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| **1.0**  |  | **General Information**  |

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| **1.1**  | **\*Please enter the full title of your study:**  |

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| Validation of ICD-9 Codes to Identify and Evaluate Treatment Outcomes for Patients with Ischemic Stroke  |

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| **1.2**  | **\*Please enter the Short Study Title:** |

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| Stroke Validation  |   |  |

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| **2.0**  |  | **Add Department(s)** |

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| **2.1**  | **List of Departments associated with this study:** |

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| **Primary Dept?** | **Department Name** |
|  | **KPCO** - Pharmacy |

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| **3.0**  |  | **Assign key study personnel(KSP) access to the study** |

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| **3.1**  | **\*Please add a Principal Investigator for the study:** |

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| Olson, Kari, PharmD  |

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| **3.2**  | **If applicable, please select the Protocol Staff personnel:**  |

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| A) Additional Investigators  |  |  |
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|  | Delate, Thomas, PhD, MS  |
|   | Co-Investigator  |
|  | Denham, Anne, PharmD  |
|   | Co-Investigator  |
|  | Lash, Lisa  |
|   | Co-Investigator  |
|  | Merenich, John  |
|   | Co-Investigator  |
|  | Rasmussen, Jon  |
|   | Co-Investigator  |
|  | Wood, Michele  |
|   | Co-Investigator  |

 |
| B) Research Support Staff  |  |  |
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| No Research Staff have been added. |

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| **3.3**  | **\*Please add a Project Manager:** |

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| 1. | Kurz, Deanna, BA, CCRP  |
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The Project Manager(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Research Assistant or the Principal Investigator themselves).  |  |  |

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| **4.0**  |  | **Level One Research Personnel** |

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| **4.1**  | **All Level One Research Staff involved in this study must be listed by name in Section 3.0 of this application. Please return to Section 3.0 if you need to identify any additional Level One Research Staff as defined here.Level One Research Staff: Likelihood of harm, protocol violation, or unanticipated problems is high if these individuals fail to follow the protocol and/or comply with regulations and KP policy for the protection of human subjects. Please see the HRPPP website (click on help tab for link) for more information and a list of characteristics that distinguish individuals who are in the Level One category.**  |

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| **5.0**  |  | **Submission Type** |

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| **5.1**  | **What type of project are you submitting?**  |

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|  | Human Subject Research   |
|  | Exemption Request   |
|  | Interregional/ Interinstitutional Research Application   |
|  | Single Patient Use   |
|  | Emergency Use   |
|  | Humanitarian Use Device   |
|  | Human Subjects research assessment form   |

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| **6.0**  |  | **IRB Submission** |

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| **6.1**  | **Is this the Principal Investigator's first submission to the KPCO IRB?** |

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|  Yes  No  |

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| **6.2**  | **Is this study going towards an academic degree or school requirement?**  |

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|  Yes  No  |

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| **6.3**  | **Please enter the start and end dates for the entire length of the study.** |

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| Study start date:  |
| 11/01/2010  |
| Study end date:  |
| 10/31/2012 |

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| **6.4**  | **Please indicate the level of risk associated with this study.**  |

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|  | \*Minimal risk   |
|  | Greater than minimal risk   |
|  | Unknown   |

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| **7.0**  |  | **Outside PI** |

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| **7.1**  | **Will there be an outside Principal Investigator involved with this study?**  |

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|  Yes  No  |

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| **8.0**  |  | **Participating Institutions** |

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| **8.1**  | **Will any outside institutions be participating in this research study?**  |

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|  Yes  No  |
| If yes, please enter the names of the participating institutions.  |
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| **9.0**  |  | **Vulnerable PopulationsPlease indicate the role, if any, that the following groups might have in this study.** |

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| **9.1**  | **Pregnant women, fetuses, in vitro fertilization:**  |

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| **9.2**  | **Children (<18 years old):**  |

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| **9.3**  | **Decisionally/Cognitively impaired:** |

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| **9.4**  | **Economically or educationally disadvantaged:**  |

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| **9.5**  | **Non-English speakers:**  |

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| **9.6**  | **Employees of Kaiser Permanente:**  |

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| **9.7**  | **Elderly:**  |

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| **9.8**  | **Prisoners:**  |

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| **9.9**  | **If there is another vulnerable population the study plans on working with, that is not listed above, please enter it below.**  |

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| Leave blank if not applicable.  |
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| **10.0**  |  | **Research Use of Internet** |

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| **10.1**  | **Will the internet be used to either transmit data OR provide access to data within or outside of KPCO OR communicate with participants, including e-mail?** |

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|  Yes  No  |

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| **11.0**  |  | **Research Use of Internet** |

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| **11.1**  | **Will participants be asked to provide any information using the internet?** |

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|  | Yes   |
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|  | N/A (data only, no participants)   |

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| **12.0**  |  | **Research Use of Internet** |

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| **12.1**  | **Will e-mail be used to send study data to investigators, vendors or others inside or outside KP?** |

