1. Research Objectives

Teledermatology can be performed using two different types of technology – “store and forward” or “real-time interactive.” (1) Store and forward teledermatology consults use “still” digital images obtained with a digital camera. These images are typically generated at the site of patient care, forwarded to a consultant dermatologist, and stored for review by that consultant at a future time. The store and forward nature of these consults separates the patient and the consultant by not only space, but also time. The alternative to store and forward technology is real-time interactive technology. Real-time interactive consults are performed using video-conferencing techniques with patients and consultants interacting with one another through audio-video communication links. Participants of real-time interactive consults are separated only by space, not by time. The nature of ambulatory dermatology, commonly comprised of sub-acute and chronic presentations with rare emergent conditions, is well-suited for an asynchronous system that does not require instantaneous communication. Our study proposes to study store and forward teledermatology consultations to address the following research objectives:

Primary objective:
To determine whether the mean change in patient quality of life, as rated by the overall score of a skin-specific quality of life index (Skindex-16©), differs between the time of randomization and 9 months for patients evaluated by store and forward teledermatology compared to conventional consult methods.

Primary hypothesis:

H₀: There is a significant difference between store and forward teledermatology compared to usual care in the mean change in quality of life, measured by the overall score of the Skindex-16©, at randomization and the 9 month follow-up visit.

Secondary objectives:

(1) To determine whether the mean change in patient quality of life, as rated by the overall score of a skin-specific quality of life index (Skindex-16©), differs at 3 months from the time of randomization between patients evaluated by teledermatology and those evaluated by conventional consult methods.

(2) To determine whether the time to initial definitive evaluation differs between patients evaluated by teledermatology and those evaluated by conventional consult methods.

(3) To obtain preliminary data on clinical course, as assessed by serial digital imaging between patients evaluated by teledermatology and those evaluated by conventional consult methods.

(4) To compare the costs and cost-effectiveness of store and forward teledermatology with conventional consult methods.
2. Background

2a. Rationale for Quality of Life as a Primary Outcome for Skin Disease. While research on teledermatology and quality of life is virtually absent, there is an abundance of research on dermatology and quality of life. For non-fatal chronic conditions, such as the vast majority of dermatologic conditions, a central health outcome is quality of life. (2, 3) Change in chronic skin diseases cannot be measured by mortality rates, laboratory tests, or even standard domains of health status such as physical functioning and general health. Their effects on patient well-being, however, can be significant. (4-7) For example, psoriasis was found to be more detrimental to quality of life than angina or hypertension and was associated with a reduction in physical and mental functioning comparable to that seen with cancer, arthritis, heart disease, diabetes, and depression. (4, 8) Many skin diseases are visible to others resulting in unique effects on patients’ social and emotional functioning. (9) In addition, physicians’ judgments of the clinical severity of dermatologic diseases cannot be used to gauge their effects on patients. (4, 10-17) Thus, self-reporting by patients of the effects of skin conditions on their quality of life represents a crucial health outcome for skin diseases. Moreover, accurate assessment of this health outcome requires a measure that can assess the unique effects of skin conditions on patient well-being.

Skindex, a validated measure tested extensively in veteran populations, is considered a superior measure for dermatology-specific quality-of-life research (18). Skindex is a self-administered questionnaire developed using strict psychometric principles. The original version was extensively tested and incrementally refined to a 16-item instrument that retained excellent measurement properties. (10, 19-21) The instrument has internal consistency, reliability, reproducibility, evidence of content and construct validity, and responsiveness to clinical change. (21)

Skindex inquires about “bother” from various potential effects of skin conditions on quality of life (Appendix D). Patients choose from a seven point scale anchored by “never bothered” and “always bothered.” For example, items inquire about bothers from itching, hurting, worry, frustration, and effects on daily activities. Three domains of skin disease are measured: symptoms, emotional effects, and effects on social and physical functioning. Scores range from 0 (no effect) to 100 (maximal effect). Skindex is a condition-specific generic tool in the sense that it can be used to measure skin-related quality of life in any skin condition. For this study, patients will be asked to respond specifically about quality of life effects related to the condition that prompted enrollment in the study.

Skindex has also been compared with a standard generic measure of health status, the Medical Outcomes Study 36-Item Short-Form (SF-36). (19) The results demonstrated that these instruments measure different, but complementary, aspects of patients’ health. Both contribute to understanding and measuring the effects of skin disease on patients’ perceived health. Dermatology patients in that study reported similar overall health status to population norms, and the scales of the generic measure were not sensitive to quality-of-life effects which may be common in dermatology patients overall. Thus, the greater sensitivity of Skindex for specific skin-related health characteristics may be important for detecting changes in the effects of disease in individual patients. (9)

2b. Preliminary Research. A hierarchy proposed by Fineberg, et al. provides a guideline of stages to be considered in addressing the efficacy and effectiveness of telemedicine technology: 1) technical accuracy, 2) diagnostic accuracy, 3) diagnostic effectiveness, 4) therapeutic effectiveness, 5) quality of life, and 6) user satisfaction. (22) Using this hierarchy, the following summarizes prior research that has brought us to an evaluation of quality of life and the other health services considerations described in this proposal.

2b(i). Technical Accuracy. Conventional color photography is a long-established method in dermatology for providing clinical care and follow-up, educational interventions, and assessing clinical competence. One study found that the clinical informativeness of color photography and digital imaging was statistically similar across a range of diagnostic categories. (23) Two other studies addressed the quantity of information present in a digital image on diagnostic decision-making, specifically the
minimum image resolution required. (24, 25) These studies found that image resolutions of 720 x 500 pixels and 768 x 512 pixels (with 24-bit color depth), respectively, were equivalent to higher resolution images. Even the lowest resolution digital cameras typically deliver at least 1200 x 800 pixels.

2b(ii). Diagnostic Reliability and Accuracy. The level of interobserver agreement, reported as simple agreement, between clinic-based dermatologists and teledermatologists using store and forward technology has ranged from 0.54 – 0.96. (26-30) One study, HSR&D IIR 95-045 (PI: Whited) conducted at the Durham VA Medical Center, compared diagnostic reliability between teledermatologists and clinic-based dermatologists compared to diagnostic agreement found among different clinic-based examiners. (30) The level of diagnostic reliability found among different clinic-based dermatologists was comparable to that found between clinic-based and teledermatologist examiner pairs. Two studies, including HSR&D IIR 95-045, have compared the accuracy of teledermatologists’ and clinic-based dermatologists’ diagnoses using a subset of skin lesions that were biopsied or had some other definitive diagnostic test applied. (30, 31) Both studies found comparable diagnostic accuracy between clinic-based dermatologists and teledermatologists. A recently completed study at the Minneapolis VAMC (HSRD IIR 01-072, PI: Warshaw) involving 2,152 patients found that while the diagnostic accuracy of clinic dermatologists was superior to that of teledermatologists for skin neoplasms, the management plans were equivalent.

2b(iii). Intermediate Clinical Outcomes and Economic Analyses. A recently funded teledermatology proposal, HSR&D IIR 98-159 (PI: Whited), evaluated an intermediate clinical outcome; access to care measured as time to initial definitive evaluation in a model of a site to site store and forward teledermatology consult system. We randomized patients who were referred to the Dermatology Consult Service to either the conventional referral process (text-based electronic consult request) or to a store and forward teledermatology consult (digital image(s) and standardized history). Subjects randomizing to teledermatology reached a point of initial intervention significantly sooner than did patients undergoing the conventional referral process based both on a scheduled visit analysis (median times of 41 days versus 127 days, p = 0.0001) and an actual visit analysis (median times of 50 days versus 137.5 days, p = 0.0027). (32) Additionally, 18.5% of the teledermatology referrals did not require a dermatology clinic visit.

As with clinical outcomes, very little data have been published on the economic impact of teledermatology. The store and forward teledermatology model tested in HSR&D IIR 98-159 also included an economic analysis. Store and forward teledermatology was the more costly alternative incurring an average cost in our base-case analysis of $36.40 per patient compared to $21.40 per patient for usual care. (33) However, teledermatology was a very cost-effective means of improving access to care based on our intermediate measure of effectiveness, time to initial evaluation. Teledermatology would cost the VA an additional $0.17 per patient per day of time to initial evaluation saved. These study results are limited by the fact that we performed an intra-medical center evaluation that did not assess a functional site-to-site teledermatology consult system. The geographic and logistical barriers present among patients being served by remote Community Based Outpatient Clinics were not present.

2b(iv). Clinical Course. Only one large study exists that assessed the clinical course of patients undergoing store and forward teledermatology compared to conventional care (Department of Defense C.2002.129, PI: Pak) (34). Using a randomized trial design, there was no evidence to suggest a difference in clinical course between patients undergoing teledermatology consultations compared to those undergoing the conventional clinic-based consult process. Sixty-three percent of teledermatology patients were rated as improved, 33% were rated as unchanged, and 4% were rated as worse. For usual care the respective proportions were 65%, 32%, and 3%. Because of VA and Department of Defense population differences in demographics, case-mix, and health care delivery methods, the Department of Defense study cannot be directly generalizable to the veteran population.
2b(v). Quality of Life. Illustrating the paucity of existing data and need for quality of life investigations, only one study has analyzed quality of life in a teledermatology population. (35) In a cross-sectional study design, the Dermatology Life Quality Index (DLQI) was administered to 123 adult patients referred for non-urgent dermatology care in a mobile nurse-led store and forward teledermatology clinic in England. The mean DLQI scores of teledermatology patients in this study were similar to previous studies of patients who were seen in-person at a Dermatology clinic with a wide-range of skin conditions. (36, 37) However, the study by Williams, et al. did not compare quality of life among teledermatology participants with participants of the conventional referral process.

