Directions for Protocol Submission

(do not include this page with your submission)

Behavioral Exempt Protocol Submissions:

If requesting Exempt Review for a Behavioral research study, submit one completed Medical/Behavioral Protocol Summary Form (containing original signatures) the entire descriptive protocol and/or grant application and all instruments (survey tools), a HIPAA Summary Form (if applicable), and two copies of other documentation as appropriate [e.g., informed consent, assent, information sheet(s), HIPAA authorization, and advertisements] to the HIC office. There is no deadline for submission of Behavioral Exempt protocols.

Medical Exempt Protocol Submissions-Do NOT use this form:

If requesting Exempt Review for a Medical research study, submit one completed Medical Exemption Form (containing original signatures), the entire descriptive protocol and/or grant application and all instruments (survey tools), a HIPAA Summary Form (if applicable), and one copy of any other documentation. There is no deadline for submission of Medical Exempt protocols

Medical/Behavioral Expedited Protocol Submissions:

If requesting Expedited Review for a Medical or Behavioral research study, submit one completed Medical/Behavioral Protocol Summary Form (containing original signatures), the entire descriptive protocol and/or grant application and all instruments (survey tools), a HIPAA Summary Form (if applicable), and two copies of other documentation as appropriate [e.g., informed consent, assent, information sheet(s), HIPAA authorization(s), and advertisement(s)] to the HIC office. There is no deadline for submission of Expedited Protocols.

Medical/Behavioral Full Board Protocol Submissions:

If requesting Full Board Review, see the HIC website for submission deadlines.

Submit one copy of the Protocol Submission Checklist, manually checking each box that reflects the item(s) being submitted with this research project. Submit 20 submission packets as follows:

- *3 collated* packets containing the HIC Protocol Summary Form (one copy containing original signatures), the entire descriptive protocol/grant application, investigator's (drug) brochure(s)/package insert(s), HIPAA Summary Form (if applicable) and copies of all other documentation as appropriate [e.g., informed consent, assent, information sheet(s), HIPAA authorization(s), all Instruments (survey tools), and any advertisements or flyers].
- *17 collated* packets containing copies of the Protocol Summary Form, informed consent/assent/information sheet(s), non-standardized instruments (survey tools-e.g., tools developed by the PI or questionnaires/surveys that deal with sensitive subjects such as drug use or sexual practices) and any advertisements or flyers. Other documentation may be included if appropriate.

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HIC Pre-Review Service (for Full Board research proposals):

For information regarding this optional service for pre-review of Full Board research proposals, please go to:
http://www.hic.wayne.edu/hicinfo/IRBPreReviewerAnnounce.doc

NOTE: HIC responses will be forwarded by mail, email or fax to the investigator approximately 7 to 10 working days following review by the HIC/IRB. *The HIC requests that you refrain from contacting the office regarding the status of a protocol before the end of the 10 working days.*

PI Name: William Lyman

Protocol Submission Checklist

☒ Protocol Summary Form
- ☐ Appendix A (International)
- ☐ Appendix B (Internet)
- ☒ Appendix C (Minors)
- ☐ Appendix D (Mentally Disabled/Cognitively Impaired)
- ☐ Appendix E (Prisoners)
- ☐ Appendix F (Drugs/Devices)
- ☐ Appendix G (Radiation)
- ☒ Appendix H (Biological Specimens)

☐ Letter of Support (State how many:)

☐ Coordinating Center Form

☐ Debriefing script

Materials to be distributed to participants or others:
- ☐ Pamphlets, brochures
- ☐ Books
- ☐ Educational/training materials

☐ Other

Letter of Approval from a scientific review committee
- ☐ Protocol Review Monitoring Committee (PRMC)
- ☐ Clinical Investigation Committee (VAMC)
- ☐ Departmental Review Board (Psychiatry)
- ☒ DMC Research Review Authorization (all research at the DMC)
  http://content.dmc.org/ResearchReviewProcess/

Advertisement/Notice/Flyer:
- ☐ Advertisement(s) (state how many)
- ☐ Notice(s)/Flyer(s) (state how many)

Consent/Assent/Information Sheet:
- ☒ Consent(s) (state how many 2)
- ☒ HIPAA Authorization Form included in consent
- ☐ Parental Permission/Research Informed Consent (state how many)
- ☐ Assent(s) (state how many)
- ☐ Information Sheet(s) (state how many)

☒ HIPAA Summary Form
☐ Grant Application/Research Protocol
☐ Investigator Brochure for a drug/device
☐ Package Insert(s) (state how many)

