

## Overview of the HCPHES Ethics Review Process

HCPHES seeks to make decisions in the interests of public health for the people, organizations, animals, and environment of Harris County using fair and just principles. We have developed an HCPHES Code of Ethics to help staff make decisions when the best or right course of action is not immediately evident. We have also established an HCPHES Ethics Advisory Committee to serve as neutral body for decisions that need a formal ethics review. The steps in this process are outlined below:

- Step 1:**  All staff should familiarize themselves with the HCPHES Code of Ethics to ensure that daily decisions reflect our values.  
*The HCPHES Code of Ethics is on the [Public Health Ethics page](#) on the HCPHES intranet.*
- Step 2:**  All staff should be able to recognize when an issue needs a higher-level review due to its ethical implications or other concerns.  
*Required ethics training for staff is on the [Public Health Ethics page](#) on the intranet.*
- Step 3:**  When a request needs higher-level review (ethics review or otherwise), staff should direct the requester to their immediate supervisor who will forward the request to the Division or Office Director as needed.  
*Staff may also submit ethics requests to their supervisor for potential review. Division/Office Directors may submit requests directly to HCPHES Executive Leadership as well.*
- Step 4:**  The Division or Office Director will work to resolve the request with the requester directly.  
*If a mutually satisfactory solution is reached, then it is reviewed by the HCPHES Executive Director or Deputy Director before next steps are determined.*
- Step 5:**  If the Division or Office Director and requester cannot reach a mutually satisfactory solution, then the Division or Office Director presents the request to HCPHES Executive Leadership, who can refer the request to the HCPHES Ethics Committee or use another decision-making process to identify a solution.  
*Only HCPHES Executive Leadership can refer issues to the HCPHES Ethics Committee.*
- Step 6:**  If and when directed by HCPHES Executive Leadership, the Ethics Committee conducts a formal review of the request. *The purpose of this review is to determine if the request meets ethical standards.* Once the review is complete, the Committee's key findings and conclusion are referred back to HCPHES Executive Leadership for their consideration.
- Step 7:**  HCPHES Executive Leadership makes a final determination on all items reviewed by the Ethics Committee and may take any/all courses of action on the matter including no action or re-review. As determined, a member of HCPHES Executive Leadership will communicate results to the original requestor.

On an on-going basis, HCPHES will provide continuing education, training, and other opportunities for staff to learn about and practice ethical decision-making. Staff can also sign-up for the HCPHES Ethics Distribution List. For more information about ethics at HCPHES, please visit the [Public Health Ethics page](#) on the HCPHES intranet.

## 2016 Ethics Review Process

### Section 1: Introduction

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Harris County Public Health & Environmental Services (HCPHES) seeks to make decisions in the interests of public health for the people, organizations, animals, and environment of Harris County using fair and just principles. HCPHES has developed a Code of Ethics to help staff make such decisions when the best or right course of action is not immediately evident (See **Appendix A: HCPHES Code of Ethics**). Training on public health ethics is also made available to staff, and verification of viewing of the Harris County ethics video is required of all HCPHES employees.

With these actions in place, there may still arise matters in which there is dissimilarity between the desires of individuals or organizations in the community and the legal duties and obligations of HCPHES. Such matters may require a formal ethical decision-making process conducted by a neutral review body that includes methods for input from impacted stakeholders or groups. This document outlines a process for addressing such matters in HCPHES through the use of an Ethics Advisory Committee formed for this purpose.

### Section 2: Ethics Advisory Committee

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#### 2.1: Authority

The HCPHES Ethics Advisory Committee (Committee) is a key component of the HCPHES Ethics Infrastructure. The Committee is an internal body with the authority to: conduct formal ethics reviews of matters sent to it from HCPHES Executive Leadership; convene hearings or other forms of public meetings on matters sent to it for ethics review including calling internal or external subject matter experts as needed; and draw conclusions on the ethical nature of matters sent to it for review, which are then submitted to HCPHES Executive Leadership for their consideration. The Committee may also be called upon to provide guidance on additional ethics activities in HCPHES such as staff training.

