of the pediatric participant, using two tests of the histamine (10 mg/mL; Hollister-Stier, Spokane, Wash) positive control solutions and two tests of the glycerol-saline (Hollister-Stier) negative control solutions during the session. At the conclusion, a mean result was determined for each test of the single use devices, and from this, intradevice variability was defined. Single device test sites were spaced at least 3 cm apart, in three row of four SPT, and marked with a pen on the back to properly identify test locations.

To maintain objectivity, the operators who performed the SPT on the back were blinded to the contents of the test solution of histamine or saline control solutions. An additional operator, who were not be present in the room during application and testing of solutions and controls, recorded the results. This operator was blinded to the devices used as well as to the particular solution placements on the back of the research participant. The largest diameter was measured first using a clear ruler, followed by the perpendicular diameter, passing through the middle of the wheal and documented. The measurement was repeated on the surrounding erythema or flare response using the same technique. Wheals greater than 3 mm in diameter were considered positive at the histamine sites and indicative of clinical allergic response.

Discussion of Measurement Techniques/ Instruments

Devices. Single headed devices were evaluated in the DNP Capstone Research Project including the Duotip (Lincoln Diagnostics) used for the prick and twist techniques and the Quintip (Hollister-Stier) used for the punch technique.

Skin prick testing. All testing was performed on the back. The wheal and flare results were recorded at 15 minutes post placement by obtaining the longest orthogonal diameters. Mean diameters were used for statistical analyses. Positive test solution was 10-mg/mL histamine (Hollister-Stier), with standard glycerol saline (Hollister-Stier) used as the negative solution. The controls were tested twice in each row to ensure reactivity and variability for each device. The different SPT studied in this protocol share clinical responsibilities for the diagnosis and treatment of pediatric allergies. In the following, the current state of knowledge about each technique was summarized and current scientific and clinical challenges were outlined.

1. **Duotip prick and twist techniques- Lincoln Diagnostics.** Duotip-Test® is the most affordable one-at-a-time SPT on the market (www.lincolndiagnostics.com, 2013).

As reported on the Lincoln Diagnostic website (2013), the Duotip is:

- Highly sensitive and specific
- Well-defined, easy-to-read reactions
- Excellent patient acceptance
- Rapid, convenient, and easily learned technique as reported by manufacturer
- Used via modified prick or rotation (twist)
- Lowest cost one-at-a-time procedure per manufacturer report
- Compact system requires little storage and disposal space
- OSHA Compliant for blood borne pathogens and needle stick prevention

2. **Quintip punch technique- Hollister-Stier.** Quintip is a SPT device manufactured by Hollister-Stier Laboratories, Spokane Washington. The Quintip is designed to perform as reported on their website (http://www.hsallergy.com):

- to apply allergen extract using a puncture technique
- Stainless steel lancet tip that protrudes from the molded plastic grip, enough to give the proper testing grip
- Is to be used once and discarded in appropriate sharp container
- Can be stored in the extract-filled trays when not in use or in shipping package
- With the Quintip perpendicular to the skin, tester presses down on the skin with medium pressure without lifting the device from the skin. Remove by lifting vertically and discard in approved sharps container. A small visible circle should remain at the test site indicating that the correct amount of pressure was applied
- The visibility of the circles will vary between patients according to thickness, fragility, and pigmentation of the patient's skin

Plan for Data Collection

Data collection and study visit schedule. This study involved collection of clinical information, medical history, medication history, brief physical findings, and SPT.

The following data was collected on study participants at enrollment and during the single study visit.

Enrollment/Study Visit 1

1. Demographics: age at entry, date of birth, gender, race and ethnicity
2. Clinical Presentation: brief history of allergic symptoms, signs, age at onset, and initial interventions

3. Current Medications and Diet History
4. Brief Physical examination: Measurements: vital signs; Appearance: skin assessment
5. Skin Prick Tests: using Duotip prick and twist technique and Quintip punch technique

Table 4. Study Visit

The single study visit included the following:

EVALUATION	VISIT 1
Informed Consent	X
Eligibility	X
Medical History	X
Medication History	X
Brief Physical Examination	X
Skin Prick Tests	X
Discharge	X

Plan for Data/ Statistical Analysis

Wheal results were analyzed using repeated-measures ANOVA (Analysis of Variance) with the limited factors of back body site of 68 pediatric research participants and device. When calculating sensitivity and specificity, a positive test had a wheal of 3 mm or greater, and the negative test had a wheal of less than 3 mm. If the histamine results were less than 3 mm, the result was considered a false negative. Wheals greater than 3 mm in diameter were considered positive and indicative of clinical allergic response.

Skin prick test results were recorded using the largest diameter (D1) measured first using a clear ruler, followed by the perpendicular diameter (D2), and passing through the middle of the wheal. The measurement was repeated on the surrounding erythema or flare response using the same technique. The mean diameter (MD) was calculated using the formula:

$$MD = (D1 + D2)/2.$$

Sensitivity of each technique was calculated using the true positive result of 3 mm for the mean diameter (MD) of each wheal. Similar to the analyses of Masse et al. (2011) research study and Carr et al., (2005) research study, sensitivity was calculated by dividing true positive results by the sum of true positive and false negative results. Specificity of each technique was calculated by using the true negative results divided by the sum of the true negative and false positive results. The positive predictive value (PPV) is the proportion of subjects that are actually positive, among those that are predicted to be positive. The negative predictive value (NPV) is the proportion of subjects that are actually non-positive, among those that are predicted to be non-positive, and was calculated using the formula**.**

Interpatient reproducibility (using the same technique on multiple patients) and intrapatient reproducibility (same patient but using different techniques) were researched in this study. To assess intrapatient (same patient) reproducibility, the coefficient of variation (CV) between the mean diameters (MD) of the results using the same technique were calculated using the following formula (Masse et al., 2011):

$$CV\ intrapatient = SD\ intrapatient / \mu\ intrapatient$$

where the SD and μ are the standard deviation and the MD of the results.

Interpatient (different patient, same technique) variation of wheal size comparing different patients using same technique were calculated using the following formula (Masse et al., 2011):

$$CV\ interpatient = SD\ interpatient / \mu\ interpatient$$

The coefficient of variation represented the ratio of the standard deviation to the mean and was an essential statistical measurement used to compare the degrees of variation from one device and technique to another regardless how different the means were to one another.

The formal statistical method to measure the variability in wheal size for each of the three techniques was performed using a single multilevel model. As noted by Werther et al., (2012), this allowed for "correlations between observations taken by the same operator and carried out on the same receiver using random effects". The model separated the variability in SPT measurements into 3 components: variability between operators, variability between receivers, and variability within operators and receivers".

With the assistance from the Dr. Ronina Covar at the facility, sensitivity and specificity were calculated and variation defined between SPT techniques and devices.

Results

Study hypotheses. The following hypotheses were tested in this study:

1. Each of the three SPT techniques- Quintip device puncture technique, Duotip device twist technique, and the Duotip prick technique- produce a positive wheal $\geq$ 3mm to the positive control of histamine on the back of the pediatric research participant.
2. Variability in SPT results was greatest using the Duotip prick technique among multiple operators.
3. Variability in SPT results was the least using the Quintip device puncture technique, regardless of operator change.
4. The Quintip puncture technique was highly reproducible as compared to the Duotip prick and twist techniques.

A total of 68 children with a mean age of nine years (range: 4-16 years) participated in the study **(Figure 1).** Thirty-nine males and 29 females enrolled with their specific race and ethnicity demographics defined in **Figure 2** and **Figure 3**.

