FAKULTAS EKONOMI DAN BISNIS	**Komite Etik Penelitian FEB UI**	**Registration Number #**	
		Date	

Protocol Deviation and Violation (Non-Compliance) Reporting Form

Any non-compliance that occurs in a research protocol that has been approved by KEP FEB UI must be reported to KEP **immediately** or **within 5 working days from the discovery of the incident of non-compliance**.

Further information regarding non-compliance and its reporting procedures can be accessed on the KEP website. If you have any questions regarding this form, please contact kep@lpem-feui.org. KEP's working hours are every working day from 09.00-17.00 WIB.

I. TYPE OF REPORTING

1. **Please specify your reporting type (Select the most appropriate)**
☐Minor Non-Compliance ***Minor Non-Compliance*** *is non-compliance that* ***does not*** *increase risk, or endanger the rights and welfare of research subjects. Minor Non-Compliance also* ***does not*** *affect the integrity of the research and efforts to protect humans as research subjects.* ☐ Ketidakpatuhan Major ***Major Non-compliance*** *is non-compliance that* ***has the potential*** *to increase risk, endanger the rights and welfare of research subjects, and affect the integrity of research and efforts to protect humans as research subjects.*

II. GENERAL INFORMATION

1. **Research Title**	
2. **Principal Investigator**	
Name :	Address :
Affiliation :	
Phone Number :	Email :

III. NON-COMPLIANCE INFORMATION

In this section, you will categorize and describe the non-compliance event reported to KEP. If possible, please describe it in as much detail as possible and complete the chronology of events. When you have completed this section, you may attach any brochures, tests, consent forms, or other documentation related to the non-compliance (if any). You may attach separate documents if the description does not fit in the space provided. **Please check the box that applies to the non-compliance that occurred.** You may select more than one box.

☐ **Researchers in this study collected data without an active KEP protocol approval, and/or conducted research activities after the study expiration date** (e.g. recruitment, data collection, or data analysis)**.** *Describe all activities conducted without an approved protocol.*

☐ **The researcher in this study changed the study procedures (e.g., recruitment method, study population, number of participants, data collection techniques, wording of consent forms) without the review/approval of the KEP.** *List all the noncompliances that occurred. Specifically, explain the reasons why the study was changed and why the KEP review and approval were not sought.*

☐ **The researcher in this study failed to document the study. (Examples: failure to obtain signatures on consent forms, loss of consent forms/study data, failure to retain study information).** *Describe which study documentation requirements were not met. If any documentation was missing, please indicate the last known location, format, nature of the data, and how the noncompliance occurred.*

☐ **Other non-compliances.** *If the reported non-compliance does not fit into the categories listed above, provide a detailed description of the other non-compliance events that occurred.*

Notes, documentation, or other explanations that are important for KEP to know. *Please write the type of supporting documents in this column if you have supporting documents for non-compliance such as forms, brochures, or other documentation that you attach to the non-compliance report form for KEP.*

IV. CORRECTIVE ACTIONS FOR NON-COMPLIANCE

1. What kind of corrective actions have been taken to address this non-compliance? (Examples: Improved training, document security, additional staff, proposed changes to consent forms).

2. Please describe plans or potential solutions to avoid a recurrence of this non-compliance in the future

Reporter's Declaration

This report was filled by:

- ☐ KEP Administrator
- ☐ Reporter

My signature indicates that I am providing accurate information to the best of my current knowledge about the event. I understand and acknowledge that KEP FEB UI will review and make a decision about this event and all data collected as a result of the non-compliance.

Reporter's Signature

_____ Date_____

Full name and title (*anonymity allowed*)

_____