# The Gaps and Compatibility of Ethical Policy and Effective Study

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When examining the analyses on www.ClinicalTrials.gov, a website providing figures and statistics of clinical trial protocols worldwide, it is noticeable that the scale of clinical trials conducted in Korea has continuously increased, especially with Seoul standing first in rank for four consecutive years from 2011 through 2014 as the city conducting the highest number of clinical trials annually.

Such "qualitative growth" of clinical trials has been instrumental in the development of relevant policies focusing on "quantitative growth" of regulatory institutions of clinical research. Especially with the complete revision of the <Bioethics and Safety Act> in February 2013, not only clinical trials but PMS, observational studies and studies of human derived materials are now under the regulation of the <Bioethics and Safety Act>.

However, certain articles in the Act have been devised so that it is practically unfeasible for researchers to adhere to. This is analyzed to be due to a general approach to the regulations, undermining the unique characteristics and risks of each clinical trial - aspects not carefully examined.

This presentation aims to analyze such gaps between laws and regulations concerning clinical trials and their actual implementation, and discuss measures to bridge the gap. Such measures include focal issues in the medical world, addressing 1) the issue of linking personal identification information to public data and 2) the issue of waiver on documentation of consent (waiver of signature) and waiver of informed consent process. This presentation will conclude with proposals of methods to resolve such issues of compatibility of policy and practice.