Agenda Item #: 3S-2

PALM BEACH COUNTY
BOARD OF COUNTY COMMISSIONERS

AGENDA ITEM SUMMARY

Meeting Date:	December 18, 2018	[X] Consent [ ] Workshop	[ ] Regular [ ] Public Hearing
Department:	Fire-Rescue		

I. EXECUTIVE BRIEF

Motion and Title: Staff recommends motion to approve: an Institutional Review Board (IRB) Authorization Agreement with the University of Miami IRB for the Firefighter Cancer Cohort Study (FFCCS) effective upon approval and continuing for the duration of the County's participation as a study site.

SUMMARY: The cancer cohort study is a FEMA-funded research project, established in July 2016, that will develop and test a framework for establishing a long-term prospective study of firefighter carcinogenic exposures and health effects. The current cancer cohort study is a joint effort between the University of Miami, the University of Arizona, the National Institute for Occupational Safety and Health (NIOSH), Boston Fire Department, Tucson Arizona Fire Department and Palm Beach County Fire Rescue (PBCFR). As a participating study site, several PBCFR firefighters, who have voluntarily chosen to participate, have been trained as researchers to either collect their own biological samples (for example, blood, urine, breath, and cheek cells) or to coordinate the study at PBCFR. The research study is subject to extensive federal regulations, including review and oversight of the research study by an institutional review board pursuant to an IRB Authorization Agreement. There are no County funds required for this Agreement. Countywide (SB)

Background and Justification: NIOSH conducted a research study using US firefighters from San Francisco, Chicago and Philadelphia. The data used for the analysis was from 1950-2009. A paper was published in 2014 in the journal of Occupational and Environmental Medicine. This study suggested an excess mortality rate for cancer in firefighters compared with the general population. Firefighters are exposed to multiple carcinogens in the workplace through skin contamination and inhalation. However, we currently do not understand which individual exposures are responsible for cancer in firefighters, the mechanisms by which these exposures cause cancer, or effective means of reducing exposures. Since cancer has a long latency period, biomarkers are also needed that can measure the effects of carcinogen exposure well before the development of cancer, when interventions to prevent disease could be effective. Development of a large (>10,000 firefighter) multicenter firefighter cancer prospective cohort study will address these needs, but the framework for such a study needs to be first developed and tested among a smaller initial set of fire service partners. The original (FFCCS) was funded by FEMA through a 3-year research grant.

Attachment: Institutional Review Board Authorization Agreement

Recommended by: _____ Deputy Chief — Date

Approved by: _____ Fire Rescue Administrator — Date 11/29/18

Approved by: Nancy L. Bolton — Assistant County Administrator — Date 12/6/18

II. FISCAL IMPACT ANALYSIS

A. Five Year Summary of Fiscal Impact:

Fiscal Years	2019	2020	2021	2022	2023
Capital Expenditures					
Operating Costs					
External Revenues					
Program Income (County)					
In-Kind Match (County)					
NET FISCAL IMPACT	*				
# ADDITIONAL FTE POSITIONS (Cumulative)					

Is Item Included in Proposed Budget? Yes ___ No ___
Does this item include the use of federal funds Yes ___ No ___

Budget Account No.: Fund ___ Dept ___ Unit ___ Object/Rev Source ___
Does this item include the use of federal funds? Yes ___ No ___

B. Recommended Sources of Funds/Summary of Fiscal Impact:

* There is no fiscal impact associated with this Agreement.

C. Departmental Fiscal Review: _____

III. REVIEW COMMENTS

A. OFMB Fiscal and/or Contract Development and Control Comments:

_____ 11/29/18
OFMB

11/28 cm 11/29

_____ 12/4/18
Contract Development and Control

12/3/18 TW

B. Legal Sufficiency

_____ 12/5/18
Assistant County Attorney

C. Other Department Review:

_____
Department Director

(THIS SUMMARY IS NOT TO BE USED AS A BASIS FOR PAYMENT.)