WAYNE STATE UNIVERSITY

Human Investigation Committee
101 East Alexandrine
Detroit, MI 48201
www.hic.wayne.edu
Fax (313) 993-7122
Office (313) 577-1628

Medical/Behavioral Protocol Summary Form

All HIC Submission Forms must be the current form date and typed/computer generated

HIC Protocol Number_____

HIC Use ONLY

Section A: Principal Investigator (PI), Project Title & Endorsements

1.	Name of PI:	William Lyman	Phone:	(313) 7452400	Date:	09/21/2010
	Department:	Pediatrics	Fax:	(313) 7450282		
	Division:	Children's Research Center of MI	E-mail:	wlyman@med.wayne.edu		
	Campus Address:	Children's Hospital of Michigan 3901 Beaubien Detroit, MI 48201	Pager:	313 247 3336		
2.	NOTE: PIs who are **students** or who are **not** WSU faculty or employees of WSU or an affiliated health care institution must provide **home mailing address and phone number** in addition to the above information. (NOTE: If provided, all correspondence from the HIC office will be sent to the home address.)					
	Home Address:		Home Phone:	( )		
3.	Name of Protocol Coordinator:					N/A☒
	Phone:	( )	E-mail:			
4.	Form completed by:	William Lyman	Title:	Principal Investigator		
	Phone:	(313) 7452400	E-mail:	wlyman@med.wayne.edu		
5.	Project Title:	RT-01-M GC/MS methods to determine environmental factors on fetus and newborn				

6.	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 <u>all</u> individuals involved in research design, development, or data evaluation/analysis disclose any potential and/or real financial conflict of interest. This includes all personnel listed in response to Questions #6 and #7. 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 HIC Policy and Procedures Institutional Review Board & Institutional and Individual Financial Conflict of Interest (COI)
7.	All Investigators and other study personnel are required to take the WSU educational training program on the protection of Human Participants @ www.citiprogram.org .

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 at the time of this protocol submission and then annually or when changes occur; if this form is not submitted, the protocol cannot be approved. The form and more information are available at: www.research.wayne.edu/coi. For additional information please contact the Conflict of Interest Coordinator, 5057 Woodward, Suite 6305, Detroit, MI 48202, Fax 313-577-2159, Phone 313-577-9064.

PRINCIPAL INVESTIGATOR:

For students or individuals without a WSU faculty appointment, a WSU faculty supervisor/sponsor or authorized signatory (e.g.; official from DMC, KCI, etc.) is required.

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?

☐ NO ☐ YES

In signing the description of this research project, the PI agrees to accept primary responsibility for the scientific and ethical conduct of the research, as approved by the HIC, and abide by the HIC's policies and procedures. The project cannot begin until the investigator has received documentation of HIC review and final approval.

Signature of Principal Investigator	Title	Date
	Professor of Pediatrics	09/21/2010

FACULTY SUPERVISOR/SPONSOR:

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?

☐ NO ☐ YES

Campus Address:	Phone:	E-mail:

In signing the description of this research project, the faculty supervisor/sponsor certifies that he/she has reviewed the research plan and has approved the scientific and ethical aspects of this research. The faculty supervisor/sponsor will supervise all compliance with the HIC's guidelines.

Signature of WSU Faculty Supervisor/Sponsor	Printed name	Title	Date

DEPARTMENT CHAIR/DEAN OR AUTHORIZED SIGNATORY:

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?

☐ NO ☐ YES

In signing the submission of this research project, the Department Chair, Dean, Institute/Center Director or other authorized signatory certifies that (1) appropriate support will be provided for the research project including adequate facilities and staff, and (2) appropriate scientific and ethical oversight has been and will be provided.

Signature of WSU Dept Chair/Dean or authorized signatory (e.g.; official from DMC. KCI, etc.)	Printed name	Title	Date
	Bonita Stanton, MD	Professor and Chair of Pediatrics	09/21/2010

If PI is a student, or an individual without a WSU faculty appointment, the above signature must be that of the Chair/Dean at WSU or authorized signatory (e.g.; official from DMC, KCI, etc.).

Briefly describe their role in the study and disclose any potential and/or real financial conflict of interest. If a response is "Yes" see previous page for additional information about the "Financial Conflict of Interest Detailed Disclosure Form."

- Study 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, etc.