2b(vi). Patient, Referring Clinician, and Dermatologist Satisfaction Assessments. Reliable and validated instruments that assess patient and clinician satisfaction with telemedicine interventions do not exist. Existing research primarily consists of proprietary scales and descriptive measurements. Nonetheless, many of these scales exhibit face validity and some recurring themes have begun to emerge. Overall, patients have been largely satisfied with the teledermatology consult process. (38-43) Convenience and time savings were mentioned as specific positive features of teledermatology by patients. (39, 41, 42) Negative features voiced by patients were long waiting times to hear results of consults or a lack of follow-up. (38, 39) Referring clinicians perceive that they receive an educational benefit with teledermatology. (39, 42, 43) In two studies, the majority of referring clinicians preferred teledermatology to usual care. (39, 42) Overall, dermatologists have been satisfied with teledermatology and believe image quality is good. (39, 42, 43)

2c. Rationale for Further Research. To date, no data exist that compares quality of life outcomes – the fundamental metric to assess in an ambulatory dermatology population – between patients undergoing store and forward teledermatology consultations with patients managed by the conventional consult processes. Only one study has made a clinical course assessment, however, this was performed in a Department of Defense population. The impact that teledermatology has on health care utilities is another area absent from the literature. Our preliminary research, using an intra-medical center “model” of a site-to-site consult system suggested improved intermediate outcomes and cost-effectiveness. The fact that these outcomes have not been assessed in a functional site-to-site consult system is a major limitation of these data. The economic impact of teledermatology can only be fully assessed and directly measured within a functioning site-to-site consult system. Therefore, this study will make the following contributions to the literature:

1. Be the first study to compare quality of life outcomes between teledermatology patients and usual care patients.
2. Be the second study to assess clinical outcomes of teledermatology consultations and the first to do so in a VA population.
3. Be the first study to assess the impact that teledermatology has on health care utilities.
4. Be the first study to assess the economic impact of store and forward teledermatology in the VA using a functioning site to site consult system.

A two-site randomized clinical trial is necessary to (a) compare teledermatology with usual care in a “hub and spoke” setting that more accurately reflects the site-to-site features of functional teledermatology programs (b) provide an adequate sample size to assess our primary objective, (c) provide population diversity so that our results may be more generalizable across the veteran population, and (d) provide heretofore unavailable assessments of teledermatology’s impact on quality of life and health care utilities, and (e) provide preliminary data on clinical course which may guide future investigations.
3. Significance

3a. Importance of Teledermatology Assessment to the VA Mission. Two factors underlie the importance of evaluating teledermatology in the VA Healthcare System: 1) an unmet demand for dermatology services distributed through a nation-wide patient base and 2) a VA commitment to teledermatology research and implementation. Waiting times for next available appointments, a priority for action within the VA, are still lengthy despite efforts at improvement. The VHA national average wait time for a new patient dermatology appointment in September 2006 was 44.1 days, which is among the longest waiting times for clinic-based care in the VA. (44) This demand for dermatology care is exceeding our ability to provide it in a timely manner. Furthermore, an increased number of veterans are receiving their care in Community Based Outpatient Centers where on-site access to dermatology often does not exist. Recruitment efforts are unlikely to be successful because a nationwide shortage of dermatologists exists, especially in rural, academic, and VA settings. (45) Teledermatology has the potential to use the existing pool of VA dermatologists more efficiently, thus allowing veterans to receive the dermatologic care they need in a timely manner.

Additionally, the VA has made a commitment to develop, evaluate, and implement telemedicine systems as outlined in the Telemedicine Strategic Planning Document. (46) This document recognizes that telemedicine policy must be driven by evaluations of telemedicine’s efficacy, effectiveness, reliability, accuracy, safety, and clinical outcomes. However, VA telemedicine policy has often lacked the availability of well-designed research to use as a guide. A further measure of the VA’s commitment to telemedicine and telemedicine evaluation is the formation in 1997 of the VHA Telehealth Strategic Healthcare Group. Under the auspices of the Office of Care Coordination, the VHA Telehealth Strategic Healthcare Group fosters the development of telemedicine consult systems, encourages telemedicine research, and provides guidance for telemedicine practice. It is incumbent on the VA, a leader in telemedicine implementation, to become a leader in telemedicine research.

3b. Importance of the Primary Objective. For the majority of ambulatory skin conditions encountered in Primary Care and Dermatology Clinics the impact those conditions have on patients’ quality of life is of principal importance. Commonly encountered skin diseases such as eczema, psoriasis, acne, rosacea, and most skin cancers have little impact on a patient’s overall health status and no measurable influence on mortality. However, these types of conditions frequently result in discomfort or pain, pruritis, emotional concerns, embarrassment, anxiety, and interfere with activities of daily living, work activities, or interpersonal relations. For that reason, quality of life is a central measure when assessing the effect of an intervention on the care of skin diseases.

Teledermatology is an emerging mode of caring for the skin complaints of the veteran population. The VA has been an early adopter of teledermatology technology for reasons that are clear. The VA is challenged with an ever-expanding patient base that is becoming increasingly geographically dispersed, in part, due to the emergence of Community Based Outpatient Centers (remote primary care clinics). Dermatology resources in the VA are almost exclusively medical center-based, yet the veteran population is accessing health care in an increasingly decentralized manner. The VA, out of necessity, must find innovative ways to deliver high quality specialty care to its veteran population. However, many aspects of health care delivery using a teledermatology intervention have gone unstudied. One such outcome is the impact teledermatology may have on quality of life. If teledermatology is to be successful in delivering dermatologic health care, it necessarily must have a favorable impact on patients’ quality of life.

Nonetheless, the direction of teledermatology’s influence on quality of life is not necessarily intuitive nor can it be assumed. We hypothesize that, compared to conventional care, teledermatology will result in improved quality of life through improved access to care and a quicker intervention and treatment initiation. This hypothesis must be tested, however. It is possible that some features of clinic-based visits that cannot be easily duplicated in a store and forward teledermatology setting (e.g., patient education) may result in poorer quality of life scores for teledermatology subjects. Patients who don’t improve with
teledermatology may experience greater concern and anxiety because they were not seen in-person, reflected in poorer quality of life outcomes. The unstudied question of teledermatology’s impact on quality of life is a vitally important question for the VA to answer as its commitment to teledermatology care expands.

3c. Importance of the Secondary Objectives and Innovative Features of this Proposal. A comprehensive assessment of teledermatology’s impact on health care delivery in the VA is not solely defined by quality of life assessments. The secondary objectives we propose to study are in some cases starting points in the nascent field of teledermatology research, may prove to be hypothesis-generating in other cases, and will augment existing data in still others. We recognize that our secondary objectives may not provide definitive data, but we should not miss the opportunity to study these other features in a functional site to site consult research setting. Clinical course, particularly for the subset of skin diseases that can materially impact clinical outcomes (such as skin cancer, a high-prevalence condition in the VA) should be assessed. As always, the economic questions – is teledermatology cost saving, if not, is it a cost-effective intervention? – are vitally important to the VA. Health care utility assessments used to generate QALYs will facilitate this economic analysis. Satisfaction assessments, beginning with global assessments or scales with face validity, will likely figure prominently in teledermatology’s ultimate success or failure. Traditionally, telemedicine adoption has outpaced the evidence. Due to that current state of affairs, our study will provide a wealth of novel information that will help guide future teledermatology policy in the VA. Specifically this study will:

(1) Assess a functioning site to site teledermatology consult system, and do so using two VA sites with different demographics that will serve to expand the case mix and increase generalizability.
(2) Provide much needed and novel data on quality of life with a teledermatology intervention.
(3) Provide novel data on health care utilities with a teledermatology intervention.
(4) Take advantage of the fact that the Skindex 16©, the best instrument to assess quality of life for skin disease, has been extensively tested in a VA population (and includes the developer of this instrument as a Co-investigator).
(5) Provide the most comprehensive assessment of the broad health services outcomes of teledermatology to date
(6) Produce more comprehensive and relevant economic data, because we will study a functioning site to site consult system, to supplement the small existing database.

4. Methods

4a. Conceptual Model. Using the structure, process, and outcomes dimensions of quality as described by Donabedian we base this study on the conceptual model depicted in Appendix A. (47) Donabedian’s model has relevance for describing the clinical outcomes of telemedicine interventions just as it does for conventional clinical care (48). Teledermatology has a major impact on the structure of health care, particularly as it relates to institutional factors. The expansion of VA Community Based Outpatient Clinics (CBOCs) affects the structure of health care in three important ways. First, care is decentralized. Primary care is delivered at the CBOCs, yet specialty care remains at the medical center site. Second, CBOCs bring more veterans into the system. Veterans who normally would not use VA services due to geographic restrictions can now access the healthcare system. Finally, the VA electronic medical record links the CBOCs with the medical center in a way not possible without this system. Teledermatology has a significant impact on these structural features of health care quality. Teledermatology serves to “bring together” the remote sites of primary care and the medical center based dermatology care via this link between the two sites. Without this link the alternatives would be for patients to travel to the medical center (a barrier which prevented their use of primary care in the first place) or the inefficient requirement that the dermatologists travel to the sites of primary care. The larger patient burden experienced by the VA with the expansion of CBOCs requires that innovative means of delivering dermatology specialty
care should be considered and studied. Teledermatology is a means of achieving this goal. The VA’s electronic medical record, recognized as one of the most advanced and sophisticated in health care, provides the existing infrastructure to allow this type of teledermatology information transfer to occur without the addition of new technological requirements.