Institutional Review Board (IRB) Authorization Agreement

Name of Institution or Organization Providing IRB Review (Designated IRB):

The University of Miami Institutional Review Board

IRB Registration #: IRB00005621, IRB00005622, IRB00006078, IRB00000260, IRB00010711

Federalwide Assurance (FWA) #: FWA00002247

Name of Institution(s) Relying on the Designated IRB (Relying Institution):

Palm Beach County Fire Rescue

IRB Registration #: _____ Federalwide Assurance (FWA) #: FWA00026657

The Officials signing below agree that Relying Institution may rely on the Designated IRB for review and continuing oversight of its human subjects research described below:

(Check one)

(__X_) This agreement is limited to the following specific protocol(s):

Name of Research Project: Firefighter Cancer Cohort Study
Name of Principal Investigator: Jefferey L Burgess MD
Sponsor or Funding Agency: FEMA
Award Number, if any: EMW2015FP00213

(___) This agreement applies to all human subjects research studies conducted at Relying institution for:_____ .

Terms of Agreement

I. Mutual Terms

This Institutional Review Board Reliance Agreement ("Agreement") is to: (1) establish the Designated IRB as the IRB of Record for Relying Institution with respect to human subject research conducted through the Palm Beach County Fire Rescue and (2) to set forth the respective authorities, roles, and responsibilities of each party in such arrangement.

Both Designated IRB and Relying Institution agree that review and approval of human subjects research under this agreement shall be conducted in compliance with the federal regulations as codified in 45 CFR 46 and 21 CFR 50 & 56 (as applicable), other pertinent federal regulations, state and local laws, and all applicable human research protection program (HRPP) policies at the Designated IRB's institution.

Both Designated IRB and Relying Institution agree to maintain effective communication and cooperation with the University of Miami (Coordinating Center CC), referred to in this document as the Coordinating Center, as described in this agreement to ensure adequate protections for human research subjects including providing relevant documentation and records as needed.

Both Designated IRB and Relying Institution agree they are primarily responsible for safeguarding the rights and welfare of research participants and that the rights and welfare of participants must take precedence over the goals and requirements of the research.

Both Designated IRB and Relying Institution agree that the liability of the Designated IRB is limited to its regulatory review and oversight of research covered by this Agreement and that Designated IRB will assure the protection of the rights and welfare of human subjects and will ensure its reviews and determinations are in accordance with all applicable federal regulations and human subjects protection requirements, state and local laws, and institutional policies and procedures.

Both Designated IRB and Relying Institution agree to develop or maintain standard operating procedures consistent with this agreement.

This Agreement does not preclude the organization or the researchers from taking part in research not covered by this Agreement.

This Agreement meets federal requirements for designation of another institution's IRB as the reviewing IRB, as set forth in the Office for Human Research Protections ("OHRP") document Terms of the Federalwide Assurance current as of June 2011. This signed Agreement will be kept on file at each signatory institution and will be provided to OHRP or other federal agencies upon request.

II. General Terms

Eligibility

Relying Institution's eligibility for participation in this Agreement is contingent on (i) its participation as a Study Site and (ii) its maintenance of a current, OHRP-approved FWA.

The process for ceding IRB review of specific Research Projects is set forth in the "Single IRB of Record and Coordinating Center Standard Operating Procedures" The purpose of these standard operating procedures (SOPs) is to set forth the requirements and otherwise provide guidance to Investigators, IRBs, and Coordinating Center personnel about the processes for using a Single IRB of Record and Coordinating Center for multi-site research studies. For IRBs, these SOPs are intended to supplement, not replace, existing Human Research Protection Program (HRPP) policies and SOPs for the review of human subject research.

III. Roles, Responsibility, and Authority of Designated IRB

1. Federalwide Assurance. Designated IRB's Institution will maintain a current, approved FWA with OHRP

2. Designated IRB Review in Accordance with FWA. The Designated IRB will perform initial review and continuing oversight of the Studies included in this Agreement including review of informed consent forms, modifications to previously approved research, continuing reviews, and reportable events including unanticipated problems and noncompliance, in accordance with the human subject's protection requirements of Relying Institution's OHRP-approved FWA and the federal regulations and ethical principles referenced therein. Designated IRB will ensure provisions of grant for research funded in whole or in part by a federal entity are consistent with the proposed research. Review by the Designated IRB will take into account the requirements of the local research context identified by Relying Institution.

