Dear Dr. Claffy:

The Committee at the November 30, 2009 Institutional Review Board meeting could not reach a final determination concerning this protocol. The Committee acknowledges that CAIDA has been collecting data for 10 years, using active and passive methods of collection. The active collection includes sending out probe "packages" to random IP addresses, in order to track the pathways and linkages. Probes are random, do not identify individual users and are not ongoing. Probes also do not track content but destination. Passive collection entails collaborating with organizations that provide local and wide-area network infrastructure. Through these collaborations, they have explicit authorization to passively "tap" heavily aggregated links. The Committee also notes that the protocol includes a detailed analysis of the potential risks of the unlikely but possible linkage of a probe/tracking device to an individual user, in order to make the case that, even in this unlikely case, potential impact would be minimal.

While the above-referenced project has been considered, the PI is asked to address the following:

Please note this direct quote from Research Plan:

"This research would present a nominal legal risk to the confidentiality of that IP address, since any entity can use publicly available and legal search methods to uncover the registrant of a domain name or an IP address. The risk to the individual who might be associated with the IP address is that his/her one-time Internet activity (e.g., visit to a website) could be disclosed to vetted fellow researchers requesting this data. Given the extremely limited quality and quantity of information, and the difficulty in correlating the IP address to an individual, the collection and disclosure risk presents little potential social stigmatization or psychological injury, and no physical risk."

With the above text in mind, the PI is asked to clarify what specifically are the following "controls are instituted to eliminate the risk of intervention/interaction with individuals."? Please address.

Further, the Committee feels that there is an unresolvable tension in regard to the actual risks associated to this study. For example, it is unclear if there really is no way to link IP addresses to individuals. Secondly, how true it is that the researchers will only sample a given location once? Are the IP addresses hit more than once? In addition, the future use of the data remains questionable in that it is unclear how this data would be shared and/or how it could be used in the future to possibly identify IP addresses and users. It appears that information concerning the user could be obtained once the computer is identified.
Thus, with the above in mind, the PI is asked to provide the IRB with possible solutions to mitigate the potential risk of disclosure and to also inform the IRB of potential problems that might arise as a result of the data collected by this research. In addition, the PI is respectfully asked to revise the Research Plan to include lay terminology descriptions, as it was felt that the protocol referenced computer speak throughout the document.

Upon approval, the IRB under 46.116 General requirements for informed consent, may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that: (1) The research involves no more than minimal risk to the subjects; (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) The research could not practically be carried out without the waiver or alteration; and (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Please send your reply in the form of a cover letter that clearly describes, on a point-by-point basis, how the Committee’s requests for clarification/revision were satisfied and revised application set to the attention of the Human Research Protections Program Office, mail code 0052, or upload to this project number at http://irb.ucsd.edu, by 12/14/2009 for consideration at the 1/6/2010 meeting. Each set must include the following: 1) Your reply, 2) Face page to the application with project number, 3) The revised application with changes bolded or underlined, 4) The revised consent with changes bolded or underlined, and 5) One clean copy of the consent. If this is a CANCER protocol, 10 additional copies must also be submitted to the Cancer Subcommittee.

On behalf of the UCSD Institutional Review Boards,

Michael Caligiuri, Ph.D.
Director, Human Research Protections Program
Mailcode: 0052 Phone: 858-455-5050