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|  Yes  No  |

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| **13.0**  |  | **Research Use of Internet** |

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| **13.1**  | **Will the e-mail be encrypted?** |

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|  Yes  No  |

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| **13.2**  | **Will attachments to the e-mail be encrypted or password protected?** |

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|  Yes  No  |

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| **14.0**  |  | **Research Use of Internet** |

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| **14.1**  | **If automated email routing systems are used, what security controls will be in place? Describe your testing and disaster recovery procedures.** |

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| High (128-bit) security encryption All data will be sent behind KPCO firewalls using Kaiser Permanente employee email addresses.  |

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| **15.0**  |  | **Research Use of Internet** |

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| **15.1**  | **Will contractors or vendors have access to study participant's personal identifiable or confidential information?** |

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|  Yes  No  |

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| **16.0**  |  | **Research Use of Internet** |

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| **16.1**  | **What is the volume and frequency of data being transmitted via the internet (including e-mail)?** |

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| Data transfers will be as needed for database development, the ICD-9 code validation, chart abstraction, review/validation of events, and to complete all study activity, analysis and manuscript preparation. Approximately 15,000 charts may be accessed and a subset will be transmitted for study activities.  |

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| **17.0**  |  | **Research Use of Internet** |

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| **17.1**  | **Who is responsible for ensuring that KP policies and procedures for confidentiality and security are followed for this project? Provide name of the person responsible and his/her professional position and affiliation.** |

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|  | **Name**  | **Title**  | **Affiliation**  |
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| Kari Olson, PharmD  |

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| Principal Investigator  |

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| KPCO  |

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| **17.2**  | **Who is responsible for security administration for the information technology associated with this project? Provide the name of the person responsible and his/her professional position and affiliation.** |

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| Kaiser Permanente Health Plan  |

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| Web Manager  |

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| **18.0**  |  | **Data Management** |

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| **18.1**  | **Will data storage be internal (within KP firewall)?**  |

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|  Yes  No  |
| If yes, describe file storage on LAN (eg, data warehouse, storage facility).  |
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| All Kaiser study data will be on a KPCO LAN and will be password protected and/or kept in a locked cabinet on KPCO premises.  |

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| **19.0**  |  | **Data Management** |

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| **19.1**  | **Please describe how access to study data will be restricted to study personnel.**  |

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| Only Kaiser Permanente study personnel  will have access to the data and the data will be password protected and/or kept in a locked cabinets on KPCO premises.  |

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| **19.2**  | **Who will have access to study data?**  |

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|  | **Name**  | **Title**  | **Affiliation**  |
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| Kari Olson, PharmD  |

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| Principal Investigator  |

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| Lisa Lash, PharmD  |

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| Pharmacy Resident/Co-investigator  |

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| Michele Wood, PharmD  |

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| Pharmacy Resident/Co-investigator  |

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| Jon Rasmussen, PharmD  |

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| Chief CV Services/Co-Investigator  |

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| Anne Denham, PharmD  |

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| Clinical Pharmacy Specialist/Co-investigator  |

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| Tom Delate, PhD  |

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| Clinical Research Scientist/Co-investigator  |

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| John A. Merenich, MD  |

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| Physician/Co-investigator  |

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| **19.3**  | **What administrative safeguards will be in place?  (describe process for incident management and/or reporting of security breach)**  |

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| Access will be allowed by study team only and all data will be kept locked and or password protected. Data will be deidentified at the earliest opportunity. INCIDENT MANAGEMENT AND REPORTING WILL FOLLOW THE COMPLIANCE REGULATIONS SET FORTH IN “Reportable Events and Incident” training. Any breach will be reported to the Research Compliance Administrator and to IRB with in 10 days. |

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| **19.4**  | **Who will manage the study data?**  |

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| Kari Olson, Tom Delate, and Jon Rasmussen |

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| **20.0**  |  | **Background and Significance** |

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| **20.1**  | **Provide information about the background and significance of this study. For help with this question please click on the help button.** |

