

The Study of Environment, Lifestyle & Fibroids (SELF)

[SELF Study Page](#) (NIEHS)

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INVESTIGATORS

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OVERVIEW

The Study of Environment Lifestyle & Fibroids (SELF) is the first truly prospective epidemiologic study of fibroid incidence. African Americans, aged 23-35 who had never been clinically diagnosed with fibroids (N = 1693), enrolled in the study between 2010 and 2012. The 5-year follow-up with study visits about every 20 months concluded in June 2018 with a 91% retention rate for the final visit. In cooperation with the Henry Ford Health (HFH), multiple recruitment strategies were used to reach eligible participants residing in the Detroit, Michigan area. Each study visit included collection of questionnaire data, blood, anthropometrics, vaginal swabs and a pelvic ultrasound to identify and measure fibroids. Although participants did not have a previous diagnosis of fibroids at enrollment, 23% had prevalent fibroids detected at the first ultrasound. In addition to identifying new fibroid cases among those who were fibroid free at enrollment, fibroids identified at enrollment and during the study were followed for growth. At the conclusion of the fourth visit in 2018, 32% of the cohort had fibroids and growth metrics were available for fibroids that could be matched from one visit to the next in 434 participants.

The original hypotheses for SELF were:

1. Vitamin D insufficiency is a risk factor for fibroids.
2. Reproductive tract infections are associated with increased fibroid risk.
3. African ancestry, as assessed by genome-wide single nucleotide polymorphisms, can influence fibroid risk directly or by interacting with other risk factors.

Following the completion of the fourth study visit in 2018, two additional follow-ups were supported through partnerships with extramural collaborators and supported by external funding: 2018-2023 R01ES028235, Wegienka HFH; 2025-current R56ES028235, Wegienka HFH. Continued follow-up has allowed expanded research aims including:

4. Assess age-specific fibroid incidence from ages 25-49 years
5. Assess rate of change in fibroid burden
6. Examine association between fibroid number/volume and symptoms
7. Vitamin D deficiency is associated with increased fibroid growth.
8. Reproductive tract infections are associated with increased fibroid growth
9. Describe the possible determinants and sequelae of fibroids including subfertility, sleep health, chronotype and chronic disease.

SELF collects a broad spectrum of information including data on recognized risk factors for fibroids (e.g., early age of menarche, nulliparity), data on common exposures with inconsistent risk estimates in the literature (e.g., body mass index, exercise, and oral contraceptive use), exposures of interest for which there is very limited literature (e.g., diet, environmental exposures including cosmetics, and early-life exposures including childhood trauma), possible underlying biological pathways (e.g., inflammation/C-reactive protein, hormone levels, hemoglobin/iron status, and genetics), and detailed symptom data, especially menstrual bleeding. To better assess environmental exposures (e.g., air pollution, industrial contaminant sources, and possible geographically based social determinants of health) we geo-coded the participant addresses. Additional environmental exposure variables include blood or urinary concentrations of non-persistent and persistent endocrine disruptors measured in the biospecimens collected from participants. Stored biospecimens will be used to study exposures or conditions other than those anticipated at the design phase.

Current SELF co-PIs Drs. Chandra Jackson and Anne Marie Jukic have added additional questionnaire modules to the current visit reflecting their scientific programs. Dr. Jackson added in the Munich Chronotype Questionnaire which captures chronotype (individual preferences in sleep-wake rhythms). Dr. Jukic added questions capturing data on lifetime experiences with infertility and use of clinical fertility care, including experiences with wanting clinical help getting pregnant and experiencing barriers to accessing care. We are currently developing a module to capture time to pregnancy for pregnancies in the SELF cohort since enrollment.

This long-lasting cohort will yield an unparalleled and rich data source to analyze the impact of environmental and lifestyle exposures on fibroid development, as well as a better understanding of other health outcomes in an understudied group.