Process factors are also influenced by teledermatology. Patients may experience more timely treatment initiation, treatment delays may be averted, and waiting times for necessary on-site dermatologic care can be positively influenced. Patterns of care are also impacted by teledermatology. With teledermatology, the primary care clinician often takes a larger and different role in their patients’ care compared to conventional care. The conventional care model results in a referral to the dermatology clinic and transfer of all related care to the dermatologists. Primary care, if involved at all, is only a vicarious participant. With teledermatology, the primary care clinician will often assume a greater role in patient care. For example, the outcome of a teledermatology consult would often involve a set of recommendations to be implemented by the primary care clinician. This allows the point of care to remain at the CBOC and in the purview of the primary care clinician, but adds the dermatologist’s expertise that would normally be lacking.

The impact that these structural and process features have on clinical outcomes is the rationale for this proposal. Specifically, we believe that these structural and process features will most directly impact the quality of life of those patients undergoing teledermatology consultations. The existing barriers to timely care can be mitigated by teledermatology consultations resulting in more timely care, an earlier diagnosis, and quicker treatment initiation which we hypothesize will translate into an improved quality of life for teledermatology patients. Existing research performed in an intra-medical center setting has provided information in regard to intermediate clinical outcomes. (32, 33, 42) This includes the intermediate clinical outcome of time to initial evaluation. This proposal will allow us to describe more definitive outcomes that will focus on a quality of life assessment, but include assessments of clinical course, cost-effectiveness, and global patient satisfaction.

4b. Design

4b(i). Design Summary. The proposed trial will randomize veterans who are being referred from VA Primary Care Clinics to VA Dermatology Consult Services to either a store and forward teledermatology consultation or the conventional referral process (usual care). The Primary Care Clinics will consist of one or more Community Based Outpatient Center(s) affiliated with the Harry S. Truman Memorial Veterans Hospital (Columbia, MO “hub” site(s) for the Dermatology Service) and one remote medical center without dermatology resources (St. Cloud, MN VAMC “spoke” site) affiliated with the Minneapolis VA Medical Center (Minneapolis, MN “hub” site for the Dermatology Service).

4b(ii). Usual Care. The conventional referral process (usual care) consists of an electronically-generated consult completed by the referring clinician and forwarded to the Dermatology Consult Service. This consult process and flow of a study subject through the usual care arm of the study is depicted in Appendix B. This electronic request is the means of communication between referring clinician and consultant. A dermatologist reviews incoming consults and decides when a clinic-based visit should occur based on the perceived acuity of the textual information contained in the consult. The dermatologist consultant answers the referral with a scheduled date for the clinic visit and this information is transmitted back to the referring clinician. We will not alter the usual care consult mechanism at the proposed study sites. Therefore, none of the data collected on enrolled subjects, including the standard history collection, will be forwarded with the conventional consult as these are not elements of usual care. The consultant dermatologist will then act on the referral, using the textual information to make a triage decision. In the vast majority of cases, the consultant dermatologist will schedule the patient for a clinic evaluation. When the patient is evaluated in Dermatology Clinic the referring clinician receives a copy of the clinic note electronically. It is possible, based on the text consult, that the consultant dermatologist will not schedule the patient for a clinic visit (e.g., another
specialty service is more appropriate, the text describes a benign lesion not managed by Dermatology, etc.). Based on previous experience this is expected to occur less than 1% of the time.

4b(iii). Teledermatology. The conventional electronic request will also be forwarded from the referring clinician to the Dermatology Consult Service for subjects that randomize to teledermatology since this is a mandated medical record element and, as mentioned above, the means of communication between clinicians. This consult process and flow of a study subject through the teledermatology arm of the study is depicted in Appendix C. In addition to the conventional consult request, the teledermatologist will receive the elements of the teledermatology consult – digital images and a text-based standardized history collected by a research assistant. The consultant teledermatologist will then use this information to make a decision about whether the patient requires a dermatology clinic visit and, if so, when. If a visit is not required, the teledermatologist may transmit information back to the referring clinician for his or her consideration. This information may run the gamut from reassurance that no intervention is required, a recommendation for medical therapy to be implemented by the referring clinician, or a recommendation for a diagnostic or therapeutic intervention to be implemented by the referring clinician. The referring clinician has the option, of course, to request an in-person Dermatology Clinic evaluation if he or she does not feel comfortable instituting the recommendations.

4b(iv). Patient Presentation and Recruitment Strategies. Patients with skin complaints become known to the health care system at the time they present to their health care provider (most often their primary care clinician). There is no mechanism to review medical records or patient databases to determine or predict if, or when, a patient will present with a skin complaint. We will request that referring clinicians contact the research assistants with potentially eligible study subjects as our primary mechanism of subject enrollment. In order to facilitate enrolling patients in this manner, we will hold introductory meetings prior to study kick-off. In addition, we will route all electronically generated consults to Dermatology through the research assistant at each site. Routing electronic referrals through the research assistant provides a back-up mechanism for recruitment and allows for tracking of the proportion of enrolled versus non-enrolled subjects.

While it is most desirable to contact patients while on-site at the time the consult is placed, routing electronic consults through the research assistants will also allow for patient enrollment at a date remote from the day of their primary care visit. Recruitment with both strategies can be successful. At the Durham VAMC for HSR&D IIR 98-159 (PI: Whited) we enrolled 275 patients (in-house consults, not consults from remote clinics) in 16 months, which represented 35% of the eligible population. This was accomplished with day-of-presentation recruitment strategies only without electronic medical record consultations routed to a research assistant. At the Minneapolis VA Medical Center for HSR&D IIR 01-072 (PI: Warshaw) we enrolled 2,152 of 2,905 subjects over 2.75 years (74.1% of all eligible participants) by routing consults through the research coordinator, without day-of-presentation recruitment strategies.

To reimburse for time and travel considerations, subjects will be compensated up to $30 for completion of the study ($10 for the baseline assessment and imaging, $10 for completion of the 3 month survey, and $10 for the 9-month close-out assessment). The 9-month close-out visit will, in many cases, occur outside their normal course of care.

4b(v). Inclusion and Exclusion Criteria.

Inclusion Criteria

1. The patient is being referred from a “spoke site” (site without on-site Dermatology services) by a primary care clinician to the “hub site” (Dermatology Consult Service) using the electronic consult request system.
2. The patient is being referred for a single skin condition (Skindex was developed for a single skin condition).
3. The consult may be for a diagnostic or management question.
4. The skin condition may be on any anatomic area, including genitalia.
5. The patient is being referred for a skin condition that is visible and photographable.

**Exclusion Criteria**
1. The consult request generated by the referring clinician requests a full body examination (e.g., to follow-up a personal history of melanoma).
2. The patient is unable to read and speak English and does not pass a literacy assessment using a single question instrument described by Chew LD, et al. (49)*
3. The patient has an emergent skin condition. (Typically referred by telephone contact between the referring clinician and the dermatologist, not exclusively by an electronic consult. Based on previous experience this represents less than 1% of consults.)
4. The patient has a pending dermatology appointment in the next 9 months (study period).
5. The patient has been previously enrolled in this study.
6. The patient is in another research study unless a waiver has been granted by the local IRB for participation in more than one study.
7. The patient has an impending move from the area.

* Subjects will be asked "How often do you have someone help you read hospital materials? (1) Never, (2) Occasionally, (3) Sometimes, (4) Often, (5) Always. Prospective subjects that answer "always" will be excluded from enrollment. The specificity of detecting health literacy among patients who answer "always" is 0.98. We chose a highly specific test so that a positive test "rules-in" those prospective subjects with inadequate health literacy.

Both genders and all races/ethnicities will be eligible for the study as there is no scientific reason to include or exclude based on these factors. Therefore, we would expect the demographic make-up of enrolled subjects to approximate the demographic make-up of the participating sites.

**4b(vi). Randomization and Stratification.** Patients will be stratified by spoke site to ensure balance in intervention allocation across potential regional differences in case-mix. Prior to randomizing a patient the patient will be determined to be eligible for inclusion in the study and informed consent obtained. All baseline imaging, instrument administration, and information for the economic analysis must be completed prior to randomization. Randomization should occur within one day of the baseline visit. Patients determined to be eligible and willing to participate in the study will be randomly assigned to one of the study groups using a Web-based randomization system. The research assistant at the spoke site will be required to logon into a secure website with a hospital code, user name and password. After submitting the required information, the next intervention group in the random sequence will be assigned along with a subject randomization number. If the internet server is down, the research assistant can telephone the Hines VAMC to randomize a patient. The randomization assignment and associated code will be developed by the Hines VAMC. Permuted block randomization with random block sizes (multiple of 2, minimum of 2, maximum of 8) will be employed.

**4b(vii). Baseline Study Visit.** After consent, all subjects will undergo baseline data collection. This includes patient demographics, standard history collection, baseline digital imaging and administration of the Skindex-16, SF-12 v2, HUI2, time-tradeoff assessment, and the self-reported co-morbidity index (Appendix D). The subjects will then be randomized to either usual care or teledermatology, informed of the randomization assignment, given study investigator contact information, and a timeline of study procedures.