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| **I. Background and Rationale**      Stroke is the third leading cause of death, the most common life-threatening neurologic disorder, and the leading cause of serious, long-term disability in the United States (U.S.).1 In 2006, among adults aged 20 years or older, the estimated prevalence of stroke was 6.4 million (60% men, 40% women) and accounted for about one out of every 18 deaths in the U.S..1 Ischemic strokes account for 87% of all strokes; the remainder being hemorrhagic. The estimated direct and indirect cost of stroke for 2010 is $73.7 billion.1 Approximately 795,000 people experience a stroke, annually, of which about 185,000 (23%) are recurrent events.1After the first year, the average annual risk for recurrent stroke is 4%.2  Patients who survive at least 30 days after a first-ever stroke have an average annual risk of death of 9.1%, much of the risk due to nonstroke cardiovascular disease.3Given the limited availability of treatments for acute stroke, research tends to focus on primary and secondary prevention efforts with control of major risk factors and implementation of evidence-based medications. Pharmacotherapeutic treatment regimens involving hydroxy-3-methylglutaryl coenzyme A reductase inhibitors (“statins”), antihypertensive agents (angiotensin converting enzyme (ACE) inhibitors, and thiazide-type diuretics), antiplatelet therapy, and smoking cessation interventions have all been shown to improve long-term clinical outcomes in this high-risk population.4,5Despite the evidence supporting the use of various therapeutic interventions within the ischemic stroke population, a significant proportion of patients continue to have uncontrolled risk factors and remain undertreated.6,7 A recent prospective study of more than 4933 high-risk patients reported that, as compared to patients with coronary artery disease, patients with cerebrovascular disease are undertreated and thus less likely to achieve blood pressure (45.3% vs. 57.3%, p<0.001) and lipid (19.4% vs. 30.5%, p<0.001) targets, respectively.6 Although the reasons for the so-called “treatment gap” have not been explored specifically within this population, data from studies within the coronary artery disease population suggest that provider, patient, and health care system factors likely all contribute.  To help address the treatment gap, the American Heart Association developed **Get With The Guidelines®–Stroke** (GWTGS) to help ensure continuous quality improvement of acute stroke treatment and stroke prevention.8,9 The program focuses on care team protocols to ensure that patients are treated and discharged from hospital appropriately. It is available for implementation at acute care hospitals nationwide. While GWTGS has improved care delivery among patients admitted to hospital with acute stroke, it does not focus on long-term delivery of care for ambulatory care patients. Evaluation of health care delivery systems which focus on long-term care are needed to identify efficient, cost-effective methods that can improve outcomes of patients with ischemic stroke. Six of the 10 quality of care measures that are part of the GWTGS can potentially be augmented during ambulatory care after hospital discharge.9 They are as follows: 1) antithrombotic therapy at discharge, 2) anticoagulation for atrial fibrillation at discharge, 3) treatment at discharge if LDL >100 mg/dL or LDL not measured or on therapy at admit, 4) counseling for smoking cessation, 5) stroke education provided, and 6) stroke rehabilitation referral. If any of these measures are not met when a patient is discharged from the hospital, they can be initiated on an outpatient basis.The Clinical Pharmacy Cardiac Risk Service (CPCRS) is expanding care services to patients with ischemic stroke. Similar to that of the CAD population, CPCRS plans to develop and maintain a registry of patients with validated ischemic stroke. The service has initiated a process for validating patients with stroke. An area of deficiency identified during this process is that the accuracy of the administrative coding used for stroke is unknown.Developing a complete registry of patients across a health plan with any specific condition is challenging, and has demonstrated to be particularly challenging for ischemic stroke. The prevalence of ischemic stroke is large enough that a manual process of identifying patients is time-consuming, and therefore would delay evaluation and implementation of evidence-based care. Use of the electronic medical record (EMR) and its links with other electronic databases such as claims systems can help create a complete list of patients who have had an ischemic stroke. There are a number of examples of registries for ischemic stroke. The World Health Organization (WHO) launched its Global Stroke Initiative in 2004, requesting sites to register patients with history of stroke.10 The aim of the initiative is to gather and disseminate information on patient management globally. Numerous tools to assist providers in capturing patients with stroke have been developed, yet it remains a manual process, particularly for sites where electronic data are unavailable. The AVAIL study captured patients discharged from the hospital with a primary ICD-9 code of acute ischemic stroke or TIA and was then able to follow them for the first year after stroke to determine adherence to preventive medications.11International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9) codes have traditionally been utilized to identify patients with ischemic stroke for epidemiologic, quality of care, and cost analysis studies. The accuracy of ICD-9 codes to identify stroke patients needs to be understood in order to capture the most patients accurately. Unfortunately, in many instances disease coding is inaccurate and limits internal and external validity. For example, two separate community-based studies in Minnesota and Ohio found that only 46% to 47% of patients with a primary ICD-9 code of 430.XX-438.XX had a stroke.12 Another study of ICD-9 codes for ischemic stroke in children found coding practices were as inaccurate and unpredictable as found in adult studies.13Interestingly, one study presented case scenarios to a group of neurologists who were asked to assign specific ICD-9 codes to each case.14 The level of agreement even between neurologists was low (κ 0.38). Several studies have been conducted to determine the precision of ICD-9 codes for identifying ischemic stroke by assessing the sensitivity, specificity, and positive predictive value (PPV) of stroke ICD-9 codes 430.0-438.0.15-21 These studies have focused on inpatient and emergency room discharge ICD-9 diagnosis codes to identify patients with stroke. Among studies evaluating hospital discharge diagnosis codes, some investigators have found that limiting the ICD-9 code to the primary position in administrative databases increased the proportion of patients accurately classified as having a stroke17, while others found that stroke classification was optimal using discharge diagnosis for ischemic stroke in any position.18 The coding for intracerebral hemorrhage and subarachnoid hemorrhage is generally more accurate than that for ischemic stroke.17To date, ICD-9 codes associated with a stroke diagnosis lack PPV. According to one study, ICD-9 codes 434.XX and 436.XX have the best PPV with 85% and 77% of patients having a confirmed ischemic stroke, respectively.15 On the other hand, ICD-9 code 433.XX is often inaccurate with less than 2% of patients with this code having a valid acute stroke diagnosis.15 The study concluded that if investigators wish to track trends in costs and patterns of care for patients with acute ischemic stroke, focus should be directed to patients with ICD-9 codes 434.XX and 436.XX while patients with ICD-9 code 433.XX should be excluded.15 One study attempted to address limitations to past studies by using modifier codes to improve the accuracy of ICD-9 coding for ischemic stroke.15 However, despite the use of modifier codes, still 15% to 20% of patients with primary ICD-9 codes suffered from conditions other than acute ischemic stroke.There are several limitations to the current published studies. Many studies limited data to patients discharged from a hospital admission, therefore if the patient was not admitted or received care at an outside facility, the stroke event would not be captured. At Kaiser Permanente Colorado (KPCO), very few patients are actually hospitalized (either because they had their stroke prior to KPCO membership) or the stroke occurred and did not result in hospitalization. Patients with stroke who are not hospitalized need to be identified and enrolled in a follow-up program to ensure optimal secondary prevention treatment. Thus for patients not admitted to hospital with stroke (i.e. stroke diagnosed as an outpatient encounter) or with stroke prior to health plan membership, the accuracy of codes for this subset of patients is not known. Except for one study, prior studies have not extensively evaluated how the use of modifiers, such as antiplatelet medications, can improve diagnostic accuracy.The objectives of this proposal are to 1) identify a set of criteria that most reproducibly and accurately identifies patients with ischemic stroke to then 2) develop an ischemic stroke registry using administrative and clinical data from Kaiser Permanente Colorado’s administrative data and 3) utilize the registry to describe current treatment practices of ischemic stroke at KPCO. It is our hope that accurate identification of ischemic stroke patients will enable KPCO to provide long-term care to improve clinical outcomes for these patients. Furthermore, this study will also have utility in future studies by our research group, who rely on administrative data to identify stroke events.  This study supports a number of KPCO strategic objectives. The study supports 1) “Enhanced Customer and Member Engagement” by providing a consistent, reliable, and accessible services while nurturing long-term relationships with members and 2) Coordinated care through member-centered teams by delivering care that is seamless across specialties and locations*.* The goal behind developing an ischemic stroke registry is to improve long-term health outcomes for patients enrolled at CPCRS. The CPCRS has developed long-term relationships with patients with coronary artery disease which has demonstrated to improve long-term health and outcomes, and plans expand care to patients with ischemic stroke. These relationships have improved members’ long term health. |