	Name	Division/Dept	Research Role
a.	Michael Diamond	OB/GYN	Investigator
	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? ☐ No ☐ YES		
	Signature:		
b.	Alan Dombkowski	Pediatrics	Investigator
	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? ☐ No ☐ YES		
	Signature:		
c.	Dawn Bielawski	Pediatrics	Investigator
	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? ☐ No ☐ YES		
	Signature:		
d.	Ronald Thomas	Pediatrics	Biostatistician
	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? ☐ No ☐ YES		
	Signature:		
e.	TBD	Pediatrics	Study Coordinator
	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? ☐ No ☐ YES		
	Signature:		
f.	TBD	Pediatrics	Research Assistant
	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? ☐ No ☐ YES		
	Signature:		
	Additional study personnel list @www.hic.wayne.edu/hicforms/AdditionalStudyPersonnelList.doc		

8.	Check the type of IRB committee review.	☒ Medical	☐ Behavioral
9.	Is this request for Clinical and Translational Science Award (CTSA review)? PI must have HIC Chairman approval for CTSA review.	☒ No	☐ Yes
10.	Is this a Clinical Trial? http://clinicaltrials.gov/ct2/info/about	☒ No	☐ Yes If yes, NIH Registration number
11.	Check the applicable type of review being requested. Include the category for exempt or expedited review. (Check only one) * Guidance on review categories is available at www.hic.wayne.edu/hicsub.html NOTE: For Medical EXEMPT Protocols, please use the Medical Exemption Protocol Form.	☐ Exempt Review * for **Behavioral Research** ONLY (enter category #):	
		☐ Expedited Review * for Behavioral or Medical Research (enter category #):	
		☒ Full Board Review for Behavioral or Medical Research	
12.	State age range of participants' for this proposed research		
	a. Adult Age Range:	18to 45	
	b. Child (<18 years) Age Range:	0to 18 (NOTE: For research outside of Michigan, check local laws for legal definition of a "child.")	
13.	Status of Principal Investigator (Check all that apply)	☒ WSU Faculty ☐ VAMC Staff ☐ DMC Staff ☐ KCI Staff	☐ Resident/Fellow ☐ Graduate ☐ Undergraduate ☐ Other (explain):
14.	Type of Project	☒ Research Proposal ☐ Thesis/Dissertation	☐ Master's Project ☐ Other (describe):

Section B: Narrative Summary

15	Provide a **complete** and **concise** description of the protocol in non-technical language (lay terms). The completed summary should be **1-3 pages** in length, with up to ¾ of a page allowed for the response to each question. If the narrative summary exceeds the allowed page length, an additional page(s) can be added. **Do not 'paste'** text from the full protocol or refer to protocol page numbers. Literature citations should **not** be included in this section. The narrative summary below does not take the place of the full descriptive protocol and/or grant application.

a. Describe the background and rationale for the study:	The goal of this project is to determine if current technology can be used to establish whether exposure of the human fetus to a class of chemicals called phthalates, which are known to negatively affect the endocrine (hormone) system alters male sex hormone gene expression in the newborn. The basis for this research is founded on the evidence that, in animal models and in vitro tests, phthalates, which are found ubiquitously in the environment, can disrupt the endocrine system with specific effects in male neonates. Because there is mounting evidence that the prevalence of undescended testicles and abnormal penile openings are increasing in human males, this research proposal may have significant public health importance. In contrast to males, the question about the effect of phthalates on female development is less clear. Although the prevalence of abnormal early puberty in pre-teen girls is increasing, the potential relationship between this occurrence and fetal or early childhood exposure to phthalates is still to be determined. The potential impact of phthalates on human growth and development also includes its effect on metabolism as there is mounting evidence that these compounds contribute to the childhood obesity epidemic that is afflicting the United States. Phthalates have been detected in medicines, nutritional supplements, emulsifying agents, adhesives, agricultural products, building materials, personal-care products, detergents and packaging. More importantly, phthalates are found in children's toys and alimentation products. Phthalate exposure can be through direct or by indirect routes. Diet is believed to be the most common source, with foods such as milk, butter, and meats being major sources. However, absorption through the skin and via inhalational of low-molecular-weight phthalates may occur because some phthalates are volatile. A recent study reported that the use of infant lotion, infant powder, and infant shampoo were associated with increased infant urine concentrations of phthalate metabolites. Additionally, a 2005 study reported that increased human phthalate exposure during pregnancy resulted in decreased anogenital distance between the scrotum and anus among baby boys. Phthalate metabolites were measured in urine samples collected from pregnant women and their male babies. Boys born to mothers with the highest concentrations of phthalates were 7 times more likely to have shortened anogenital distances.
b. State the goals/aims/ hypothesis for the study:	The research project is designed to determine if a combination of gas chromatography/mass spectrometry (GC/MS) and high-throughput microarray gene technology can be used efficiently in the National Children's Study (NCS) to analyze the potential effect of phthalate on fetal and newborn male gene expression.
c. List inclusion criteria:	Pregnant women who consent to this study and deliver their newborn boys at Hutzel Hospital. We will determine which woman will deliver a boy by a chart review in which there is a prenatal ultrasound that documents the sex of the fetus.
d. List exclusion criteria:	Women who have had a previous baby with severe endocrine abnormalities.
e. Describe the methods/ procedures of the study:	After the women consent to the study, we will collect a sample of their urine and that of the baby before it leaves the hospital. We will also collect the foreskin after circumscion and photocopy the baby's handprint.