**4b(viii). First Dermatology Visit.** It is anticipated that virtually all subjects randomizing to usual care will be scheduled for a dermatology visit. In addition, those teledermatology subjects that are deemed by
the teledermatologist consultant to need a dermatology clinic-based visit will also be scheduled for an in-person visit. When subjects present for their first dermatology clinic visit (if one was scheduled or occurs as described above) they will undergo re-imaging of the referred skin condition. Patients may present sooner or later than their originally scheduled visit (e.g., patient reports a change in acuity to the primary care clinician who then contacts dermatology, patient cancelling or not showing for their appointment, etc.) or they may subsequently present for a clinic visit even if a visit was not originally recommended (change in acuity of the condition as described above). The research assistant will track all dermatology clinic visits and obtain images at the time of each subject’s first clinic visit. If subjects present for subsequent visits prior to the 9 month close-out visit, they will not be re-imaged. If a subject either is not scheduled and/or does not present for a clinic visit prior to the 9 month close-out visit then only baseline and 9 month image sets will be obtained. Thus, subjects will undergo either 2 or 3 imaging procedures – baseline, first clinic visit (if one occurs), and 9 month close-out visit.

4b(ix). Interim Mailings. At 3 months subjects will receive, via mail, the Skindex-16, SF-12 v2, and the HUI2. We chose interim mailings rather than telephone interviews to maintain the consistency of the method of instrument self-administration. If subjects do not return the mailings within two weeks of the due date, they will receive a reminder phone call. We will also send out a second set of questionnaires with a request to complete the instruments.

4b(x). Nine Month Close-out Visit. All subjects will be scheduled for a close-out visit 9 months from the date of referral. The rationale for this close-out visit is two-fold. First, this allows us to collect our final set of study instruments and re-image all subjects for purposes of the clinical course rating. This gives us a set time point for clinical course ratings and a measure of long-term outcomes. It also allows us to image those subjects who did not require clinic visits and, therefore, did not undergo re-imaging at a clinic visit. This ensures that all participants have at least one image other than baseline in which the clinical course rating can be made. Second, the 9 month close-out visit enhances patient safety. All subjects have the chance to interact with a dermatologist within 9 months of the referral date, especially those who were randomized to teledermatology and did not require a clinic visit. If a subject presents to dermatology clinic within 30 days of their scheduled 9 month close-out visit, that visit date will serve as the close-out date.

If a subject informs the study staff that they cannot or are unwilling to attend the scheduled close-out visit, but they indicate they are willing to complete the final set of self-administered study instruments via mail, we will send the subject the relevant study instruments. The subjects will be informed that they will be reimbursed at the $10.00 rate when they return the completed forms. This mechanism will only be used if the subject indicates that a change of circumstances has prevented them from traveling for the in-person nine month visit or makes them unwilling to do so.

4b(xi). Short-term and Long-term Outcomes. For those outcomes that rely on serial measurements (quality of life and health care utilities), we will collect data on both long-term and short-term outcomes. The long-term outcome is defined as a change score between the time of randomization and the 9 month assessment. The short-term outcome is defined as a change score between the time of randomization and the 3 month assessment. Although short-term outcomes are a secondary data element, we wish to collect this data to provide a better description of how teledermatology impacts the health care outcomes of interest. An important unstudied feature of teledermatology is whether only short-term gains are detected with teledermatology’s effect extinguishing over time versus any potential benefits that may be sustainable over time.

Long-term outcomes are our primary outcome of interest. Teledermatology has been shown to improve time to evaluation (32) and thereby may improve short-term clinical outcomes for patients. However, it is important to determine if short-term improvements, if any, are sustainable or whether they attenuate over time. Alternatively, teledermatology interventions may only become manifest over time. We believe the most important health state assessments are made at the most remote time from the
baseline evaluation in this study. Therefore, we are using the time period from randomization to 9 months as our primary outcome of interest.

4c. Outcome Measures

4c(i). Primary Outcome Measure – Quality of Life. Skindex-16 will be administered at baseline, 3 months, and 9 months to all participants. The 9 month assessment will be the primary outcome of interest. Skindex-16 is a self-administered questionnaire. To assist patients in recalling their skin condition of interest, a body diagram designating the location of the condition will be completed by the research assistant at the baseline visit. A copy of this body diagram will be included with all subsequent administrations of Skindex-16. The baseline and 9 month questionnaires will be self-administered during the research visits. The 3 month questionnaires will be mailed with return postage-paid envelopes. Skindex-16 scoring and interpretation will be performed in the standard method as described by Chren. (21) Briefly, responses will be reported on a 0 (never bothered) to 100 (always bothered) scale. Skindex-16 generates a total score (average of three subscale scores) that will be our primary outcome of interest. (50) Three subscales scores – emotions, symptoms, and functioning – will be used for secondary analyses.

In addition to Skindex-16, we will also administer the SF-12 v2 survey instrument to assess overall health care status. This instrument will be self-administered in the same method described above except there will be no accompanying body diagram. SF-12 v2 scoring will be performed in the standard method described by Ware (51). The SF-12 v2 will assist us in determining the global disease status of each study group. We will also use the SF-12 v2 to assess quality of life aspects of skin disease on overall health status longitudinally, and can compare skin disease to other organ system diseases.

4c(ii). Secondary Outcome Measure – Time to Initial Definitive Evaluation. Long queues for appointments, as described above, may result in long delays before patients experience an initial definitive contact with a dermatologist. We will record a measure of access to care, time to initial definitive evaluation, describing a point of contact with dermatologic care that initiates the diagnostic and management processes. Additionally, time to initial definitive evaluation will be correlated with clinical course. Time to initial definitive evaluation will be defined in both study arms as follows:

(1) For those referrals that do not require a dermatology clinic visit, the number of days from the randomization date to the date the consult was answered defines time to initial definitive evaluation.

(2) For those referrals that do require a dermatology clinic visit, the number of days from the randomization date to the date of the scheduled clinic visit defines the time to initial definitive evaluation.

4c(iii). Secondary Outcome Measure – Clinical Course. Clinical course is a secondary outcome, in part, because we believe a study on the scale we are proposing would most likely be underpowered to detect a clinically meaningful difference. We are basing this on expert opinion that a 10% difference is a minimum clinically significant difference and the previous study that suggested that 1-2% differences in clinical course rating are expected (34). The ability to detect this difference would require a sample size that is beyond the scope of the current proposal. However, because of the scarcity of data on teledermatology and clinical course, we believe we should take the opportunity to collect data that may be useful in future considerations of this clinically important question. Alternatively, we may find larger differences in clinical course in this population than we might expect which provides a secondary rationale to collect this data.

Patients in both study arms will undergo digital imaging at either two or three timepoints to facilitate our assessment of clinical course. Patients will be imaged at baseline (time of referral), at the time of the first clinic-based visit with a dermatologist (if a visit is required), and at the 9 month close-out visit. This imaging schedule will allow us to correlate clinical course with two clinically relevant timeframes: (1)
the variable timeframe from referral date to time of initial definitive evaluation, and (2) the fixed
timeframe of referral date to 9 months.

We will use an image review process similar to that used in three other studies of teledermatology
(Department of Defense C.2002.129; Teledermatology Subprotocol of VA CSP #458 – National Health
Survey of Gulf War Era Veterans and their Families; and HSRD IIR 01-072). An expert panel of three
dermatologists, not otherwise involved in the study protocol and blinded to the study arm assignment, will
review the digital images on a computer screen and arrive at a consensus opinion of the clinical course.
The course will be rated as (a) resolved, (b) improved, (c) unchanged, not clinically relevant, (d)
unchanged, clinically relevant, or (e) worse. (Table 1) Differences between baseline and first clinic visit
and baseline and 9 months will be assessed.

Table 1. Clinical Course Rating

<table>
<thead>
<tr>
<th>Clinical Course Rating</th>
<th>Resolved</th>
<th>Improved</th>
<th>Unchanged, not clinically relevant</th>
<th>Unchanged, clinically relevant</th>
<th>Worse</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Usual Care</strong></td>
<td>Baseline to 9 months (and first visit)</td>
<td>A</td>
<td>B</td>
<td>C</td>
<td>D</td>
</tr>
<tr>
<td><strong>Tele-dermatology</strong></td>
<td>Baseline to 9 months (and first visit)</td>
<td>A</td>
<td>B</td>
<td>C</td>
<td>D</td>
</tr>
</tbody>
</table>

The panel will be given the following guidelines for assigning the serial digital images a clinical
course rating:

**Resolved** – a skin condition that has been replaced either by normal skin or has been replaced by
normally-healing skin after a surgical/therapeutic intervention.

**Improved** – a skin condition that does not meet the guideline of “resolved” but, in aggregate, has shown
an improvement in any metrics deemed relevant by the reviewers such as size, distribution, color, spatial orientation, etc.

**Unchanged, not clinically relevant** – a skin condition for which the state of unchanged is unlikely to
impact mortality, morbidity, or response to treatment (examples are skin tags, epidermal cysts, benign nevi).

**Unchanged, clinically relevant** – a skin condition for which the state of unchanged is likely to impact
mortality, morbidity, or response to treatment (examples are cutaneous malignancies that may have a
similar visual appearance but can become more invasive and/or increase their metastatic potential).

**Worse** – a skin condition that, in aggregate, has shown a worsening or progression of any metrics deemed
relevant by the reviewers such as size, distribution, color, spatial orientation, etc.

The primary analysis will collapse the five categories into the following dichotomous outcomes:

**Favorable** = Resolved + Improved + Unchanged, not clinically relevant

**Unfavorable** = Unchanged, clinically relevant + Worse
The relative proportions of patients with clinical outcomes in each of the five categories will also be presented as a descriptive measure.

4c(iv)(a). Rationale for the Clinical Course Rating Scale. There is no unifying scale or measure available to rate the clinical course of the diverse spectrum of skin disease. Clinical course for dermatologic conditions is largely measured by its visual appearance. Skin conditions may resolve (spontaneously or with medical or surgical intervention) or the visual appearance may suggest an improvement (less skin surface involvement, smaller size, improvement in distribution or spatial features). In some cases, the skin condition may remain unchanged but be of no clinical significance.