SELF Leadership

Dr. Donna Baird (NIEHS) initiated the Study of Environment, Lifestyle & Fibroids (SELF) in 2010 and led the study as PI until her retirement at the end of 2023. Although Dr. Baird continues to be involved in SELF as an emeritus researcher, Drs Chandra Jackson and Anne Marie Jukic became SELF co-PIs at the start of 2024. Dr. Quaker Harmon was the SELF staff scientist with Dr. Baird and continues in this role under Drs. Jukic and Jackson. As SELF has expanded in scope and use by extramural researchers, an Executive Committee (EC) was established in 2024 to meet monthly and evaluate newly proposed research projects and track all on-going research. The

SELF EC includes Drs. Jackson, Jukic, Harmon, Baird (ex-officio) from NIEHS, Dr. Wise (Boston University), and Dr. Wegienka (Henry Ford Health).

Background and Rationale for SELF

Uterine leiomyomata (fibroids) are the leading indication for hysterectomy in the United States. The direct medical costs exceed \$2 billion per year, not including indirect costs for managing the symptoms of bleeding, pain, urinary incontinence, and reproductive dysfunction. Fibroids are non-cancerous tumors of smooth muscle that develop during reproductive years and tend to regress after menopause. Estrogen and progesterone both increase proliferation of tumor tissue *in vitro*, and hormonal responsiveness is confirmed by *in vivo* data. Though hormonally dependent, the etiologic pathways are not understood. Compared to U.S. whites, African Americans are at significantly higher risk, with onset approximately 10 years earlier. An estimated 20% of African American women have a hysterectomy for fibroids before menopause, nearly three times the proportion in white women. The reasons for marked ethnic differences are unknown. Epidemiologic studies of uterine fibroids have been limited. Most of the early work focused on patients who required surgery or used clinical diagnosis of fibroids as the outcome. Thus, the associations found in such studies could have arisen because the factors studied were associated with tolerance of symptoms, access to care, or attitudes toward surgery, rather than fibroid incidence or development. In addition, studies of clinically diagnosed fibroids, which may have been present for years, are not able to fully address the temporality of exposures. Finally, 'non-cases' in studies without ultrasound screening will include those with fibroids that have not yet come to clinical attention. SELF was designed to address these methodological issues by enrolling young women and following them prospectively with regular ultrasound screening to detect incident fibroids and assess the growth of fibroids.

Given the high tumor burden and early age of fibroid onset, SELF was designed to enroll only participants who self-identified as African American or Black, ages 23-35. Inclusion of a non-African American sample would have required recruitment of older non-African American participants to capture incident fibroids. The differences in age between racial/ethnic groups would result in differential recall due to older age in non-African Americans and would require stratified analyses which would impact sample size requirements. The enrollment of only African Americans allowed for an efficient study design focused on the group who have the highest burden of disease. In addition, as a community-based cohort of young African American or Black women with relatively few exclusion criteria, SELF is a resource for studying many other exposure-outcome associations in a population which has historically been understudied.

Recruitment and Enrollment

Inclusion and exclusion criteria for SELF are shown in Figure 1. Recruitment was completed in collaboration with the Henry Ford Health System (HFHS) in Detroit, Michigan area. Recruitment methods were designed to saturate the metropolitan area with information about the study and included: (1) direct mail to HFHS patients, (2) newsletter announcements and emails to groups such as HFHS employees, city and county government employees, and educational centers (e.g., colleges and technical training schools), (3) community flyers, posters, and information booths at clinics and community events, and (4) radio and television announcements.

