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## Implementing a COVID 19 Policy for Telehealth

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**Implementing a COVID 19 Policy for Telehealth**

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NSC 994: DNP Project

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### **Abstract**

The proposed DNP Project explored the implementation of a COVID-19 telehealth policy to clarify evidence-based practice, promote use of safe medications, and reduce hospitalizations. Providers were recruited from a telehealth organization, educated on current guidelines, and given a pocket card for reference and re-enforcement of training. Data was collected to examine guideline utilization, confidence in treating COVID-19, and efficacy of pocket card. COVID-19 patients also received follow up calls to determine if hospitalization was required post treatment. Chart audits were then completed to review compliance with guidelines. The results indicated both objective and clinical improvement in provider confidence treating COVID-19. Implications for future practice include the ability to use the framework of the project to build other policies based on evidence-based practice. Ultimately, the project can further improve telehealth by disseminating the policy through journals, online training and social media.

*Keywords:* Telehealth, COVID-19, Coronavirus 2019, COVID-19 policy

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### **Implementing COVID-19 Policy for Telehealth**

Since the beginning of the COVID-19 (aka Sars-CoV2) pandemic the Centers of Disease Control and Prevention (CDC) and the World Health Organization (WHO) have recommended that providers treat their patients via telehealth to avoid the spread of the virus (Centers for Disease Control and Prevention, 2022b; World Health Organization, 2020). Guidance for telehealth treatment of COVID-19 has changed rapidly over the last 3 years as new data has emerged. The purpose of this proposal is to develop and implement a COVID-19 policy for telehealth platforms to improve guideline utilization, improve provider confidence, and promote improved patient outcomes.

### **Background and Significance**

COVID-19 pandemic began strong and rapidly spread worldwide (World Health Organization, 2020). It was initially unclear how to treat the COVID-19 virus and prevent severe complications and death. According to the WHO COVID-19 dashboard there have been 152,265,980 confirmed COVID-19 cases. In the Americas 1,977,835 deaths have occurred since the beginning of the pandemic (World Health Organization, 2022). Additionally, the COVID-19 virus has mutated and there are currently 5 variants of concern circulating according to the World Health Organization (2023). Variants affect how the virus transmits and the symptoms a patient feels after being infected, potentially causing future variants to be more lethal than the original virus (World Health Organization, 2023).

According to the CDC, a patient diagnosed with COVID may experience fever, chills, cough, shortness of breath, fatigue, muscle or body aches, headache, loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea (Centers for Disease Control and Prevention, 2022b). Symptoms may vary based on underlying medical conditions.

Underlying lung and heart conditions may be exacerbated. Symptoms may also vary based on variant mutation of COVID-19 (Centers for Disease Control and Prevention, 2022b).

COVID-19 has placed unprecedented strain on the healthcare system. According to Sara Berg (2021) half of healthcare workers have reported feeling burnout since the beginning of the pandemic. Healthcare workers have dealt with frequently changing guidelines, new regulations, and emotional trauma from their environment. Workers have reported lack of support and increased nurse to patient ratios due to short staffing as emergency protocols were put into place.

Additionally, the strain of COVID-19 expanded to the national economy, with a considerable reduction in healthcare spending during Q1 of 2020 (Boserup, McKenney, & Elkbuli, (2021). As hospitals have postponed elective surgeries, this has deprived hospitals of roughly 30% of annual revenue. Additionally, emergency room visits had declined 15% in March of 2020 when compared to March of 2019 (Boserup, McKenney, & Elkbuli, (2021). During March to May of 2020, emergency room visits for non-COVID related concerns decreased 10-23% (French et al, 2021). French, et al (2021) estimated that if ICU bed capacity exceeded 100% an excess 80,000 deaths would occur in the 2 weeks following. By understanding the fiscal and mortality data, additional resources are needed to be made to patients suffering from chronic conditions.

### **Expansion of Telehealth**

Telehealth was rapidly implemented during the COVID-19 pandemic to avoid enclosed settings and virus transmission. Telehealth is defined as a way to speak to a health care provider via phone or video, which may include vital signs, live chat, text-based messaging, email, or file exchange (Health Resources and Services Administration, 2021). Koonin et al (2020) explains that telehealth encounters increased by 50% in the first 3 months of the pandemic, compared to

the same time period in 2019. Initially telehealth encounters focused on non-COVID related concerns, however COVID related telehealth visits began to expand starting in March 2020 (Koonin et al, 2020). Demeke et al (2021) found that overall telehealth visits continued to average 30.2% of overall healthcare visits in 2020. Bestsenny et al (2021) explains the financial growth of telehealth in the last 6 years, increasing from 6 billion in investments in 2017 to 14.6 billion in 2020.

Despite recommendations to treat patients with non-life-threatening illness via telehealth, little guidance was initially available to provide structure for treatment, testing for the novel COVID-19 virus was not available. As of present time, there is a significant amount of emerging research with conflicting recommendations for treatment of COVID-19. Adults with non-life-threatening symptoms are still recommended to be treated via telehealth. The partnering organization provides test kits and clinician consultation for review of symptoms and appropriate treatment. During the COVID-19 pandemic, HIPAA guidelines and controlled substance guidelines were relaxed (Telehealth.hhs.gov, 2022b). Medicare also expanded care during the pandemic to cover more costs of telemedicine (Telehealth.hhs.gov, 2022a).

### **Standards of Care**

COVID-19 is diagnosed via sample collected on nasal swab, buccal swab, or blood sample (Centers for Disease Control and Prevention, 2022a). Patients may connect with a practitioner via telemedicine or in person after an initial positive result is obtained. Vaccination is recommended for prevention of severe disease and reduction in spread of the virus. Use of masks and social distancing is recommended as primary prevention by the CDC (Centers for Disease Control and Prevention, 2022a). Pre-exposure prophylaxis is available for those with severe immunocompromise (National Institutes of Health, 2022).



Pharmacological treatment consists of antiviral treatments or monoclonal antibodies. Several other medications have been tested and are currently not recommended for use by the CDC. The four main pharmacological treatments recommended are Nirmatrelvir with ritonavir (Paxlovid), remdesivir (Veklury), bebtelovimab, and molnupiravir (Lagevrio). Of these, nirmatrelvir with ritonavir and molnupiravir can be taken orally, while Remdesivir and Bebtelovimab are intravenous infusion (IV). Acetaminophen (Tylenol) and Ibuprofen (Motrin) are recommended for minor aches and fever reduction (Centers for Disease Control and Prevention, 2022a).

### **Opportunity to Improve & Proposed Intervention**

Currently, guidelines are not well understood in the telehealth community. There is a lack of information regarding IV infusion medications, lack of guidance on use of approved vs non-approved medications, and lack of follow-up with COVID-19 patients (Centers for Disease Control and Prevention, 2022a). Emerging concepts such as COVID rebound and when follow up pharmacological treatment is appropriate have begun to be addressed by the NIH. The frequency of COVID rebound after ritonavir-boosted nirmatrelvir have not been established at this time. Currently, longer treatment courses of ritonavir-boosted nirmatrelvir are not recommended based on the emergency use authorization. Despite the pressing matter of COVID-19, further recommendations of next steps have not been made (National Institutes of Health, 2022). Follow up recommendations include use of telehealth, however frequency of follow-up and duration has not been well established by either the CDC or NIH (Centers for Disease Control and Prevention, 2022a; National Institutes of Health, 2022).

The proposed project is to develop and implement a policy to treat adult patients for COVID-19 via telehealth consistent with current evidence-based recommendations. The policy

will include recommendations on medications, quarantine, use of PPE, vaccinations, and follow-up care. The policy will be reinforced by use of training, pocket references, and chart audits with feedback to providers on performance as a group. Ultimately, the goal is to provide evidence-based care and avoid COVID related hospital admissions.

### **Review of Literature**

A formal review of literature was conducted to answer the question, "In telehealth, what treatments for COVID-19 are appropriate in the adult population (18 and older) to prevent hospitalization?" The databases searched included CINAHL, NCBI, and PubMed. The keywords used were *COVID-19 AND treatment OR intervention OR therapy, outpatient, nirmatrelvir with ritonavir, molnupiravir, redese mavir*. The findings were further narrowed by limiting the publications to English, publications within the last 3 years, and full text articles. In total 20,455 studies were found, which were narrowed to 635 studies that fit the aforementioned limits. After completing a hand search of the titles and abstracts 6 studies were selected for inclusion. All evidence was appraised using the Melnyk-Fineout Overholt Rapid Critical Appraisal Forms.