4c(iv)(b). Clinical Course Rating Panel. The panel will be made up of three board-certified dermatologists. Other than making the clinical course assessment, these three dermatologists will not be connected with the study. They will be blinded to the randomization assignment of the images they are reviewing. For serial image assessments, we will instruct the panel that they must arrive at a consensus opinion. Prior to starting the review process, the panel will discuss the rating scale, the definitions, and the goals of the clinical course review. Additionally, a run-in phase using test images will be performed prior to review of study subject images. Using only the image sets and the diagnostic category assigned to the skin condition by the dermatologist performing the 9-month close-out visit, we will ask the panel to make their best assessment of the disease course from a clinical perspective. The panel will not be supplied with any other additional information, such as history or quality of life ratings, and we will ask them to not assume any changes in patient status other than the images they will have before them. We are not asking the panel to deliver clinical care to the research subjects and, likewise, we are not asking them for their specific diagnosis.

4c(v). Diagnostic Subgroup Analysis and Satisfaction Assessment. At the 9 month close-out visit, we will also ask the research assistant, in cooperation with the dermatologist performing the nine-month close-out visit, to place the diagnosis given for the referred skin lesion into one of 17 diagnostic subcategories (Appendix E). The diagnostic subgroups used for this study were chosen by a panel of three dermatologists based on both frequency within the veteran population and clinical morphology. The diagnostic categorization will be used to further describe, in a descriptive manner, the clinical course data. We recognize that we will likely be underpowered to make statistically significant inferences about the diagnostic categorizations. However, we want to designate a priori clinically important diagnostic categories for further evaluation in case any diagnosis-related effects exist. A single global question assessing patient satisfaction with both consult modalities will also be administered at the 9 month follow-up visit as stated in the Case Report Forms.

4d. Economic Analysis

4d(i). Costs. We will estimate the average cost per subject over a 9-month period from the provider (VA) and societal perspectives. Costs from the provider’s perspective include direct healthcare costs and travel costs reimbursed by VA. Direct healthcare costs include costs of the initial evaluation and dermatology-specific healthcare costs over the 9-month follow-up period. We will estimate dermatology-specific costs from the perspective of the VA and of all providers (both VA and non-VA). Costs from the societal perspective encompass costs to all stakeholders stemming from the treatment choice and consist of direct healthcare costs to all providers and travel costs to both patients and the VA. In addition, societal costs include the costs for time patients spend receiving healthcare. To account for inflation, we will adjust all costs using the Consumer Price Index (CPI) from the last year of the study. Average cost per patient will not include costs for events or procedures that occurred solely for research purposes. Cost categories and data sources are summarized in Table 2.
### Table 2. Cost Categories and Data Sources

<table>
<thead>
<tr>
<th>Data Sources</th>
<th>Patient Group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Direct Healthcare Costs</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Initial Evaluation</strong></td>
<td></td>
</tr>
<tr>
<td>Initial Primary Care Visit</td>
<td>HERC* cost estimates</td>
</tr>
<tr>
<td>Teledermatology Procedure</td>
<td></td>
</tr>
<tr>
<td>Equipment costs</td>
<td>Purchase price</td>
</tr>
<tr>
<td>Personnel costs</td>
<td>Time Study/VA wages</td>
</tr>
<tr>
<td>Overhead costs</td>
<td>DSS NDE†</td>
</tr>
<tr>
<td><strong>Teledermatology Evaluation</strong></td>
<td></td>
</tr>
<tr>
<td>Equipment costs</td>
<td>Purchase price</td>
</tr>
<tr>
<td>Personnel costs</td>
<td>Time Study/VA wages</td>
</tr>
<tr>
<td>Overhead costs</td>
<td>DSS NDE†</td>
</tr>
<tr>
<td><strong>9-Month Follow-Up</strong></td>
<td></td>
</tr>
<tr>
<td>VA Dermatology Care</td>
<td></td>
</tr>
<tr>
<td>Initial Dermatology Clinic Visits</td>
<td>HERC* cost estimates</td>
</tr>
<tr>
<td>Subsequent Outpt. Dermatology Visits</td>
<td>HERC* cost estimates/Record Review</td>
</tr>
<tr>
<td>Subsequent Inpt. Dermatology Admits</td>
<td>HERC* cost estimates/Record Review</td>
</tr>
<tr>
<td>Dermatology-Related Prescriptions</td>
<td>DSS NDE‡ for Pharmacy/Record Review</td>
</tr>
<tr>
<td>Non-VA Dermatology Care</td>
<td>Patient survey/RVUs‡</td>
</tr>
<tr>
<td>VA Non-Dermatology Care</td>
<td></td>
</tr>
<tr>
<td>Outpatient Visits</td>
<td>HERC* costs</td>
</tr>
<tr>
<td>Inpatient Admits</td>
<td>HERC* costs</td>
</tr>
<tr>
<td>Prescriptions</td>
<td>DSS NDE‡ for Pharmacy</td>
</tr>
<tr>
<td><strong>Travel Costs</strong></td>
<td></td>
</tr>
<tr>
<td>Travel to healthcare facility</td>
<td>Distance to facility /Federal or VA reimbursement rates</td>
</tr>
<tr>
<td><strong>Patient Time Costs</strong></td>
<td></td>
</tr>
<tr>
<td>Time receiving healthcare</td>
<td>US hourly wages</td>
</tr>
</tbody>
</table>

* HERC = VA Health Economics Resource Center  
† DSS NDE = VA Decision Support System National Data Extract  
‡ RVUs = Relative Value Units. We will use RVUs from the Medicare Resource-Based Relative Value System to estimate costs (52).

**4d(ii). Costs of the Initial Evaluation.** Costs of the initial evaluation include costs of the initial primary care visit for the dermatological condition, costs of the teledermatology imaging procedure, and costs of the teledermatology evaluation. To account for less than perfect efficiency, time and attribution studies will be performed using activity logs (see below). Additionally, in a sensitivity analysis, all labor costs will be calculated at an 85% productivity rate. (53)

**Initial Primary Care Visit.** We will derive the costs of the initial primary care visit for the dermatological condition for patients in both the intervention and usual care arms of the trial, using outpatient cost data from the VA’s Decision Support System (DSS), which is available at the Austin Automation Center. (54)
Teledermatology Imaging Procedure. Following the initial primary care visit for the dermatological condition, all patients in the study will have a digital image made of their skin condition at baseline. However, we will attribute imaging cost only to patients randomized to the teledermatology arm. Costs for the imaging procedure will be estimated using “micro-costing” techniques in which we itemize each component of the procedure and estimate a cost (55). Imaging procedure costs include 1) costs for the equipment, 2) labor costs for personnel, and 3) overhead costs. Equipment costs include costs for the digital camera and accessories, laptop and desktop computers, photo editing software, and a printer. These equipment costs represent one-time purchases at each of the study sites. Using purchase price information and estimates of useful life from the manufacturer, we will apply straight-line depreciation techniques and the opportunity cost of capital to estimate an annual cost of the equipment. To be conservative, we will assume that the opportunity cost of capital is the current replacement cost and that the equipment will have zero residual value at the end of its useful lifetime. Annual costs for equipment maintenance will also be included. Dividing the annual equipment cost estimate by the annual number of imaging procedures likely to be conducted at each site will produce a cost per patient per imaging procedure that would occur if teledermatology were adapted as standard practice. Labor costs for imaging personnel include the time cost for training and the taking and transmitting of the digital images. At each site, study personnel will record the time (in minutes) spent in these activities for a sample of survey dates using an activity log approach suggested by the VA Health Economics Resource Center. (56) Personnel will record their activities, time taken for each activity, and whether that activity was related to the intervention being studied. We will use this information as a proxy for the average time needed to image all study patients at the site. To estimate the labor cost of the technician, we will multiply this time estimate by a wage rate per minute, based on the technician’s U.S. Office of Personnel Management’s General Schedule (GS). To estimate the training cost per procedure, we will aggregate the training time, multiply it by the respective hourly wage rates, and divide by the number of procedures at a site.

Teledermatology Evaluation. The teledermatology evaluation consists of the dermatologist reviewing the digital images and making a recommendation. Costs for the teledermatology evaluation include 1) the equipment costs, 2) labor costs of the dermatologist and 3) overhead costs. Equipment cost includes the computer and software for viewing the digital images. Labor costs for the evaluation include costs for the dermatologists’ time and costs for training to read the images. We will estimate equipment, labor, and overhead costs for teledermatology evaluation in the same manner as described above for estimating costs for the imaging procedure. To estimate the overhead costs, we will calculate an overhead rate for the site, using data in the outpatient DSS NDE. Using this rate, we will estimate overhead costs as a proportion of equipment and labor costs.

4d(iii). 9-Month Follow-up Costs.

VA Dermatology-Specific Follow-up Costs. We will estimate the total costs of dermatological care received by patients over the 9-month period after the initial primary care visit. We will obtain patients’ healthcare utilization in the VA from the NPCD Medical SAS® Outpatient and Inpatient Datasets. (57-59) With input from dermatologists and other clinicians, we will determine which diagnostic and procedure codes (i.e., International Classification of Disease – 9th revision [ICD-9] and Current Procedural Terminology [CPT]) are related to dermatological conditions, and we will use these codes to identify which healthcare events were dermatology related. We will also identify visits to dermatology clinics based on VA stop codes. After determining which healthcare events were for dermatological care, we will identify these healthcare events in the HERC outpatient and inpatient cost datasets (60, 61) and obtain the cost estimates for these events. In addition, we will obtain pharmacy costs from the DSS NDE for Pharmacy, and with input from dermatologists, we will determine which medications are for the patient’s dermatological care. We will sum these costs and calculate an average cost per patient.