Inclusion criteria

- Age 23-34 years at time of recruitment
- Self-identify as African American, Black, or partly African American
- Intact uterus (i.e., no previous hysterectomy)
- Residence in the United States
- Ability to attend clinic visits in Detroit, MI
- Stated commitment to remain in the study for 5 years
- Willing to provide contact information for tracing (contact information for 3 persons who could be asked about their whereabouts, or their social security number and contact information for 1 person who would know their whereabouts)

Exclusion criteria

- Any prior diagnosis of fibroids
- Any prior diagnosis of cancer that required radiation or chemotherapy
- Any prior diagnosis of lupus, Grave's disease, Sjogren's, scleroderma, or multiple sclerosis that required medication

Delayed entry

- Any woman who was pregnant at recruitment had enrollment delayed until 3-4 months after the pregnancy ended to assure accurate ultrasound assessment of fibroids

Figure 1. Inclusion and exclusion criteria for Study of Environment, Lifestyle & Fibroids. Detroit, Michigan 2010-2012

The enrollment process was designed to select for women motivated and able to continue in a long-term study. Women had to initiate the enrollment process (i.e., women who heard about the study and were interested in learning more about it emailed or phoned the study contacts). Full enrollment required several steps: (1) a telephone eligibility screening, (2) completion of orientation—a detailed 30–60-minute description of the study procedures that could be done one-on-one by phone or as a group activity at HFH, (3) completion of a self-administered “Pre-enrollment Questionnaire”, (4) provision of contact information for themselves and information to facilitate tracing if they could not be located, (5) signing the informed consent document, (6) scheduling and completing all clinic visit activities, both the telephone interview and computer assisted questionnaire (usually done before the clinic visit). Monetary compensation was provided at the end of the clinic visit when enrollment activities were complete. During the enrollment period 3200 women were screened and 89% were found to be eligible for the study. Though nearly all those eligible initially agreed to participate, many did not attend an orientation or complete all enrollment activities. Final enrollment was 1693 (53% of those screened).

Follow-up visits were scheduled at approximately 20-month intervals through the 4th visit. A fifth visit was completed in 2023. A sixth visit began in January 2025. Visits were delayed until 3-4 months post-partum if participants were pregnant. Participants who missed one or more visits were invited to attend later visits. Retention in the study is high. Of the original cohort, 81% of the original cohort attended visit 5, 8-10 years after study initiation (Figure 2).

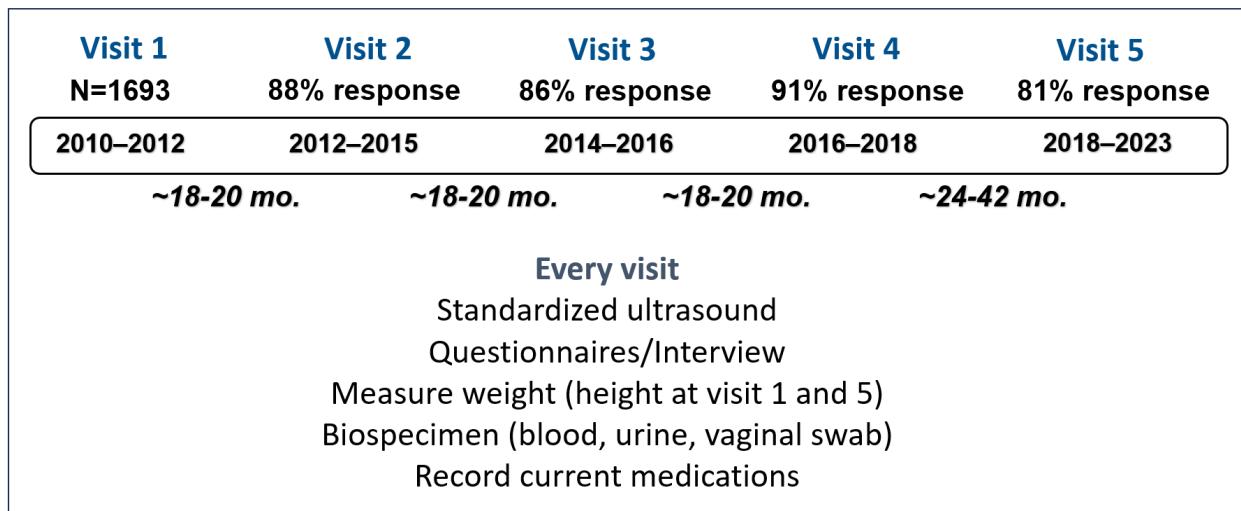


Figure 2. Study design and retention for the Study of Environment, Lifestyle & Fibroids. Detroit, Michigan 2010-2023

Study Population

At enrollment participants were evenly distributed across the recruitment age range of 23-34, though a few had turned 35 by actual enrollment, 78% had at least some college education, 62% were employed and, in keeping with the economic environment of Detroit, 45% had a household income below \$20,000. Almost a quarter (24%) had a BMI $\geq 40 \text{ kg/m}^2$ (Table 1).

