



**IRB Administration Office
Additional Key Personnel/Change Request**

Submission Instructions and Information

Clearly label document as “Additional Key Personnel Form” and submit to IRB per instructions noted on the main submission request (e.g. Key Personnel Change, Initial External IRB, External IRB Modification, etc.)

Open and save form using Adobe or software that allows for digital signature.

CITI Training and Key Personnel

1. **ALL** personnel being added must have completed the CITI training program at <https://www.citiprogram.org/Default.asp>.
Affiliate with WSU for courses to count. Further directions at: <http://irb.wayne.edu/mandatory-training.php>
- Standard Mandatory Courses:**
- (I) Basic Course in Human Subjects Research: Biomedical or Social Behavioral Investigators (Refresher course is required every 3 years)
 - (II) Responsible Conduct of Research (RCR) Biomedical or Social Behavioral Investigators
 - (III) Health Information Privacy and Security (HIPS) Module (per research role)
- a) Have **all** of the personnel taken: HIPS RCR & Basic/Refresher Course for Human Subjects?
 Yes No - **STOP: do not submit this form until above trainings are complete for ALL personnel.**
- Additional Courses based on Participant Population enrolled in study and research type:**
- Children included as participants (CITI module: 152332 or 152335)
 - Pregnant Women, Fetuses or Neonates included as participants (CITI module: 152332 or 152335)
 - Prisoners included as participants (CITI module: 152333 or 152336)
 - Students included as participants (CITI module: 152334 or 152337)
 - Internet Research (CITI module: 152338)
 - International Research (CITI module: 153207)
- b) If any of the key personnel listed completed training under a different name (e.g. maiden name), what is that name?

2.

Key Personnel Financial Conflict of Interest (FCOI) and Research Role

Endorsements and Financial Conflict of Interest Disclosure:

Objectivity in research is a key component of any research project. One method for maintaining objectivity is to have all individuals involved in research design, development, or data evaluation/analysis disclose any potential and/or real financial conflict of interest.

Examples of relevant relationships for potential conflict of interest include but are not limited to:

- (1) receiving past, current, or expecting future income in the form of salary, stock or stock options/warranties, equity, dividends, royalties, profit sharing, capital gain, forbearance or forgiveness of a loan, interest in real or personal property, or involvement in a legal partnership with the sponsor
- (2) receiving past, current, or expecting future income in the form of consulting fees, honoraria, gifts, gifts to the University, or payments resulting from seminars, lectures, or teaching engagements, or service on a non-federal advisory committee or review panel
- (3) serving in a corporate or for-profit leadership position, such as executive officer, board member, fundraising officer, agent, member of a scientific advisory board, member of a scientific review committee, or member of a data safety monitoring committee, regardless of compensation
- (4) inventor on a patent or copyright involving technology/processes/products licensed or expected to be licensed to the sponsor.

See *Financial Conflict of Interest policies*: <http://research.wayne.edu/coi/docs/wsu-financial-conflict-of-interest-and-commitment-research-policy.pdf> and <http://www.irb.wayne.edu/policies-human-research.php>

- **FCOI Disclosure:** More information are available at www.research.wayne.edu/coi For additional information please contact the Conflict of Interest Coordinator at *Phone* 313-577-9064, 5057 Woodward, Suite 6304, Detroit, MI 48202, *Fax* 313-577-2159
- ***Research Role:** Briefly describe their role in the research project. (co-investigator, research nurse, research coordinator, etc)

***Key personnel** are persons engaged in the collection of data or have access to data through intervention or interaction with the participant, including the consent process, or have access to the participant's identifiable private information. This may include collaborators, fellows, residents, research assistants, research nurses, Co-investigators, etc. Co-PIs are not allowed— only Co-Investigators.

Key Personnel Research Role and Obligations. By signing below key personnel are attesting to the following: (I) Agree to complete the required human participant research training and update every three years and (II) Agree to follow the direction of the Principal Investigator to adhere to the IRB approved study protocol, institutional policies, and research regulations.

The individual key personnel must complete the response for the COI question below, and then digitally sign this form.

Digital Signatures are required for this form. Open and save form using Adobe or software that allows for digital signature.

Study Title:

Additional Key Personnel/Change Request Form

List and briefly describe the role of all personnel in the study and disclose any potential and/or real financial conflict of interest.

If any response below is "yes," there must be a **"Financial Conflict of Interest Detailed Disclosure Form"** submitted directly to the **Financial Conflict of Interest Committee** **prior** to the time of this submission and then annually or when changes occur.

If any response below is "yes," the **FCOI committee communication** **must be included** with this submission. If this communication is not included, then the key personnel request **cannot** be submitted to the IRB.

	Name	Division/Dept	Research Role	E-Mail Address
a.				
Do you, your spouse or domestic partner, or any of your dependent children have a potential and/or real financial conflict of interest with the sponsor of this project, including all secondary sources? Date Signed & COI Disclosure:				
<input type="checkbox"/> No <input type="checkbox"/> YES—see additional directions above.				
Signature:				
b.				
Do you, your spouse or domestic partner, or any of your dependent children have a potential and/or real financial conflict of interest with the sponsor of this project, including all secondary sources? Date Signed & COI Disclosure:				
<input type="checkbox"/> No <input type="checkbox"/> YES—see additional directions above.				
Signature:				
c.				
Do you, your spouse or domestic partner, or any of your dependent children have a potential and/or real financial conflict of interest with the sponsor of this project, including all secondary sources? Date Signed & COI Disclosure:				
<input type="checkbox"/> No <input type="checkbox"/> YES—see additional directions above.				
Signature:				
d.				
Do you, your spouse or domestic partner, or any of your dependent children have a potential and/or real financial conflict of interest with the sponsor of this project, including all secondary sources? Date Signed & COI Disclosure:				
<input type="checkbox"/> No <input type="checkbox"/> YES—see additional directions above.				
Signature:				
e.				
Do you, your spouse or domestic partner, or any of your dependent children have a potential and/or real financial conflict of interest with the sponsor of this project, including all secondary sources? Date Signed & COI Disclosure:				
<input type="checkbox"/> No <input type="checkbox"/> YES—see additional directions above.				
Signature:				