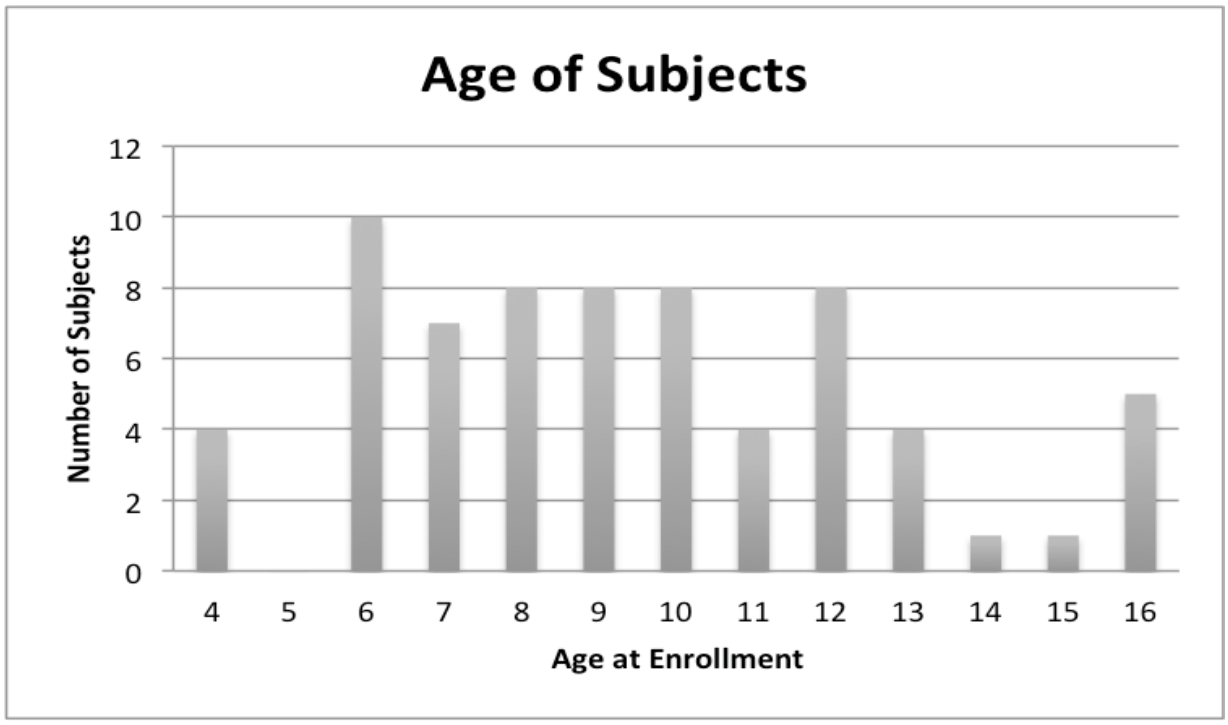


Figure 1. Age of subjects at time of enrollment

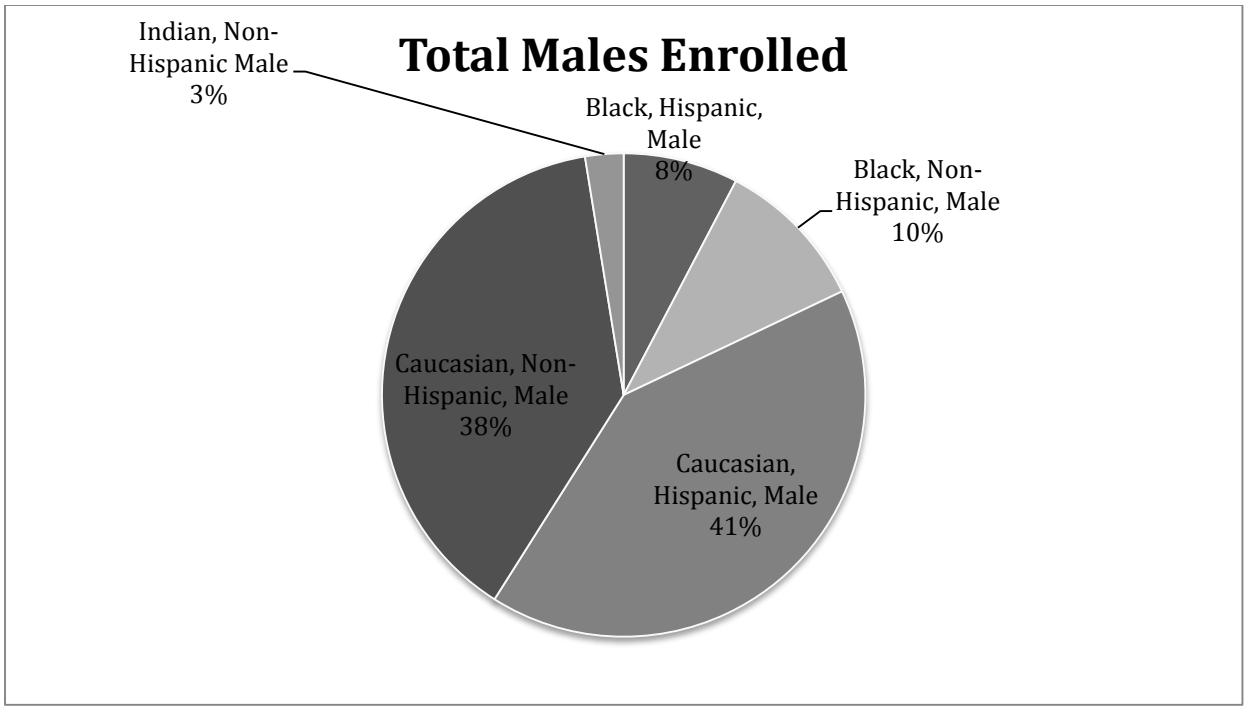


Figure 2. Race and ethnicity results of males enrolled

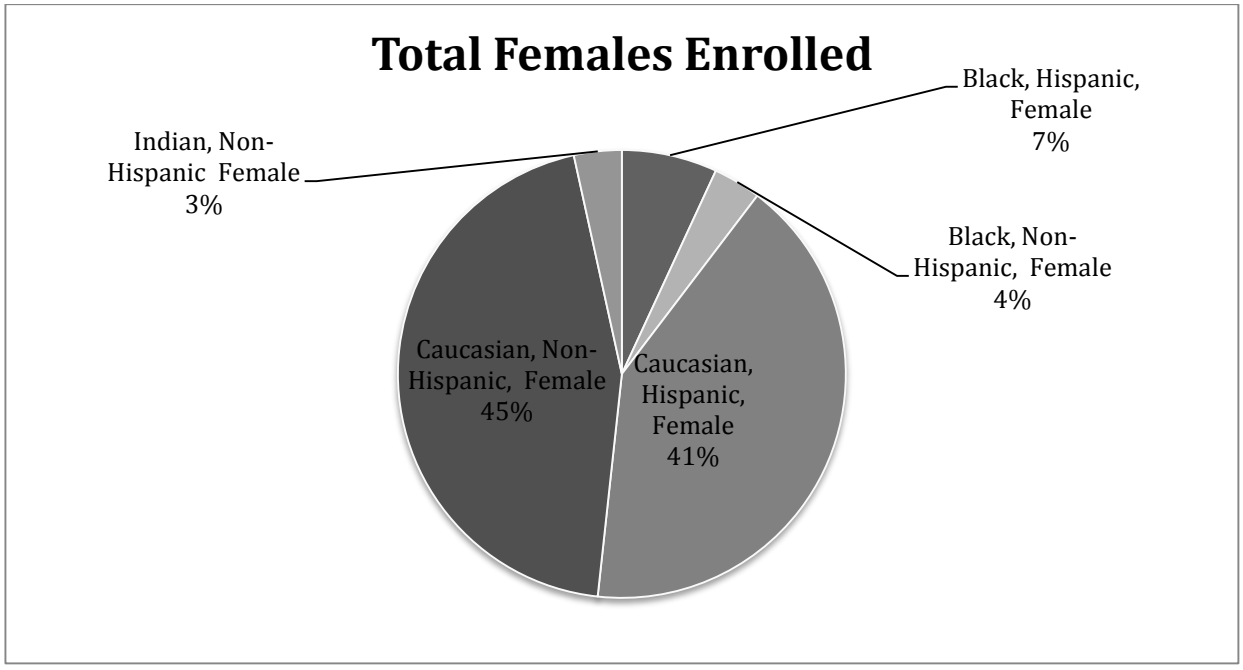


Figure 3. Race and ethnicity results of females enrolled

Study Hypothesis #1: Each of the three SPT techniques- Quintip device puncture technique, Duotip device twist technique, and the Duotip prick technique- produce a positive wheal ≥ 3mm to the positive control of histamine on the back of the pediatric research participant.

Results revealed that each of the three SPT techniques- Quintip device puncture technique, Duotip device twist technique, and the Duotip prick technique- produced positive wheals ≥ 3mm to the positive control of histamine on the back of the pediatric research participants, supporting the research hypothesis **(Table 5).**

Each subject had at least one True Positive (TP) wheal defined as ≥ 3 mm in mean diameter and one True Negative (TN) wheal < 3mm in mean diameter.

Each of the three SPT techniques- Quintip device puncture technique, Duotip device twist technique, and the Duotip prick technique- produce a positive wheal ≥ 3mm.

Table 5. Median Wheal Size

Technique	Minimum	10%	25%	Median	75%	90%	Maximum
Prick/Lift	0	2.35	4	**5**	6.5	7.5	12
Punch	0	2	4	**5**	5	6.5	8
Twist	0	4	5	**6.5**	7.5	8.5	14.5

Using a non-parametric statistical method, Wilcoxon test, to rank each test in numerical order against each test and then against each technique using the median value in 4 different quartiles, the analysis revealed that all three techniques produced positive wheals when exposed to the positive antigen of histamine. Each subject had at least one True Positive (TP) wheal

defined as ≥ 3 mm in mean diameter and one True Negative (TN) wheal < 3mm in mean diameter.

Mean diameter of wheals, small red bumps developed on the skin where the allergens were placed, were recorded at precisely 15 minutes later by a second trained operator. For this study, the size of the wheals only represented positive skin prick tests and did not indicate the severity of the symptoms or sensitivity to the histamine (true positive) or saline (false positive).

Table 6. Sensitivity and Specificity

Technique/device	TP	FN	Sensitivity %	Specificity %
Quintip Punch	117	19	86%	96.3%
Duotip Prick/Lift	121	15	88.9%	97%
Duotip Twist	132	4	97%	83.8%

Comparing results between the three techniques and two devices, the twist method was most sensitive (97%) as compared to the punch technique (86%) and prick/lift technique (89%). Only 2.8% of those tested using the twist technique produced false negative responses to histamine as compared to 14% (Quintip punch) and 11.1% (Duotip prick/lift).

The SPT with 100% sensitivity correctly identifies all subjects with the positive histamine response. The overall SPT sensitivity detected 91% of subjects with a true positive response to histamine and a 9% of false negative responses to histamine (false negative). Sensitivity is paramount when the SPT is used to make treatment decisions, open diets, and allow exposure to allergens.

Table 7. Contingency Analysis of Positive (H) vs. Negative (S)

Technique	**Test**	**ChiSquare**		**Prob>ChiSquare**
PrickLift	Pearson	202.634		<.0001
Punch	Pearson	186.446		<.0001
Twist	Pearson	181.114		<.0001
Technique	**FN**	**FP**	**TN**	**TP**
PrickLift	15	4	132	121
Punch	19	5	131	117
Twist	4	22	114	132
Number	**Test**	**ChiSquare**		**Prob>ChiSquare**
816	Pearson	31.940		<.0001

Measures of Association- Pearson Test ChiSquare was used for this study as defined in **Table 7**. Since the rows and columns in a table were completely independent of each other, the entries in the table (distribution of mass) were reproduced from the row and column totals alone, or row and column comparison analysis. The sums of the frequencies across the columns must be equal to the row totals, and the sums across the rows equal to the column totals. The results for this DNP study were found to be statistically significant as represented by the p value <.0001.

Study Hypothesis #2: Variability in SPT results was greatest using the Duotip prick technique among multiple operators.

Variability in the SPT results to histamine was greatest using the Duotip prick technique among multiple operators.

Table 8. Variability in SPT to Histamine

HISTAMINE				
Technique/Device	**Number**	**Mean**	**Standard Deviation**	**Co-efficient of Variation**
Prick/Lift	136	4.95221	2.17722	44.0
Punch	136	4.35662	1.74686	40.1
Twist	136	6.46750	2.36714	36.6

The one-way AVONA analysis using parametric measurements and a p value of less than 0.0001 suggested that the Duotip prick lift method was highest as compared to the other methods as defined by the Co-efficient of Variation, or the variation in the ability to repeat the test in same tests in patients.

Duotip twist method was highly sensitive as noted on the previous slide (97%) even though the mean (6.5) and standard deviation are largest (2.36714). Results indicate the twist tests are highly reproducible as noted with the lowest coefficient of variation (36.6).

Study Hypothesis #3: Variability in SPT results was the least using the Quintip device puncture technique, regardless of operator change.