Table 1 Baseline characteristics SELF cohort (N=1693) Detroit, Michigan 2010-2012

Characteristic		No. (%)
Age (Years)	23-25	378 (22)
	26-28	423 (25)
	29-31	459 (27)
	32-35	433 (26)
Highest Education	High School/GED or Less	369 (22)
	Some College/Associates/Technical	848 (50)
	Bachelors/Masters/PhD	475 (28)
Yearly Household Income	<\$20,000	766 (45)
	\$20-50,000	628 (37)
	\$50,000+	287 (17)
Employment Status	On leave	3 (0)
	Unemployed	640 (38)
	Employed	1050 (62)
Body Mass Index (kg/m ²)	Healthy Weight (<25)	335 (20)
	Overweight (25 to <30)	350 (21)
	Obese Class I (30 to <35)	328 (19)
	Obese Class II (35 to <40)	279 (16)
	Obese Class III (40 and above)	401 (24)
Age at Menarche	Before Age 11	310 (18)
	Age 11	334 (20)
	Age 12	458 (27)
	Age 13	286 (17)
	After Age 13	305 (18)
Gravidity/ Parity	Never Pregnant	451 (27)
	0 Births	206 (12)
	1-2 Births	744 (44)
	3+ Births	292 (17)

Abbreviations: GED General Education Diploma. Missing: Education (N=1), Income (N=12)

Data Collection

Questionnaires

The first four SELF visits included a computer-assisted telephone interview, a computer assisted questionnaire completed on computer or phone, and hard-copy questionnaires. The interview and questionnaires were to be completed before the visit, if possible. Visit five and six have similar data collected through a REDCap questionnaire available to the participants via computer or phone prior to their clinic visit.

Computer-assisted telephone interview (CATI) The following topics were queried at every visit: occupation, physical activity, contraception history, detailed pregnancy history, menstrual history and cycle characteristics, medical history, time spent outside. Questions on use of specific medication were added for follow-up visits. In addition, residential history was asked once during follow-up. For visit 4, the section on time outside was modified: most time-outside questions were cut, and questions on vitamin D testing, treatment for low D, and use of D supplement were added. An additional module on exposure to polycyclic aromatic hydrocarbons was also added for visit 4 and 5.

Computer assisted web-based questionnaire (CAWI) The following topics were queried at every visit: gynecologic health, history of reproductive tract infections, sleep, body weight and weight changes, stress, views and perceptions of racism, alcohol and cigarette use, and income. The enrollment CAWI also included questions on early life experiences and exposures, as well as history of occupational exposures. All follow-up visits included added questions on use of tobacco products in addition to cigarettes, use of selected supplements and diet. In addition, the following modules were asked once between visit 2 and 4 (depending on which visit participant attended first after baseline), and then again at visit 5: quality of life, a more extensive list of supplements, well-being (including depression screening), exposure to household and personal care products, and trauma in childhood (only asked once) and adulthood.

Post-visit menstrual diary (hard copy) This instrument was provided to participants at each clinic visit to be completed at home and returned by mail (visits 1-4), or through a REDCap questionnaire (visit 5). It was designed for women to prospectively record daily information about their first post-visit menstrual period (date of menses onset, bleeding amount, and menstrual symptoms). For visits 1-4, participants who failed to return the form, were contacted by phone (when possible) to collect a subset of the questions.