#### 2.2: Membership

The Committee shall have at least 12 members representing, at a minimum, the following Divisions, Offices, programs, perspectives, and designated external roles:

- Animal control
- Chronic disease prevention and control
- Direct patient care
- Community stakeholder representative (external member)
- Disease surveillance
- Emergency preparedness

- Employee/employer relations
- Ethics advisor (external member)
- Health equity
- Inspected facilities
- Protection of human subjects (IRB member)
- Legal counsel
- Vector control

Committee members should also exhibit the following characteristics:

- Interest in public health ethics;
- Basic understanding of core ethical concepts, including social determinants of health;
- Knowledge of their HCPHES Division, Office, program, or role broadly and particularly of those tasks with the potential for ethical concern;
- Completion of a nationally-endorsed online self-study training course on public health ethics (to be provided upon and completed within one month of appointment);
- Institutional memory; and
- Time and commitment to actively participate in the process.

Seats on the Committee shall be considered permanent; however, the individual who fills each seat may be replaced as needed by, first, the HCPHES Division or Office Director identifying a staff person (or external representative) matching the needs of the seat and, second, through final appointment by the HCPHES Executive Director. Confirmed Committee members will receive a written appointment letter signed by the HCPHES Executive Director.

### 2.3: Roles and Responsibilities

The Committee shall have the following specific member roles until otherwise determined by the Committee or by HCPHES Executive Leadership based on the needs of the Committee and on the capacity of current members:

#### *Ethics Chair*

Appointed by the HCPHES Executive Director for a period of no less than one year, the Ethics Chair convenes and leads meetings of the Committee and ensures that members understand their roles and expectations. The Chair also ensures all Committee members have the opportunity for input and are equally valued. The Chair serves as the liaison between the Committee and HCPHES Executive Leadership to convey ethics review referrals and conclusions and to facilitate needed resources; therefore, the Chair must also be a member of the HCPHES Executive Leadership Team.

#### *Committee Coordinator*

The Committee Coordinator is responsible for planning and implementing Committee activities, including member notifications and training, scheduling meetings and reviews (including convening subject matter experts as needed), and ensuring completion of Committee products and deliverables (such as meeting minutes, ethics review forms, research for ethics reviews, deliberation summaries, etc.). The Coordinator also acts as an ethics champion for HCPHES, managing the ethics distribution list and intranet page and arranging for continuing education opportunities for staff. Lastly, the Coordinator is a liaison to the Chair and Committee members to address any needs or concerns. *The Coordinator is not a member of the Committee and does not contribute to or vote in ethics reviews.*

### *Community Stakeholder Representative (External Member)*

The Community Stakeholder Representative is affiliated with a community-based health and human services agency and should be able to represent the interests of community members and other impacted stakeholders in the process of reviewing HCPHES ethical concerns. The Representative also provides guidance to the Committee on various options for community and stakeholder input during an ethics review.

### *Ethics Advisor (External Member)*

The Ethics Advisor should be an expert in ethics theory and practice in a public health setting and is typically affiliated with an academic institution. The Ethics Advisor provides guidance to the Chair, Coordinator, and Committee on the implementation of ethics reviews. The Ethics Advisor also provides guidance on internal processes to help ensure effective outcomes such as training for the Committee and staff and the development of the ethics review process.

### *Legal Counsel*

Legal Counsel (as represented by the HCPHES Assistant County Attorney designee) provides the Committee with guidance regarding the legal considerations and limitations to its ethics reviews. In particular, Legal Counsel prepares brief written legal assessments and/or advisories on matters sent to the Committee for ethics review.

Administrative support for the Committee shall be determined by the Chair using staff from their Division or Office or from another Division or Office as approved by HCPHES Executive Leadership. In the absence of such support, the Committee Coordinator will provide administrative functions.

## 2.4: Meetings

The Committee shall meet monthly while conducting ethics reviews. When no reviews are in progress, the Committee may meet as determined by the Chair. Meetings shall be called by the Chair (or their designee). When possible, meeting schedules will be determined by members at the end of each *prior* meeting. Otherwise, meeting notice shall be made no less than 14 days prior to the meeting, except in the case of an expedited review. Committee decisions will be made by consensus. In cases where consensus cannot be attained, a vote of the Committee may be called and counted by the Chair.

## 2.5: Confidentiality

Committee members are to keep discussions and actions confidential during ethics reviews. Members are *not* to discuss the content or conclusions of ethics reviews with anyone outside of the Committee, which includes their Division or Office Director, unless explicitly instructed to do so for the purpose of information-gathering. Hearings or other public meetings of the Committee are *not* subject to Open Meeting Law; however, minutes, reports, or other written documentation of Committee activities (including members' hand-written notes) are subject to requests submitted per the Public Information Act.