Non-VA Dermatology-Specific Follow-up Costs. To determine the total cost of dermatological care, we will also estimate the costs of dermatological care that patients receive outside of the VA. At the 3 and 9 month follow-up surveys after enrollment, subjects will be asked if they received any dermatological care outside of the VA during the previous three months. We will use Medicare’s
Resource-Based Relative Values Scale (RBRVS) and Diagnostic Related Group (DRG) reimbursement rates to assign costs to non-VA resource utilization. (62)

4d(iv). Travel Costs. Given the potential distances that may exist between patients and the sites of care, travel costs may be a non-trivial issue. We will estimate the costs of travel to seek dermatological care from the provider (i.e., the VA) and the societal perspectives (i.e., VA and non-VA). To estimate travel costs from the VA’s perspective, study personnel will consult with the financial offices or travel offices of the study facilities to determine whether travel costs were reimbursed for any of the dermatological clinic visits. To estimate costs of travel to non-VA facilities and the societal perspective, we will apply the federal mileage reimbursement for a privately owned automobile to the distance estimates based on zip-code based distance figures available from the Planning Systems Support Group.

4d(v). Patient Time Costs. We will estimate costs of patients’ time spent traveling to, waiting for, and receiving dermatological care from the societal perspective. Because it is difficult to collect such data accurately, we will make a simplifying assumption that it takes either a half-day (4 hours) or full-day (8 hours) for an outpatient clinic visit. In the follow-up survey, we will ask the subjects which of these two choices best describes their visit duration. For inpatient visits, we will attribute 16 hours of patient time cost for each day of their length-of-stay. (63) After we have obtained a time estimate for each subject in hours, we will multiply this time estimate by the age/gender-specific average hourly wage in the U.S. from the Current Population Survey (CPS) to obtain an estimate of each patient’s time costs.

4d(vi). Cost Analyses. A persistent challenge when assessing the cost of new technology is correctly accounting for the fixed cost. The fixed costs associated with the teledermatology intervention include the purchase of new equipment and personnel training costs. Because the impact of these fixed costs on average per-patient costs depends on the volume of imaging procedures and evaluations, we will estimate this volume and then examine the effect on intervention costs per patient as the procedure volume varies. To compare the costs of dermatology care over 9 months we will estimate average costs of dermatology care for the intervention group and control group. Cost data are typically skewed due to some patients incurring high costs. Therefore, we will use both parametric and non-parametric tests to assess whether the cost difference between the two groups is statistically significant. We will also calculate 95% confidence intervals around the cost differences using bias corrected and accelerated bootstrapping methods. (63, 64)

4d(vii). Effectiveness. From an economic perspective, there are two effectiveness measures that are relevant to decision makers when assessing the cost-effectiveness of teledermatology. The first effectiveness measure is time to initial definitive evaluation. While it seems logical that time to evaluation favorably impacts clinical course, it is unclear whether or not that will be observed. Nonetheless, waiting times for contact with specialty medical care is an administrative priority in the VA. In addition, waiting times are a factor in influencing patient satisfaction with a health care system. We believe that time to initial definitive evaluation, although an intermediate outcome, is an important and informative outcome to consider in a cost-effectiveness analysis. Therefore, the first effectiveness measure we will consider in the economic analysis is number of days to initial definitive evaluation saved.

While time to evaluation is informative about dermatology, it does not facilitate comparing interventions across illnesses and patient populations. To do this, the Panel on Cost Effectiveness in Health and Medicine convened by the U.S. Public Health Service recommended that the QALY be the standard effectiveness measure when conducting cost-effectiveness analyses. (65) We have adopted the Panel’s recommendation and will use QALYs as our second effectiveness measure for the economic analysis.
4d(viii). Utility Measurement and Analysis. In order to calculate QALYs, we will need to measure the utilities experienced by the patients in the study. We will use both a generic utility measurement instrument (Health Utilities Index Mark II or HUI2) and the time trade-off to measure utilities. Of the two commonly used generic utility measurement instruments (HUI2 and EQ-5D), we chose to use the HUI2 for two reasons. First, it measures six quality-of-life domains that may be relevant to dermatology conditions, whereas EQ-5D measures five domains. Second, whereas EQ-5D has only three levels of disability (none, some, and total disability), there are four or five levels of disability for the HUI2 domains pertinent to dermatology. Because many dermatology conditions are relatively mild compared to other diseases, with more domains and more delineations of disability, the HUI2 is more likely to be sensitive and less likely to exhibit ceiling effects when eliciting utility values. Nonetheless, the HUI2 may be insensitive to dermatology health states. Therefore, we will also use the time trade-off method to elicit utility scores. We chose time trade-off over the standard gamble method because mortality is a rare dermatology-related event and thus is likely to have low face validity for this study. Also, research by Chen et al., showed that the time trade-off is a sensitive instrument in many dermatology conditions. The HUI2 domains and their respective levels of morbidity and a sample script of the bidding game we will use to elicit time trade-off scores are provided in Appendix D. We will use the utilities derived from time trade-off to calculate individual QALYs in the base-case analysis and the HUI2-derived utilities will be used to calculate QALYs in sensitivity analyses.

4d(ix). Base-case Cost-Effectiveness. The total costs and effectiveness measures for each intervention described above will be combined and considered in aggregate. This will lead to one of four possible results. The first two results are that teledermatology either dominates usual care or is dominated by usual care. The term dominant means that one of the interventions is both more effective and less costly, on average. If this is the case, we will present the average cost, average effectiveness, and the average cost-effectiveness ratio for each intervention. The second two possible results are that either teledermatology or usual care is more effective but also more costly, on average, than its counterpart. If this is the case, we will present the base-case results in terms of the incremental cost-effectiveness ratio (ICER). The ICER compares the incremental costs and incremental effectiveness of both interventions and is represented by the following equation:

\[ \text{ICER} = \frac{TC_{TD} - TC_{UC}}{E_{TD} - E_{UC}} \]

TD = teledermatology  UC = usual care
TC = total cost   E = effectiveness measure (days to intervention saved and QALY)

To calculate the ICER, we will use the distributions of cost and effectiveness variables discussed above as parameter inputs in a decision analytic model to generate ICER results using Monte Carlo simulation. We will use TreeAge Pro Suite (TreeAge Software, Inc, Williamstown, MA) to conduct the analysis.

4d(x). Sensitivity Analyses of Cost Effectiveness. After the base-case ICER is calculated, we will assess the precision of the ICER using the Monte Carlo simulation to calculate a 95% confidence interval around the ICER. We will also conduct one-way sensitivity analyses of the model parameters to identify the variables that are the main drivers of the ICER result.

Although the base-case analysis will be conducted from the VA’s perspective, in sensitivity analysis we will also consider the societal perspective. This perspective is important for capturing all costs because many veterans have health care coverage through private insurance or Medicare. Also, there are travel and productivity loss costs associated with seeking health care. If teledermatology mitigates some of these costs, it should be taken into consideration in the economic analysis. Lastly, if teledermatology reduces the wait time of the average patient, it is possible that it can increase the number of dermatology patients that can be diagnosed and treated in a given year. We will use the time to evaluation results of
the study to estimate this increase in throughput and what impact, in turn, this increased throughput would have on costs.

4e. Digital Imaging Time Table and Technique

All sites will be trained in the standard protocols for imaging techniques and quality control. Details of the digital imaging time table and digital imaging technique appear in Appendix F. Digital imaging equipment will be uniform across sites. We will use similar imaging and training techniques used in previous teledermatology studies. (30, 69, 70) In brief, at our kick-off meeting we will train all research assistants in the use of the equipment and imaging techniques. We will also train at least one other research team member as a “super-user” who can train individuals in the future (e.g., new research assistants). Trainees will be instructed on imaging protocol and quality control techniques that consist mainly of review of images prior to uploading to the medical record. We will obtain standard image sets based on the skin conditions’ features.

4f. Schedule of Observations

Table 3 depicts the schedule of observations for instrument administration. The Skindex-16©, SF-12 v2, and HUI2, are self-administered at baseline and 9 months. At months 3 these instruments will be mailed to the subjects. The time-tradeoff assessment requires interaction between the research assistant and the subject and will only be administered at the two in-person assessments (baseline and 9 months). The self-reported co-morbidity index is administered at baseline and 9 months. (Table 3) A self-administered global assessment of each subject’s satisfaction with the care of their skin condition will also be made at the 9 month close-out visit.

Table 3. Schedule of observations for instrument administration.

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Baseline</th>
<th>Month 3</th>
<th>Month 9 (close-out visit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skindex-16©</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>SF-12 v2</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>HUI2</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Time tradeoff assessment</td>
<td>X</td>
<td></td>
<td>X*</td>
</tr>
<tr>
<td>Self-reported co-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>morbidity index</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Global satisfaction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>assessment</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

* Time tradeoff will not be administered if a mailing is performed for close-out data collection.

4g. Biostatistical Considerations. The primary hypothesis is:

\[ H_0: \text{There is no difference between store and forward teledermatology compared to usual care in the mean change in quality of life, measured by the overall score of the Skindex-16©, at randomization and the 9-month follow-up visit.} \]

\[ H_A: \text{There is a significant difference between store and forward teledermatology compared to usual care in the mean change in quality of life, measured by the overall score of the Skindex-16©, at randomization and the 9 month follow-up visit.} \]
Secondary hypotheses include:

**Hₐ:** There is a significant difference between store and forward teledermatology compared to usual care in the mean change in quality of life, measured by the overall score of the Skoindex-16©, between randomization and 3 months.