Additional one-time baseline questionnaires

Pre-enrollment questionnaire (hard copy) This instrument included screening questions for study eligibility, family history of fibroids, ease of access to health care, past medical history, and physical activity in past 7 days.

Computer-assisted food frequency questionnaire (FFQ) This was a validated web-based semi-quantitative Block FFQ covering average intake in the previous 12 months.

Early life questionnaire (hard copy) This questionnaire was formatted in two ways with the same questions. Participants who reported being able to speak with their mothers (90%) were given the questions in an interview format so that the questions could be systematically asked of their mothers. The remaining participants were instructed to get help in answering from relatives and family friends who were present during their childhood. Topics queried were *in utero*

exposures, infant exposures, childhood sleep and physical activity. This was distributed at enrollment but could be returned at any time through visit 4.

Additional questionnaires completed at a single visit between visit 2-4 (hardcopy) or at visit 5 (REDCap module)

Body hair and acne This module includes an assessment of hirsutism using pictures (modified Ferriman-Gallwey assessment), a question on concern about excess body hair, and questions and pictorial assessment about acne.

Medical conditions and treatments This questionnaire, administered at visit 4 and 5, queried medical condition history to add data on conditions not previously asked.

Menstrual bleeding, premenstrual symptoms pelvic pain, non-menstrual pain This questionnaire, administered at the visit 4 and 5, included questions to identify women with symptoms consistent with premenstrual syndrome. It also included questions about body pain.

Pittsburgh Sleep Quality Index was introduced at visit 5 to assess multiple domains of sleep quality.

Hysterectomy Experience At visit 5, participants who had ever had a hysterectomy answered questions about their decision-making process to have a hysterectomy, and pain and other symptoms related to the surgery.

New modules included in visit 6 (REDCap)

Infertility experiences Collects data on episodes of infertility and use of infertility services, including wanting to access medical for help getting pregnant but not being able to.

As a part of a P50 award to Wegienka and Wise examining life course stress and fibroid development visit 6 adds a series of validated questions to capture further data on major experiences of discrimination, everyday discrimination, and workplace discrimination as well as positive resources and geospatial measures of community-level stressors

Sleep chronotype The Munich Chronotype Questionnaire captures chronotype (individual preferences in sleep-wake rhythms).

Clinic-Visit Data and Specimen Collection

Ultrasound Data

Ultrasound examination At the clinic visit a transvaginal ultrasound examination was conducted to assess fibroids using the Muram criteria extended to small lesions (0.5 cm in diameter or larger). Ultrasound examinations were conducted throughout the study with Phillips IU-22s, with the exception of 1 GE Logic 9 machine. Study sonographers had at least 3 years of gynecologic ultrasound experience and extra training for the study to assure consistency in differential diagnoses, measurement, and documentation. The uterus and up to six fibroids were measured in three perpendicular planes. The uterus was measured at two separate times during the ultrasound examination and each fibroid at three separate times. The uterine location of each fibroid was recorded. For fibroid analysis, a volume for each of the three replicates was calculated based on the ellipsoid formula, and these were averaged to estimate the volume of each fibroid. Video and still images were archived, and an 8% sample for each sonographer, oversampled for

fibroid cases, was reviewed by the lead sonographer for quality control purposes. Whenever possible a fibroid from one visit was matched to a fibroid at the next visit so that fibroid growth could be assessed. The lead sonographer and PI used archive images and fibroid location to identify the matched fibroids across visits.

Ultrasound data form Data collected includes technical or other difficulties with scan, pregnancy/fetal details, thickness of endometrial stripe, uterine echotexture and dimensions, and fibroid number, location, and dimensions.

Past 24-hour questionnaire Collected at every clinic visit, includes questions related to specific exposures in the prior 24-hours, prior week and prior month. Participants brought medication and supplements used in the prior 24-hours and this information was coded using the Sloane Drug Dictionary.

Clinic measurements At all visits weight and blood pressure were measured; height and skin reflectance were measured only at baseline. The protocol for these clinic measures is described in supplemental material of Baird (2015). In a subset of participants at the fifth visit, based on the timing of their visit, height was re-measured and new measures of waist circumference and bioimpedance were added.