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| **21.0**  |  | **Hypothesis and Objectives** |

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| **21.1**  | **Explain the hypothesis and objectives for this study.  -  For help with this section of the form please click on the help button.** |

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| **Phase 1****A. Primary Aim:**To determine the administrative criteria which most accurately identifies patients with stroke, using sensitivity, specificity, and PPV.**B. Secondary Aims:**1.       To determine administrative criteria which most accurately identifies patients with ischemic stroke and hemorrhagic stroke using sensitivity, specificity, and PPV.2.       To determine how/if ICD-9 codes limited to outpatient encounters only can be used to accurately           identify patients with ischemic stroke. **Phase 2****A. Primary Aim:**1.       To evaluate treatment patterns for patients with validated ischemic stroke. *Hypothesis:Less than 40% of patients with ischemic stroke will have achieved the recommended lipid and blood pressure treatment goals.* **B. Secondary Aim:**2.     To determine if treatment patterns differ between men and women and patients < or > 65 years of age.         Hypothesis: There will be significant treatment differences and goal attainment (LDL and BP) based on gender and age. 2.       To identify factors associated with achieving the LDL-c and blood pressure treatment goals among patients with ischemic stroke. |

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| **22.0**  |  | **Study Methods** |

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| **22.1**  | **Provide a description of how the study question (hypothesis) will be tested and how participants or their health information will be involved in the study. For help with this question please click on the help button.** |

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| **A. Study Design and Setting**This study will consist of 2 phases. Phase 1 will be a retrospective, medical record review to identify ICD-9 codes which most accurately identify patients with ischemic and hemorrhagic stroke in order to develop a stroke registry. Phase 2 will be a cross-sectional study of patients identified with ischemic stroke in order to evaluate evidence-based treatment practices among the cohort.Kaiser Permanente Colorado (KPCO) is an integrated health care delivery system providing care to       over 500,000 members in Colorado. KPCO has integrated administrative, claims, and laboratory       databases and electronic medical records. Additionally, KPCO uses internal pharmacies with   automated pharmacy records which include all medications dispensed at each outpatient facility.        KPCO uses electronic medical records which capture all office visit, vital, laboratory, and pharmacy data. The majority of members receive prescription medications from KPCO pharmacies for a copayment.   The study will be submitted to the Research Review Committee and Institutional       Review Board for approval prior to initiating any study related activities. **B. Informed Consent and HIPAA**The study investigators are requesting a waiver of informed consent and HIPAA for the entire study given this is a retrospective, data-only investigation. **C. Study Population****Phase 1:**Adults (≥18 years of age) who were members of KPCO and who had at least one ICD-9 code 430.XX-438.XX between 01/01/01-12/31/09 are eligible for Phase 1. There are no pre-specified exclusion criteria for this phase. **Phase 2**Inclusion:-          Patients ≥18 to 85 years of age, who are active KPCO members for at least 6 months, as of **December 31, 2010 or the date most proximal but before the date they were enrolled into the Clinical Pharmacy Cardiac Risk Service (CPCRS) (index date), ,** and-          Have a valid diagnosis of non-cardioembolic ischemic stroke or transient ischemic attack (TIA) as identified in Phase 1,  Exclusion:The following patients will be excluded from the study:-          Enrolled in the Clinical Pharmacy Cardiac Risk Service (CPCRS) for some other reason than stroke (i.e coronary disease, peripheral arterial disease, etc)-          Have ~~TIA,~~ hemorrhagic or subarachnoid hemorrhage as their only validated stroke history **D. Study Procedures****Phase 1**Phase 1 will consist of both chart reviews and administrative data pulls to identify and validate patients with stroke and the subset of patients with ischemic and hemorrhagic stroke. Patients with ICD-9 codes 430.XX to 438.XX (TIA, ischemic stroke, intracranial hemorrhage (ICH), subarachnoid hemorrhage (SAH)) between 01/01/2001-12/31/2009 will be administratively pulled from any emergency room/hospital inpatient (primary or secondary discharge position) and outpatient visit. The prevalence of each of the codes for each patients will be displayed in tabular format. The date of the first ICD-9 code identified between 01/01/2001-12/31/2009 will be used for classification. A standardized chart abstraction tool will be developed by the research team to be used by abstractors to identify patients with stroke. The clinical practice guidelines for identifying and treating stroke will be used as a basis for developing the criteria for stroke diagnosis.4,5 An initial version will be developed and be tested by randomly extracting 20 patients with ICD-9 codes for stroke and having two individuals (LL and MW) chart review these patients to determine whether they indeed had a stroke and the type of stroke experienced (SAH, ICH, TIA, ischemic, other, none). Inter-rater reliability testing will be done with a goal of obtaining a κ score of 0.6 or higher. In the event that inter-rater reliability is not obtained, training or chart abstraction tool modifications will occur and the procedures repeated with an additional 20  patients. These procedures will be repeated until the pre-specified κ score of 0.6 or higher is obtained.The chart review for ischemic stroke will be used as the “gold standard’ by which to validate ICD-9 and pharmacy claims data. Using the final chart abstraction tool, a random list of X patients representing a weighted sample of each of the ICD-9 codes will be administratively identified. The two abstractors (LL and MW) will review the charts to determine patients with and without a stroke diagnosis and the stroke type. A series of administrative data queries will be used to determine the sensitivity, specificity, and PPV  for the various ICD-9 codes, including whether the code is from an emergency room, inpatient hospital discharge, or outpatient visit. Additionally, ICD-9 codes coded by a primary care physician versus a neurologist will be evaluated. To determine the value of adding specific modifiers to improve the accuracy of the codes, queries will also include specific pharmacy medications (ticlopidine, clopidogrel, dipyridamole, and dipyridamole/ASA (Aggrenox®)). To be included in the evaluation, pharmacy dispensations are required to have occurred within 180 days of the date of the ICD-9 code. Indicators will be evaluated individually and then combined to determine the most accurate and reproducible coding structure for ischemic stroke. **Phase 2**Patients will be screened for inclusion and exclusion criteria by the data analyst via an administrative database query of HealthTrac®, Membership, *National Pharmacy Data Warehouse*, *General Lab DVBR* Universe and *Outpatient Services (Util) DVBR* Universe. Data will not be pulled in the form of a limited date set or a de-identified dataset.  Only the required PHI to verify eligibility will be used and a waiver of Authorization will be requested for all study activities.Demographics and medical co-morbidities of each patient identified as of ~~12/31/10~~ the index date will be collected. Age (as of the index date~~12/31/10~~), sex, cardiac event history (acute myocardial infarction (AMI), percutaneous coronary intervention ± stent, coronary artery bypass graft (CABG) surgery), hypertension, diabetes mellitus, congestive heart failure, peripheral artery disease, ~~cerebrovascular accidents~~, current smoking status and atrial fibrillation ~~and dyslipidemia~~ will be identified by queries of diagnosis codes from the electronic database (specific International Classification of Diseases, 9th Revision [ICD-9] available upon request from investigators). Chronic renal insufficiency will be defined as chronic disease stage III or greater as determined by the modification of diet in renal disease (MDRD) calculation (glomerular filtration rate <60 ml/min). Laboratory data will be obtained from the KPCO integrated, electronic laboratory database. Fasting lipid profiles (FLP) within the previous 365 days will be obtained.  Among patients with FLPs available, the most proximal to the index date ~~12/31/10~~ will be used for study purposes and outcome assessment. Instances of triglycerides >400 mg/dL, in which an LDL-c can not be calculated and reported via the Friedewald formula, a direct LDL-c will be utilized, when available. Blood pressure values will be obtained from any outpatient encounters, including but not limited to primary care office visits, hypertension group visits.  Blood pressures obtained from emergency room, hospital, or specialty office visits will be excluded. Among patients with blood pressure values available, values within the previous 365 days of the index date ~~12/31/10~~ will be obtained with the most proximal value being used for outcome assessment. Data on medications purchased at KPCO will be obtained from queries of the KPCO integrated, electronic pharmacy database using Generic Product Identifier (GPI) codes. Over 90% of the KPCO population fills their prescriptions within the KPCO system. Lipid-lowering therapy will be defined as statins, fibric acid derivatives, bile acid sequestrants, niacin, and ezetimibe. As over-the-counter medications are not easily tracked through prescription databases, these are not be included in the list of lipid-lowering medications. Antihypertensive therapy will include thiazide or loop diuretics, angiotensin converting enzyme (ACE) inhibitors/angiotensin receptor blockers (ARBs), β-blockers, calcium channel blockers, alpha blockers, and others. Antiplatelet/anticoagulant therapy will include dipyridamole, dipyridamole/ASA (Aggrenox®), clopidogrel, and ticlopidine, and warfarin.  Patients will be considered to be taking any of these medications if the sold date that overlaps 12/31/10.   |

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| **23.0**  |  | **Data Analysis** |

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| **23.1**  | **Describe the data analysis plan for this study. For help with this question please click on the help button.**  |

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| **IV. Study Outcome Measures****Phase 1:**The primary outcome for phase 1 is the administrative criteria which most accurately identifies patients with overall stroke, and the with ischemic versus hemorrhagic stroke sub-types. To meet this study outcome, sensitivity, specificity, and PPV will be calculated for various codes and combinations. **Phase 2:**The primary outcome measure is the proportion of patients with an LDL <100 mg/dL based on recommendations by the American Heart Association.4,55The proportion of patients with LDL-c <70 mg/dL will also be determined. As a secondary lipid goal, the proportion of patients with nonHDL<100 mg/dL and <130 mg/dl will be assessed.The proportion of patients with a blood pressure <130/80 mmHg and <140/90 mmHg will be determined. The AHA does not recommend an absolute blood pressure target for patients with ischemic stroke, thus this outcome measure is based on KPCO national recommendations.The proportion of patients receiving treatment with statins (vs. other lipid-lowering agents), antiplatelets, and diuretics ± ACE inhibitors/ARBs (vs. other antihypertensives) will be determined based on recommendations by the AHA.r4,5**V. Sample Size Determination****Phase 1:** A convenience sample of 500 patients will be reviewed for phase 1.   Phase 2: All patients with ischemic stroke, using the most accurate codes identified from Phase 1, will be included for phase 2. The sample to be included is unclear at this time but is estimated to be approximately 5000 patients.  **VI.  Statistical Analysis**Data analyses will be performed at KPCO by using either SAS, version 9.1.3 (SAS Institute Inc., Cary, NC) statistical software or Excel 2003.Inter-rater reliability for developing and testing the chart review abstraction tool for identifying and classifying stroke type determining ischemic stroke from chart review will be calculated using κ scores. A κ score of 0.6 or higher will be considered good agreement between reviewers.Using standard definitions of sensitivity, specificity, and PPV, the performance of stroke classification and pharmacy claims algorithms will be compared with the results of the chart reviews. The chart review determination of the presence of stroke and stroke type (ischemic vs. hemorrhagic) will be considered the gold standard. Percentages will be presented with 95% confidence intervals. The estimates of sensitivity, specificity, and PVV for each of the stroke types will be based on a 2x2 table (administrative diagnosis of stroke type yes/no versus chart review diagnosis of the stroke type (yes/no).  Patient characteristics will be reported as means, medians, and standard deviations for interval- and ratio-level variables (e.g., age, mean lipid levels) and proportions for nominal- and ordinal-level data (e.g., sex, LDL <100 mg/dL). Interval-level outcome variables will be assessed for normality of their distributions and appropriate tests (e.g., t-test, rank-sum test) will be used to assess differences in mean values between groups. To assess differences in proportions between groups on dichotomous outcome variables, Pearson’s chi-square test of association will be utilized. Multivariate logistic regression analysis will be utilized to identify factors (demographics, co-morbidity, and treatments) for achieving LDL-c and blood pressure goals. Factors with a *P*-value < 0.2 in the bivariate analyses will be incorporated in the multivariate analysis. A two-sided alpha level will be set at < 0.05. All data will be compared between men and women and by age (≤ vs. >65 yrs).Additionally, patients at both the LDL-c and BP goals as of the index date~~12/31/10~~ will be compared to patients not at these goals to determine differences in demographics, co-morbidities, and treatments. |

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| **24.0**  |  | **Risks and Benefits** |

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| **24.1**  | **Provide justification for the risks and benefits of this study.   For help with this question please click on the help button.**  |

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| As this is a retrospective, data-only analysis with minimal risk to its subjects, any potential risks, discomforts, or inconveniences to subjects are reasonable in relation to the potential benefits. No human subjects will be contacted or receive any intervention as part of this study. The greatest risk, therefore, will be a breech of confidentiality of PHI. A locked cabinet (If required) and a password-protected database will be maintained for study activities and for analyses of datasets. Patient profiles will only be assessed for the minimum set of variables required for study activity and analysis; therefore, limiting the amount of PHI used. Only the identified study team will have access to the study data. Patient identifiers will not be revealed in any professional presentation or publication and upon completion of the study, all study materials that do not need to be retained for compliance reasons will be promptly destroyed. |

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| **25.0**  |  | **Study Type** |

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| **25.1**  | **Please identify what type of research study this is:** |

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| **26.0**  |  | **Data Collection** |

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| **26.1**  | **What type of data will you be accessing?** |

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|  | Chart review/chart components  |
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| Please describe your specific data sources, e.g., HealthTRAC, VDW, PIMS, etc.  |
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| All KPCO patients will be administratively captured using KPCO claims databases (Claims and Referral System (CARS); Clarity; HealthTRAC® disease management; the Data Marts; and the Decision Support System (DSS) using relevant ICD-9 (both diagnosis and procedural codes), HealthConnect, and pharmacy databases. |

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| **26.2**  | **How many individual's medical records will be accessed.** |

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| **26.3**  | **Please indicate the date range for the data you will be working with:** |

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| **27.0**  |  | **HIPAA Privacy Rule Authorization Questionnaire** |

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| **27.1**  | **Will any Protected Health Information (PHI) be used or accessed for this study?** |

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| **28.0**  |  | **HIPAA Privacy Rule Authorization Questionnaire** |

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| **28.1**  | **Does the data used in this study ALREADY EXIST in the form of a LIMITED DATASET or a DE-IDENTIFIED Data set?** |

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| **29.0**  |  | **HIPAA Waiver** |

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| **29.1**  | **The waiver is being requested for (CHECK ONE):** |

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|  | The USE of Protected health Information (PHI) by members of the KPCO workforce within the KPCO Region   |
|  | The USE and DISCLOSURE (sharing) of PHI within the KPCO Region and with individuals or entities outside the KPCO Region.   |

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| **30.0**  |  | **HIPAA Waiver** |

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| **30.1**  | **Describe in detail what PHI will be used.** |

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| The HealthTrac-*CAD®* registry, electronic medical record and KPCO administrative, claims, pharmacy, and laboratory data as outlined previously will be used for data collection. MRNs, patient characteristics include demographics (age (date of birth), sex, race), co-morbidities, and pharmacy-specific data. |

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| **31.0**  |  | **HIPAA Waiver** |

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| **31.1**  | **Will the PHI be used to develop a de-identified dataset or a limited dataset?** |

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|  | de-identified dataset   |
|  | limited dataset   |
|  | No / Neither   |

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| **32.0**  |  | **HIPAA Waiver** |

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| **32.1**  | **Does the use and/or disclosure of PHI involve more than minimal risk to the privacy of participants?** |

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|  Yes  No  |

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| **33.0**  |  | **HIPAA Waiver** |

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| **33.1**  | **Describe the plan to protect identifiable information from improper use and disclosure:** |

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| Files will be stored on the the investigators KPCO P: drive with password protection.Records will be stored in a secure KPCO password-protected computer server.Access to the files and dataset will be limited to those directly involved in the design, implementation, and analysis of the dataPHI that will be utilized for the conduct of this study will not be reused or disclosed to any other entity except as required by lawAll data will be analyzed and reported in aggregate form only  Data will only be on a KPCO server and accessed with a password by the study team as described. |

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| **33.2**  | **Describe the plan to destroy the PHI at the earliest opportunity. If there is a health, research or, legal   justification why PHI must be retained please describe.** |

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| PHI that will be utilized for the conduct of this study will not be reused or disclosed to any other entity except as required by law.PHI will be destroyed at the earliest opportunity after publication of the findings is complete.  |

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| **33.3**  | **Explain why the research could not be done without the waiver:** |

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| This is a retrospective data analysis study and it would be difficult if not impossible to obtain informed consent from all potential subjects since some patients may be deceased, are no longer KPCO members, and/or may be inaccessible to provide consent and authorization.  |

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| **33.4**  | **Explain why the research could not feasibly be conducted without access and use of PHI.** |

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| Identification and screening for patient eligibility and assessing the specified study outcomes could not be done without the waiver. |

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| **34.0**  |  | **Informed Consent Questionnaire** |

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| **34.1**  | **Are you requesting a waiver of Informed Consent?** |

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|  Yes  No  |

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| **35.0**  |  | **Rationale and Justification for the Waiver of Informed Consent** |

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| **35.1**  | **Does the proposed research present no more than minimal risk to the study participants?** |

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|  Yes  No  |

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| **35.2**  | **Could there be legal or psychosocial risks to the study participants?** |

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|  Yes  No  |

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| **36.0**  |  | **Rationale and Justification for the Waiver of Informed Consent** |

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| **36.1**  | **Explain how the waiver of informed consent will not adversely affect the rights and welfare of the participants:**  |

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| This study involves no more than minimal risk. The potential benefits are high as the knowledge gained from this study may help KPCO administratively identify patients with stroke and to evaluate current treatment practices to better understand areas of focus for secondary stroke prevention. It is the opinion of the PI that the minimal risks that this study poses are far outweighed by the potential benefits. Individual patient information will not be disclosed or shared. |

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| **36.2**  | **Explain why this research cannot practically be carried out without a waiver of informed consent:** |

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| It is not practical to obtain consent and authorization as some of the potential subjects may be deceased, terminated KPCO membership, and/or be inaccessible to provide consent and authorization. |

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| **36.3**  | **Describe plans for the dissemination of your findings to the relevant study population. If this study is not designed to yield information that would be pertinent to this population, please explain why.** |

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| We have no plans to provide study participants with information pertinent to the study at this time, however, if results are published, participants would have access to the results. Also, the results of this study may influence the care patients receive. Results will be shared/discussed with stakeholders with in KPCO in aggregate form**.** |

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| **37.0**  |  | **Risk Assessment and Mitigation Process (RAMP)** |

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| **37.1**  | **Check any of the following that are applicable for this research application: Does the study involve the disclosure of KPCO PHI to a collaborator\*?** |

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| Please click on the help tab to see the new definition of COLLABORATOR |
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|  | NO, this study does not require the disclosure of KP PHI to a collaborator. I will inform the IRB of any proposed study modification that will result in sharing KP PHI with a collaborator.    |
|  | YES, This study does require the disclosure of KP PHI to a collaborator in the form of a Limited Data Set (LDS). I understand that the LDS can only include: elements of an address greater than street address; dates of birth; death or service. Prior to disclosure of the LDS, KP will execute a Data Use Agreement with the collaborator. I understand that the use of an LDS mitigates risks to the Participant's privacy and security. I will inform the IRB of any change of disclosure more than a LDS.    |
|  | YES, this study does require the disclosure of KP PHI to a collaborator. I will conduct a thorough and accurate data security risk assessment as required using the RAMP tool. I will indicate all data privacy, security, and confidentiality risks.    |

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| **38.0**  |  | **Principal Investigator's Assurance** |

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| **38.1**  | **The Principal Investigator assures to comply with each of the following statements:**  |

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| Check each box to indicate your agreement with each statement:  |
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|  | Accept responsibility for the ethical conduct of the study and the protection of the rights, safety, and welfare of the participants.  |
|  | Assure a thorough literature review of risks/benefits has been completed.  |
|  | Conduct this study in compliance with the protocol as reviewed and approved by the Institutional Review Board (IRB).  |
|  | Accept responsibility that co-investigators and study personnel have appropriate qualifications to conduct this research in accordance with the approved protocol.  |
|  | Keep current in training of bioethics and human subjects research and assure all key study personnel are in compliance.  |
|  | Use only the currently approved copy of the informed consent to obtain legally effective informed consent from participants, or request a waiver of informed consent as appropriate.  |
|  | Keep complete copies of all study records, including all signed participant consent forms and privacy rule authorizations for a period of 6 years after the study has been completed and the IRB has accepted the final report.  |
|  | Submit all proposed study changes and obtain prospective IRB approval prior to implementing these changes.  |
|  | Submit all personnel changes of Principal Investigator and Co-Investigators to the IRB.  |
|  | Report upon discovery all unanticipated problems protocol violations, breaches of confidentiality, or serious adverse events to the IRB. Also report these events as required per study protocol and/or contract agreement to the funding agency, if applicable.  |
|  | Submit continuing review reports and/or final reports in a timely manner and in anticipation of the IRB approval expiration date. Failure to comply may result in expiration and/or termination of IRB approval. When a study loses IRB approval, all study activities must stop immediately.  |
|  | Arrange for a co-investigator to assume direct responsibility in the event that I am unavailable to direct this research personally. This person should be designated on this application or a modification should be submitted to the IRB to advise them of this change.  |
|  | Assure that PHI will be used and disclosed only as described in this application (i.e. PHI will not be re-used or disclosed to any other individual or entity), except as required by law. Any changes to the use or disclosure must be prospectively reviewed by the IRB prior to implementation.  |
|  | Assure that I have read the KPCO Conflict of Interest Policies and that I and any individuals who are responsible for the design, conduct or reporting of the research project submitted in this application will abide by these requirements.  |
|  | Assure that I have read the KPCO Scientific Misconduct and Responsibilities of the Principal Investigator policies and will abide by these requirements.  |

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