## 2.6: Role of HCPHES Executive Leadership

Although the authority, composition, and expectations of the Committee are outlined above, the HCPHES Executive Director (or Deputy Director when the Executive Director is unavailable) will have ultimate and final authority for the Committee's process, composition, findings, and conclusions reached from ethics reviews. Other HCPHES Executive Leadership will have the roles and responsibilities outlined in this process unless otherwise determined.

## **Section 3: Ethics Review Process**

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HCPHES recognizes that the practice of public health has inherent ethical considerations that can arise at any time during the routine planning and implementation of programs, policies, services, interventions, and communications and that a mechanism for the ongoing identification of and deliberation on such issues, both from within the organization and from the community, is needed in order to maintain the ethical principles outlined in the HCPHES Code of Ethics. The steps below describe the process of a formal ethics review by the HCPHES Ethics Advisory Committee (Committee); these steps are also depicted visually in **Appendix B: HCPHES Ethics Review Process Map** (labeled below as Steps 1-5).

### 3.1: Intake

- 3.1.1: The Committee review process shall begin when the Chair sends a completed HCPHES Ethics Initiation Form from an internal or external requester to Committee members (**Step 1**). The Initiation Form includes, at minimum: a brief description of the matter (history, rationale for change, prior efforts, etc.), a recommendation for a solution to the matter, the requester's contact information, and contact information for at least one additional source of information. This and all future actions on the case are given a disposition in the HCPHES Ethics Review Tracking Log by the Coordinator.
- 3.1.2: Prior to conducting the ethics review, it must also be determined if the Committee (and, by extension, the organization) has legal authority to address (change) the matter as presented in the Initiation Form. Therefore, the Committee's Legal Counsel will next provide a brief written legal assessment of the matter that considers federal, state, and local laws and ordinances as well as case law (**Step 2**).
- If the request meets the legal parameters to be addressed (changed), then the ethics review continues as outlined below (Step 3).
  - If the request does *not* meet the legal parameters to be addressed (changed), the concern is considered resolved, and no further action by the Committee is taken. The Chair (or their designee) completes the HCPHES Ethics Review Closure Form (described below) and routes it to HCPHES Executive Leadership.

### 3.2: Review

Once it is determined that the Committee (and, by extension, the organization) has legal authority and precedent to address (change) the matter as presented in the Initiation Form, two types of ethics reviews are possible. HCPHES Executive Leadership shall determine if the matter will receive an expedited review (Step 3a) or a full review (Step 3b) by the Committee.

3.2.1: *Expedited Review (Step 3a)*. For issues requiring immediate action, the Committee will conduct an expedited ethics review with at least five Committee members as soon as schedules permit. In an expedited review, the Chair serves as lead reviewer. Steps in the expedited review process are as follows, and, at each, disposition is tracked by the Coordinator:

- a. The completed Initiation Form and brief written legal assessment are again sent to Committee members for their review.
- b. At least one hearing or other public meeting is held during which the Chair leads Committee members through the ethical decision-making framework (See **Appendix C: HCPHES Ethical Analysis Framework**) in order to determine major findings in the case and to reach a conclusion on the request.

*Possible outcomes are:*

1. The Committee reaches a conclusion on the matter based on its review findings with no further review recommended; or
2. The Committee reaches an *interim* conclusion on the matter based on its review findings while a full review is also conducted.

In each outcome, the Chair (or their designee) completes the HCPHES Ethics Review Closure Form for putting forth findings and conclusions to HCPHES Executive Leadership (Step 4).