Section C: Research Project Characteristics

16	Check the applicable type of submission	☒ Initial Submission ☐ HIC requested Resubmission	☐ Resubmission of expired study If applicable provide HIC #
17	Funds for this project are being provided by or requested from: *Must answer question #18	☐ Private/Pharmaceutical* ☐ Industry* ☒ Governmental agency* ☐ Foundation* ☐ Non-Profit Organization*	☐ WSU Institute* ☐ Drug/Device Provider* ☐ Departmental (WSU/DMC/VAMC) ☐ None ☐ Other (describe):
18	Sponsor(s): *FOR WSU Must match FES Form*	1. Prime: National Institute of Child Health and Human Development Subcontract from: Michigan State University) 2.	☐ N/A
	Contact Name:	Katherine Cook	
	Address:	301 Administration Building, MSU, E Lansing, MI 48824	
	Phone:	517 355 5040, ext 237	
	Grant Number:	HHS275200800007C	
	SPA Proposal Number from FES Form (eight digit number)	00002509	
	If there are more than one funding source please list the Sponsor who is supplying the funds first		
19	Status of Funds:	☒ Approved ☐ Pending	☐ N/A
20	Check **all** applicable performance sites where this research will be conducted. It is essential that this information is accurate. All human research conducted at DMC, KCI or VAMC sites require authorization through their institutional review process in addition to HIC approval.	☐ Wayne State University: site ☐ University Physician Group (UPG): site ☐ Kresge Eye Institute Outpatient Care Detroit Medical Center Hospital or Institute: ☒ Children's Hospital of Michigan ☐ Detroit Receiving Hospital/University Health Center ☐ Harper University Hospital ☐ Huron Valley/Sinai Hospital ☒ Hutzel Women's Hospital ☐ Kresge Eye Institute Operating Room ☐ Michigan Orthopedic Specialty Surgery Hospital ☐ Rehabilitation Institute of Michigan ☐ Sinai-Grace Hospital ☐ Barbara Ann Karmanos Cancer Institute ☐ John D. Dingell Veterans Administration Medical Ctr. ☐ Other:	☐ N/A

Section C: Research Project Characteristics

21	Provide the names of all other locations where the WSU PI will perform this research (e.g., non-UPG outpatient clinic, unaffiliated hospital(s) [e.g. other cancer centers, Henry Ford Hospital, St. Johns, etc.] school, home, church, community center, etc.). ➢ Attach a letter of support and/or IRB approval if the research is being done (1) outside of the PI's department or WSU/DMC/Practice Plans, and/or (2) at a location not affiliated with WSU.		☒ N/A
	a. Are any of the facilities/locations listed in the response to Q#21outside of the United States?	☐ No	☐ Yes If checked, complete Appendix A and complete the optional CITI module for International Research, if not already complete.
NOTE: An approval letter must accompany research from facilities that require scientific review prior to submission to the HIC. Scientific review committees are in place to review all research being conducted at or from researchers from (1) the Veterans Administration Medical Center (Clinical Investigation Committee), (2) the Department of Psychiatry and Behavioral Neuroscience (Departmental Review Board), (3) the Karmanos Cancer Institute (Protocol Review Committee) for review of all cancer-related research, and (4) Detroit Medical Center (Research Review Authorization).			
22	Is this a multicenter study or clinical trial (i.e., more than one investigator at different sites, drug company study, cooperative group, etc.)?	☒ No	☐ Yes ☐ N/A
	a. IF YES, IS WSU the Coordinating Center for this study?	☐ No	☐ Yes If yes, complete the Coordinating Center Form, available on the HIC website, and include with this application.
23	Is the local PI conducting research outside of Michigan?	☒ No (GO TO QUESTION #24)	☐ Yes
	If yes: Does the research include adults unable to consent as participants?	☐ No	☐ Yes If yes, complete Appendix D
	Does the research include children as participants?	☐ No	☐ Yes If yes, complete Appendix C and complete the optional CITI module for Research with Children/Minors if not already complete.
24	FOR MEDICAL RESEARCH ONLY - Is this is a treatment/intervention study?	☒ No	☐ Yes ☐ N/A