3. Investigator Conflicts of Interest. The Designated IRB will have the authority to impose additional prohibitions or conflict management requirements more stringent or restrictive than what Relying Institution has implemented that are necessary for the Designated IRB to approve the Study. The Designated IRB will apply its standard policies regarding confidentiality of review information to disclosures and other information submitted to it regarding conflicts of interest.

4. Suspension or Termination of IRB Approval. The Designated IRB has the authority to suspend or terminate approval of all or part of a research study that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval includes a statement of the reasons for the IRB's action and is reported promptly to the Coordinating Center, appropriate institutional officials, department or agency head and regulatory agencies in compliance with 45 CFR 46.103(b)(5)(ii), 45 CFR 46.113, 21 CFR 56.108(b)(3) and 21 CFR 56.113.

5. Informed Consent Form. The Designated IRB will review informed consent forms for each study included under this Agreement. The forms will be consistent among sites except for site-specific language included by Relying Institution. Designated IRB will provide approved informed consent forms for each site to the Coordinating Center to distribute to Investigators for use at their sites.

6. HIPAA Authorization. The Designated IRB will perform the determinations required by the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act of 2009, and their implementing regulations (collectively, "HIPAA") with respect to the mechanisms for permitting the use and disclosure of Protected Health Information ("PHI") for the Studies included in this Agreement, namely authorization and waivers of authorization for use and disclosure of PHI as applicable. When an authorization will be used, the Designated IRB will also provide as part of the approved informed consent form authorization for use and disclosure of PHI. Such authorization shall explicitly permit PHI to be used and shared by and with the Designated IRB, the Designated

IRB's Institution, the Coordinating Center, the Relying Institution, and all Study Sites and their investigators participating in a Study as necessary for conducting, reviewing, and overseeing the Study (including investigation and evaluation of events) as contemplated by the protocol and this Agreement.

Each party shall be independently responsible for its own HIPAA compliance and obligations (for example, minimum necessary requirements, or accounting of disclosures of PHI made pursuant to a waiver of authorization) in connection with the Studies included in this Agreement other than the initial determinations regarding mechanisms for use and disclosure of PHI referenced in this Agreement.

7. Reports to Sponsors and Oversight Authorities. Designated IRB will report to sponsors/funding agencies, OHRP, FDA, and/or other oversight authorities of unanticipated problems involving risks to subjects or others, serious or continuing non-compliance, and suspension or termination of IRB approval in connection with the Studies included in this Agreement, and will provide a copy of the report to the Coordinating Center. The Designated IRB will provide the Relying Institution the opportunity to review and comment on the report before it is sent. Submission of such report by the Designated IRB does not preclude Relying Institution from submitting report.

8. Designated IRB Decisions; Minutes. Determinations made by the Designated IRB will be communicated to the Coordinating Center in writing. Designated IRB will maintain IRB records in accordance all applicable federal, state, and local regulations including 45 CFR 46.115, and will make records available when and as required by law. Relevant minutes of the Designated IRB's meetings pertaining to an included Study will be made available to the Coordinating Center upon request.

9. Post-Approval Monitoring. The Designated IRB reserves the right to conduct post-approval monitoring of Studies included in this Agreement. Designated IRB agrees that Relying Institution may also conduct post-approval monitoring of Studies included in this Agreement either in addition to, or in conjunction with the Designated IRB. Designated IRB and Relying Institution will notify Coordinating Center of such post-approval monitoring.

10. Coordinating Center. The Designated IRB agrees to accept IRB submissions from and communicate with the Coordinating Center for all studies included in this Agreement. The Designated IRB agrees that the Coordinating Center serves the role of collecting information from sites, completing IRB submissions, responding to IRB queries, and distributing notifications of IRB determinations to participating Investigators and Relying Institutions promptly.