**Hₐ:** There is a significant difference between store and forward teledermatology compared to usual care in time to initial definitive evaluation.

**Hₐ:** There is a significant difference between store and forward teledermatology compared to usual care in the proportion of subjects that achieve a favorable clinical course between randomization and 9 months.

**Hₐ:** Store and forward teledermatology is a cost-effective intervention compared to usual care.

**4g(i). Quality of Life.** As mentioned earlier, only one study has evaluated quality of life in a teledermatology population. (35) That cross-sectional study did not directly compare quality of life in teledermatology participants and participants in the conventional referral process, although quality of life scores of the teledermatology participants were typical of those reported in previous studies of dermatology patients with a wide range of skin conditions.

There are no existing data that directly inform judgments about the likely magnitude of quality of life differences between teledermatology and usual care patients. Because we hypothesize that skin-related quality of life of patients who receive teledermatology will be improved compared to that of patients who receive usual care, we have selected sample sizes to permit us to detect at least a minimal meaningful difference in quality of life scores between the groups. We have selected a value of 10 points as the minimal meaningful difference in Skindex scores. Our rationale for selecting this value is based on four categories of information: (1) previous studies of Skindex, (2) previous studies examining minimal meaningful changes in quality of life measured with other instruments, (3) expert consensus opinion, and (4) clinical trials utilizing other skin-specific quality of life instruments.

First, previous studies of Skindex have suggested that scores of groups that are likely dissimilar in skin-related quality of life differ by at least 10 points. For example, Skindex-16 scores for patients with inflammatory dermatoses were at least 10 points higher for all subscales than scores of patients with non-inflammatory isolated lesions such as moles. (21) Similarly, another study of Skindex-29 scores in patients with mild, moderate, and severe neurofibromatosis found that the mean between-group difference for patients with mild and severe disease was 15-17.5 points. (71) In addition, preliminary data suggest that the minimal meaningful change in Skindex scores is 10 points. Chren, et al. (21) examined changes in Skindex-16 scores in 485 patients before and one week after treatment for skin cancer. These scores were compared to changes in patients’ responses to the global question, "Overall, during the past week, how often have you been bothered by this skin problem?" All items had 7-response choices, and based on previous work with a similar quality-of-life instrument (72-75) the investigators decided a priori that a difference in 1 or 2 response choices to the global question corresponded to a minimal meaningful change. Based on this strategy, the minimal meaningful change in Skindex scores was determined to be 10 points; changes for improvement or deterioration were similar. (personal communication, Mary-Margaret Chren, M.D.)

Second, our selection of 10 points as the minimal important difference is also supported by other studies of change in quality-of-life instruments that, like Skindex-16, have 7-point response choices (73, 76, 77). These studies have demonstrated that this value for minimal important change is consistent across domains and for both improvement and deterioration.

Third, consensus among the clinicians in our planning committee was that a 10% difference was the minimum clinically significant difference we should attempt to detect between study groups. This conclusion is consistent with the few studies powered to detect a difference in quality of life as a primary
outcome for skin disease (eczema, psoriasis, hand dermatitis) which also suggested a 10% difference should be used (78, 79).

Finally, a minimum 10% difference in quality of life between groups is typical of that found in a majority of clinical studies (Table 4) (80-88). In most cases, a difference of 10% or greater was detected. In only two studies was the difference between experimental and control groups less than 10%.

### Table 4. Summary of Data that Assessed Quality of Life Differences in Dermatology

<table>
<thead>
<tr>
<th>Reference</th>
<th>Skin Condition</th>
<th>Experimental Group</th>
<th>Control Group</th>
<th>Observed Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carlin (82)</td>
<td>Psoriasis</td>
<td>Alefacept</td>
<td>Before and after comparison</td>
<td>85%</td>
</tr>
<tr>
<td>Feldman (83)</td>
<td>Psoriasis</td>
<td>Efalizumab</td>
<td>Before and after comparison</td>
<td>82%</td>
</tr>
<tr>
<td>Gordon (84)</td>
<td>Psoriasis</td>
<td>Alefacept</td>
<td>Placebo</td>
<td>9%</td>
</tr>
<tr>
<td>Thomson (85)</td>
<td>Eczema</td>
<td>Patch testing</td>
<td>Before and after comparison</td>
<td>10%</td>
</tr>
<tr>
<td>Thompson (86)</td>
<td>Idiopathic urticaria</td>
<td>Fexofenadine</td>
<td>Placebo</td>
<td>10%</td>
</tr>
<tr>
<td>Bergstrom (87)</td>
<td>Psoriasis</td>
<td>Clobetasol propionate foam</td>
<td>Clobetasol cream &amp; solution</td>
<td>7%</td>
</tr>
<tr>
<td>Shikiar (88)</td>
<td>Psoriasis</td>
<td>Efalizumab</td>
<td>Placebo</td>
<td>33%</td>
</tr>
<tr>
<td>Mazzotti (89)</td>
<td>Psoriasis</td>
<td>Standard Treatment</td>
<td>Before and after comparison</td>
<td>10%</td>
</tr>
<tr>
<td>Parsad (90)</td>
<td>Vitiligo</td>
<td>Standard Treatment</td>
<td>Before and after comparison</td>
<td>12%</td>
</tr>
</tbody>
</table>

### 4g(ii). Sample Size/Power/Level of Significance

Our primary outcome is a change in quality of life scores between baseline and 9 months. For standard deviation estimates, we chose 30 points based on a large prospective study of 1200 patients comparing three different treatments for non-melanoma skin cancer. In this study the 2-year changes for the three Skindex-16 subscales ranged from 1.4-24.8 points with standard deviations of between 16.3-30.3 points. (89) Table 5 contains statistical power for a mean difference of 10 points in the change score of the Skindex-16 for the range of standard deviations observed by Chren, et al. (89) using a two-sided t-test with $\alpha = 0.05$.

### Table 5. Sample Size Estimate for Quality of Life

<table>
<thead>
<tr>
<th>Power</th>
<th>Alpha</th>
<th>N1</th>
<th>N2</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.95</td>
<td>0.05</td>
<td>235</td>
<td>235</td>
</tr>
<tr>
<td><strong>0.90</strong></td>
<td><strong>0.05</strong></td>
<td><strong>190</strong></td>
<td><strong>190</strong></td>
</tr>
<tr>
<td>0.85</td>
<td>0.05</td>
<td>162</td>
<td>162</td>
</tr>
<tr>
<td>0.80</td>
<td>0.05</td>
<td>142</td>
<td>142</td>
</tr>
</tbody>
</table>

Choosing a power of 90%, we will need to enroll 190 subjects in each study arm, or a minimum of 380 subjects total. Adjusting for a 20% dropout rate, we will need to enroll 228 subjects in each study arm or a minimum of 456 subjects total.

In the teledermatology study HSR&D IIR 98-159 (PI: Whited), there were 976 total referrals from eligible clinics. Of these, 789 met inclusion/exclusion criteria (187 or 19%, were not eligible). Two hundred seventy-five patients were enrolled (35% of all eligible subjects or 28% of the overall referrals).
At the Minneapolis VA Medical Center for HSR&D IIR 01-072 (PI: Warshaw) 2,152 of 2,905 eligible subjects (74.1% of all eligible participants) were enrolled by routing consults through the research coordinator. In a separate dermatology clinical trial locally funded by the Minneapolis VA Medical Center involving 306 patients, loss to follow-up was 4.9% (15 of 306) over 18 months. For the current proposal, a dropout rate of 20% will be assumed.

4g(iii). Statistical Analysis of Quality of Life at 9 Months. The primary analysis for quality of life will use a t test to measure the difference in the change in the overall Skindex score between treatment groups at the end of the 9-month follow-up visit. The overall Skindex score will be computed in the standard manner by averaging the three subscale scores. (50) This analysis will also be based on intent-to-treat principles. If a patient is missing a 9-month Skindex score, then the most recent score (3-month) will be used to estimate the 9-month score. Each of the three subscale scores from Skindex-16 (emotions, function, symptoms) will be analyzed in the same manner as the overall score.

Analysis of covariance will be used to test for differences between treatment groups with respect to the 9-month change in the overall Skindex-16 score, while adjusting for baseline covariates. These variables will include: age, gender, diagnostic categories of skin conditions, baseline skin-related quality of life, baseline PCS and MCS scores of the SF-12 v2, time to initial evaluation, and any co-morbid conditions that may be imbalanced between the two treatment groups.

4g(iv). Statistical Analysis of Secondary Outcomes.

4g(iv)(a). Quality of Life at 3 Months. In order to account for patients who may not return their Skindex-16 questionnaire at the 3-month visit, scores from the 9-month visit will be used as an estimate for the 3-month value. The t test will be used to measure the difference in the change in the overall Skindex score between treatment groups at the 3-month evaluation. Analysis of covariance will be used to test for differences between treatment groups with respect to the 3-month change in the overall Skindex-16 score, while adjusting for baseline covariates as described above. These variables will include: age, gender, diagnostic category of the skin condition, baseline skin-related quality of life, baseline PCS and MCS scores of the SF-12 v2, time to initial evaluation, and any co-morbid conditions that may be imbalanced between the two treatment groups. Each of the three subscale scores from Skindex-16 will be analyzed in the same manner as the overall score.