Section C: Research Project Characteristics

	a. If Yes, describe your plan to protect and monitor the study data to ensure safety of the participants (e.g., Data Safety Monitoring Board, safety committee, PI oversight, etc.) See HIC Policy/Procedure: Data Safety Monitoring Board		
	b. Provide the name of the board, if applicable, and its contact information		☐ N/A

Section D: Data Collection

25	What is the approximate number of participants/ documents / specimens to be enrolled /collected?	At WSU/DMC	800	At non-WSU/DMC (e.g., multicenter sites)		
26	Prospective Data Collection Methods (Check all that apply): * If using medical records from the DMC/practice plans or a database created from medical records from the DMC/practice plans, complete a HIPAA Summary Form. FOR SOCIAL/BEHAVIORAL RESEARCH ONLY- COMPLETE THE "HIPS" MODULE FOR THE CITI TRAINING. ** Provide a copy of each data collection instrument and/or interview script with this submission. *** Audiotapes and/or videotapes can be a significant risk to the participant's confidentiality. Consequently, such materials should be destroyed at the end of the study unless specified in the consent form and the participant has given explicit permission for their retention. ****All human research conducted at DMC sites requires DMC Research Review Authorization including the use of medical records, specimens, imaging, etc.. http://content.dmc.org/ResearchReviewProcess/	☒ Medical Records/Database*,**** Site: ☒ Specimens**** Site: Hutzel Hospital ☐ Non-Medical Documents/Records/Database ☐ Observation of participants (i.e. their behavior) ☐ Questionnaire/Survey** ☐ Diaries** ☐ Interview** ☐ Psychological testing ** ☐ Educational testing/evaluations** ☐ Focus groups** ☐ Audio/video taping *** ☐ Internet If checked, complete Appendix B and complete the optional CITI module for Internet Research if not already complete. ☐ Imaging**** Site: ☐ Other (describe):				☐ N/A

#	Section D: Data Collection		
27	Retrospective data sources (Check all that apply) * If using medical records from the VAMC/DMC/practice plans or a database created from medical records from the VAMC/DMC/practice plans, complete a HIPAA Summary Form. FOR SOCIAL/BEHAVIORAL RESEARCH ONLY- COMPLETE THE "HIPS" MODULE FOR THE CITI TRAINING. **All human research conducted at DMC sites requires DMC Research Review Authorization including the use of medical records, specimens, imaging, etc.. http://content.dmc.org/ResearchReviewProcess/ *** Provide a copy of each data collection instrument with this submission.	☐ Archival data**, *** Site: ☐ Specimen repository**, *** Site: ☐ Database*,**, *** Site: ☐ Medical records/Database*, *** Site: ☐ Non-Medical Documents/Records/Database*** ☐ Internet If checked, complete Appendix B and complete the optional CITI module for Internet Research if not already complete. ☐ Imaging** Site: ☐ Other (describe):	☒ N/A
28	Identify any material(s) to be distributed to participants or others. ➢ Provide a copy of each.	☐ Pamphlets, brochures ☐ Educational Materials (e.g., curriculum) ☐ Training Materials ☐ Other (describe): Consent form	☒ N/A
29	Over what period of time will each participant spend doing research-related activities?		☒ N/A
	a. State total number of visits	1	
	b. State length of each visit	Less than 60 minutes	
	c. State the total expected duration (including long-term follow-up) for each participant's involvement? (e.g., three 15 minute visits, two 10 minute visits for a total of 65 minutes over 2 months)	One visit only	
30	Will deception or experimental manipulation be used without the participant's knowledge?	☒ No ☐ Yes	☐ N/A
	a. If Yes, explain why deception is necessary, and		
	b. describe the debriefing plan and attach a debriefing script.		

#	Section D: Data Collection			
31	Will a "control" group (e.g., normal healthy volunteer, participants with an absence of the condition under study, participants who are receiving standard of care, placebo or no intervention, etc.) be used in the study?	☒ No	☐ Yes	☐ N/A
	a. If yes, explain what is meant by "control"? See the HIC Policy/Procedure: "Vulnerable Participants: Normal Volunteers"			
32	Indicate if any of the below apply to this research study : (Check all that apply)			
	a. Pregnant women are excluded See the HIC Policy/Procedure: "Inclusion of Pregnant Women in Research"	☒ No	☐ Yes	☐ N/A
	➢ If Yes, provide scientific justification			
	b. Research participants are selected based on racial/ethnic criteria See the HIC Policy/Procedure: " Inclusion of Women and Minorities in Research"	☒ No	☐ Yes	☐ N/A
	➢ If Yes, provide justification			
	c. Research participants are selected based on gender. See the HIC Policy/Procedure: "Inclusion of Women and Minorities in Research"	☐ No	☒ Yes	☐ N/A
	➢ If Yes, provide justification	Study requires pregnant women and male newborns		
33	Indicate if the research involves participants likely to be vulnerable to coercion or undue influence. (Check ALL that apply) See the HIC policies/procedures on vulnerable participants Complete the CITI module for the specific	☒ Pregnant Women, Fetus(es), Neonates (birth to 4 weeks) * If checked for neonates, complete Appendix C and complete the optional CITI module for Research Involving Pregnant Women and Fetuses in Utero and/or Research involving Children/Minors if not already complete.		☐ N/A