### **Guidelines**

The National Institutes of Health (NIH) (2022) have released COVID-19 treatment guidelines for clinicians including inpatient and outpatient guidelines. Guidelines were developed with expert opinion from a large body of experts. Recommendations are graded for strength and quality. According to the NIH, patients should be treated via telehealth whenever possible with a strength of strong and evidence rating of expert opinion. Most recommendations for medications made in this report are based on Moderate to strong evidence with some form of randomized trial. Recommendations include first line nirmatrelvir with ritonavir or remdesivir. Second line or alternative therapies for outpatient treatment include bebtelovimab or

molnupiravir. Steroids or other medications are not recommended at this time (NIH, 2022).

The CDC currently follows the same path with oral and IV medications, however, has added tixagevimab plus cilgavimab and vaccines in the guidelines for treatment and prevention of COVID-19 (Centers for Disease Control and Prevention, 2022a).

### ***Evidence 1***

Kumar Singh et al. (2022) describes in a randomized controlled trial the use of molnupiravir for COVID-19 and the comparison with other agents which have received emergency use authorization. Molnupiravir is an oral antiviral medication which has received approval for emergency use authorization in several countries. Molnupiravir has shown to reduce risk of hospital admission and death compared to placebo and is significantly cheaper than other antiviral agents. The relative risk reduction for overall mortality, however, was not significant with the use of Molnupiravir. There were no reports of short term severe adverse events with the use of Molnupiravir. Recommendations are to start a 5-day course of pharmacological treatment within 5 days of COVID-19 symptom onset (Kumar Singh et al., 2022). Molnupiravir is currently recommended for use by the NIH only when neither ritonavir-boosted nirmatrelvir or remdesivir are available. Data on the use of Molnupiravir is important to know for telehealth, as this would be the second line recommendation for patients unable to obtain or unable to take ritonavir-boosted nirmatrelvir, and unable to get IV infusion medications (Centers for Disease Control and Prevention, 2022a; National Institutes of Health, 2022).

### ***Evidence 2***

Adeoye et al. (2020) reviewed chloroquine, azithromycin, lopinavir, oseltamivir, remdesivir, and ribavirin for use against COVID-19 virus. Adeoye et al. (2020) conducted an in vitro study to determine binding capability and risk of toxicity. Each medication was shown to

have benefits against COVID-19 and capability with binding to proteins displayed on the virus. According to the authors, binding of the medications to the virus prevents cellular entry of the virus. Chloroquine did show some capability of binding to the virus, however, was not as effective as other medications. Oseltamivir, azithromycin, and ribavirin all showed good binding with low toxicity (Adeoye et al., 2020). Currently, neither the CDC or NIH has made recommendations for or against use of azithromycin for COVID-19, however have recommended for the use of remdesivir as a first line agent (Centers for Disease Control and Prevention, 2022a; National Institutes of Health, 2022).

### ***Evidence 3***

Popp et al. (2021) performed a systematic review of literature available through the Cochrane Library and published information on the use of Ivermectin for prevention and treatment of COVID-19. Based on a review of 14 studies it was concluded that Ivermectin cannot be recommended with any certainty for the treatment of inpatient, outpatient, or the prevention of COVID-19 infection. Mortality and relative risk reduction showed no conclusive evidence of benefit with the use of Ivermectin. High risk of bias was reported with most studies. Therefore, use of Ivermectin would not be recommended for use in telehealth.

### ***Evidence 4***

Westendorf et al. (2022) have evaluated in vitro use of Bebtelovimab for binding capability and neutrality of COVID-19 using donor blood samples. In vivo use has not yet been determined using Bebtelovimab. The study showed that bebtelovimab significantly neutralized the COVID-19 virus including all know variants. Currently, use of bebtelovimab is recommended via IV infusion as a second line agent (Centers for Disease Control and Prevention, 2022a; National Institutes of Health, 2022).

***Evidence 5***

Hammond et al. (2022) reviewed use of nirmatrelvir plus ritonavir for the use of COVID-19. Results were reported for all cause mortality at day 28, viral load reduction, and safety of therapy. Overall, no deaths were reported in the treatment group, versus 13 in the control group. Risk of hospitalization was lower in the nirmatrelvir group  $P < 0.001$ . Viral load was diminished by a mean of  $-0.868 \log_{10}$  copies per milliliter. Risk of adverse events in both groups were similar. Ritonavir-boosted nirmatrelvir is currently the number one recommended treatment for COVID-19 (Centers for Disease Control and Prevention, 2022a; National Institutes of Health, 2022).

**Summary of Evidence**

The strongest evidence found shows good benefit with the use of ritonavir-boosted nirmatrelvir and remdesivir for COVID-19 (Centers for Disease Control and Prevention, 2022a; National Institutes of Health, 2022). Additional medication treatment with molnupiravir and Bebtelovimab shows some benefits. In vitro use of chloroquine, azithromycin, lopinavir, oseltamivir, remdesivir, and ribavirin is promising, however no in vivo studies have yet proven safety of these medications. Research on Ivermectin use for prevention and treatment is inconclusive and highly biased.

**Application to Evidence Based Practice Nursing**

For the purpose of this project, use of ritonavir-boosted nirmatrelvir via oral dosing and use of remdesivir via IV infusion will be recommended as first line medications. Second line bebtelovimab via IV infusion and molnupiravir via oral administration will be recommended. As a third line for only those unable to take first- and second-line medications, azithromycin may be considered.

## Theory

The nursing theory that best relates to development of a specific COVID-19 telehealth treatment policy is Ida Jean Orlando's Deliberative Nursing Process Theory. Through Assessment of the problem (lack of policy), planning the policy, implementation, evaluation, and reassessment the policy will develop and be maintained. Nursing skills are needed to both develop the policy and to assess, diagnose and treat the patient.

### Figure 1

*Representation of Ida Jean Orlando's Deliberative Nursing Process Theory*



## Agency Description

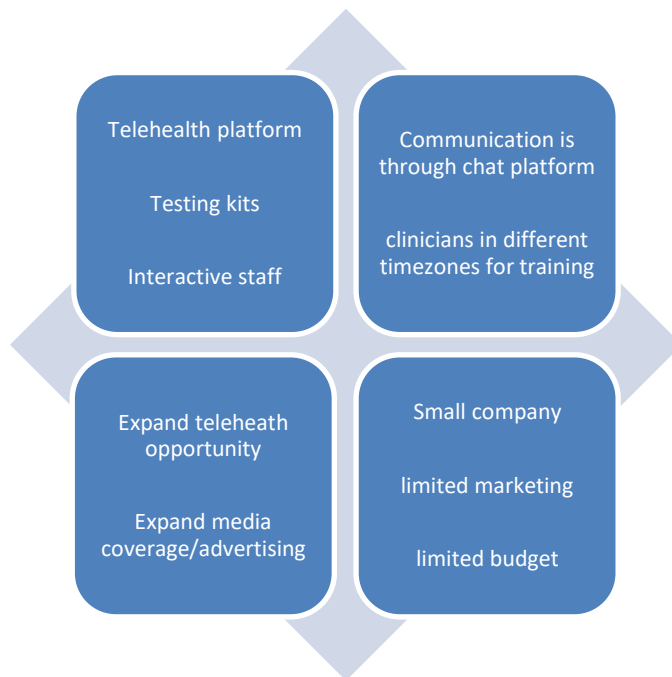
The author is partnering with an online urgent care clinic which provides services for many common illnesses. The clinic also has a revolutionary platform for COVID, strep throat, influenza, and urinary tract infections which allows the patient to purchase a test kit, take and upload a photo of their completed test, and receive proper pharmacological and non-pharmacological treatment from the comfort of their own home. The purchase price of the test kit includes a consultation with a licensed health care provider. Visits are often started and completed within 30 minutes of entering the virtual waiting room.

The mission of the company is “a mission to create an affordable virtual care experience that is comparable to a doctor’s visit, with an accurate diagnosis, via a virtual care experience” (Physician360.co, 2022). Project stakeholders include the founders, the clinicians on staff, the technology team, pharmacies that stock the testing kits and partner for care, and patients.

This telehealth platform has provided a revolutionary way of treating patients with take home testing kits that are bought from local pharmacies. The test results are uploaded, and the patient connected with a provider in 30 minutes or less. The weakness of the organization includes a chat platform to communicate with clinicians across several time zones, making communication less efficient than brick and mortar offices. The platform has an opportunity to continue to expand and become a leader in COVID-19 telehealth treatment. Threats include other large organizations with more available funding (Figure 2.0).