Variability in the SPT results to histamine was least using the Duotip twist technique among multiple operators **(Table 9).**

Table 9. Variability in SPT- Mean, Median, and CV

	HISTAMINE		
Technique/Device	**Median**	**Mean**	**Co-efficient of Variation**
Prick/Lift	5.0 (4.0, 6.5)	5.0±2.2	44.0
Punch	5.0 (4.0, 5.0)	4.4±1.7	40.1
Twist	6.5 (5.0, 7.5)	6.5±2.4	36.6

Variability in SPT results was the least using the Quintip device puncture technique, regardless of operator change.

Using the Wilcoxon test to conduct non-parametric analysis using the median data and ANOVA test to conduct parametric analysis using the mean data, resulted in the same message that the twist method using the Duotip device had the least variation in results.

Research Hypothesis #4: The Quintip puncture technique was highly reproducible as compared to the Duotip prick and twist techniques.

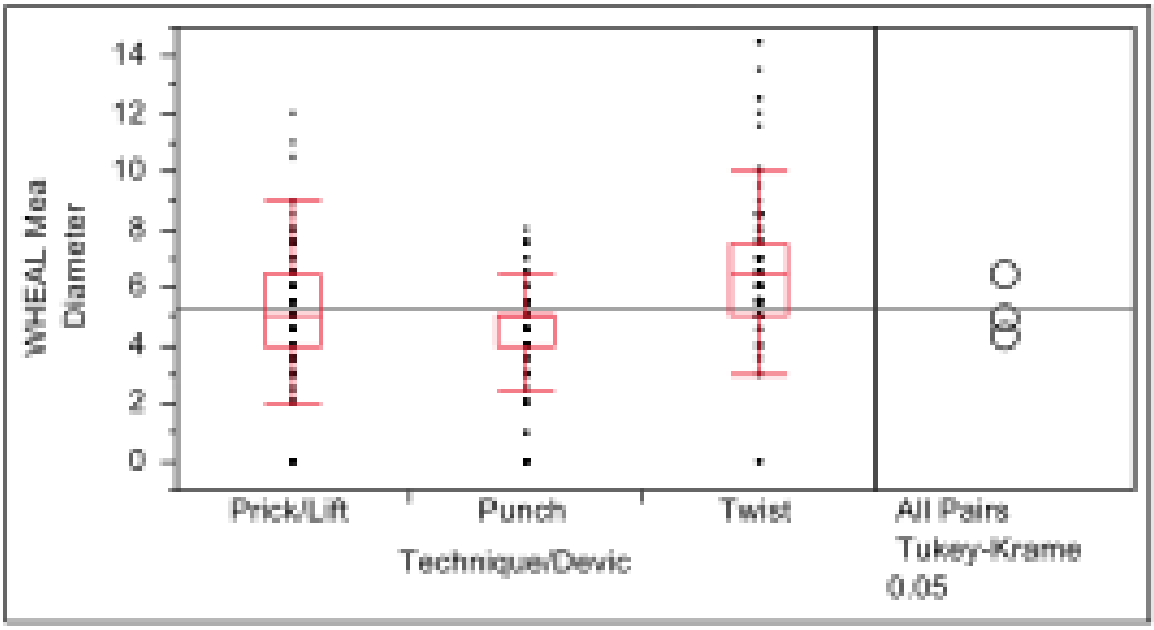
Table 10. Reproducibility of Techniques

HISTAMINE							
Technique/ Device	**Median**	**Mean**	**CV**	**TP**	**FN**	**Sensitivity**	**Specificity**
Prick/Lift	5.0 (4.0, 6.5)	5.0±2.	44.0	121	15	89%	97%
Punch	5.0 (4.0, 5.0)	4.4±1.	40.1	117	19	86%	97%
Twist	6.5 (5.0, 7.5)	6.5±2.	36.6	132	4	97%	84%

The Quintip puncture technique was highly reproducible as compared to the Duotip prick and twist techniques as defined by the differences in wheal means and standard deviations of the data between the different techniques. The one-way AVONA analysis using parametric measurements and a p value of less than 0.0001 further suggested that the Duotip twist method was highly sensitive and able to provide true positive results while limiting false negative SPT results when conducted on the back of children.

The Coefficient of variation, or the variation in the ability to repeat the same test in patient, is the lowest with the twist, using histamine and saline, as compared to the other two techniques **(Table 10).**

Table 11. Mean Wheal Diameter



The median wheal diameter is largest with the twist (6.5) as compared to the prick/lift and punch (5). In addition the twist has the largest histamine wheal (14.5) when compared to the prick/lift (12) and punch (8). This may be reflective of the "twisting" or traumatic nature of the technique.

Another way to look at the data included comparing the two histamines within a given column and comparing the overall pairs to one another. The statistical differences in matched pairs within columns were identified and compared to all matched pairs in total to identify the mean differences. The Prick Lift had the greatest mean difference in histamine measurements between H1 and H2 as reflected by the P value of 0.0387.

The twist technique was the least variable and most reproducible with the mean difference of -0.082 between H1 and H2.

Table 12. Agreement between H1 and H2

Agreement between H1 and H2 using continuous variables			
Technique	**Test**	**Result**	**Statistical Significance**
PrickLift	H2	5.213	
PrickLift	H1	4.691	
Prick Lift	Mean Difference	0.522	0.0387
Punch	H2	4.125	
Punch	H1	4.588	
Punch	Mean Difference	-0.463	0.0878
Twist	H2	6.426	
Twist	H1	6.508	
Twist	Mean Difference	-0.082	0.7937

In conclusion, with proper education and training the skin prick test can be used to identify and treat severe allergies to drugs, foods and environmental allergens. This inexpensive test has the potential the yield enormous results at a single visit and dictate life saving treatment, which is patient specific. This prospective, head-to-head comparison of the performance of two single use skin test devices using the Duotip twist method and Quintip punch method as compared to the Duotip prick/lift method. This study was performed under the best of clinical circumstances, with operators trained by representatives of the manufacturers, and who performed all skin testing, and another trained skin test operator who read all of the results. We found significant differences among all devices to be tested.

Dissemination of Study Results

Data results were shared once all research participants were enrolled, study visits complete and data analyzed. Information was shared internally at the Pediatric Faculty meeting and staff meetings within the Pediatric Care Unit and Pediatric Clinic in the study site.

Implication for Practice and Future Research

Interestingly, even though SPT is associated with minimal pain and yielding significant, very little research has occurred to verify its reliability or define clinical treatment protocols for its use. As new devices and techniques are being produced, continued evaluation of these devices will be to be conducted to determine potential for variability and reproducibility among SPT operators across all age groups.

Following the outcome of this DNP Capstone Research Project, future research investigations may include:

- Food, Environmental, and Medication allergen testing on pediatric patients
- RAST results correlated to SPT results
- SPT results correlated to Oral Food Challenges
- New devices and techniques compared to the outcome of this study

Recommendations for on-going skin prick testing. Skin prick testing research must be continual and new devices must be assessed before implementation regardless of the age group for intended use. With proper education and training, the skin prick test can be used to identify and treat severe allergies to drugs, foods and environmental allergens. Overall, skin testing is associated with minimal pain, and individual physicians commonly use the test to diagnose and treat drug, food and environmental allergies. As new devices and techniques are being produced,

continued evaluation of these devices will be to be conducted to determine potential for variability and reproducibility among skin test operators.

In summary, this Doctor of Nursing Practice (DNP) Clinical Research Project aimed to discover knowledge of skin prick test (SPT) technique to enhance diagnosis and treatment of potentially life threatening allergies in the pediatric population at National Jewish Health's NJ4Kids Program. The results will integrate research, clinical and educational efforts to positively impact clinical care through evidence-based research in the pediatric population.

Timeframe and Budget/ Resources

Table 13. Logic Model for the Doctor of Nursing Practice Clinical Research Project

Resources-Input	Activities	Constraints	Outputs	Outcomes	Impacts
Funding in the form of supplies supporting Capstone Research Project	Provide immediate SPT results for allergen testing	Devices and allergens are eliminated	Deliver prompt diagnostic results for food, drug, and environmental allergens	Early and immediate diagnosis of allergic triggers	Project funded with supplies through August 2014 (revised December 2014)
Research and Grant infrastructure of the facility	Comprehens ive grant manage-ment of clinical research study including regulatory and clinical research activities.	Delay in IRB approval	Adherence to grant policy and procedures as mandated by local internal review board.	Regulatory oversight for Participant and Principal Investigator	First clinical research study submitted to IRB-December 2013 (Revised March 2014)
The facility Infrastructure	Outpatient, laboratory and Pediatric Care Unit facilities	Potential lack of clinical space due to busy daily clinics	Attend scheduled research visit	Increased patient satisfaction by providing comprehensi ve care in clinic	Adequate space and support
Immediate access to the facility for validation of initial diagnosis	Early intervention with laboratory and clinical diagnostic evaluations	Allergist unavailable	Validation of initial positive SP	Results evaluated immediately and plan discussed with patient	Early intervention and treatment for identified allergies

Study Timeline

Planned duration of the entire study. It was anticipated that enrollment would begin in March 2014 and conclude within two months. Data was analyzed and prepared for submission for publication in Winter 2014.

- CITI Training for SPT Operators- December 2013
- Regis DNP Proposal Presentation- March 2015
- IRB submission to the facility's Institutional Review Board- March 2014
- IRB submission to Regis University Review Boards- May 2014
- Medical Liaison Training Presentations- January 2014
- Research Protocol Presentation to the facility Faculty and Staff- June 2014
- Enrollment Period- August-October 2014
- Data Analysis- November-2014 -August 2015
- Final Presentation- September 2015

Duration of participation for each participant. Each research participant's involvement in this research study occurred on a single day with the study visit lasting less than two hours. This included the informed consent discussion and SPT procedure.

Study Budget/ Resources

In 2012, the State of Colorado elected to not reimburse for the SPT and instead would only provide financial coverage for oral food challenges. Specialists from the facility and other allergy practices pleaded with the State Health Department and state lawmakers to reconsider, arguing the oral food challenges place the patients at extreme risk that are unknown beforehand if SPT is not performed ahead of time. The State of Colorado reversed their decision and now reimburse for the tests (Gelfand, 2013). Most private insurance companies and health

maintenance organizations pay for this service and prefer to limit oral food challenges until deemed safe to do so.

References

American Academy of Allergy, Asthma and Immunology (AAAAI) (2013). *Skin prick testing.* Retrieved from http://www.aaaai.org/conditions-and-treatments/library/at-a-glance/allergy-testing.aspx.

American Psychological Association. (2010). *Publication Manual of the American Psychological Association* (6th ed.). Washington, DC: Author.