#	Section D: Data Collection		
	vulnerable group (www.citiprogram.org) * Not required for chart reviews. **Prisoners are defined as individuals (children or adults) who are being held in a jail, prison, or treatment facility or who have been convicted or are awaiting arraignment, trial, or sentencing. This includes those who are in hospitals, alcohol and drug treatment facilities under court order and children in detention facilities as an alternative to prison.	☒ Children (under 18 years of age) *If checked, please complete Appendix C and complete the optional CITI module "Research involving Children/Minors" if not already complete. If students are involved complete the optional CITI modules "Students in Research-SBR" and if applicable, "Research in Public Elementary & Secondary Schools-SBR" if not already complete. ☐ Mentally disabled/cognitively impaired adults who are unable to give consent *If checked, please complete Appendix D ☐ Prisoners **If checked, please complete Appendix E and complete the optional CITI module for Research with Prisoners if not already complete. ☐ Non-consenting participants, in emergency situations ☐ Terminally ill ☐ Other – explain	
34	Provide specific justification for inclusion of any vulnerable participants identified in the previous question.	Need to address both prgnant women and male infants	☐ N/A
35	Are students and/or employees of WSU/DMC/VAMC the target population to be enrolled in this protocol? See the HIC policy/procedures: "Vulnerable Participants: Students, Trainees and Employees" If students are involved complete the optional CITI modules "Students in Research-SBR" and if applicable, "Research in Public Elementary & Secondary Schools-SBR" if not already complete.	☒ No ☐ Yes	☐ N/A
	a. If Yes, describe how the PI and/or recruiters will avoid potential coercion of students/employees		

Section D: Data Collection

36	How will participants be recruited? (Check all that apply) For Recruitment guidance, see HIC policy/procedures: "Recruitment of Research Participants," "Advertising for Research Participants," and "Finder's Fee." For VA Studies: recruitment of non-Veterans is allowed only when there are insufficient Veterans available to complete the study.	☒ Direct person-to-person solicitation ☒ Clinician/Nurse ☒ Co-Investigator/Collaborator ☒ Primary Care Provider ☐ Principal Investigator ☐ Research Nurse ☐ Research Assistant ☐ Resident/Fellow ☐ Student/Student Assistant ☐ Psychology Student Pool ☐ WSU Pipeline If checked, complete Appendix B and complete the optional CITI module for Internet Research if not already complete. ☐ Internet If checked, complete Appendix B and complete the optional CITI module for Internet Research if not already complete. ☐ Other (specify): ☐ Advertisement (state posting location and attach verbatim copies) ☐ Notice/flyer (state posting location and attach verbatim copies)	☐ N/A
37	Provide a narrative description of the recruitment procedures and informed consent process including measures to protect personal privacy.		☐ N/A
	a. Describe recruitment procedures For behavioral research: note that teachers, service providers, or supervisors cannot recruit their own students, clients, employees, etc. Verify that the study introduction will include: (1) the study involves research, (2) the topic of research, (3) the time commitment required, (4) the basic procedures (e.g., interview, survey, observation, etc.) and (5) study participation is voluntary.	Dr. Diamond will review the medical record of women who arrive in the Labor and Delivery service at Hutzel to give birth. He will determine if the sex of their fetus is known. For those women who will give birth to a male baby, Dr. Diamond will approach them and tell them that we are conducting a research study which is examining the potential for environmental factors to negatively affect their male babies. Dr. Diamond will then ask if they are willing to hear about the study.	