3.2.2: *Full Review (Step 3b)*. For issues not requiring immediate action, the Committee will conduct a full review with all Committee members present and lasting no longer than three months after the Initiation Form is received. Steps in the full review process are as follows, and, at each, disposition is logged by the lead reviewer(s) (or their designee):

- a. The Chair (or their designee) conducts a Conflict Assessment of all Committee members using the HCPHES Ethics Advisory Committee Conflict of Interest Form.
- b. The Chair selects a lead reviewer(s) for the matter per the results of the Conflict Assessment (per the conflict of interest policy, a member with disclosed conflict in the matter cannot serve as a lead reviewer; they can, however, participate in the review process or serve as a subject matter expert).
- c. The completed Initiation Form and brief written legal assessment are again sent to Committee members for their review.
- d. As requested by the Committee, the lead reviewer(s) collect additional information on the matter including, if needed, written or verbal input from the requester, other impacted community members or stakeholders, and/or (internal or external) subject matter experts (which may or may not include the Division or Office Director to which the matter pertains).
- e. The lead reviewer(s) present the information on and lead Committee members through the ethical decision-making framework (See **Appendix C: HCPHES Ethical Analysis Framework**) in order to determine major findings in the matter and to reach a conclusion on the request.

*Possible outcomes are:*

1. The Committee reaches a conclusion on the matter based on its review findings with no further review recommended;

2. The Committee decides to gather *additional* secondary information (research) on the matter; re-convenes to review the new pertinent facts; and then reaches a final conclusion with no further review recommended; or
3. The Committee convenes a hearing or other public meeting to engage the requester, other impacted community members and stakeholders, and/or (internal or external) subject matter experts. The Committee then reaches a final conclusion based on its review findings with no further review recommended.

In each outcome, the Chair (or their designee) completes the HCPHES Ethics Review Closure Form for putting forth findings and conclusions to HCPHES Executive Leadership (Step 4).

### 3.3: Conclusion

As noted above, the HCPHES Executive Director (or Deputy Director when the Executive Director is unavailable) has ultimate and final authority on conclusions reached by the Committee as a result of formal ethics reviews. Therefore, once the Committee reaches a final conclusion on a matter, it is submitted for the Executive Director's review in collaboration with the HCPHES Executive Leadership team.

3.3.1: As noted in each outcome above, the Chair (or their designee) completes an HCPHES Ethics Review Closure Form (and prepares any needed attachments) (**Step 4**) once the Committee's review is complete. The Closure Form includes, at a minimum: a brief description of the Committee's treatment of the matter (meetings held, materials reviewed, subject matter experts consulted, etc.), key findings from the application of the HCPHES Ethical Analysis Framework, and the Committee's conclusion. At a minimum, the following key findings should be addressed in the Closure Form:

- Finding #1: Is there legal authority for HCPHES and Harris County to engage in the requested practice?
- Finding #2: Has the requested practice occurred in the past? If so, what ethical concerns arose at that time, if any?
- Finding #3: Is there a public health risk with this request?
- Finding #4: Are there alternatives to this request, and do they meet an ethical standard?
- Finding #5: Are there any additional considerations related to this request to ensure the ethical standard is met?

3.3.2: The Chair (or their designee) will route the complete HCPHES Ethics Review Closure Form and attachments to HCPHES Executive Leadership (**Step 5**). Once this step is complete, the concern is considered resolved by the Committee, and no further action or review is required. The Coordinator closes the matter in disposition and drafts a deliberation summary.

## **Section 4: Ethical Analysis Framework**

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The Committee has selected the ethical analysis decision-making framework recommended by the Centers for Disease Control and Prevention (CDC) (Gaare-Bernheim R., et al, 2007) (See **Appendix C: HCPHES Ethical Analysis Framework**) as its official decision-making

process for both expedited and full ethics reviews. In addition to the components of this framework, each review will include consideration of the CDC's Key Quality Attributes of an Ethics Review to assure a quality process and to identify future areas for improvement.

## **Section 5: Revisions**

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This Ethics Review Process shall be re-opened by the Chair and its contents reviewed by the Committee no less than annually, followed by review and re-approval by HCPHES Executive Leadership. Revisions made to the process at that time become effective upon signature and apply to all ethics reviews by the Committee going forward. Should actions occur in the interim of a scheduled update that warrant an immediate and material change to the process, the Chair may implement such changes immediately providing the Committee and HCPHES Executive Leadership are aware of and concur with the changes.

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### **Appendices:**

- Appendix A: HCPHES Code of Ethics
- Appendix B: HCPHES Ethics Review Process Map
- Appendix C: HCPHES Ethical Analysis Framework

### **Committee Forms:**

1. Sample HCPHES Ethics Review Initiation Form
2. Sample HCPHES Ethics Closure Form
3. HCPHES Ethics Advisory Committee Conflict of Interest Form