Since mixed modeling procedures can accommodate missing values, repeated measures analysis employing mixed modeling will be performed to estimate the difference in the overall Skindex scores between treatment groups and to evaluate changes in the overall Skindex score over time (0, 3, and 9 months). Each of the three subscale scores from Skindex will be analyzed separately using the same repeated measures analysis.

4g(iv)(b). Time to Initial Definitive Evaluation. The time from randomization to the first initial definitive evaluation will be compared for the two treatment groups. Kaplan-Meier survival curves will be compared using the log-rank test. For patients whose referrals do not require an initial dermatologic clinic visit, the number of days from the randomization to the date the consult was answered defines time to initial definitive evaluation. Patients who do not have an initial evaluation and return for the 9-month evaluation will be censored at that point. Patients who do not have an initial evaluation and die, are lost to follow-up, or withdraw their consent will be censored at the time of the event.

Cox proportional hazard regression analysis will be performed to evaluate whether the observed treatment effect is modified after adjustment for covariates and to identify other predictors of time to evaluation. Adjustments will be made for the following variables: age, gender, diagnostic category of the skin condition, baseline skin-related quality of life, baseline PCS and MCS scores of the SF-12 v2 and any co-morbid conditions that may be imbalanced between the two treatment groups.
**4g(iv)(c). Clinical Course at 9 Months.** Although we expect our clinical course outcome to be underpowered, we will perform statistical tests to assess for significance. The proportion of patients who show a favorable clinical course at the 9-month follow-up visit will be evaluated using intent-to-treat principles. For patients who miss the 9-month evaluation, results from their initial evaluation will be used. This analysis will be performed with the chi-square test.

A logistic regression analysis will be performed to evaluate whether the observed treatment effect is modified after adjustment for covariates and to identify other predictors of the primary outcome. Adjustments will be made for the following variables: age, gender, diagnostic category of the skin condition, baseline skin-related quality of life, baseline PCS and MCS scores of the SF-12 v2, time to initial evaluation, and any co-morbid conditions that may be imbalanced between the two treatment groups.

**4g(iv)(d). Clinical Course at Initial Evaluation.** Likewise, we expect clinical course at initial evaluation to also be underpowered. The proportion of patients who show improved clinical course at the time of the initial evaluation will be analyzed as follows. A certain percentage of patients randomized to teledermatology will not undergo the initial clinical evaluation because the consultant dermatologist will determine that the skin condition does not warrant a dermatology clinic evaluation and/or can be managed by the referring clinician. This may bias the analyses against the teledermatology group. The 9-month evaluation for clinical course will be used as an estimate for the missing value at the initial evaluation, unless the medical record indicates an intervention for a dermatologic condition occurred during follow-up. In these instances, the clinical course will be classified as “unfavorable.” Differences in clinical course at the initial evaluation will be performed with the chi-square test. A logistic regression analysis will be performed to evaluate whether the observed treatment effect is modified after adjustment for covariates and to identify other predictors of the primary outcome. Adjustments will be made for the following variables: age, gender, diagnostic category of the skin condition, baseline skin-related quality of life, baseline PCS and MCS scores of the SF-12 v2, time to initial evaluation, and any co-morbid conditions that may be imbalanced between the two treatment groups.

**4g(iv)(e). Subgroup Analysis.** Clinical course at the 9-month evaluation will be analyzed separately for each of the diagnostic categories of skin conditions as defined in Appendix E.

A logistic regression analysis will be performed separately for each of the diagnostic categories to evaluate whether the observed treatment effect is modified after adjustment for covariates and to identify other predictors of the primary outcome. Adjustments will be made for the following variables: age, gender, baseline skin-related quality of life, baseline PCS and MCS scores of the SF-12 v2, time to initial evaluation, and any co-morbid conditions that may be imbalanced between the two treatment groups.

**4g(iv)(f). Cost Effectiveness.** Details for the cost effectiveness analysis are presented above.

**4g(iv)(g). Other Analyses.** Baseline patient characteristics will be compared between the two intervention groups (teledermatology versus usual care) to determine if the intervention groups differ with respect to any important variables. The chi-square test will be used for categorical variables and the t-test for two independent samples will be used for continuous variables.

Baseline patient characteristics will be compared between dropouts and those who remain in study to assess withdrawal bias. The chi-square and t-test will be used where appropriate. Any baseline variables that are imbalanced between randomization groups or study completers/dropouts will be included in the various covariate analyses described above.

All analyses will be intention-to-treat analyses unless otherwise specified. Statistical tests will be done at α=0.05 for all outcomes. All tests will be two-sided.

**4g(iv)(h). Data Missing Not at Random Assessment.** To minimize the magnitude missing data we have carefully chosen our exclusion criteria and the principal investigators, based on their successful
experience with prior teledermatology projects, will insure that research personnel are well trained on study procedures and data collection techniques. Therefore, we anticipate that only a small proportion of data will be missing for our 3 month and 9 month Skindex-16© evaluations and for the 9 month clinical course assessment. We expect that those missing data will be missing at random, and most likely will be missing completely at random. A larger proportion of data will be missing for the clinical course assessment at the time of initial evaluation, primarily in the teledermatology group. These data, again, are expected to be missing at random.

However, we will assess and account for the possibility that our missing data may be missing not at random. Reasons for missed visits will be collected and patients will be classified according to the missed visit pattern. For each pattern, baseline characteristics of patients with missing data will be compared to those with complete data. In addition, for those patients that have one missing Skindex-16© score and one completed score, we will compare the one completed score with those patients that have completed both Skindex-16© assessments. Should it be determined that any of these data must be considered to be missing not at random, pattern-mixture modeling techniques will be used to evaluate changes in quality of life or clinical course. Pattern-mixture modeling is used when longitudinal data cannot be considered missing at random.

4h. Quality Control Procedures

4h(i). Study Initiation. Training of study personnel will take place during a 1-2 day kick-off meeting. All participating investigators and research assistants will be in attendance. The kickoff meeting will include a detailed review of the study protocol, operations and procedures, case report forms, and patient evaluation procedures.

4h(ii). Teledermatology Research Assistant and Coordinator Training. During the initial three-month start-up period and before enrolling study patients, the two hub site coordinators and two spoke site research assistants will spend two weeks at their respective hub sites. This two week training session will include: 1) instruction on photographic imaging and study procedures; 2) discussion of introductory dermatology terms (all coordinators and assistants will be provided with the basic packet given to University of Minnesota medical students during their three-week dermatology course); 3) hands-on experience “shadowing” a dermatology resident during general dermatology; and 4) provision of a standard introductory dermatological atlas (Fitzpatrick’s Color Atlas and Synopsis of Clinical Dermatology).

4h(iii). Digital Imaging. This is discussed in other sections and Appendix F. Research assistants will be trained on standardized equipment that will be used for the study. The training session will provide the research assistants with instruction on digital imaging and the image protocol. A point of emphasis will be review of the images prior to releasing the subject and forwarding of images as a quality control measure. Digital imaging cannot be completely standardized due to lesion location, skin tone, and ambient lighting. Most often, adjustments in lighting are required to obtain high quality images. During the training session we will underscore the requirement that images be reviewed and the expectation that many times re-imaging will be required.

4h(iv). Blinded Review of Diagnosis and Clinical Course. A panel of three dermatologists, not otherwise connected with this study, will be convened as described above. The panelists will be blinded to the patients’ study assignment of the images they are reviewing. The panel will be instructed that they must arrive at a consensus opinion. They will review the serial digital images and arrive at a consensus opinion of the clinical course using the above rating scale.
4h(v). **Masking.** Only the Hines VAMC will have access to the group assignment scheme. In addition, study investigators including personnel at the Principal Investigator’s and Co-principal Investigator’s sites will not have access to intervention outcome data until the final analysis phase of the study.

5. **Dissemination/Implementation Plan.**

5a. **Dissemination.** Dissemination will be targeted to VA Medical Centers, telemedicine organizations, dermatology organizations, and dermatology workforce task groups. Specifically, we will apprise the VHA Telehealth Office of our study results when applicable. We will also use this data to update the Teledermatology Toolkit (co-authored by the PI of this protocol) produced by the VHA Telehealth Office. (91) This is a web-based resource that can be accessed by VA and non-VA personnel, however, it is targeted for VA VISN Telemedicine Coordinators and VA dermatologists. Another avenue for distribution is the American Telemedicine Association, specifically the Teledermatology Special Interest Group. This special interest group has functioned as a resource for information sharing among users and researchers of teledermatology applications for several years. We also plan presentations at several venues including the VA HSR&D Annual Meeting, the American Telemedicine Association Annual Meeting, the meeting of the Telemedicine Task Force at the American Academy of Dermatology Annual Meeting, and the Society for Investigative Dermatology Annual Meeting. In addition, manuscripts would be prepared for submission to peer-reviewed journals.

5b. **Gantt Chart**

<table>
<thead>
<tr>
<th>Project Title: Impact of Teledermatology on Health Services Outcomes in the VA</th>
<th>Project Period: 36 Months</th>
<th>Dates: 4/1/2008 through 3/31/2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity</td>
<td>2008</td>
<td>2009</td>
</tr>
<tr>
<td>Kick-off meeting, study meetings with sites of recruitment, research assistant training (Months 0-3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recruitment phase, data collection (Months 3-23)</td>
<td>x</td>
<td>xxxxxxxxxxxxx</td>
</tr>
<tr>
<td>Final enrollees follow-up phase, data collection (Months 23-32)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data analysis, final report writing, begin manuscript writing (Months 32-36)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Protocol Version 2009-2
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