Atkins, F. M., Steinberg, S. S., & Metcalfe, D. D. (1985). Evaluation of immediate adverse reactions to foods in adult patients: I. Correlation of demographic, laboratory, and prick skin test data with response to controlled oral food challenge. *Journal of Allergy and Clinical Immunology, 75*(3), 348-355.

Bernstein, I. L., Li, J. T., Bernstein, D. I., Hamilton, R., Spector, S. L., Tan, R., ... & Weber, R. (2008). Allergy diagnostic testing: an updated practice parameter. *Annals of Allergy, Asthma & Immunology, 100*(3), S1-S148.

Blackley, C. H. (1873). *Experimental Researches on the Causes and Nature of Catarrhus Aestivus (Hay-Fever or Hay-Asthma*). Retrieved from http://www.archive.org/stream/experimentalres00blacgoog#page/n4/mode/2up.

Carr, W. W., Martin, B., Howard, R. S., Cox, L., & Borish, L. (2005). Comparison of test devices for skin prick testing. *Journal of Allergy and Clinical Immunology, 116*(2), 341-346.

Carr, T. F., & Saltoun, C. A. (2012, May). Skin testing in allergy. *Allergy and Asthma Proceedings 33*(3), S6-S8.

Chafen, J. J. S., Newberry, S. J., Riedl, M. A., Bravata, D. M., Maglione, M., Suttorp, M. J., ... & Shekelle, P. G. (2010). Diagnosing and managing common food allergies. *JAMA: The Journal of the American Medical Association, 303*(18), 1848-1856.

Cox L, Williams B, Sicherer S, Oppenheimer J, Sher L, Hamilton R, Golden D; American College of Allergy, Asthma and Immunology Test Task Force; American Academy of Allergy, Asthma and Immunology Specific IgE Test Task Force (2008). Pearls and pitfalls of allergy diagnostic testing: report from the American College of Allergy, Asthma and Immunology/American Academy of Allergy, Asthma and Immunology Specific IgE Test Task Force. *Annals of Allergy, Asthma and Immunology, 101*(6): 580–592.

Corder, W. T., Hogan, M. B., & Wilson, N. W. (1996). Comparison of two disposable plastic skin test devices with the bifurcated needle for epicutaneous allergy testing. *Annals of Allergy, Asthma & Immunology, 77*(3), 222-226.

Demoly, P., Bousquet, J., Manderscheid, J. C., Dreborg, S., Dhivert, H., & Michel, F. B. (1991). Precision of skin prick and puncture tests with nine techniques. *Journal of Allergy and Clinical Immunology, 88*(5), 758-762.

Eigenmann, P. A., & Sampson, H. A. (1998). Interpreting skin prick tests in the evaluation of food allergy in children. *Pediatric Allergy and Immunology, 9*(4), 186-191.

European Academy of Allergy and Clinical Immunology. *Allergy Skin Testing*. Retrieved from http://www.eaaci.org.

Faino, A. (2013). *Statistical analysis*. Retrieved on December 06, 2013.

Food and Drug Administration (2013). *Biologics, Blood, and Vaccines.* Retrieved from http://www.fda.gov/downloads/BiologicsBloodVaccines/Allergenics/

Fitzpatrick, J., & Whall, A. (2005). *Conceptual models for nursing: analysis and application*. Upper Saddle River, New Jersey: Pearson Prentice Hall.

George, J. B. (2011). *Nursing theories: The base for professional nursing practice* (6th ed.). Boston, MA: Person.

Heinzerling, L., Frew, A. J., Bindslev- Jensen, C., Bonini, S., Bousquet, J., Bresciani, M., ... & Zuberbier, T. (2005). Standard skin prick testing and sensitization to inhalant allergens across Europe–a survey from the GA2LEN network*. *Allergy, 60*(10), 1287-1300.

Heinzerling, L., Mari, A., Bergmann, K. C., Bresciani, M., Burbach, G., Darsow, U., ... & Lockey, R. (2013). *The skin prick test–European standards. Clinical and Translational Allergy, 3*(1), 3.

Hollister-Stier Laboratories. *Quintip device*. Retrieved from http://www.hsallergy.com/sites/www/Uploads/Files/Products/ProductInserts/385415-H05.pdf

Houser, J., & Oman, K. S. (2011). *Evidence-based practice: An implementation guide for healthcare organizations*. Sudbury, MA: Jones and Bartlett.

Institute for Healthcare Improvement. (n.d.). *Asthma-skin testing*. Retrieved from http://www.ihi.org/IHI/Topics/PatientSafety/Asthmas/Resources.htm

Jasovsky, D., Morrow, M., Clementi, P., & Hindle, P. (2010). Theories in action and how nursingpractice changed. *Nursing Science Quarterly, 23*(1), 29-38.

Krau, S. D., McInnis, L. A., & Parsons, L. (2010). Allergy skin testing: what nurses need to know. *Critical Care Nursing Clinics of North America, 22*(1), 75-82.

Lewin, K. (1947). Frontiers in group dynamics: concept, technique and reality in social science; social equilibria and social change. *Human relations, 1*(4), 5-41.

Lincoln Diagnostics, Inc. *Duotip device*. Retrieved from http://www.lincolndiagnostics.com/products/duotip-test.

Masse, M. S., Granger Vallée, A., Chiriac, A., Dhivert-Donnadieu, H., Bousquet, Rouanet, L., Bousquet, P. J., & Demoly, P. (2011). Comparison of five techniques of skin prick tests used routinely in Europe. *Allergy, 66*(11), 1415-1419.

National Jewish Health (2013). *Find a Doctor*. Retrieved from http://www.nationaljewish.org/about/people-search/detail/?id=112.

Nelson H.S., Knoetzer J., Bucher B. (1997). Effect of distance between sites and region of the body on results of skin prick tests. *Journal of Allergy and Clinical Immunology*, *97*(2): 596-601.

Nelson, H. S., Lahr, J., Buchmeier, A., & McCormick, D. (1998). Evaluation of devices for skin prick testing. *Journal of Allergy and Clinical Immunology, 101*(2), 3-6.

Nelson, H. S., Rosloniec, D. M., McCall, L. I., & Iklé, D. (1993). Comparative performance of five commercial prick skin test devices. *Journal of Allergy and Clinical Immunology*, 92(5), 750-756.

Nibert, M. 2.5.1 *Boyer's Model of Scholarship*. Retrieved from http://www.pcrest.com/PC/FGB/test/2_5_1.htm

NIH MedlinePlus.gov. *How to control your seasonal allergies*. Retrieved from http://www.nlm.nih.gov/medlineplus/magazine/issues/spring13/articles/spring13pg22-23.html

Rancé, F., Abbal, M., & Lauwers-Cancès, V. (2002). Improved screening for peanut allergy by the combined use of skin prick tests and specific IgE assays. *Journal of Allergy and Clinical Immunology*, *109*(6), 1027-1033.

Rhodius, R., Wickens, K., Cheng, S., & Crane, J. (2002). A comparison of two skin test methodologies and allergens from two different manufacturers. *Annals of Allergy, Asthma & Immunology*, *88*(4), 374-379.

Rogers, E. M. (1995). *Diffusion of Innovation* (4th ed.). New York: The Free Press.

Stillwell, S., Fineout-Overholt, E., Melnyk, B., & Williamson, K. (2010). Evidence-Based Practice, Step by Step: Asking the Clinical Question A Key Step in Evidence-Based Practice.

American Journal of Nursing, 110(3), 58-61.

Spergel, J. M., Andrews, T., Brown-Whitehorn, T. F., Beausoleil, J. L., & Liacouras, C. A. (2005). Treatment of eosinophilic esophagitis with specific food elimination diet directed by a combination of skin prick and patch tests. *Annals of Allergy, Asthma & Immunology, 95*(4), 336-343.

United States Joint Council of Allergy, Asthma and Immunology. *Skin Prick Testing*. Retrieved from http://www.jcaai.org.

Werther, R. L., Choo, S., Lee, K. J., Poole, D., Allen, K. J., & Tang, M. L. (2012). Variability in Skin Prick Test Results Performed by Multiple Operators Depends on the Device Used. *World Allergy Organization Journal, 5*(12), 200-204.

Yoder-Wise, P. S. (2007). *Leading and managing in nursing* (4th ed.). Mosby: St. Louis, MO

Yoon, I. K., Martin, B. L., & Carr, W. W. (2006, November). A comparison of two single-headed and two multi-headed allergen skin test devices. *Allergy and Asthma, 27*(6), 473-478.

Zaccagnini, M. E., & White, K. W. (2011). *The DNP essentials: A new model for advanced practice nursing*. Sudbury, MA: Jones and Bartlett.

Appendix A

SWOT ANALYSIS

STRENGTHS

1. What are your strengths?
2. What do you do better than others?
3. What unique capabilities and resources do you possess?
4. What do others perceive as your strengths?

- Small tertiary facility
- Specialty hospital focusing on pulomonary, asthma and allergy, and immunology medicine
- World reknown xpertise in several specialty areas
- Main hospital and several offsite clinics
- Local partnerships with adult intensive care units
- No patient will be turned away regrdless of financial status
- Significant research experience- bench and clinical
- Seen at the center of "last resort" by patients and referring physicians
- Patients referred from around the world

WEAKNESSES

1. What are your weaknesses?
2. What do your competitors do better than you?
3. What can you improve given current situation?
4. What to others perceive as your weaknesses?

- Large institution
- Multiple divisions covering all disciplines and facets to make the organization work -
- Supportive of hospital-wide quality improvement
- Expertise in multiple specialty areas/world-renowned healthcare providers
- Advanced technological infrastructure- EMR
- Regional coverage through network of care sites
- Regional partnerships with other healthcare networks – broadened market share
- Allow customers of all payer mixes
- Magnet designated

OPPORTUNITIES

1. What trends or conditions may positively impact you?
2. What opportunities are available to you?

- Letter of Intent signed with SCL/St. Joseph's Hospital as first step of a Joint Operating Agreement
- Funded research activities
- Partnerships with local and national respected academic medical facilities
- Department of Medicine has continued to attract highly sought after physicians
- Development has had a banner year despite the national economic struggles
- 48 hour appointments within the department of pediatrics has increased business 13-16%

THREATS

1. What trends or conditions may negatively impact you?
2. What are your competitors doing that may impact you?
3. Do you have solid financial support?
4. What impact do your weaknesses have on the threats to you?