Past 24-hour vaginal exposure questionnaire Exposures in the last 24-hours including powder, douching, sprays, lubricant, spermicide, condom, and sperm.

Specimen collection Blood, urine, and vaginal swabs were collected at each clinic visit. Collection, processing, and storage procedures are described in detail in supplemental material of Baird (2015).

Medical Abstraction Forms

At each follow-up visit participants were asked if they would give consent for study staff to request medical records for cervical diagnostics and treatments, uterine imaging, and uterine surgical procedures. For those who consented, medical records collected through the fourth visit were abstracted by trained staff. Abstraction forms were created to document: cervical procedures, uterine/pelvic ultrasound and MRI, and uterine procedures including ablation, myomectomy, uterine artery embolization, and hysterectomy.

Biomarkers

Biomarker	Participant & Visit details
25-hydroxyvitamin D (serum)	All participants, visits 1-5
High sensitivity C-reactive protein (serum)	All participants, visits 1-4
Hemoglobin	All participants, visits 1-4
Urinalysis	All participants, visits 1-4
Genotyping (Global Diversity Array)	All participants
Chlamydia serology testing	All participants, visit 1
Bacterial vaginosis (Nugent score)	All participants, visit 1
Herpes simplex virus 2 serology	All participants, visit 1
Thyroid stimulating hormone (TSH)	All participants, visit 1
Luteinizing hormone (urine)	Selected participants (N=802) based on menstrual cycle phase, up to 2 visits
Serum testosterone	Selected participants (N=1248), single visit
Serum vitamin D binding protein	Selected participants (N=100), single visit
Vaginal swab qPCR (<i>M. genitalium</i> , 9 Bacterial Vaginosis-associated bacteria, 4 <i>Lactobacillus</i> species)	200 participants, visit 1
Additional biomarkers in collaboration with extramural researchers	
Blood metals (Upson/Wise)	All participants, visit 1
Plasma PFAS panel (Wise)	All participants, visit 1
Plasma organochloride pesticides (Wise)	~750 participants, visit 1
Plasma flame retardants (Wise)	~750 participants, visit 1
Plasma PCBs (Wise)	~750 participants, visit 1
Urinary phthalates (Wise)	~750 participants, up to 3 visits
Urinary phenols, parabens, triclocarban (Wise)	~750 participants, up to 3 visits
Serum anti-Mullerian hormone (Marsh)	All participants, visits 1-4
Under analysis through HHEAR	
Untargeted metabolomics (plasma) (Wegienka)	~550 participants, up to 3 visits
Urinary phenols and phthalates (Wegienka)	~900 participants, up to 3 visits

Data Management and Processing

Telephone and web-based interviews for visits one through four were conducted through the EB's Support Services Contract (DLH Corp. Inc., previously named Social & Scientific Systems (SSS)), and all other data collection occurred at Henry Ford Health (HFH). The CATI and CAWI had built-in consistency checks to optimize collection of high-quality data. If a question was not answered in the CAWI, the next screen presented the same question again. Only then could participant refuse. Self-administered hard-copy questionnaires completed or turned in at the clinic visit were scanned for completion by the study staff who guided participants through the visit. These methods resulted in high completion rates for each question. Additional quality control and cleaning procedures before analysis file preparation were done to evaluate inconsistencies (some of which were resolved by a phone call with respondent) and to categorize fill-in-the-blank questions. Data files for analysis are created by the contractor (DLH) for NIEHS researchers and collaborators.

Data for visit five and six, collected through a REDCap instrument has internal logic checks to minimize implausible and inconsistent responses.

Data Sharing and Collaboration

With rich data on a wide range of exposures and outcomes in an historically under-studied population, SELF has become the parent study for several collaborative investigations within NIEHS and in the wider scientific community. Requests for collaboration (<https://www.niehs.nih.gov/research/atniehs/labs/epi/resources/data-sharing>) are reviewed monthly by an Executive Committee to ensure relevance, importance, and suitability of SELF data for the proposed research. Members of the Executive Committee also review manuscripts and abstracts prior to submission and work closely with all collaborators to ensure optimal use of the SELF data including use of appropriate statistical methods and rigorous interpretation of results. All collaborators follow protocols to protect study data and the confidentiality of participants.

Ancillary Studies

SELF has facilitated extramurally and intramurally supported add-on studies with additional data collection. These data are now available for collaborative research addressing secondary hypotheses.

Multiple stress pathways and positive resources in uterine fibroid incidence and growth

PI: Ganesa Wegienka (Henry Ford Health), David Williams (University of Michigan), Lauren Wise (Boston University)

Co-Investigator: Donna Baird

This P50 study (P50HD115356) will examine the associations between life course adversity and stress, as well as the mediating effects of positive resources, and fibroid incidence and growth. This study will add new validated questionnaires to the sixth SELF visit to collect data on stress, positive resources and community level measures of stress.

Early life adversities and risk of uterine fibroids

PI: Anissa Vines (University of North Carolina at Chapel Hill)

Significant Contributors: Donna Baird, Quaker Harmon

This R21 study (R21HD114037) uses existing SELF data to explore the hypothesis that exposure to adverse childhood events contribute to uterine fibroid incidence and growth. The grant will also examine the buffering effects of psychosocial resources and the impact of adverse childhood experiences on adult measures of c-reactive protein, a marker of inflammation.

Per- and polyfluoroalkyl substances (PFAS) mixtures and pregnancy outcomes

PI: Samantha Schildroth (Boston University)

This K99 (K99ES036288) will leverage measured PFAS mixtures in SELF to examine associations with birth outcomes including birth size and preterm birth and how the associations are modified by perceived stress. Additional work will include metabolomics data to identify relevant biological pathways.

SELF COVID-19 Experiences

PI: Donna Baird

DIR funded the development and deployment of a COVID-19 REDCap survey to assess the SELF cohort member's experiences of the COVID-19 pandemic. This survey included questions about their own, their family's, and their community's infections, as well as their vaccination status. They were also asked about employment and health care challenges, issues regarding their children, and their own economic and emotional stress associated with the pandemic. The letter describing the study, along with the link to the web-based survey, was sent during the summer of 2022. Those who preferred a paper questionnaire were mailed one along with a prepaid return envelope. This project also served as a participant engagement activity during a time when other SELF research was limited.

Endocrine disrupting chemicals and risk of uterine fibroids: a prospective study

PI: Lauren Wise (Boston University)

This grant (R01ES024749) funded the laboratory analysis of endocrine disrupting chemicals (phthalates, PCBs, phenols including bisphenol A) in a case-cohort of SELF participants and the statistical analysis of these exposures in relation to fibroid incidence.

Study of ovarian aging and reserve in young women

PI: Erica March (Michigan State University)

NIEHS: Donna Baird

This NIH funded study (R01HD088638) has measured anti-Müllerian hormone (AMH) in blood at every SELF visit. Researchers are examining cross-sectional and longitudinal associations between reproductive factors, use of contraception, body mass index, sleep and other lifestyle factors and AMH concentration. This study is also supported an additional clinical visit for a subset of SELF participants. Data collected at the visit include antral follicle count assessed by ultrasound, markers of glucose metabolism (oral glucose tolerance test and HgA1c), and measures of adipose tissue (bioelectrical impedance analysis).

Early reproductive aging: stress and uterine fibroid risk among Black women

PI: Anissa Vines (University of North Carolina at Chapel Hill)

NIEHS: Donna Baird

This R21 funded study (R21HD105461) examined the societal and structural pressures experienced by African American women and fibroid incidence and growth. Detailed baseline measures and trajectories of stress and trauma will be examined along with the mediating effects of markers of resilience and early-life challenges.

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SELF PUBLICATIONS [Collection of SELF Publications](#)

2025

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