Section D: Data Collection

	b. Describe the informed consent **process** including measures to protect personal privacy. (Note: Consent process begins when a potential research participant is initially contacted.)	Women who have agreed to hear about the study will be asked at the end of this presentation if they and their male babies would like to potentially participate. If they say yes, the approved informed consent will be given to them and they will be asked to read it, have it read to them or translated, if needed. After all of their questions about the study and related issues are answered, they will be asked to sign the informed consent document.	☐ N/A
	c. If HIPAA applies (research that will be accessing medical records): state who will **introduce** the study to participants **and** specify their clinical relationship, if any, to the participants (i.e., employer, teacher, service provider, etc.)	Dr. Diamond	☐ N/A
	d. Describe any safeguards in place for PI and/or recruiters to protect participants likely to be vulnerable to coercion or undue influence.	Potential participants can refuse to be in the study Participants can withdraw from the study at any time (until unmarked foreskin and urine are matched - no patient identifiers will be recorded - and transported to the study laboratory) There will be no loss of privacy	

Section E: Consent of Research Participants

38	Identify the personnel who will be responsible for **obtaining informed consent** of the participants. (Check all that apply). NOTE: These individuals **must** be among those identified as "key personnel" in question #7.	☐ Principal Investigator ☒ Co-Investigator/Collaborator ☐ Research Nurse ☐ Research Assistant ☐ Resident/Fellow		☐ N/A
		☐ Other (specify):		
39	Will more than one consent document (consent, assent, parental permission form, information sheet) be used?	☒ No	☐ Yes	☐ N/A
	If Yes, in total how many will be used?			
40	Select the type of Consent/Assent that will be used (check all that apply). NOTE: Attach copies of <u>all</u> consents / assents / information sheets / oral scripts that will be used.			☐ N/A
	a. **Written** Consent/Parental Permission:	☒ Adult participants ☒ Parents or guardians		

Section E: Consent of Research Participants

	b. Assent for children	☐ Written (age 13-17) ☐ Oral (age 7-12) ☐ Information Sheet (age 13-17)		
	c. Internet Information Sheet	☐ Adult participants ☐ Parents or guardians If either is checked, complete Appendix B and complete the optional CITI module for Internet Research if not already complete.		
	d. Information Sheet (indicate who it will be given to):	☐ Adult participants ☐ Parents or guardians		
	i. State rationale for use of an Information Sheet rather than a Written Consent.			
	e. Oral informed consent using a script that will be read to potential participants:	☐ Adult participants ☐ Parents or guardians		
	i. State rationale for use of an Oral rather than Written Consent.			
	ii. Describe how oral consent will be documented.			
41	Will a Non-English consent/assent/information sheet be used? NOTE: Refer to the HIC Policy: "Informed Consent Involving Non-English Speaking Participants."	☒ No	☐ Yes	☐ N/A
	If Yes, specify language(s)			
42	FOR MEDICAL RESEARCH ONLY: Is a waiver of consent for emergency situations being requested? See HIC policy available at http://www.hic.wayne.edu/HRPP_Manual/11-6_Planned_Emergency_Research.pdf	☒ No	☐ Yes	☐ N/A
	If Yes, explain the rationale for waiver of consent in emergency situations, and			
	describe the consent process.			
43	Is a waiver of consent for other reasons (e.g., chart review, database analysis) being requested? See federal regulations 45 CFR 46.116(d) and 46.408(c) available at www.hic.wayne.edu/hicreg.html	☒ No	☐ Yes	☐ N/A
	If Yes:			
	a. Is the risk more than minimal?	☐ No ☐ Yes		
	b. Will the waiver adversely affect the rights and welfare of the research participants?	☐ No ☐ Yes		

Section E: Consent of Research Participants

	c. Can the research be practicably carried out without the waiver?	☐ No ☐ Yes	
	d. Will the participants be provided with additional pertinent information after participation, **if appropriate**?	☐ No ☐ Yes	☐ N/A
	e. Provide protocol-specific justification for requesting a waiver of consent.		
	f. Are you requesting a waiver of the requirement to obtain written documentation of the consent process? (Consent will be obtained, but there will be no signed form documenting consent) i. If yes, provide a written description of the information to be provided orally to subjects.	☒ No ☐ Yes	

Section F: Confidentiality

44	How will the research participants/documents/ specimens be identified on case report forms, questionnaires, survey tools, field notes, data collection tools, etc.? NOTE: Social Security numbers, medical record numbers, employee numbers, or school identification numbers can be directly linked to individuals and must NOT be used as a code number.	☐ No identifier (i.e., no one can identify a participant/document/specimen from the information recorded) Go to Q #45 ☐ Coded Identifier (i.e., a code name/number that could be used to identify a participant/documents/specimens) Must answer questions a-e	
		☒ Other (describe):	Each paired set of samples (maternal and newborn urine plus the foreskin and handprint) will received a unique identifier that are matched and recorded for this sample set. However, this sample set will not be linked to any hospital record or other source that could link it to a particular patient. Hence, these samples will all be anonymous.
	Is there a list that contains information that can link the code name/number to a specific participant / document / specimen?	☒ No	☐ Yes
	If Yes:		