- Competitor growing extremely fast
- Competitor's large workforce make standard processes difficult to sustain and implement
- Competitor has extremely recognizable brand and excellent marketing efforts, allowing for solid financial support from community and foundation
- Competitor seeking to see every pediatric medical visit in the Rocky Mountain region- Huge competition

Appendix B

Study Budget

Full Study Title: Reducing Variability Among Multiple Operators Using a Single Technique and Device for Skin Prick Testing in Children
Protocol Number: HS 2826
Principal Investigator: Elizabeth Esterl RN, MS
Sponsor: PI Initiated. Unfunded
Coordinator: Elizabeth Esterl RN, MS
Date: February 01, 2014

Facility IRB and Administrative Invoiced Fees				
These fees are to be paid immediately upon receipt of invoice.				
Initial Review Fee (subject to change)	waiver submitted	IRB	Non-negotiable	waived
Consent - Spanish Translation Fee $40.00 per page/ 8 pages total	$200.00	Translation	Non-negotiable	Fixed Direct

These fees are subject to change upon notification from the local IRB

Full Study Title: Reducing Variability Among Multiple Operators Using a Single Technique and
Protocol Number: HS 2826
Principal Investigator: Elizabeth
Esterl RN, MS
Sponsor: PI Initiated. Unfunded

This is a 12 month budget and pricing wil be increase 7% each year thereafter based on the date of the contract.

[ ] Budget accepted with Non-Refundable Start up Fees and Alacarte Menu of Fee for Services			Comments	Cost per Hour	Total Hours
Non-Refundable Start up Fees:					
Protocol Development- Principal Investigator	$2,400.00	PI	variable cost	60.00	40
Protocol Review- Medical Director	$500.00	Medical Director	variable cost	250.00	2
Site Evaluation	$240.00	Department	variable cost	60.00	4
IRB/Regulatory Document Preparation and Submission	$960.00	PI	variable cost	60.00	16
Contract Preparation and Budget Development/Negotiation	$440.00	Finance	variable cost	55.00	8
Study Preparation and Set-up: pre enrollment	$2,400.00	PI	variable cost	60.00	40
Pharmacy Preparation and Set-up	$120.00	Pharmacy	variable cost	60.00	2
Site Initiation	$240.00	Department	variable cost	60.00	4
Ongoing Financial Oversight including registration and scheduling, invoicing, and monthly/study conclusion financial reconciliation	$660.00	Finance	variable cost	55.00	12
Total Non-refundable Start-up Fees	**$7,960.00**				
Principal Investigator					
This fee is to be paid immediately upon receipt.					
Study management and Oversight	**$9,960.00**	PI	10% Time and Effort of Base Salary	60.00	166
			Direct fixed cost		
On-Going Regulatory Fees Performed by the PI					
These fees are to be paid immediately upon receipt of invoice.	***Fees may vary depending on IRB used***				

Regulatory Fees					
Annual Reviews- Preparation and Submission	$480.00	PI	variable cost	60.00	8
Changes to Research (each item billed separately)					
1. Protocol Amendment/Revisions	$240.00	PI	variable cost	60.00	4
2. Consent Form Modifications	$120.00	PI	variable cost	60.00	2
3. New or Updated Recruitment/Retention Materials	$120.00	PI	variable cost	60.00	2
4. Other Changes to Research Requiring Board Review	$120.00	PI	variable cost	60.00	2
Adverse Event Report Submission	$120.00	PI	variable cost	60.00	2
Local SAE Reporting	$120.00	PI	variable cost	60.00	2
Study Close Out with IRB	$120.00	PI	variable cost	60.00	2
Monitor Visit Fee (per visit)	$240.00	PI	variable cost	60.00	4
Meetings And Conferences Invoiced Fees					
Investigator/ Coordinator Meetings (Investigator)-including travel time	$480.00		variable cost	60.00	8
Conference Calls- (Investigator)	$60.00		variable cost	60.00	1
Other Fees:					
Query fees will be invoiced by site following conclusion of activity.					
Storage box request fee (after final study close out visit)	$100.00 per retrieval		Fixed Cost	100.00	1
Query request fee per hour (after final study close out visit)	$75.00 per hour		Fixed Cost	75.00	1

Per Patient Budget

Schedule of Activities						
Study Costs	Cost per Unit	Service	Single Study Visit	Comments	Cost per Hour	Total Hours
CLINICAL SERVICES:						
Informed Consent	30.00	PI	x	Direct fixed cost	60.00	0.5
Inclusion/Exclusion	15.00	PI	x	Direct fixed cost	60.00	0.25
Vital Signs	30.00	Nurse Assistant	x	Direct fixed cost	30.00	
Height and Weight	included on VS charge *	Nurse Assistant	x	Direct fixed cost	*	*
Pulse Oximetry Testing	included in VS charge *	Nurse Assistant	x	Direct fixed cost	*	*
Spirometry	119.00			Direct fixed cost	119.00	
Medical, Surgical History	15.00	PI	x	Direct fixed cost	60.00	0.25
Physical Exam-Brief	15.00	PI	x	Direct fixed cost	60.00	0.25
Skin Prick Testing	408.00	SPT Operator	x	Direct fixed cost	408.00	34.00 x 12 tests
Skin Prick Test Recording	included in SPT charge above **	SPT Operator	x	Direct fixed cost	**	**
Adverse Event Collection	15.00	PI	x	Direct fixed cost	60.00	0.25
Concomitant Medication Collection	15.00	PI	x	Direct fixed cost	60.00	0.25
LABORATORY TESTS						
Review previous RAST testing	30.00	PI	x	Direct fixed cost	60.00	0.5
Questionnaires:						
Source Document	30.00	PI		Direct fixed	60.00	0.5

				cost		
Pharmacy:						
SPT Tray Dispensing- per dispense	44.00	Pharmacy	x	Direct fixed cost	44.00	1
SPT Tray Accountability- per dispense	44.00	Pharmacy	x	Direct fixed cost	44.00	1
Patient Expense						
Patient Expense (parking, stipend)		Patient	none	N/A	none	
Facility Fee:						
Clinic Visit - (facility fee)	156.00	Facility	x	Direct fixed cost	156.00	1
Study Personnel Costs:						
SPT Operator	18.00	SPT Operator	x	Direct fixed cost	18.00	1
Principal Investigator	60.00	PI	x	Direct fixed cost	60.00	1
Additional Personnel		other				
Total Per Patient Direct Cost						
Total Study 26% Indirect Cost						23.23 %
Total Per Patient Cost						
Total Study Cost- Enrolling 68 Patients						68

		Fixed	Variable
IRB Fees			
	Fixed Costs	200.00	0.00
	Variable Costs	0.00	0.00
Non-Refundable Startup Costs			
	Fixed Costs	9,960.00	
	Variable Costs		7,960.00
Per Patient Budget- Total Study			
	Fixed Costs	70,992.00	
	Variable Costs		16,491.44
Sub Total		81,152.00	24,451.44

Total Study Costs	**105,603.44**

In the clinical setting, SPT has a direct cost of 34.00 per prick.	34.00	direct cost per SPT
Once the study is complete, the costs will be offset when 3106 SPT are complete	3,106	clinical SPT
On average each patient has 20 SPT at a given visit,	20	SPT per patient
taking approximately 155 patients to recoup costs.	155	patients to offsite study costs
On average, there are 50 patients each week requiring SPT	50	patients/week
Time in weeks to recover costs	3	weeks

Appendix C

State of Colorado Proclamation

Proclamation

WHEREAS, as many as 15 million Americans have food allergies, and nearly 6 million of these individuals are children under the age of 18; and

WHEREAS, research shows that the prevalence of food allergy is increasing among children; and

WHEREAS, eight foods cause 90% of all food allergy reactions in the U.S.: shellfish, fish, milk, eggs, tree nuts, peanuts, soy, and wheat; and

WHEREAS, symptoms of a food-allergic reaction can include hives, vomiting, diarrhea, respiratory distress, and swelling of the throat; and

WHEREAS, according to the Journal of Allergy and Clinical Immunology, food allergy causes more than 200,000 emergency department visits each year, including about 90,000 for probable anaphylaxis. Reactions typically occur when an individual unknowingly eats a food containing an ingredient to which they are allergic; and

WHEREAS, there is no cure for food allergy, and therefore strict avoidance of the offending food is the only way to prevent an allergic reaction; and

WHEREAS, anaphylaxis is a serious allergic reaction that is rapid in onset and may cause death; and

WHEREAS, Food Allergy Research & Education (FARE) is a national, nonprofit organization dedicated to ensuring the safety and inclusion of individuals with food allergies while relentlessly seeking a cure;

Therefore, I, John W. Hickenlooper, Governor of the State of Colorado, do hereby proclaim May 11-17, 2014,

FOOD ALLERGY AWARENESS WEEK

in the State of Colorado.

GIVEN under my hand and the Executive Seal of the State of Colorado, this eleventh day of May, 2014

John W. Hickenlooper
Governor

Appendix D

Facility Institutional Review Board Approval Letter

National Jewish Health®
Science Transforming Life®

1400 Jackson Street
Denver, Colorado 80206
303.388.4461
800.423.8891
www.nationaljewish.org

NOTICE OF IRB APPROVAL

To: **Pia Hauk, MD**
Elizabeth Esterl, DNPc, RN

Re: **HS-2826 - REDUCING VARIABILITY AMONG MULTIPLE OPERATORS USING A SINGLE TECHNIQUE AND DEVICE FOR SKIN PRICK TESTING IN CHILDREN**

Date: **March 24, 2014**

The National Jewish Health IRB has approved the above research study.

On 2/13/2014, the convened IRB reviewed the study and assessed the risk level as minimal risk. The approval period is for 12 months from the convened IRB's review.

Your study number is HS-2826. Please be sure to reference this number in any correspondence with the IRB.

The IRB approval includes the following specific review determinations:

- For minors participating in this study, the IRB assessed the Child Research Assessment Category as 45 CFR 46.404. For the purposes of informed consent documentation, a child may be enrolled in the study with the signature of only one parent/guardian.

Continued approval is conditional upon your compliance with the following requirements:

- A stamped copy of the Informed Consent and Authorization Document is enclosed. No other consent forms should be used. A photocopy of the stamped copy must be signed by each subject prior to initiation of any protocol procedures. Each subject must be given a copy of the signed consent form.
- All protocol amendments and changes to approved research must be submitted to the IRB and not be implemented until approved by the IRB except where necessary to eliminate apparent immediate hazards to the study subjects.
- All unanticipated problems must be reported to the IRB per the National Jewish Health IRB SOP, *Review of Research: Unanticipated Problems Involving Risks to Subjects or Others.*

Complete and submit renewal or completion reports to the IRB as follows:

Renewal of the study: Complete and return the Continuing Review Report six weeks prior to the expiration of the approval period. A continuing review notice may be provided as a courtesy. The Principal Investigator is responsible for ensuring timely submission of renewal documents.