IV. Roles, Responsibility, and Authority of Relying Institution

1. Local Research Context: State/Local Law; Conflicts of Interest; Other Local Ancillary Committee Reviews. The role of the Relying Institution is to conduct a review of the protocol for local context issues and to provide documentation of such review to the Coordinating Center. The Coordinating Center will provide Relying Institution with the protocol and Certification of

Local Context Review form to complete. Relying Institution may also use own form to document local context review as long as all issues noted below are addressed. The Relying Institution will document the review and will submit the form to the Coordinating Center for submission to the Designated IRB.

The local context issues to be assessed by the Relying Institution include but are not limited to the following:

- Specific state or local laws, regulations, or policies applicable to Relying Institution or the study
- Qualifications (includes having the required professional staff appointments, credentialing, insurance coverage and background checks for the assigned role in the research) and human subject protection training of Investigators and study staff.
- Financial conflicts of interest of Investigators related to the research
- Ethical concerns pertaining to the study population to be included in the research
- Radiation safety review
- Biosafety Review
- Insertion of institution-specific language into the model informed consent

It shall be the sole responsibility of Relying Institution to identify, interpret, and ensure compliance with the requirements of its applicable state or local laws, regulations, policies, and ancillary review processes as are relevant to specific Studies, and to communicate such requirements to the Designated IRB.

2. Federalwide Assurance. Relying Institution will maintain a current, approved FWA with OHRP for the duration of this Agreement. Relying Institution will notify the Designated IRB promptly in writing if its FWA is threatened, terminated, or expires for any reason.

3. Acceptance of and Cooperation with Designated IRB Decisions; Amendments. Relying Institution will accept the decisions and requirements of the Designated IRB with respect to the Studies included in this Agreement.

4. Notification of Investigator Status. The Relying Institution and site Investigator(s) and study team agree to promptly inform the Coordinating Center of suspension or termination of Investigator duties or privileges pertaining to the studies included in this Agreement.

5. Investigator Responsibilities. The Relying Institution will ensure its Investigators are aware of their responsibilities in the conduct of human subjects research including, but not limited to the following:
   a. Investigator is responsible for complying with the determinations and requirements of the Designated IRB.
   b. Investigator is responsible for record keeping and reporting, and for providing information requested by the Coordinating Center, should there be any, in a timely manner.
   c. Investigator agrees to disclose to both Coordinating Center and Relying Institution any changes in financial conflicts of interest and to abide by the Conflict of Interest

Management Plan, including additional restrictions as determined by Designated IRB, if applicable.

d. Investigator agrees not to implement any changes to the research (including informed consent form) without prior approval from Designated IRB, except where necessary to eliminate an immediate risk of harm to participants. Any such change and the perceived risk shall be promptly reported to the Relying Institution and Coordinating Center.
e. Investigator agrees to maintain human subject's protection education in accordance with Relying Institution's policies and procedures.
f. Investigator agrees to report unanticipated problems to Coordinating Center promptly, in accordance with Designated IRB's policies.

6. Compliance with SOPs. The Relying Institution and its Researchers shall comply with the SOPs. Only Research Studies for which both the Relying Institution and the Designated IRB have agreed that IRB review will be ceded to the Designated IRB in accordance with the SOP will be included in this Agreement.

7. Obligation to Update Information. Relying Institution will provide written notification to the Designated IRB (via the Coordinating Center) promptly upon any material changes to the information provided as part of its participation in the Research Study or otherwise about its site, its human research program, or the local research context in connection with this Agreement or any Research Study.

8. The Relying Institution is responsible for investigating all research subject complaints related to Studies. Complaints that meet the criteria of an unanticipated problem involving risks to subjects or others or serious or continuing noncompliance must promptly be reported to the Designated IRB via the Coordinating Center.

V. Notices and Primary Contacts. Any notices to the undersigned institutional officials or correspondence regarding IRB review and oversight must be addressed as follows:

Designated Institutional Review Board Primary Contact:

Name:	Evelyne Bital MA, CIP
Title:	Associate Director, Privacy and Regulatory Affairs
Address:	1400 NW 10th Avenue (M-809), Suite 1200A, Miami, FL 33136
Email:	EBital@med.miami.edu
Phone:	305-243-9977

Relying Institutions Primary Contact:

Name:	Bob Kropa
Title:	Battalion Chief
Address:	405 Pike Road, West Palm Beach FL 33411
Email:	Bkropa@pbcgov.org
Phone:	561-616-7000

VI. Termination

1. Term. This Agreement shall become effective on the last date signed below and shall continue for the duration of and until the cessation of Relying Institution's participation as a consortium Study Site, provided that the Agreement is not earlier terminated as provided in Section VI.2 below.