Section F: Confidentiality

	a. what is the media format of the list (e.g., paper, electronic, etc.)			
	b. Where will the list be kept?			
	c. State who will have access to the list and for what purpose.			
	d. Describe the provisions for maintaining confidentiality, including the storage of the participants' identifiers (i.e., master list) and data (e.g., audio and video tapes).			
	e. Describe the plans for eventual disposal of the participants' identifiers (i.e. master list) and data.			
45	Where will the original signed informed consent(s)/assent(s) be kept? NOTE: Signed consent documents cannot be stored with the master list.			☐ N/A
	a. State location	PI's office		
	b. State provisions for confidentiality	The file cabinet will be locked at all times		
46	Who, other than study personnel (at DMC, KCI,VA) , WSU Human Investigation Committee, Food and Drug Administration [FDA], Office for Human Research Protections [OHRP], and/or Office of Civil Rights [OCR] will have access to the research data? (CHECK ALL THAT APPLY)	☒ Sponsor ☐ National Cancer Institute ☐ Cooperative group		☐ N/A
	☐ Other (Explain):			
47	Could any part of this research activity result in the potential identification of:			
	a. Child/elder abuse	☒ No	☐ Yes*	☐ N/A
	b. Reportable communicable diseases (please refer to http://www.michigan.gov/documents/Reportable_Disease_Chart_2005_122678_7.pdf	☒ No	☐ Yes*	☐ N/A
	c. Criminal activities	☒ No	☐ Yes*	☐ N/A
	*IF "YES", THIS MUST BE NOTED IN THE RISK SECTION OF THE CONSENT DOCUMENTS NOTE: For information on obtaining a Certificate of Confidentiality, refer to: http://grants.nih.gov/grants/policy/coc/index.htm			

Section G: Benefits and Risks to Research Participants

Section G: Benefits and Risks to Research Participants

48	Describe the benefits, if any, to the research participants for involvement in this project.* (*NOTE: Financial compensation or free testing, in any form, is not a "benefit.")		☒ N/A
49	Describe the benefits to society (if any) that may result from participation in this research project.	Evidence that a ubiquitous envirnomental factor is associated with a potentially important change in a gene associated with sexual development.	☐ N/A
50	Describe the nature and degree of potential risks to research participants in lay terms. Include all risks identified in the protocol and/or Investigator's Brochure. Do not cut and paste from the consent form. See Glossary under "risk" on the HIC website for a description of the different types of risk.		
	a. Physical*		☒ N/A
	b. Psychological*		☒ N/A
	c. Social*		☒ N/A
	d. Economic*		☒ N/A
	e. Legal*		☒ N/A
	* NOTE: ALL THE ABOVE IDENTIFIED RISKS AND BENEFITS ARE TO BE LISTED IN THE INFORMED CONSENT		
51	What precautions will be taken to minimize each of the risks described above?		☒ N/A

Section H: Study Design

52	Does this study provide compensation for research participants? (HIC policy available at www.hic.wayne.edu/hicpol/compens.htm)	☒ No	☐ Yes	☐ N/A
	a. If Yes, describe the type and total amount of compensation and			
	b. Specify the amount and milestone for each payment:			
53	Will the research participants incur any additional expenses for experimental or protocol specific diagnostic tests or procedures?	☒ No	☐ Yes	☐ N/A
	a. If Yes, explain.			
54	FOR MEDICAL RESEARCH ONLY: Will any marketed drugs, experimental/investigational drugs, chemotherapeutic drugs, biological products, recombinant DNA (plasmid or non-plasmid), infectious agents, diagnostic agents or medical devices be used?	☒ No	☐ Yes (Complete Appendix F)	☐ N/A

#	Section H: Study Design			
55	Will research participants be exposed to imaging, MRI's, PET Scans or diagnostic radiation (e.g., x-rays, CT scans, etc.)?	☒ No	☐ Yes (Complete Appendix G)	☐ N/A
56.	Will **biological specimens** (e.g., blood, urine, tissue, organs, cell lines, fetal tissue, etc.) **or standard of care laboratory results** be used as part of this study? Refer to HIC policy on research studies involving biological specimens available at www.hic.wayne.edu/hicpol/specim.htm	☐ No	☒ Yes (Complete Appendix H)	☐ N/A
57	Is a specimen repository bank being established?	☐ No	☒ Yes (Complete Appendix H)	☐ N/A