**Figure 2**

*SWOT Analysis*



This project will formalize a policy for COVID-19 ensuring that each clinician has the

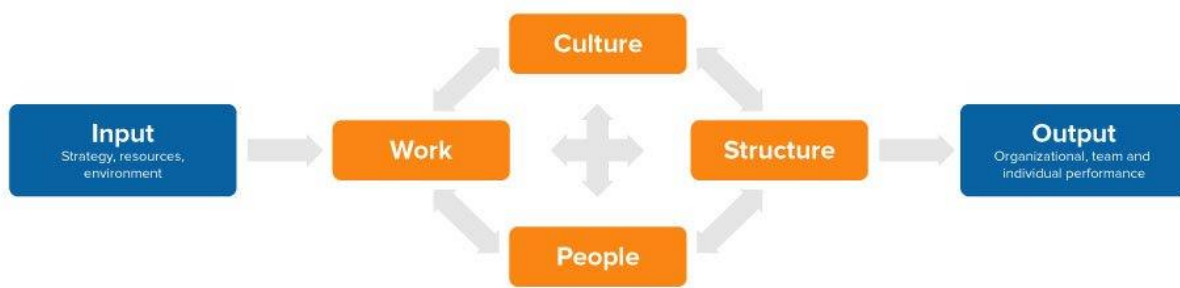
most up to date resources. Clinicians will be able to quickly reference the protocol to determine the most appropriate pharmacological and non-pharmacological treatment modalities.

**Congruence of Project to Organization**

The organization is committed to accurate and timely diagnosis of conditions with appropriate treatment. For the treatment of COVID 19, accurate and timely diagnosis are essential to prevent life-threatening complications. The Nadler-Tushman Congruence Model is a tool to understand organizational performance (Mind tools, 2022). The work done by the organization requires critical thinking ability in a fast-paced setting, empathic attitudes with precise decision making and documentation. The people are experienced clinicians and office managers that collaborate to get in touch with the patient and ensure a timely and satisfying experience. The organizational structure is an open communication platform paired with an EMR that forces the clinician to focus on one patient at a time, ensuring safe care an accurate documentation. The culture is open and welcoming, great feedback amongst peers if someone needs help to make a decision.

**Figure 3**

*The Nadler-Tushman Congruence Model*



**Statement of Mutual Agreement**

See Appendix D

**Methodology**

**Aims and Objectives**



The objective of this quality improvement project was to develop a policy for treatment of COVID-19 via telehealth. The policy served to guide clinical judgement about medication choice, risks, side effects, when to start the pharmacological treatment, when to refer to emergency services. The policy was be introduced via Slack© which is the communication platform of choice for the company. The policy was housed and accessible through a shared Google drive, as well as copies sent to each clinician.

**Objectives:**

- Developed a COVID-19 protocol for telehealth consistent with current guidelines.  
Trained 45 clinicians on the protocol within 2 weeks of implementation.
- Obtain Data:
  - Survey of provider confidence in treating COVID-19 pre and post intervention. Post intervention 80% of providers will report improved confidence.
  - Survey of provider self-efficacy in treating COVID-19 pre and post intervention. Post intervention 80% of providers will report improved self-efficacy.
  - Post intervention, 80% of providers report the pocket card useful
- Enroll 30 patients into project QI process:
  - 100% of patients treated via protocol (patient instructions given, vaccination status charted, quarantine instructions given, appropriate use of medications) will report overall 10% improvement
  - No patient will be hospitalized at 2 weeks

Enforcement of the policy will apply through record review of completed visits. Review

and updating of the policy will take place annually or as needed if new clinical recommendations come forth.

### **Implementation Framework**

The Institute for Health Improvement (IHI), Model for Improvement will guide implementation of a PDSA Cycle (Plan, Do, Study, Act). In the planning phase, the policy will be researched and written in draft form. The policy will be reviewed with the Chief medical officer (CMO) of the organization to ensure buy in from the organization. After review and approval, the pre-assessment for clinician knowledge and comfort level of treating clients will be administered via anonymous link posted on the communication platform. The policy and video explaining the policy will be posted via google share drive and pinned to the channel for clinician review.

In the study phase, after allowing one week for clinicians to review the policy, the researcher will post a follow up post-test of clinical knowledge and comfort level treating COVID-19 clients. Clinicians will also be given access to a quick reference card for recommended medications. Clients treated after the implementation date will be called at the 2-week mark to determine: 1) Have their symptoms lessened? and 2) Did they require hospital admission? In the act phase, the primary investigator and the CMO of the organization will review the data and adjust the policy if needed.

### **IRB of Record**

Eastern Kentucky University will serve as the IRB of record for this project. An Application for Expedited Review will be submitted online by the principal investigator (Appendix E). Expedited review was chosen as this project does not present more than minimal risk to the participants. Waiver of Documentation of consent will be needed.

In keeping with the principles of research ethics, the clinicians will have voluntary participation in this study. No identifiable information shall be collected, including name, date of birth, city, or state. Information collected will be via anonymous. Chart audits and follow up calls for quality improvement purposes is considered a standard of care. Therefore, patients are at no increased risk by being selected for chart review and/or follow up call. Data evaluated during the review will be de-identified by assigning a random number to the chart audit tool. Only the primary investigator will have access to the list of names and links to the numbers.

### **Recruitment & Consent**

Recruitment for clinicians will be a voluntary convenience sample. News of the training will be posted via Slack. The goal for recruitment is 45 clinicians or 90% of the clinical staff (Appendix G). The CMO will request that all clinicians participate in the study. For the quality improvement portion, patients will also be selected as a convenience sample. Inclusion criteria are being over 18 years old, diagnosed with COVID, and treated via telehealth. Exclusion criteria are pregnancy, under the age of 18 years old, those with COVID negative tests.

For the providers, an informed consent form will be given (Appendix G). A Waiver of Documentation of Consent (Appendix H) will also be submitted to the ECU IRB. Participation in data collection will be considered consent. Additional consent for patients is not required since the follow up call and chart audit is considered standard of care. All HIPPA rules for patients will be followed as consistent with routine practice.

### **Staff Training**

Staff training will consist of a power point presentation viewed after pre-implementation survey is complete. The training will consist of the current guidelines with explanation of treatment and links to current CDC guidelines. The training will take no more than 15 minutes

to complete. Staff will also be given a printable pocket card for an easy to reference reminder. Training will be presented via Slack© and pinned in the general chat channel. Providers will self-testify when training is complete (Appendix F).

## **Data Collection**

### *Provider Self-Developed Instruments*

Surveys will be developed with questions regarding demographics, confidence, and self-efficacy of treating COVID-19. Surveys will be administered pre and post training to the clinicians. A baseline survey with demographics will be administered to collect information on credentials to practice, any previous experience with COVID-19 with yes or no response, years in practice grouped by 5 years, and confidence level of treating COVID-19 on a 1-10 scale (Appendix H).

### *Validated Instrument*

An initial self-efficacy scale will also be administered based on the New General Self-Efficacy Scale by Chen, Gully, and Eden (2001). The New General Self-Efficacy Scale is a validated instrument. The Cronbach alpha is 0.82 to 0.86 of this instrument. Providers will be asked to answer this survey in the context of treating COVID-19 (See Appendix I).

### *Chart Audits*

During chart audits, key outcomes of guideline compliance will be reviewed and from patient encounters. These include vaccination status reviewed, quarantine guidelines given, patient instructions given. A convenience sample of 30 charts will be randomly selected. To compare an audit will be done of 30 charts from the previous two months.

### *Patient Follow-Up*

Patients who were treated for COVID over an eight-week time period will be contacted

for follow up. Follow-up phone calls will take place 2 weeks post consultation and will include two questions: 1) Did you need to go to the hospital? and 2) Did your symptoms improve on a scale of 1 to 10? This follow-up will allow for data to determine efficacy of the treatments provided. Follow-up is considered a standard of care, so no additional permissions will be required.

### *Program Evaluation*

For program evaluation, the primary researcher will collect a post-implementation survey at the end of the program. The primary researcher will conduct an evaluation of the training, documentation progress, and of the pocket card provided to the providers.

### **Data Analysis**

Data analysis will take place via an excel document Demographic information and the patient post-visit questionnaire will be evaluated using measures of central tendency. The self-efficacy tool, post-implementation survey, and program evaluation will be analyzed using paired sample *t* tests. Open ended responses will be reviewed by two investigators and coded for common themes.