2. Termination. Any parties to this Agreement may terminate this Agreement with or without cause upon fourteen (14) days prior written notice to the other party(ies) as provided in Section V. Cause may include, but is not limited to, breach of the Agreement by a party that is not cured to the reasonable satisfaction of the non-breaching party(ies) within said fourteen (14)-day notice period, and in the case of
Designated IRB evidence of material changes in any information provided by Relying Institution referenced in this Agreement. In the event that any party's FWA is threatened, terminated, or expires, the other party(ies) may terminate the Agreement immediately.

3. Effect of Expiration or Termination; Survival. In the event of any termination of this Agreement, the parties will work together to determine the effect of such termination on any Study(s) and associated research activities being conducted under the Agreement at the time of termination. In the event of any expiration or termination of this Agreement, Relying Institution will remove the Designated IRB from the list of designated IRBs on its FWA (if it had included the Designated IRB on this list) and will notify the Designated RB (via the Coordinating Center) that this has been done.

VII. Indemnification

Designated IRB shall protect, defend, reimburse, indemnify and hold Relying Institution, its agents, employees and elected officers harmless from and against all claims, liability, expense, loss, cost, damages or causes of action of every kind or character, including attorney's fees and costs, whether at trial or appellate levels or otherwise, arising during and as a result of the Designated IRB's performance of the terms of this Agreement or due to the acts or omissions of Designated IRB.

VIII. Miscellaneous.

1. This Agreement may be amended only by a written agreement signed by authorized representatives of all parties. If any provision of this Agreement shall be held to be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions of this Agreement shall not be affected thereby. The failure of a party to insist upon the performance of any of the terms of this Agreement shall not be construed to be a waiver or relinquishment of any of the terms of the Agreement or of the whole Agreement. All the titles and headings contained in the Agreement are inserted only as a matter of convenience and reference and do not define, limit, extend, or describe the scope of this Agreement or the intent of any of its provisions. This Agreement is not assignable in whole or in part, and any attempt to do so shall be void.

2. This Agreement is not intended to create nor shall be construed to create any relationship between the parties other than that of independent entities contracting for the purpose of effecting provisions of this Agreement. Other than as expressly set forth in this Agreement, no third persons or entities are intended to be or are third party beneficiaries of or under this Agreement. Nothing in this Agreement shall be construed to create any liability on the part of the parties or their respective directors, officers, trustees, faculty, employees or agents, as the case may be, to any such third parties for any act or failure to act of any party hereto.

3. The Designated IRB and Relying Institution agree to notify each other, via the Coordinating Center, when a federal regulatory agency has conducted or will conduct an audit or review of a Study and will notify each other of the outcome of such review.

4. Change in Law: This Agreement is intended to comply with existing federal, State and local laws, rules and regulations. However, the parties acknowledge that the existing law and regulations may change and that the courts, or federal or State agencies with appropriate jurisdiction, may change their interpretation of existing law. Upon the enactment or amendment of any federal, State or local law or regulation, or upon the issuance of any judicial or administrative ruling or interpretation that a party believes affects the interpretation or validity of this agreement, either party may notify the other party of such event. The parties shall use their best efforts during a thirty (30) day period after such notice is sent to mutually agree to such amendments to this Agreement as to permit its valid and legal continuation. If after such thirty (30) day period, the parties are unable to agree to amend this Agreement, this Agreement shall automatically terminate.

5. The Relying Institution is committed to assuring equal opportunity in the award of contracts and complies with all laws prohibiting discrimination. Pursuant to Palm Beach County Resolution R2017-1770, as may be amended, the Designated IRB warrants and represents that throughout the term of the Agreement, including any renewals thereof, if applicable, all of its employees are treated equally during employment without regard to race, color, religion, disability, sex, age, national origin, ancestry, marital status, familial status, sexual orientation, gender identity or expression, or genetic information. Failure to meet this requirement shall be considered default of the Agreement.