Completion, termination, or non-renewal of the project: Send the report within 30 days of study completion.

The study cannot continue after **2/12/2015** until re-approved by the IRB.

Please call me if you have any questions about the terms of this approval.

Richard Weber, MD
IRB Co-Chairman

Copy:
File

Attachments:
Protocol, dated 03/15/2014
New Protocol Application, dated 03/15/2014
Child Research Assessment form, dated 03/15/2014
Researcher Acknowledgment / Conflict of Interest and Scientific Misconduct disclosure – Pia Hauk, signed 01/31/2014
Researcher Acknowledgment / Conflict of Interest and Scientific Misconduct disclosure – Elizabeth Esterl, signed 01/31/2014
Researcher Acknowledgment / Conflict of Interest and Scientific Misconduct disclosure – Erwin Gelfand, signed 02/03/2014
Researcher Acknowledgment / Conflict of Interest and Scientific Misconduct disclosure – Kelly Buller, signed 01/31/2014
Researcher Acknowledgment / Conflict of Interest and Scientific Misconduct disclosure – Suseth Figueroa, signed 01/31/2014
Researcher Acknowledgment / Conflict of Interest and Scientific Misconduct disclosure – Lauren Foster, signed 01/31/2014
Researcher Acknowledgment / Conflict of Interest and Scientific Misconduct disclosure – Kelly Seeley, signed 01/31/2014
Researcher Acknowledgment / Conflict of Interest and Scientific Misconduct disclosure – Wendy Sherman, signed 01/31/2014
Researcher Acknowledgment / Conflict of Interest and Scientific Misconduct disclosure – Anna Faino, signed 03/21/2014
Researcher Acknowledgment / Conflict of Interest and Scientific Misconduct disclosure – Amber Jandreau, signed 02/03/2014
Informed Consent (and Authorization form), dated 03/15/2014
Assent form, dated 03/15/2014

Recruitment Authorization to be Contacted for Research (HIP-001), undated
Recruitment Flyer, undated
Source worksheets, undated
Histamine package insert, revised 08/2013

Appendix E

Regis University Institutional Review Board Approval Letter

REGIS UNIVERSITY
Academic Grants
3333 Regis Boulevard, H-4
Denver, Colorado 80221-1099
303-458-4206
303-964-5528 FAX
www.regis.edu

IRB – REGIS UNIVERSITY

July 23, 2014

Elizabeth Esterl
1400 Jackson Street
Denver, CO 80206

RE: IRB #: 14-236

Dear Dr. Esterl:

Your application to the Regis IRB for your project, "Reducing Variability among Multiple Operators Using a Single Technique and Device for Skin Prick Testing in Children," was approved as an expedited study on July 18, 2014. It is approved per OHRP Category of Research #1B.

If changes are made in the research plan that significantly alter the involvement of human subjects from that which was approved in the named application, the new research plan must be resubmitted to the Regis IRB for approval. Projects which continue beyond one year from their starting date require IRB continuation review. The continuation should be requested 30 days prior to the one year anniversary date of the approved project's start date. A completion report of the findings of this study should be sent to the IRB.

In addition, it is the responsibility of the principal investigator to promptly report to the IRB any injuries to human subjects and/or any unanticipated problems within the scope of the approved research which may pose risks to human subjects. Lastly, a final report should be submitted at completion of the project and it is the responsibility of the investigator to maintain signed consent documents for a period of three years after the conclusion of the research.

Sincerely,

Patsy Cullen

Patsy McGuire Cullen, PhD, PNP-BC
Chair, Institutional Review Board
Professor & Director
Doctor of Nursing Practice & Nurse Practitioner Programs
Loretto Heights School of Nursing
Regis University

cc: Dr. Erwin Gelfand

A JESUIT UNIVERSITY

Appendix F

National Jewish Health Letter of Support

National Jewish Health®
Science Transforming Life™

Main Health Campus
1400 Jackson St
Denver, CO 80206
303.388.4461
800.423.8891
njhealth.org

Regis University
3333 Regis Boulevard
Denver, Colorado 80221

June 4, 2014

To Whom It May Concern:

I, Erwin Gelfand, give my permission to allow Elizabeth Esterl, as a Regis University DNP Student, to complete the study titled, "Reducing Variability Among Multiple Operators Using a Single Technique and Device for Skin Prick Testing in Children" within the Department of Pediatrics at National Jewish Health.

Regards,

Erwin Gelfand, MD
Chairman, Department of Pediatrics
Professor
National Jewish Health
1400 Jackson Street
Denver, Colorado 80206

Appendix G

Research Study Forms

National Jewish Health®
Science Transforming Life®

1400 Jackson Street
Denver, CO 80206
njhealth.org

Skin Prick Test Study

National Jewish Health IRB
APPROVAL
Date 03/24/2014
Signed WC

Researchers at National Jewish Health want to find ways to learn more about two skin prick test devices and how operators use the devices to find out which one device and technique works best in children. Research is always voluntary!

Would the study be a good fit for me?
This study might be a good fit for you if:

- You are between 1 year and 16 years of age
- Are not taking medications such as antihistamines that will interfere with the results

What would happen if I took part in the study?
If you decide to take part in the research study, you would:

- Be asked to sign a consent and HIPAA authorization form
- Have a brief physical exam
- Complete 12 skin prick tests

For more information and to enroll in this study, please contact:
Elizabeth Esterl, DNPc, RN

Principal Investigator:
Pia Hauk, MD
Co-Investigator:
Elizabeth Esterl DNPc, RN

Elizabeth Esterl 303-398-1275 Elizabeth Esterl 303-398-1275 Elizabeth Esterl 303-398-1275 Elizabeth Esterl 303-398-1275 Elizabeth Esterl 303-398-1275 Elizabeth Esterl 303-398-1275 Elizabeth Esterl 303-398-1275 Elizabeth Esterl 303-398-1275 Elizabeth Esterl 303-398-1275 Elizabeth Esterl 303-398-1275

National Jewish Health
Science Transforming Life

National Jewish Health IRB
APPROVAL
Date 03/24/2014
Signed WC

IRB Number- HS 2826

Expiration Date 02/13/2015

NATIONAL JEWISH HEALTH
INFORMED CONSENT FORM FOR RESEARCH WITH HUMAN SUBJECTS

Protocol Title: Reducing Variability Among Multiple Operators Using a Single Technique and Device for Skin Prick Testing in Children

Principal Investigator: Pia Hauk, MD **Co-Investigator:** Elizabeth Esterl, DNPc, RN
Version Date: March 15, 2014
24 Hour Contact Number: 303-398-1239

You are being invited to participate in a research study. Research studies include only people who choose to take part. Please take your time making a decision. Feel free to discuss it with your friends, family, and doctors. Before agreeing to take part in this research study, it is important that you read this consent and authorization form because it describes the study and any of the risks that it may involve. No guarantees or promises can be made regarding your experience in the study. Please ask the study doctor or the study staff to explain any words, ideas, or information not clear to you.

In this consent and authorization form, "you", always refers to the subject. If you are a legally authorized representative (such as the parent), remember that "you" refers to the study participant.

Why is this study being done?

You are being asked to take part in a research study of learn more about two skin prick test devices and how operators use the devices to find out which one device and technique works best in children. You are being asked to be in this study because you are a current patient at National Jewish Health's NJ4Kids Program and are between the ages of 1 year and 16 years.

A common diagnostic procedure during the initial evaluation and on-going follow-up care for a person with allergic disease is the skin prick test. This test involves placing allergen solutions on the skin and then pricked using a disposable device. The results of the skin prick test provide valuable information used to confirm diagnoses and develop treatment plans. Skin prick testing is a key test in identifying allergens causing allergic symptoms, prescribed immunotherapy treatment, and avoidance diets.

This study will compare two different skin prick test devices using three different techniques including:

- Duotip (Lincoln Diagnostics) bifurcated plastic needle using prick/lift technique
- Duotip (Lincoln Diagnostics) bifurcated plastic needle using twist technique
- Quintip (Hollister-Stier) steel lancet using punch technique

Other people in this study

Up to 68 local subjects with will be enrolled in this research study at National Jewish Health. This study will not done at any other clinic or hospital. Taking part in this study is completely voluntary. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

What happens if I join this study?

If you agree to join the study, you will be asked to sign this form. Next the following information will be obtained during the single study visit:
Enrollment/Study Visit 1

1. Demographics: age at entry, date of birth, gender, race/ethnicity.
2. Clinical Presentation: brief history of allergic symptoms, signs, age at onset, initial interventions
3. Current Medications and Diet History
4. Brief Physical examination: Measurements: vital signs; Appearance: skin assessment;
5. Skin Prick Tests: using Duotip prick, Duotip twist techniques and Quintip punch technique. A total of 12 skin prick tests will be completed on your back and recorded 15 minutes later. Each device will be tested using two histamine solutions (positive control and expected to react during test) and two glycerol-saline solutions (negative control and expected to not react during test), in three vertical columns and spaced equally apart. The operator and person recording the result will not know what solution has been placed where. This is called being "blinded" to the test.

Table - Study Visit

The single study visit will include the following:

EVALUATION	VISIT 1
Informed Consent	X
Eligibility	X
Medical History	X
Medication History	X
Brief Physical Examination	X
Skin Prick Tests	X

Once the skin prick tests are completed, your participation in the study is complete. The duration of the study visit will last approximately 30 minutes and the 12 skin prick tests will take less than 2 minutes to complete and recorded 15 minutes later.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include brief minimal localized site pain is associated with the skin prick test procedure which will resolve immediately without treatment

once the prick is completed. No additional treatment is necessary to resolve pain. Histamine solution (10 mg/mL; Hollister-Stier, Spokane, Wash) as the positive control will cause itching at the site. After recording the results after 15 minutes, your back will be washed with warm water and the itching should resolve quickly without further treatment.

There is a potential risk of loss of confidentiality, but we will do everything to maintain the confidentiality of your personal information by keeping all research records and results in a locked file cabinet within a locked office of the principal investigator. However, confidentiality cannot be guaranteed.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about the two skin prick test devices and the three different ways that we use them.

This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

Are there alternative treatments?

You may elect to not participate in the study.

The treating clinician may be both your health care provider and the investigator for this study. This clinician is interested both in your clinical welfare and in the conduct of this study. Before entering this study, or at any time during the study, you may ask for a second opinion about your care from another clinician who is not associated in any way with the study.

Will I be paid for being in the study?

You will not be paid to be in the study.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

What happens if I am injured or hurt during the study?

In the event of an injury or illness resulting from your participation in this research study, your study doctor will assist you in receiving appropriate health care, including first aid, emergency treatment and follow-up care either at National Jewish Health or another appropriate health care facility. If medical costs are incurred, your insurance company may be billed. In accordance with general policy, National Jewish Health makes no commitment to provide free medical care of compensation for injury or illness resulting from your participation in this study. By signing this form you have not given up your legal rights. For further information, please contact Pia Hauk, MD or Elizabeth Esterl DNP, RN, investigators for this study. They can be reached at phone number is 303-398-1239.

If you believe you have experienced any study related illness, adverse event, or injury, you must notify the study doctor as soon as possible.

☐ This has been explained to me and all my questions have been answered

_____ Subject/ Parent/Legal Guardian Initials

Who do I call if I have questions?

The researchers carrying out this study are Pia Haul, MD and Elizabeth Esterl DNP, RN. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Hauk or Elizabeth Esterl at 303-398-1239. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Hauk or Elizabeth Esterl with questions. You can also call the responsible Institutional Review Boards at National Jewish Health and Regis University. You can call them at 303-398-1477 (NJH) and 303-934-3616 (Regis University) or email Regis University IRB at IRB@regis.edu.

Who will see my research information?

National Jewish Health and Regis University have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.
The institutions involved in this study include:

- National Jewish Health
- Regis University

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside National Jewish Health and Regis University may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed. At minimum, we will remove identifying data and use coding for your information. We will also keep your records in a locked office. All records relating to research that is conducted will be retained for at least three years after completion of the research.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Pia Hauk, MD
Principal Investigator

Elizabeth Esterl DNPc, RN
Co-Investigator

National Jewish Health- NJ4Kids Program
1400 Jackson Street A220
Denver, Colorado 80206
303-398-1239

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Boards that are responsible for overseeing this research
- The principal investigator and study team associated with this study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis (es), History and Physical, Medication History, Diet History, Laboratory Results, Skin Prick Test results
- Research Visit and Research Test record

What happens to Data that is collected is collected in this study?

Coded data collected in this study will be stored in a secure, password protected research database. If you decide to withdraw from this study, data collected up to this time will be kept and used for analysis.

Agreement to be in this study and use my data

I have read and initialed each page of this informed consent and HIPAA authorization form (or it was read to me). I was informed about the possible risks and benefits of being in this study. I know that being in this study is voluntary. I choose to be in this study. I know I can stop being in this study at any time. I will get a copy of this form after it is signed.

Patient Signature:_____Date:_____

Print Name: _____

_____ Date_____
Parent/Legally Authorized Representative/ Proxy Decision Maker Signature

Print Name: _____

_____ Date: _____
Consent form explained by: Signature

Print Name: _____

National Jewish Health
Science Transforming Life

National Jewish Health IRB
APPROVAL
Date 03/24/2014
Signed [signature]

IRB Number- HS 2826

Expiration Date 02/12/2015

NATIONAL JEWISH HEALTH
INFORMED ASSENT FORM

Protocol Title: Reducing Variability Among Multiple Operators Using a Single Technique and Device for Skin Prick Testing in Children

Principal Investigator: Pia Hauk, MD **Co-Investigator:** Elizabeth Esterl, DNPc,RN
Version Date: March 15, 2014
24 Hour Contact Number: 303-398-1239

What is this study about?
I am being asked if I want to be in this research study. The goal of this study is to learn more about two skin prick test devices and three different ways to use them for do the skin prick test procedure.

Why are you asking me?
I am being asked to be in the study because I am a patient at National Jewish Health and between the ages of 1 year and 16 years.

What Do I Have to Do or What Will Happen to Me?
If I am in the study, I will:

- Have a brief physical exam
- Let the research staff look at my medical records
- Have 12 skin prick tests done at one visit on my back

If I am in this study I will be asked questions. I will be asked about:

- My age, sex, and race
- My medical history
- Medication history
- Diet
- Lab results
- Previous skin prick tests

Will this Hurt?
There may be a small amount of pain when the skin prick test is performed but it will only last a few seconds then go away on its own.

Can I ask Questions?
I can ask questions about the study now. These questions will be answered now. If I think of any questions later, I'll be able to ask them too. I will get answers to those questions as well.

If I want to, I can call:

Pia Hauk, MD
Principal Investigator

Elizabeth Esterl DNPc, RN
Co-Investigator

National Jewish Health- NJ4Kids Program
1400 Jackson Street
Denver, Colorado 80204
303-398-1239

Do I Have to Do This?
I know that I do not have to be in this study. No one will be mad at me if I say no.

I want to be in the study at this time. ☐ YES ☐ NO

I will get a copy of this form to keep.

Child's Printed Name:_____

Child's Signature:_____**Date**_____

Parent/Legal Guardian Printed Name:_____

Parent/Legal Guardian Signature:_____ **Date**_____

I have explained the research at a level that is understandable by the child and believe that the child understands what is expected during this study.

*Printed Name of Person Obtaining Assent*_____

*Signature of Person Obtaining Assent:*_____*Date:*_____

Expiration Date 02.12.2015

National Jewish Health
Science Transforming Life

National Jewish Health IRB
APPROVAL
Date 05.07.2014
Signed

IRB Number- HS 2826

NATIONAL JEWISH HEALTH
INFORMED CONSENT FORM FOR RESEARCH WITH HUMAN SUBJECTS

Protocol Title: Reducing Variability among Multiple Operators Using a Single Technique and Device for Skin Prick Testing in Children

Principal Investigator: Pia Hauk, MD
Co-Investigator: Elizabeth Esterl, DNPc, RN
Version Date: April 30, 2014
24 Hour Contact Number: 303-398-1239

You are being invited to participate in a research study. Research studies include only people who choose to take part. Please take your time making a decision. Feel free to discuss it with your friends, family, and doctors. Before agreeing to take part in this research study, it is important that you read this consent and authorization form because it describes the study and any of the risks that it may involve. No guarantees or promises can be made regarding your experience in the study. Please ask the study investigators or the study staff to explain any words, ideas, or information not clear to you.

In this consent and authorization form, "you", always refers to the subject. If you are a legally authorized representative (such as the parent), remember that "you" refers to the study participant.

Why is this study being done?

You are being asked to take part in a research study to learn more about two skin prick test devices and how operators use the devices to find out which one device and technique works best in children. You are being asked to be in this study because you are a current patient at National Jewish Health's NJ4Kids Program and are between the ages of 1 year and 16 years. The co-investigator, Elizabeth Esterl DNPc, RN, is completing this study in partial fulfillment of the Doctor of Nursing Practice (DNP) degree at Regis University in Denver, Colorado.

A common diagnostic procedure during the initial evaluation and on-going follow-up care for a person with allergic disease is the skin prick test. This test involves placing allergen solutions on the skin and then pricked using a disposable device. The results of the skin prick test provide valuable information used to confirm diagnoses and develop treatment plans. Skin prick testing is a key test in identifying allergens causing allergic symptoms, prescribed immunotherapy treatment, and avoidance diets.

This study will compare two different skin prick test devices using three different techniques including:

- Duotip (Lincoln Diagnostics) bifurcated plastic needle using prick/lift technique

- Duotip (Lincoln Diagnostics) bifurcated plastic needle using twist technique
- Quintip (Hollister-Stier) steel lancet using punch technique

Other people in this study

Up to 68 local subjects with will be enrolled in this research study at National Jewish Health. This study will not be done at any other clinic or hospital. Taking part in this study is completely voluntary. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

What happens if I join this study?

If you agree to join the study, you will be asked to sign this form. Next, the following information will be obtained during the single study visit:
Enrollment/Study Visit 1

6. Demographics: age at entry, date of birth, gender, race/ethnicity.
7. Clinical Presentation: brief history of allergic symptoms, signs, age at onset, initial interventions
8. Current Medications and Diet History
9. Brief Physical examination: Measurements: vital signs; Appearance: skin assessment;
10. Skin Prick Tests: using Duotip prick, Duotip twist techniques and Quintip punch technique. A total of 12 skin prick tests will be completed on your back and recorded 15 minutes later. Each device will be tested using two histamine solutions (positive control and expected to react during test) and two glycerol-saline solutions (negative control and expected to not react during test), in three vertical columns and spaced equally apart. The operator and person recording the result will not know what solution has been placed where. This is called being "blinded" to the test.

Table - Study Visit

The single study visit will include the following:

EVALUATION	VISIT 1
Informed Consent	X
Eligibility	X
Medical History	X
Medication History	X
Brief Physical Examination	X
Skin Prick Tests	X

Once the skin prick tests are completed, your participation in the study is complete. The duration of the study visit will last approximately 30 minutes and the 12 skin prick tests will take less than 2 minutes to complete and recorded 15 minutes later.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include brief minimal localized site pain is associated with the skin prick test procedure which will resolve immediately without treatment once the prick is completed. No additional treatment is necessary to resolve pain. Histamine solution (10 mg/mL; Hollister-Stier, Spokane, Wash) as the positive control will cause itching at the site. After recording the results after 15 minutes, your back will be washed with warm water and the itching should resolve quickly without further treatment.

There is a potential risk of loss of confidentiality, but we will do everything to maintain the confidentiality of your personal information by keeping all research records and results in a locked file cabinet within a locked office of the principal investigator. However, confidentiality cannot be guaranteed.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about the two skin prick test devices and the three different ways that we use them.

This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

Are there alternative treatments?

You may elect to not participate in the study.

The treating clinician may be both your health care provider and the investigator for this study. This clinician is interested both in your clinical welfare and in the conduct of this study. Before entering this study, or at any time during the study, you may ask for a second opinion about your care from another clinician who is not associated in any way with the study.

Will I be paid for being in the study?

You will not be paid to be in the study.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

What happens if I am injured or hurt during the study?

In the event of an injury or illness resulting from your participation in this research study, your study doctor will assist you in receiving appropriate health care, including first aid, emergency treatment and follow-up care either at National Jewish Health or another appropriate health care facility. If medical costs are incurred, your insurance company may be billed. In accordance with general policy, National Jewish Health makes no commitment to provide free medical care of compensation for injury or illness resulting from your participation in this study. By signing this form you have not given up your legal rights. For further information, please contact Pia Hauk, MD or Elizabeth Esterl DNPc, RN, investigators for this study. They can be reached at phone number 303-398-1239.

If you believe you have experienced any study related illness, adverse event, or injury, you must notify the study doctor as soon as possible.

☐ This has been explained to me and all my questions have been answered

_____ Subject/ Parent/Legal Guardian Initials

Who do I call if I have questions?

The researchers carrying out this study are Pia Hauk, MD and Elizabeth Esterl DNPc, RN. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Hauk or Elizabeth Esterl at 303-398-1239. You may also call Dr. Diane Ernst, Regis University, DNP student project advisor for co-investigator, Elizabeth Esterl at 303-964-5768 or dernst@regis.edu.

You may have questions about your rights as someone in this study. You can call Dr. Hauk or Elizabeth Esterl with questions. You can also contact the responsible Institutional Review Boards (IRB) at National Jewish Health and Regis University. You can call the National Jewish Health IRB at 303-398-1477 and/or Regis University IRB at 303-458-4206 or email at irb@regis.edu.

Who will see my research information?

National Jewish Health and Regis University have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.
The institutions involved in this study include:

- National Jewish Health
- Regis University, Denver, Colorado

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not give us your permission, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside National Jewish Health and Regis University may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed. At minimum, we will remove identifying data and use coding for your information. We will also keep your records in a locked office. All records relating to research that is conducted will be retained for at least three years after completion of the research.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Pia Hauk, MD
Principal Investigator

Elizabeth Esterl DNPc, RN
Co-Investigator

National Jewish Health- NJ4Kids Program
1400 Jackson Street A220
Denver, Colorado 80206
303-398-1239

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Boards that are responsible for overseeing this research
- The principal investigator and study team associated with this study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. However, we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigators.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)

- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis (es), History and Physical, Medication History, Diet History, Laboratory Results, Skin Prick Test results
- Research Visit and Research Test record

What happens to data that is collected in this study?

Coded data collected in this study will be stored in a secure, password protected research database. If you decide to withdraw from this study, data collected up to this time will be kept and used for analysis.

Agreement to be in this study and use my data

I have read and initialed each page of this informed consent and HIPAA authorization form (or it was read to me). I was informed about the possible risks and benefits of being in this study. I know that being in this study is voluntary. I choose to be in this study. I know I can stop being in this study at any time. I will get a copy of this form after it is signed.

Patient Signature:_____Date:_____

Print Name: _____

_____ Date_____

Parent/Legally Authorized Representative/ Proxy Decision Maker Signature

Print Name: _____

_____ Date: _____

Consent form explained by: Signature

Print Name: _____

Source Document
Elizabeth Esterl RN, MS
Reducing Variability Among Multiple Operators Using a Single Technique and Device for Skin Prick Testing in Children

Patient Name_____/ID#____
Date_____

INFORMED CONSENT and HIPAA AUTHORIZATION PROCEDURES

The following must be completed at THE SCREENING VISIT prior to any study procedures:

[ ] Parent/Legal Guardian has READ the IRB approved Informed Consent and HIPAA Authorization Form (ICF)

Relationship of person signing the ICF to subject. The person signing consent MUST be the subject's biological parent or *legal* guardian.

[ ] Biological Mother [ ] Biological Father [ ] Parent by Legal Adoption
[ ] Legal Authorized Representative by Court Decree [ ] Other_____

If person signing is not the biological parent, legal documentation (typically, a court order or decree) should be available for review. Court documents should indicate full legal adoption (of adopted children) or specify that guardianship allows for authorization of voluntary medical treatment and participation in a research study.

Is the last name of the parent/Legally Authorized Representative different from that of the subject?

[ ] No
[ ] Yes = Explain_____

[ ] Parent/Legal Guardian provided with a copy of the signed and dated IRB approved consent and HIPAA authorization form
[ ] Original signed Informed Consent and HIPAA Authorization form has been retained in the subject's research record.

Is the subject of age for the required Assent by IRB?

[ ] No = Continue
[ ] Yes = Assent must be completed
[ ] Parent/Legal Guardian provided with a copy of his/her child's signed assent
[ ] Original signed Assent has been retained in the subject's research record.

Did the Parent/Legal Guardian provide written informed consent and HIPAA authorization prior to participation in the trial (Prior to any study procedures performed)?

[ ] **No = Do not enroll the subject**
[ ] YES

National Jewish Health IRB
ACKNOWLEDGED
Date 03/24/2014
Signed WL

Date of Informed Consent_____/_____/2014 **Time:**_____
Day Month Year 24 hour clock

Informed Consent Verification

a. Was the subject provided ample time and opportunity to inquire about the details of the study? [ ] Yes [ ] No
b. Were all questions about the trial answered to the satisfaction of the subject? [ ] Yes [ ] No
c. Was written Informed Consent obtained prior to study participation? [ ] Yes [ ] No
d. Was a signed copy given to the subject's parent/legal guardian? [ ] Yes [ ] No

Signature of person reviewing the informed consent and study information with the subject:_____

STUDY VISIT - DATE_____

INCLUSION CRITERIA:
[ ] Age 1 year to 16 years of either sex and any race
[ ] English speaking
[ ] Medications, including but not limited to antihistamines, withheld for appropriate time period as per hospital protocol

EXCLUSION CRITERIA
[ ] Inability to comply with skin prick testing
[ ] Failure of the family/patient to sign the informed consent and HIPAA authorization form

Patient has met all inclusion & exclusion criteria? [ ] Yes [ ] No

DEMOGRAPHIC DATA:

Date of Birth_____

Race: [ ] Caucasian [ ]Asian
[ ] Black [ ] Other –Specify

Ethnicity: [ ] Hispanic [ ] Non-Hispanic

Sex: [ ] Male [ ] Female

WEIGHT: _____kilograms [ ] Not Done
HEIGHT: _____centimeters [ ] Not Done

SIGNIFICANT MEDICAL HISTORY FOR ALLERGIC DISEASE

[ ] Asthma

[ ] Food Allergy

	Food Name	Type of Reaction
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

[ ] Drug Allergy

DRUG ALLERGIES:

	Drug Name/ Class	Type of Reaction
11.		
12.		
13.		
14.		
15.		
16.		
17.		
18.		
19.		
20.		

[ ] Environmental Allergy

ENVIRONMENTAL ALLERGIES:

	Environmental Allergy	Type of Reaction
21.		
22.		
23.		
24.		
25.		

SIGNIFICANT MEDICAL HISTORY
[ ] Not done [ ] No significant medical history

DISEASE SYNDROME – SPECIFY		**PERTINENT DETAILS**
Non Drug Allergies (specify substance & manifestations)		Include surgeries/dates
1._____	[ ] past	_____
	[ ] present	_____
2._____	[ ] past	_____
	[ ] present	_____
3._____	[ ] past	_____
	[ ] present	_____
4._____	[ ] past	_____
	[ ] present	_____
5._____	[ ] past	_____
	[ ] present	_____
6._____	[ ] past	_____
	[ ] present	_____
7._____	[ ] past	_____
	[ ] present	_____
8._____	[ ] past	_____
	[ ] present	_____
9._____	[ ] past	_____
	[ ] present	_____
10._____	[ ] past	_____
	[ ] present	_____
11._____	[ ] past	_____
	[ ] present	_____
12._____	[ ] past	_____
	[ ] present	_____
13._____	[ ] past	_____
	[ ] present	_____
14._____	[ ] past	_____
	[ ] present	_____
15._____	[ ] past	_____
	[ ] present	_____

PHYSICAL EXAMINATION:
[ ] Not done [ ] Not required at this visit as per protocol
Date (dd/MMM/yyyy): _ _/_ _ _/ _ _ _ _

Site		Describe Abnormalities
General Appearance	[ ] Normal [ ] Abnormal [ ] Not Done	
Head	[ ] Normal [ ] Abnormal [ ] Not Done	
Lungs	[ ] Normal [ ] Abnormal [ ] Not Done	
Heart	[ ] Normal [ ] Abnormal [ ] Not Done	
Abdomen	[ ] Normal [ ] Abnormal [ ] Not Done	
Skin	[ ] Normal [ ] Abnormal [ ] Not Done	

SKIN PRICK TESTS-

Operator: _____

[ ] Not done Date (dd/MMM/yyyy): _ _/_ _ _/ _ _ _ _

Tray used: [ ] A [ ] B [ ] C

Reading left for right when looking at patient's back:
Column 1- [ ] Duotip Prick Lift [ ] Quintip Punch [ ] Duotip Twist
Column 2- [ ] Duotip Prick Lift [ ] Quintip Punch [ ] Duotip Twist
Column 3- [ ] Duotip Prick Lift [ ] Quintip Punch [ ] Duotip Twist
DO NOT REVEAL INFORMATION REGARDING TECHNIQUE USED TO ANYONE

15 minutes timer started_____ (time)

Comments on causes of clinically significant abnormalities:

CONCOMITANT MEDICATION RECORD:

[ ] Not done
[ ] None

Drug Name	Indication	Route	Daily Dose	Dates Taken	Prestudy YES NO
					[ ] Yes [ ] No
					[ ] Yes [ ] No
					[ ] Yes [ ] No
					[ ] Yes [ ] No

ADVERSE EVENTS:

[ ] Not done
[ ] None

Adverse Event	Relationship to Skin Prick Test	Grade	Start	Stop	Action Taken

Skin Prick Test Result Form

Recorder:_____

Time: _____skin prick test results recorded.

When looking at the participant's back

Solution Top to Bottom	Column 1 Left	Column 2 Middle	Column 3 Right
1	**wheal:** _____ x _____ **erythema:** _____ x _____	**wheal:** _____ x _____ **erythema:** _____ x _____	**wheal:** _____ x _____ **erythema:** _____ x _____
2	**wheal:** _____ x _____ **erythema:** _____ x _____	**wheal:** _____ x _____ **erythema:** _____ x _____	**wheal:** _____ x _____ **erythema:** _____ x _____
3	**wheal:** _____ x _____ **erythema:** _____ x _____	**wheal:** _____ x _____ **erythema:** _____ x _____	**wheal:** _____ x _____ **erythema:** _____ x _____
4	**wheal:** _____ x _____ **erythema:** _____ x _____	**wheal:** _____ x _____ **erythema:** _____ x _____	**wheal:** _____ x _____ **erythema:** _____ x _____

COORDINATOR COMMENTS

[ ] Not done

Date (dd/MMM/yyyy): _ _/_ _ _/ _ _ _ _

Time of contact (24 hour clock) _ _: _ _

Comments;_____

Visit completed by _____ Date_____