### **Data Security**

Anonymous survey data will be collected and stored on an Excel document for analysis. Data will be retained in Faculty Office, Rowlett 214 on Campus. The primary researcher will use the last 4 digits of the patient's primary phone number as a tracking number for data analysis. No other information will be collected on the patient.

### **Results**

Implementation began after IRB approval by posting the pre-survey and demographics questionnaire. All active providers were asked to participate in the training and surveys. Of the

45 hired providers, only eight providers were active at the time of recruitment.  $n = 8$ , 100% of active providers were recruited for the study. Results of each instrument are discussed below.

### **Demographic Information**

Eight providers responded to the demographics survey done pre-training. Of the eight, seven were Nurse Practitioners (NP) and one is a Medical Doctor (MD). One hundred percent of respondents had experience with COVID-19. The number of years in practice varied widely with: 37.5% ( $n = 3$ ) respondents having 0-5 years' experience, 25% ( $n = 2$ ) respondents having 6-10 years' experience, 12.5% (1) respondent having 16-20 years of experience, and 25% (2) respondents having 25 or more years' experience. On a scale of 1 to 10, with 1 being not confident and 10 being very confident, the respondents answered as follows: 25% reported a confidence level of five, 37.5% reported a level of 7-9, and 37.5% reported a level of ten. In sum, the majority had some margin to improve.

### **Survey of Self Efficacy**

The respondents were asked to take a survey of self-efficacy pre and post-training to objectively obtain information on their confidence levels treating COVID-19, and the effectiveness of the policy. There were seven questions on the survey of self-efficacy. Three participants (37.5% of the sample) were lost to follow up. Paired sample t-tests were used to determine if there is a statistical significance post training. The p value of question one was  $p = 0.01$ . Question two "When facing difficult tasks, I am certain that I will accomplish them" had a  $p = 0.11$ . Question three "In general, I think that I can obtain outcomes that are important to me" had a  $p = 0.17$ . Question four "I believe I can succeed at almost any endeavor to which I set my mind" had a  $p < 0.05$ . Question five "I will be able to successfully overcome many challenges" had a  $p < 0.05$ . Question six "I am confident that I can perform effectively on many different

tasks” had a  $p = 0.11$ . Question seven “Compared to other people, I can do most tasks very well” had a  $p = 0.11$ . Finally, Question eight “Even when things are tough, I can perform quite well” had a  $p < 0.05$ . Overall, half of the questions were rated with statistically significant improvement. Although half of the questions did not show statistical improvement, this was a small sample size and providers reported clinical improvement.

### **Chart Audits**

Chart audits were performed on 100% of COVID-19 visits,  $n=13$ . Key areas which were audited included: vaccination status reviewed, quarantine guidelines given, and patient instructions given. Vaccination status was reviewed and documented in 13 charts, 100%. Quarantine guidelines were reviewed and documented in 13 charts, 100%. Patient instructions were given in 100% of charts. To compare pre- and post-training, 30 random charts were audited prior to the start of the training. Vaccination status was documented in 4 of 30 charts, quarantine guidelines in 8 of 30 charts, and patient instructions in 23 of 30 charts. Through small reminders providers have improved documentation overall.

### **Patient Follow-up Calls**

Patients who were treated for COVID ( $n=13$ ) were contacted for follow-up 2 weeks post-consultation. The following follow-up questions were asked: 1) Did you need to go to the hospital? and 2) Did your symptoms improve on a scale of 1 to 10 (1 being not at all and 10 being completely resolved)? For question one, 100% of patients did not need to go to the hospital. For question two, 100% of patients reported a 9 or 10 level of improvement. No patients reported a relapse of symptoms.

### **Program Evaluation**

Participants were asked to post their thoughts on the policy via the Slack© platform.

Participants responded with: “Great Work!”, “Very helpful, thank you!”, and “Well written, easy to follow.” One participant noted that the links within the policy for medication interaction checker was “helpful to choose which medication to use.” Participants responded to the posting of the pocket card with an emoji symbol to confirm receipt. No further comments were posted.

### **Discussion**

Although the total participation was expected to be higher, the number of active providers recruited for participation was 100%. The total number of COVID patients during this time was significantly lower than the practice had seen in the past and is expected to ebb and flow with the natural cycle of illness in the US. Overall, participants reported an improvement in their confidence level of treating COVID. This can be measured in both objective and clinical measurements. Providers reported feeling more confident and better prepared to treat COVID. Patients reported no hospitalizations during the study period and improvement or resolution of symptoms.

Limitations of the project were a small sample of providers and patients. In the future, limitations can be overcome by duplicating the project at a larger organization with more providers and patients to follow. Additionally, the project can be run over a longer period of time allowing for more patients to follow.

### **Implications**

This was a small QI project of a policy for treating COVID-19 via telehealth. As this is a small company, it has a more informal practice and communication style. The patients receive quality treatment, and the providers actively discuss questions amongst each other. This project shows that the policy was well received and written in a way to aid the providers. The patients received timely and quality care and further strain on the hospital system was avoided.



## Education

Providers can be trained to stay up to date in rapidly changing guidelines by first acknowledging that there is a situation with rapidly changing guidelines such as COVID-19. The organization can appoint a provider or a team of providers to keep in contact with key organizations, such as the CDC. On a personal level, providers should bookmark key sites on their devices, such as CDC and NIH to be able to quickly review for updated posts. Unfortunately, at the beginning of the COVID-19 pandemic these sites were not always well maintained. Additional resources are databases such as CINAHL, NCBI, and PubMed which can be searched if the provider has a specific query.

## Policy

Other policies that should be available in this organization include policies on other diseases as the company expands. Additionally, annual dates of standards of practice updates should be posted in the policy itself for quick access. At the state level, the Board of Registered Nursing and the Boards of Medicine should have protocols in place to notify their participants in changes to pandemic guidelines. Currently, there is outdated information on the board of registered nursing website, and no information was found on the California Board of Medicine website. The boards of nursing and medicine would be a prime level to disseminate the newest guidelines via email to licensees within their territory. At the federal level, efforts were made to keep the information in one place. However, as information changed quickly, the posts from differing organizations were often conflicting. Inclusion of collaboration amongst medical societies and the government ran organizations may help to ease this confusion.

## Quality

Quality healthcare and perceived quality by the patient can be different and may be

difficult to balance. Perceived quality can include medications which may not be appropriate for treatment, including patients requesting ivermectin for COVID-19. There is conflicting evidence of ivermectin being appropriate for use. Clinical quality includes timely care, gathering knowledge of symptoms and risk factors, appropriate prescribing, and avoidance of harm. To obtain clinical quality, providers should ensure that knowledge of risk factors and allergies are gathered and documented. Appropriately entering information into the EMR will aid in medication decisions. Additionally, policies should be reviewed by the providers and by the organizations on a routine basis. This policy focuses on clinical quality and includes links to help the provider choose the most appropriate treatment. There is a significant focus on educating the patient regarding self-care and current guidelines. Updates should be made when new evidence becomes available. An on-going date to review and update the COVID-19 policy was built into the policy to ensure up to date guidelines within the company.

### Safety

Lack of safety mechanisms, such as policy review leave the company and the providers open for errors. Medication errors cause a significant burden on the healthcare system. Erroneous errors can lead to loss of license for the providers and patient harm or death. Errors may be made by providers when prescribing or by patients not understanding the directions. Using the policy, providers have a link to enter the patients list of medications and receive a suggestion for the most appropriate COVID-19 treatment for use in the outpatient setting. Also, in the policy there is a chart to help the provider triage the patient into the appropriate setting, such as treating via telehealth or referring to the hospital. Using annual review this chart will be updated to keep treatment consistent and safe for the patient.

### **Sustainability**

This study provides a framework for future policy development within the company. The basics of the policy such as development and implementation may be applied to other disease processes. As this is an online company with recruitment of a small number of providers every month, the recruitment team can send out the policies via email, as well as keep the policies pinned via Slack© for quick access. Questions can be addressed when the need arises. Policy changes can also be made quickly as guidelines change.

### **Future Scholarship**

The policy can be disseminated through contact with various organizations and through submission to journals. The most appropriate journals for submission would include the Journal for Telemedicine and Telecare, Telehealth and Medicine Today, and The Journal for Nurse Practitioners. Additionally, the author can submit to the Journal of the American Association of Nurse Practitioners, who also has a social media platform to increase engagement with the policy. The Northwest regional telehealth resource center also has online education and training, as well as annual conferences. The author is able to apply for submission of the project as a training course. If accepted, it will be available to the public for free.

### **Conclusion**

COVID-19 has prompted a rapid change in the way that patients are treated during an acute illness. As COVID-19 is a newly introduced disease, research is being conducted and protocols for treatment have rapidly changed in the last 3 years. During this study, the author implemented a telehealth protocol for the treatment of COVID-19 that is user friendly. The findings included improvement of provider confidence and self-efficacy in the treatment of COVID-19. This study will help further improve the world of telemedicine and provide a framework for other telemedicine companies to implement COVID-19 protocols.

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**Appendix A**

**Table 1. Summary of levels of evidence**

Melnyk Level	Kumar-Singh, 2022	Adeoye, 2020	Popp, 2021	NIH, 2022	Westendorf, 2022	Hammond, 2022
I	x		X			
II						x
III		X				
IV						
V						
VI					X	
VII				X		



**Appendix B**

**Table 2. Summary of evidence by intervention**

Intervention Details	Kumar Singh, 2022	Adeoye, 2020	Popp 2021	NIH, 2022	Westendorf, 2022	Hammond, 2022
Molnupavir	x			x		
Nirmatrelvir and ritonavir (Paxlovid)				x		x
Remdesivir		x		x		
Ivermectin			x	x		
Bebtelovimab				x	x	

### Appendix C

### Statement of Mutual Agreement

**Eastern Kentucky University**  
**Doctor of Nursing Practice (DNP) Program**  
 Statement of Mutual Agreement

The purpose of this document is describe the nature of the agreement for the Doctor of Nursing Practice (DNP) Project between:

Student Name: Ashley Morello  
 Partnering Organization Name: Physician 360

This statement of mutual agreement is completed in the DNP Project planning phase as a precursor to the Institutional Review Board (IRB) and to show general organizational support for the DNP Project.

General Information:

DNP Project Title:	Implementing a COVID 19 policy for telehealth
Partnering Organization:	Name of Organization: Physician 360 Name of Organizational Contact: Dr. Rob Lapporte Phone: 360-361-6199 Email: RLapporte@physician360.co

Brief Description of the Project:

Identified Problem/Gap:	Lack of COVID 19 policy and guidelines for telehealth
Proposed Intervention(s):	Implement new policy built on CDC guidelines
Proposed Evaluation of: <ul style="list-style-type: none"> <li>Outcomes</li> <li>Process</li> </ul>	pre and post self efficacy survey chart audit of documentation <del>patient follow up survey 2 weeks post treatment</del>
Description of On-Site Activities: <ul style="list-style-type: none"> <li>Student's Role</li> <li>Meetings</li> <li>Access to Data</li> </ul>	Student will meet w/ Dr. Lapporte for implementation, track data and outcomes and follow up w/ Dr. Lapporte for evaluation and any future changes
Intellectual Property: <ul style="list-style-type: none"> <li>Ownership</li> <li>Plans for Dissemination</li> </ul>	No identifiable data will be stored plan to store on student protected google drive

<ul style="list-style-type: none"> <li>• Non-disclosure expectations</li> <li>• Publication Plans</li> </ul>	<p><i>Permission will be obtained if student wants to publicize full article</i></p> <p>*** All EKU DNP Projects will require at minimum a de-identified abstract to be uploaded into the digital repository as a marker of academic work.</p>
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Institutional Review Board:

<p>EKU is the IRB of Record</p>	<p>The organization agrees to let EKU be the IRB of Record.</p> <p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Other: (Explain)</p> <p><input type="checkbox"/></p>
<p>Organization is the IRB of Record</p>	<p>The organization prefers to be the IRB of Record.</p> <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Other: (Explain)</p>

Other elements for clarification prior to implementation of the DNP Project. Describe.

DNP Student Signature: *[Signature]*  
 Date: 11/16/22

Partnering Organization's Signature: *Rob. Lapporte*      11/28/2022  
 Date:



## Appendix D

### IRB Application

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# Eastern Kentucky University Institutional Review Board Application for Expedited Review

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This application is to be used to request an expedited review for IRB approval. The investigator must receive approval prior to engaging in research activities involving human subjects.

In order for human subjects research to be reviewed under expedited review procedures, the study must represent not greater than minimal risk to its participants and include only activities that fall within the categories listed in this application (see Section 2).

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

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### Instructions for Applying for Expedited Review

1. All applications for IRB review must be submitted online by the principal investigator.
2. After completing this application form and all required attachments, access the online submission system at [eku.infoready4.com](http://eku.infoready4.com). Choose Expedited Review Application from the list of available opportunities and click the **Apply** button on the right. If needed, you can filter the category column by Institutional Review Board (Human Subjects Research).
3. If you are a current EKU employee or student, click the option to log in as an EKU user. Your user name and password are the same as what you use to log in to EKU's network. Your user name is not your email address.
4. Complete the basic information in the online application and upload this application form and all required attachments in their original file formats (i.e., Microsoft Word documents). **Please do not convert files to PDFs. PDFs are allowable for signed documents, CITI training documentation, and other files that were provided to you in PDF format. If you copy and paste text into the application's form fields, please format your text to Tahoma font in size 10 prior to copying.**
5. Upon receipt of a new online application, the IRB administrator will review the submission for completeness and return incomplete applications for updates prior to processing.
6. Once an application is accepted by the IRB administrator, it will be assigned to the faculty advisor (if the principal investigator is a student) and the department chair for approvals prior to being reviewed by the IRB.
7. If the IRB reviewers have questions or request updates to the application materials, the principal investigator will be notified by email and asked to resubmit application materials by email.
8. Once the IRB has approved the application, the principal investigator will be notified by email.

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### Application Checklist

In order for the IRB to consider an application for expedited review, the following items are required:

- Expedited Review Application (this application)
- CITI Training Completion Reports for all investigators, key personnel, and faculty research advisors  
*Note that the Basic Course for Social Behavioral or Biomedical Researchers is required. The Refresher Course cannot be accepted unless the investigator has previously completed the Basic Course and is using the Refresher Course to renew training credentials.*
- Informed Consent Documents (check all that apply):
  - Informed Consent Form

- Parent/Guardian Permission Form (for parents/guardians of subjects who are children)
- Child Assent Form(s) (for subjects who are children)
- Request for Waiver of Informed Consent Documentation

As applicable:

- Recruitment materials (i.e., advertisements, verbal scripts, cover letters, etc.)
- Instrument(s) to be used for data collection (i.e., surveys, questionnaires, interview questions, assessments, etc.)
- Letter(s) granting permission to use off-campus facility for research

*All documents that will be provided to subjects must include the title of the study.  
This includes recruitment, consent, and data collection documents.*

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## Application for Expedited Review

### Section 1: General Information

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#### 1. Title of Study:

**Implementing a COVID 19 Policy for Telehealth**

#### 2. Principal Investigator:

Principal Investigator Name: Ashley Morello  
Department: CHS, School of Nursing  
Position: DNP student

#### 3. Degree Program, Faculty Advisor, and Committee Members:

(Skip to Item 4 if principal investigator is not an ECU student)

Degree Program: DNP

Faculty Research Advisor: Wanda France, DNP

Committee Members (required for theses, dissertations, scholarly projects, field experience, or other studies guided by an academic committee):

Molly Bradshaw, DNP

#### 4. Other Investigators: Identify all other investigators assisting in the study. If additional lines are needed, please attach a Continuation Page for Other Investigators.

Name: Click and type. Authorized to obtain consent? Yes No

Responsibility in Project: Click and type.

Name: Click and type. Authorized to obtain consent? Yes No

Responsibility in Project: Click and type.

Name: Click and type. Authorized to obtain consent? Yes No

Responsibility in Project: Click and type.

Name: Click and type. Authorized to obtain consent? Yes No

Responsibility in Project: Click and type.

Name: Click and type. Authorized to obtain consent? Yes No

Responsibility in Project: Click and type.

Please check if a Continuation Page for Other Investigators is attached.

#### 5. Estimated Duration of Research Project: upon IRB approval through 6/1/2023

*Note that research may not begin until IRB approval has been granted. Projects may be approved for a period of up to three years, after which time, a new application is required.*

#### 6. Funding Support: Is the research study funded by an internal grant or an external grant or contract? Yes No

Funding Agency: [Click and type.](#)

**7. Is the proposed study a clinical trial?** Yes No

Please respond to the following questions to determine whether a study meets the clinical trial definition:

- Does the study involve human participants? Yes No
- Are the participants prospectively assigned to an intervention? Yes No
- Is the study designed to evaluate the effect of the intervention on the participants? Yes No
- Is the effect being evaluated a health-related biomedical or behavioral outcome? Yes No

If the answers are all "yes," the study is a clinical trial. If any answers are "no," the study is not a clinical trial

**8. Risk Category:**

- Not greater than minimal risk
  - Greater than minimal risk, but of direct benefit to individual participants – *Please complete full review application instead of this form.*
  - Greater than minimal risk and no direct benefit to individual participants, but likely to yield generalizable knowledge about the subject's disorder or condition – *Please complete full review application instead of this form.*
-

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## Application for Expedited Review

### Section 2: Expedited Review Categories

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Research activities may be reviewed through expedited review procedures when the only involvement of human subjects falls within one or more of the categories below and the study represents not greater than minimal risk to its participants. If the study represents greater than minimal risk or if any activities fall outside the categories below, the project is not eligible for expedited review, and the investigator is required to instead apply for full review.

#### 1. Select one or more of the categories below that apply to the research project:

- Category 1:** Clinical studies of drugs and medical devices only when condition (a) or (b) below is met.
  - (a) Research on drugs for which an investigational new drug application is not required. Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.
  - (b) Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows (check one):
  - (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
  - (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
- Category 4:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
- Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes.
- Category 7:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program

evaluation, human factors evaluation, or quality assurance methodologies.

**2. Will the study involve any procedures that fall outside the categories selected in Item 1 of this section?**

No       Yes (apply for full review)

**3. Will the project involve prisoners?**  No       Possibly Incidentally       Yes (full review required)

Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects requires full review except for research aimed at involving a broader subject population that only incidentally includes prisoners (i.e., a web-based survey that an inmate may be able to access from a prison computer without the researcher being aware of the prisoner status).

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## **Application for Expedited Review**

### **Section 3: Research Description**

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#### **1. Background:**

- a. Provide an introduction and background information for the study and provide a discussion of past research findings leading to this study. Cite literature that forms the scientific basis for the study.**

Due COVID-19 being a previously unseen virus in the human population, the pandemic began strong and rapidly spread worldwide (World Health Organization, 2020). It was initially unclear how to treat this virus and prevent severe complications and death. According to the WHO COVID-19 dashboard there have been 152,265,980 confirmed COVID-19 cases in the Americas with 1,977,835 deaths since the beginning of the pandemic (World Health Organization, 2022). Guidance for telehealth treatment of COVID-19 has changed rapidly over the last 3 years as new data has emerged. Conflicting guidelines are available for review regarding treatment, however no clear telehealth guideline is available.

The proposed DNP Project will explore implementation of a COVID-19 telehealth policy to clarify evidence-based practice, promote use of safe medications, and reduce hospitalizations. Providers will be recruited from a telehealth organization, educated on current guidelines, and given a pocket card for reference and re-enforcement of training. Data will be collected to examine guideline utilization, confidence in treating COVID, and efficacy of pocket card. COVID patients will receive follow up calls to determine if hospitalization was required post treatment. Chart audits will also be completed to review compliance with guidelines. Ultimately, the goal is to promote evolving standards of care and improve patient outcomes.

#### **2. Research Objectives:**

- a. List the research objectives.**

The objective of this quality improvement project is to develop a policy for treatment of COVID-19 via telehealth. The policy will serve to guide clinical judgement about medication choice, risks, side effects, when to start the treatment, when to refer to emergency services.

#### **Objectives:**

- Develop a COVID-19 protocol for telehealth consistent with current guidelines. Train 45 clinicians on the protocol within 2 weeks of implementation.
- Obtain Data:
  - Survey of provider confidence in treating COVID-19 pre and post intervention. Post intervention 80% of providers will report improved confidence.
  - Survey of provider self-efficacy in treating COVID-19 pre and post intervention. Post intervention 80% of providers will report improved self-efficacy.
  - Post intervention, 80% of providers report the pocket card useful
- Enroll 30 patients into project QI process:
  - 100% of patients treated via protocol (patient instructions given, vaccination status charted, quarantine instructions given, appropriate use of medications) will report overall 10% improvement
  - No patient will be hospitalized at 2 weeks

**3. Project Location:****a. Where will the study take place?**

Online Telehealth Platform – Physician 360

**b. If the study will take place at a location other than ECU, attach a letter from an authorized representative of the organization granting permission to use facility for research purposes.**

ECU only     Letter(s) attached

**c. Will any data be collected through organizations other than ECU?**

No     Yes, complete the following:

- Will personnel of the organization be involved in the data collection process or have access to data after collection?  No     Yes - If yes, list personnel in Section 1, include CITI training documentation, and define role here: Click and type.

**4. Subject Population:****a. What criteria will be used to determine the *inclusion* of participants in the study?**

All clinicians will be included – adults, over 18 years old, licensed to practice medicine and treat COVID patients.

**b. What criteria will be used to determine the *exclusion* of participants in the study?**

Non-clinicians will be excluded

**c. Anticipated Number of Participants (*maximum*): 45****d. Age Range of Participants:** 18-75**e. Gender of Participants:**  Male     Female    or     Gender not considered in subject selection**f. Ethnicity of Participants:** Click and type. or  Ethnicity not considered in subject selection**g. Health Status of Participants:** Click and type. or  Health status not considered in subject selection**h. Which of the following categories of subjects will be included in the study? Please check all that apply.**

- Adults
- College Students age 18 and older
- Children (under age 18) – complete Section 4
- Subjects who do not speak and/or read English – *see Translation Certification form and guidance*
- Pregnant Women (other than by chance)
- Fetuses/Neonates
- Hospital Patients
- Patients at Inpatient Mental Health Facilities
- Individuals with Impaired Decision-Making Capacity – *complete Section 5*
- Institutionalized Individuals with Impaired Decision-Making Capacity – *complete Section 5*
- Prisoners (other than incidentally without the investigator's knowledge) – *apply for Full Review instead of Expedited Review*
- Other – Please Describe: Click and type.

**5. Recruitment of Participants:****a. How will prospective participants be identified for recruitment into the study?**

At the request of the organizations leadership team, all clinicians within the system will be included

and receive notification of the project via an announcement in the company's learning management system.

**b. Describe the recruitment procedures to be used with potential participants identified for the study.**

Staff will receive notification of the project via a message in their learning platform. The informed consent will be provided. Then participants will be asked to participate in a required training.

**c. Recruitment materials to be used:** Check all that will be used and attach copies. The study's title must be included on all documents.

- None      Advertisement      Flyer      Verbal Recruitment Script      Cover Letter  
Other: Written script on communication platform

**6. Ensuring Voluntary Participation**

**a. Who will be responsible for seeking the informed consent of participants?**

Primary Investigator

**b. What procedures will be followed to ensure that potential participants are informed about the study and made aware that their decision to participate is voluntary?**

Written communication via Slack (the learning management system)

**c. How will consent be documented?** If you are requesting a waiver of documentation, please explain here and attach a completed waiver request form.

Informed consent will be given. Consent and waiver are attached below.

**d. What consent documents will be used in the study?** Attach copies of all.

- Informed Consent Form    Parent/Guardian Permission Form    Child/Minor Assent Form    Oral Script  
Other: Waiver of Documentation of Consent

**7. Research Procedures**

**a. Describe in detail the research procedures to be followed that pertain to the human participants.** Be specific about what you will do and how you will do it. If applicable, differentiate between standard/routine procedures not conducted for research purposes and those that will be performed specifically for this study.

First, Staff training will consist of a power point presentation viewed after pre-implementation survey is complete. The training will consist of the current guidelines with explanation of treatment and links to current CDC guidelines. The training will take no more than 15 minutes to complete. Staff will also be given a printable pocket card for an easy to reference reminder. Training will be presented via Slack© and pinned in the general chat channel. Providers will self-testify when training is complete. Surveys with questions regarding demographics, confidence, and self-efficacy of treating COVID-19 will be utilized. Surveys will be administered pre and post training to the clinicians.

Second, a quality improvement cycle will be initiated to assess clinician application of recommended guidelines. Quality improvement is routine in healthcare and considered a standard of care. During chart audits, key outcomes of guideline compliance will be reviewed and from patient encounters. These include vaccination status reviewed, quarantine guidelines given, patient instructions given.

Patients who were treated for COVID over an eight-week time period will be contacted for follow up. Follow-up phone calls will take place 2 weeks post consultation and will include two questions: 1) Did you need to go to the hospital? and 2) Did your symptoms improve on a scale of 1 to 10? This follow-up will allow for data to determine efficacy of the treatments provided. Follow up is considered a standard of care, so no additional permissions will be required.