6. Notwithstanding anything contained herein, as provided under Section 119.0701, F.S., if the Designated IRB: (i) provides a service; and (ii) acts on behalf of the Relying Institution as provided under Section 119.011(2) F.S., the Designated IRB shall comply with the requirements of Section 119.0701, Florida Statutes, as it may be amended from time to time. The Designated IRB is specifically required to:

   A. Keep and maintain public records required by the Relying Institution to perform services as provided under this Contract.

   B. Upon request from the Relying Institution's Custodian of Public Records, provide the Relying Institution with a copy of the requested records or allow the records to be inspected or copied within a reasonable time at a cost that does not exceed the cost provided in Chapter 119 or as otherwise provided by law. The Designated IRB further agrees that all fees, charges and expenses shall be determined in accordance with Palm Beach County PPM CW-F-002, Fees Associated with Public Records Requests, as it may be amended or replaced from time to time.

   C. Ensure that public records that are exempt, or confidential and exempt from public records disclosure requirements are not disclosed except as authorized by law for the duration of the Agreement term and following completion of the Agreement, if the Designated IRB does not transfer the records to the public agency.

   D. Upon completion of the Agreement the Designated IRB shall transfer, at no cost to the Relying Institution, all public records in possession of the Designated IRB unless notified by Relying Institution's representative/liaison, on behalf of the Relying Institution's Custodian of Public Records, to keep and maintain public records required by the Relying Institution to perform the service. If the Designated IRB transfers all public records to the Relying

Institution upon completion of the Agreement, the Designated IRB shall destroy any duplicate public records that are exempt, or confidential and exempt from public records disclosure requirements. If the Designated IRB keeps and maintains public records upon completion of the Agreement, the Designated IRB shall meet all applicable requirements for retaining public records. All records stored electronically by the Designated IRB must be provided to Relying Institution, upon request of the Relying Institution's Custodian of Public Records, in a format that is compatible with the information technology systems of Relying Institution, at no cost to Relying Institution.

Failure of the Designated IRB to comply with the requirements of this article shall be a material breach of this Agreement. Relying Institution shall have the right to exercise any and all remedies available to it, including but not limited to, the right to terminate for cause. Designated IRB acknowledges that it has familiarized itself with the requirements of Chapter 119, F.S., and other requirements of state law applicable to public records not specifically set forth herein.

IF THE DESIGNATED IRB HAS QUESTIONS REGARDING THE APPLICATION OF CHAPTER 119, FLORIDA STATUTES, TO THE DESIGNATED IRB'S DUTY TO PROVIDE PUBLIC RECORDS RELATING TO THIS AGREEMENT, PLEASE CONTACT THE CUSTODIAN OF PUBLIC RECORDS AT RECORDS REQUEST, PALM BEACH COUNTY PUBLIC AFFAIRS DEPARTMENT, 301 N. OLIVE AVENUE, WEST PALM BEACH, FL 33401, BY E-MAIL AT RECORDSREQUEST@PBCGOV.ORG OR BY TELEPHONE AT 561-355-6680.

7. It is the understanding and intent of the parties that the Designated IRB is not acting on behalf of the Relying Institution as provided under Section 119.011(2) Florida Statutes.

8. The Relying Institution's performance and obligation to pay under this Agreement for subsequent fiscal years are contingent upon annual appropriations for its purpose by the Board of County Commissioners.

[signature page follows]

Institutional Review Board:
THE UNIVERSITY OF MIAMI
INSTITUTIONAL REVIEW BOARD

By: _____
John L. Bixby, PhD
Vice Provost for Research

Date: 11/20/18

ATTEST:

SHARON R. BOCK
CLERK AND COMPTROLLER

By: _____
Deputy Clerk

Relying Institution:
PALM BEACH COUNTY
BOARD OF COUNTY COMMISSIONERS

By: _____
, Mayor

APPROVED AS TO FORM
AND LEGAL SUFFICIENCY

By: _____
County Attorney

APPROVED AS TO TERMS
AND CONDITIONS

By: _____
Department Director

Date: