FRANKLIN UNIVERSITY

MANDATED REPORTING TO EXTERNAL AGENCIES

Franklin University policy requires compliance with all applicable accreditation, local, state, and federal reporting requirements in the conduct of research involving human participants. The IRB or IRB Office notifies appropriate officials when research falls under the purview of a federal regulatory agency and one or more of the following occurs:

- Unanticipated problems involving risks to participants or others; and/or
- Serious or continuing noncompliance with the regulations or requirements of the IRB; and/or
- Suspension or termination of IRB approval for research due to noncompliance.

Reporting to regulatory federal agencies is not required if the Principal Investigator (PI) voluntarily closes down a study to new participant accrual or temporarily halts the research procedures. The IRB, IRB Chair, IRB Office, or administrative officials may recommend voluntary closure to the PI, but the PI makes the decision whether closure is appropriate. However, if the IRB or IRB Chair requires suspension or termination, then the incident may be reportable under this policy.

Lapses of approval as outlined in the Continuing Review SOP are not reportable under provisions of the SOP.

PROCEDURES

Unanticipated Problems Involving Risks to Participants

1. When the IRB finds that research has experienced unanticipated problems involving risks to the participant or others, the IRB Office prepares a report within 15 days from the date the IRB conducts final review of the unanticipated problem. The report includes the title of the research protocol and/or grant proposal; name of the PI on the protocol; IRB number assigned to the research protocol; the number (project identifier) of any applicable federal award(s) (grant, contract, or cooperative agreement); the nature of the event; the findings of Franklin University or the IRB; and actions taken by the PI, Franklin University, and/or the IRB to address the issue. The IRB Chair approves the report, which the IRB Office sends to the federal agency with a copy to the IRB Chair, PI, and other University administrators as determined by the IRB.

2. If the US Department of Health and Human Services (HHS) conducts or funds the research, the IRB Office sends the report to the Office for Human Research Protections (OHRP).

3. If an agency that is participant to the “Common Rule,” other than the HHS, conducts or funds the research, the IRB Office sends the report to the agency as required by the agency and the OHRP.

4. The IRB Office maintains a copy of the federal report(s) and any final IRB actions and keeps the report(s) in the IRB study file.

Serious or Continuing Noncompliance

1. When the IRB finds that research involves serious or continuing noncompliance, the IRB Office prepares a report within 15 days from the date the IRB conducts final review of the serious and/or continuing noncompliance. The report includes the title of the research protocol and/or grant proposal; name of the PI on the protocol; IRB number assigned to the research protocol; the number (project identifier) of any applicable federal award(s) (grant, contract, or cooperative agreement); the nature of

the event; the findings of Franklin University or the IRB; and actions taken by the PI, Franklin University, and/or the IRB to address the issue. The IRB Chair approves the report, which the IRB Office sends to the federal agency with a copy to the IRB Chair, PI, and other University administrators as determined by the IRB.

2. If the HHS conducts or funds the research, the IRB Office sends the report to OHRP.

3. If an agency that is participant to the "Common Rule," other than the HHS, conducts or funds the research, the IRB Office sends the report to the agency as required by the agency and OHRP.

4. The IRB Office maintains all correspondence relating to the serious or continuing noncompliance. The IRB Office keeps a copy of the federal report(s) and any final IRB actions in the IRB study file.

Suspension or Termination of Research

1. When the IRB suspends or terminates approval of a research protocol, the IRB Office prepares a report to the applicable federal agency within 15 days from the date the IRB conducts final review of the suspension or termination. The report includes the title of the research protocol and/or grant proposal; name of the PI on the protocol; IRB number assigned to the research protocol; the number (project identifier) of any applicable federal award(s) (grant, contract, or cooperative agreement); the nature of the event; the findings of Franklin University or the IRB; and actions taken by the PI, Franklin University, and/or the IRB to address the issue. The IRB Chair approves the report, which the IRB Office sends to the federal agency with a copy to the IRB Chair, PI, and other University administrators as determined by the IRB.

2. If the HHS conducts or funds the research, the IRB Office sends the report to the OHRP.

3. If an agency that is participant to the "Common Rule," other than the HHS, conducts or funds the research, the IRB Office sends the report to the agency as required by the agency and OHRP.

4. The IRB Office maintains all correspondence relating to the suspension or termination. The IRB Office keeps a copy of the federal report(s) and any final IRB actions in the IRB study file.