A convenience sample of 30 charts will be randomly selected. To compare an audit will be done of 30 charts from the previous two months. The data will be de-identified and collected by the primary investigator.

Finally, a program evaluation will take place. For program evaluation, the primary researcher will collect a post-implementation survey at the end of the program. The primary researcher will conduct an evaluation of the training, documentation progress, and of the pocket card provided to the providers.

## 8. Potential Risks

- a. Describe any potential risks, including physical, psychological, social, legal, or other risks.** Note that if identifiable data is used, there are risks to the participants' confidentiality.

Risk of breach of confidentiality is the only foreseen risk. However measures are in place to prevent this.

- b. What procedures will be followed to protect against or minimize any potential risks?**

Anonymous survey link posted in channel, no collection of demographics, providers will be asked to create a unique 4-digit pin for tracking of pre and post survey data.

- c. How are the risks reasonable in relation to the anticipated benefit to participants and in relation to the importance of the knowledge that may reasonably be expected to result from the study?**

There are no risks of harm to the participants. The benefits to the medical community include a protocol base for COVID-19 that can be rapidly implemented in telehealth situations.

- d. Will alternative choices be made available to participants who choose not to participate?**

No  Yes, Describe: Click and type.

## 9. Incentives and Research Related Costs

- a. Will incentives be offered to participants?**  No  Yes, complete the following items:

- 1) What incentives will be offered? Click and type.
- 2) If monetary compensation will be offered, indicate how much the participants will be paid and describe the terms of payment. If gift cards will be used as incentives, please see Guidance for Projects Using Gift Cards as Subject Payments. Click and type.
- 3) Describe the method of ensuring that the incentives will not compel individuals to agree to participate in the study. Click and type.
- 4) Describe how the incentives will be funded. Click and type.

- b. Will there be any costs to the subjects for participating?**  No  Yes, complete the following item:

- 1) Describe any costs that will be the responsibility of the subjects as a consequence of their participation in the research. Click and type.

## 10. Research Materials, Records, and Confidentiality

- a. What materials will be used for the research process?** Include a description of both data collected through the study as well as other data accessed for the study. Copies of all data collection instruments must be attached and must include the title of the study.

The researcher will use a google survey created and stored in Faculty Office, Rowlett 214 on Campus. The data will be anonymous and stored until the end of the study.

- b. Who will have access to the data?** If anyone outside the research team will have access to the data, provide a justification and include a disclaimer in consent documents.

Only the primary investigator and faculty listed on this document.

- c. Describe how and where research records will be stored.** Note that all research-related records must be securely maintained for a period of three years from the study's completion and are subject to audit. Following the completion of the study and throughout the records retention period, student research records must be maintained by the faculty advisor identified in Section 1, Item 3 of this application or provided to the IRB for records maintenance.

retained in Faculty Office, Rowlett 214 on Campus

- d. How will data be destroyed at the end of the records retention period** (i.e., shredding paper documents, deleting electronic files, physically destroying audio/video recordings)?

Deletion of electronic files

- e. Describe procedures for maintaining the confidentiality of human subjects data.**

There will be no collection of identifiable information.

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## Application for Expedited Review

### Section 4: Research Involving Children as Subjects

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In Kentucky, a child is an individual who is less than 18 years of age unless the individual has been legally emancipated. Some Federal agencies and other states define children differently. If the study is to be funded by a Federal agency, that agency's definition applies; if a study is to be conducted outside Kentucky, that state's definition applies.

**1. Will this study involve children as subjects?**

- No (skip remainder of this section)  
 Yes (complete all items in this section)

**2. Risk Level:** Expedited review procedures can be used only when the research represents not greater than minimal risk to its participants. Minimal risk means that the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams or tests. Explain why the research is classified with a risk level of not greater than minimal risk.

Click and type.

**3. Suitability of Subjects:** Explain why children are suitable subjects for this research.

Click and type.

**4. Previous Research on Adults:** Has this research previously been conducted with adults as subjects?

- No       Yes (respond to 4.a. below)

**a.** Explain indications that the proposed research will benefit or at least not be harmful to the children.

Click and type.

**5. Number of Children Subjects:** Provide a justification for the number of children proposed for enrollment in the project.

Click and type.

**6. Parent/Guardian Permission Process:** Describe procedures for soliciting the permission of at least one parent/guardian.

Click and type.

**7. Assent Process:** Describe procedures for soliciting the assent of the children, following permission from the parents/guardians.

Click and type.

**8. Understandable Language:** Describe what efforts have been made to present information about the study in a language that is understandable to the children who will be recruited (i.e, informational documents, recruitment flyers, assent forms, data collection instruments).

Click and type.

**9. Wards as Subjects:** Will the study involve wards as subjects?

- No       Yes (respond to 9.A. and 9.B. below)

**A. Research Classification:** The use of wards as subjects in research is permissible in only the following two situations. Indicate which classification below applies to the proposed research.

- The proposed research is related to the subjects' status as wards of the state.  
 The proposed research is to be conducted in schools, hospitals, or similar settings in which the majority of children involved in the study are not wards.

**B. Ward Advocate:** A ward advocate must be appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate(s) must have the background and experience to act in, and agree to act in, the best interests of the child for the duration of the child's participation in the research and may not be associated in any way with the research, the investigator(s), or the guardian organization. Please explain how these ward advocate requirements will be met.

Click and type.

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## Application for Expedited Review

### Section 5: Research with Subjects Who Have Impaired Decision-Making Capacity

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When a prospective research participant lacks the ability necessary to understand and use information relevant to an informed consent process, additional precautions and protections are required.

**1. Will this study involve individuals with impaired decision-making capacity as subjects?**

- No (skip remainder of this section)  
 Yes (complete all items in this section)

**2. Risk Level:** Expedited review procedures can be used only when the research represents not greater than minimal risk to its participants. Minimal risk means that the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams or tests. Explain why the research is classified with a risk level of not greater than minimal risk.

Click and type.

**3. Suitability of Subjects:** Individuals with impaired decision-making capacity should be used as research subjects only in situations where they are the only population who can provide the data needed for the study and only when the potential risks are balanced with expected benefits. Explain why individuals with impaired decision-making capacity are suitable subjects for this research.

Click and type.

**4. Subject Advocate:** What procedures are in place to allow a subject advocate to assist subjects in navigating the research process?

Click and type.

**5. Competency to Consent:** Describe who will determine individuals' competency to consent and the criteria to be used in determining competency (i.e., use of standardized measurements, consultation with qualified professional, etc.).

Click and type.

**6. Consent for Individuals Incapable of Consenting on Their Own Behalf:** Explain how you will identify who is authorized to give legally valid consent on behalf of any individual(s) determined to be incapable of consenting on their own behalf.

Click and type.

**7. Expectations, Obligations, and Authority of Legally Authorized Representatives:** Explain the expectations, obligations, and authority of the legally authorized representative for each subject and describe how this information will be conveyed to the representative (i.e., through a written information sheet).

Click and type.



**8. Assent:** Explain the criteria you will use to determine when assent is required for subjects who are not able to provide consent and describe the assent process to be used with these subjects.

Click and type.

**9. Evaluating Dissent:** Explain the methods to be used for evaluating dissent (i.e., description of behaviors that would indicate that an individual does not want to participate, such as moving away or displaying certain facial expressions or head movements).

Click and type.

**10. Re-Consent/Re-Assent:** Explain procedures to be followed for periodic re-consent and/or re-assent and define the documentation interval.

Click and type.

**11. Monitoring Capacity to Consent:** Describe the process for monitoring capacity to consent and describe procedures for protecting the subjects' rights in the event they lose their capacity to consent or their capacity to withdraw during the course of the research (i.e., use of legally authorized representative).

Click and type.

**12. Use of Institutionalized Individuals:** Does the proposed research involve individuals who are institutionalized?

No

Yes (Respond to item below and attach approval from an authorized representative at the institution)

- Provide a justification for the use of institutionalized individuals and explain why individuals who are not institutionalized cannot be substituted.

Click and type.

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## Appendix E

### Provider Training

#### Lesson Plan:

The purpose of the provider training is to reinforce key elements of the clinical practice guidelines related to the treatment of patients with COVID. As a result of this training, the participants will:

- Review who can be treated for COVID-19 via the telehealth platform
- List medications recommended for treatment
- Discuss guidelines and template for documentation of patient encounter
- Examine quarantine guidelines and PPE guidelines
- Utilize pocket cards for reference in clinical practice to reinforce training

## Appendix F

### Informed Consent Form

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# Consent to Participate in a Research Study

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## Implementing a COVID 19 Policy for Telehealth

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**Upon approval of your study, the IRB will place a stamp with a protocol number here. You are required to use only the stamped version when enrolling participants in**

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## Key Information

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You are being invited to participate in a research study. This document includes important information you should know about the study. Before providing your consent to participate, please read this entire document and ask any questions you have.

### **Do I have to participate?**

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide to participate, you will be one of about 45 people in the study.

### **What is the purpose of the study?**

The purpose of the study is to implement a COVID-19 Telehealth policy. COVID-19 is a relatively new disease requiring a rapid development of policy that can be rapidly changing.

### **Where is the study going to take place and how long will it last?**

The research procedures will be conducted at telehealth premises. You will not need to travel for this study. The pre and post implementation surveys will take approximately 10 minutes of your time.

### **What will I be asked to do?**

You will be asked to participate in a pre and post implementation survey with creation of a unique identifier to keep your information private. You will be asked your credentials, years of practice, previous experience with COVID-19, and to fill out a self-efficacy scale. You will be asked to fill out your unique identifier and a repeat self-efficacy scale at the end of the study in 8 weeks. You will be asked to include patient vaccination status in your notes. You will also be asked to ensure you send the patient information on quarantine, self-care, and follow-up care.

### **Are there reasons why I should not take part in this study?**

Anyone under the age of 18 should not participate in this study.

### **What are the possible risks and discomforts?**

To the best of our knowledge, the things you will be doing have no more risk of harm or

discomfort than you would experience in everyday life.

**What are the benefits of taking part in this study?**

You are not likely to get any personal benefit from taking part in this study. Your participation is expected to provide benefits to others by providing a framework for implementation of COVID-19 protocol in other workforces.

Now that you have some key information about the study, please continue reading if you are interested in participating. Other important details about the study are provided below.

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**Other Important Details**

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**Who is doing the study?**

The person in charge of this study is Ashley Morello at Eastern Kentucky University. She is being guided in this research by Dr. Molly Bradshaw. There may be other people on the research team assisting at different times during the study.

**What will it cost me to participate?**

There are no costs associated with taking part in this study.

**Will I receive any payment or rewards for taking part in the study?**

You will not receive any payment or reward for taking part in this study.

**Who will see the information I give?**

Your information will be combined with information from other people taking part in the study. When we write up the study to share it with other researchers, we will write about this combined information. You will not be identified in these written materials.

This study is anonymous. That means that no one, not even members of the research team, will know that the information you give came from you.

We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained via the Internet. Third-party applications used in this study may have terms of service and privacy policies outside of the control of the Eastern Kentucky University.

**Can my taking part in the study end early?**

If you decide to take part in the study, you still have the right to decide at any time that you no longer want to participate. You will not be treated differently if you decide to stop taking part in the study.

The individuals conducting the study may need to end your participation in the study. They may do this if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the University or agency funding the study decides to stop the study early for a variety of reasons.

**What happens if I get hurt or sick during the study?**

If you believe you are hurt or get sick because of something that is done during the study, you should call Ashley Morello at 909-856-8541 immediately. It is important for you to understand that Eastern Kentucky University will not pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, Eastern Kentucky University will not pay for any wages you may lose if you are harmed by this study. These costs will be your responsibility.

Usually, medical costs that result from research-related harm cannot be included as regular medical costs. Therefore, the costs related to your care and treatment because of something that is done during the study will be your responsibility. You should ask your insurer if you have any questions about your insurer’s willingness to pay under these circumstances.

**What else do I need to know?**

Physician 360 is involved in this study by providing the platform for study and access to participants.

You will be told if any new information is learned which may affect your condition or influence your willingness to continue taking part in this study.

We will give you a copy of this consent form to take with you.

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**Consent**

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Before you decide whether to accept this invitation to take part in the study, please ask any questions that come to mind now. Later, if you have questions about the study, you can contact the investigator, Ashley Morello at 909-856-8541. If you have any questions about your rights as a research volunteer, you can contact the staff in the Division of Sponsored Programs at Eastern Kentucky University at 859-622-3636.

If you would like to participate, please read the statement below, sign, and print your name.

*I am at least 18 years of age, have thoroughly read this document, understand its contents, have been given an opportunity to have my questions answered, and voluntarily agree to participate in this research study.*

\_\_\_\_\_  
Signature of person agreeing to take part in the study

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of person taking part in the study

\_\_\_\_\_  
Name of person providing information to subject

## Appendix G

### Waiver of Documentation of Informed Consent

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## Eastern Kentucky University Institutional Review Board Request for Waiver of Informed Consent Documentation

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Informed consent is a foundational component of protecting human research subjects and is at the core of the IRB's ethical values. In general, all studies involving human subjects must include a formal informed consent process that is documented with signatures from participants. In a limited number of situations, however, Federal regulations permit an IRB to authorize a waiver of informed consent documentation. When a study is approved with a waiver of informed consent documentation, this means that signatures from subjects are not required on consent forms. However, such a waiver does not eliminate the ethical requirement to provide information to potential subjects and allow them to make an informed decision about voluntarily participating. Investigators are still required to follow a process of obtaining consent and to outline this process in the application for IRB review.

In unique situations where a study cannot be practicably carried out with informed consent documentation, this form may be used to request a waiver of the informed consent documentation requirements. If approved, the waiver will be specifically outlined in the approval notification.

### 1. Title of Study:

#### Implementing a COVID 19 Policy for Telehealth

### 2. Principal Investigator and Faculty Advisor:

Principal Investigator Name: Ashley Morello

Primary Faculty Advisor (required only if principal investigator is a student): Dr. Molly Bradshaw

### 3. Category of Waiver Request:

Please indicate which of the following situations apply and respond to the items that follow each category.

- A.** The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. In this case, each subject (or legally authorized representative) must be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
  - Describe the procedures to be followed for offering this choice to each subject.  
Click to enter text.
- B.** The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
  - Provide a justification describing how the proposed study meets this criteria.  
No identifiable information is to be collected. Participants will be asked to choose a 4 digit unique identifier and to remember this identifier for pre and post survey data. No other identifiable data will be collected or stored.
- C.** The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal

risk of harm to subjects, and an alternative mechanism will be used for documenting that informed consent was obtained

- Identify and provide background on the cultural group and cite references for views on signing forms.

Click to enter text.

- Describe the alternative mechanism to be used for the documentation of informed consent.

Click to enter text.

**4. Explain how the waiver will not adversely affect the rights and welfare of the subjects.**

Waiver of informed consent will not affect the rights and welfare of the subjects, as no identifiable information is to be collected.

**5. Explain why the research could not practicably be carried out without the waiver.**

The documentation of informed consent would require that identifiable information is stored with the researcher which would risk breach of confidentiality.

**Appendix H**

## Recruitment

Hi Team, as we are continuing to see COVID-19 cases frequently we would like to introduce the current guidelines and recommendations for treatment. Attached you will find a link to a pre-implementation survey. The answers to this survey are anonymous and will be collected by Ashley Morello, NP. The total number of answers will be used to determine if all providers have answered. In a week, we will release the training and will expect that this is also completed within 1 week. Implementation of the recommendations will be monitored also anonymously. Please understand that these are strong recommendations for best practice.



**Appendix I**  
Demographic Information

1. Please choose your credentials:
  - a) MD
  - b) DO
  - c) NP
  - d) PA
2. Do you have any previous experience treating COVID-19?
  - a) Yes
  - b) No
3. How many years have you been in practice?
  - a) 0-5
  - b) 6-10
  - c) 11-15
  - d) 16-20
  - e) 25+
4. What is your current Confidence level when treating COVID-19 on a scale of 1-10, with 1 being not confident at all and 10 being very confident?
  - a) Free text box answer

## Appendix J

### Survey of Self Efficacy

Using a five-point rating scale (see below) survey respondents should answer based on their confidence treating COVID-19 patients.

#### Response Format

1 = strongly disagree; 2 = disagree; 3 = neither agree nor disagree; 4 = agree; 5 = strongly agree.

#### Survey Questions

1. I will be able to achieve most of the goals that I have set for myself.
2. When facing difficult tasks, I am certain that I will accomplish them.
3. In general, I think that I can obtain outcomes that are important to me.
4. I believe I can succeed at almost any endeavor to which I set my mind.
5. I will be able to successfully overcome many challenges.
6. I am confident that I can perform effectively on many different tasks.
7. Compared to other people, I can do most tasks very well.
8. Even when things are tough, I can perform quite well.