

Community Cancer Concerns

I. Policy

It is the policy of Toledo-Lucas County Health Department (TLCHD) to appropriately respond to all community cancer concerns within Lucas County, Ohio using the Community Cancer Concern standard operating procedure.

II. Scope

The *Community Cancer Concerns* procedure applies to epidemiology staff and all other TLCHD staff involved in responding to a cancer concern in the community.

III. Purpose

The Ohio Department of Health (ODH) has determined that it is the primary responsibility of local health departments to be the first responders to cancer concerns in their communities.

The Community Cancer Concern procedure complies with measure 2.2.2 (A) 3 in the Public Health Accreditation Board's (PHAB) Standards and Measures. Measure 2.2.2 (A) 3 requires the health department to have a protocol for responding to and investigating disease clusters in the community.

IV. Background

TLCHD's knowledge of the community and its relationships with residents, elected officials, media, clinicians, academia, and community groups enables TLCHD to better communicate with the local community and address concerns in a timely and effective manner. Adapted from the ODH *Ohio Community Cancer Concerns Response Protocol (2014)*, the TLCHD *Community Cancer Concerns* procedure ensures appropriate surveillance and documentation of cancer assessments and cancer cluster investigations within Lucas County, Ohio. This protocol should be reviewed and updated as necessary and annually by the Office of Epidemiology.

The Centers for Disease Control and Prevention defines a cancer cluster as a greater than expected number of cancer cases that occurs within a group of people in a geographic area over a defined period of time (CDC, 2013). Cancer cluster inquiries are often requested by community members or medical professionals concerned about what appears to be an unusually high number of diagnosed cases of cancer in a particular geographic area, such as a community, workplace, family, or school.

The following seven steps outline the response to a community cancer concern:

Step 1. First Contact and Response

Step 2. *Verify Reported Cancer Cases*

Step 3. *Determine TLCHD Resource Availability*

Step 4. *Establish Case Definition and study population*

Step 5. *Conduct cancer assessment*

Step 6. *Release assessment findings*

Step 7. *Conduct cancer cluster investigation*

Most suspect cancer cluster investigations are not likely to result in the determination of an environmental cause of cancer. Investigations to find environmental causes of cancer have not been successful, in part, because of the complexities of cancer etiology. These complexities include data quality, population migration, disease latency, small case numbers, and political issues (Kingsley et al, 2007).

Most community cancer concerns can be resolved through a response letter and education. However, it is important for TLCHD to appropriately respond to all community cancer concerns and carefully document the entire process. ODH (2014) has provided the *Community Cancer Communications Toolkit* and *Cancer Data Toolkit* to assist with cancer concern response and education. Both toolkits are located on the Ohio Public Health Communication System (OPHCS) Website <https://ophcs.odh.ohio.gov/> under Documents/Cancer Concerns Protocol Toolkit.

Transparency, education, and consultation availability should be maintained throughout the process of responding to a community cancer concern (CDC, 2013).

V. Activation of the Emergency Response Plan

If, at any point, a cancer cluster investigation or outbreak causes the epidemiology staff and/or in-house resources to be overwhelmed, members of administration at TLCHD can be requested to activate the Emergency Response Plan. Activation will be sought if a situation-dependent threshold has been reached including, but not limited to, scare or exhausted resources, overwhelming scope of the outbreak, or the etiology traces to a regional or national source (e.g., radiologic dispersal, systemic failure or contamination of environmental or water infrastructure, etc.).

VI. The Seven Step Procedure

Step 1. First Contact and Response

Collect the necessary information from the concerned resident, evaluate the initial concern, provide educational information, and send a timely follow-up response. Responders should be empathetic and work with the caller to complete the Ohio Community Cancer Concerns Reporting

Form (**Step 1.A**, below). If this form was completed through ODH, the form will be forwarded to an identified contact at TLCHD. The responder at TLCHD may wish to convene a team of stakeholders to assist in evaluating the concern.

A. TLCHD will collect all pertinent information from the concerned resident(s) on the Ohio Community Cancer Concerns Reporting Form.

1. Date received, name, address, telephone number, e-mail, institutional affiliation, title, method of inquiry, preferred method of contact.
2. Nature of the concern – high rate of cancer (type[s]), environmental exposure (e.g., air/water/soil pollution, radiation, hazardous waste site), time period of concern (many years vs. several weeks)
3. Population of concern – geographic area (e.g., city, township), demographic subgroup (e.g., children, African American males)
4. Information on the alleged cancer cases/deaths – name, current address, site/type of cancer, date of diagnosis, demographics (including age at diagnosis, vital status, race, gender, date of birth), residence at diagnosis
5. Information on perceived environmental exposure(s) – source of exposure (e.g., air, water, soil, hazardous waste site), geographic location, chemicals of concern
6. Any other additional notes regarding inquiry

B. Provide information and discuss initial impressions.

1. TLCHD will contact the resident to provide information and discuss initial impressions.
 - a. If the resident is only seeking general information about cancer, information about risk factors, or information on available resources for residents with cancer, ensure that sufficient information is provided, send a written response, and end the assessment.
 - b. Provide information on cancer prevention, what is known and unknown regarding risk factors, promote early cancer detection with screening, and promote reducing exposure to known carcinogens.
 - c. Discuss initial impressions of the concern while considering the following facts provided by the American Cancer Society (2016):
 - 1) One in three Americans will develop cancer during their lifetime.
 - 2) The chance of developing cancer increases with age.
 - 3) Different types of cancer may have different origins.
 - 4) Cancer is multifactorial. Genetic, environmental, and lifestyle factors interact to cause disease.
 - 5) Some cancers may take 20 or more years to develop after an exposure to a known carcinogen.
 - 6) Some diseases occasionally “cluster” in a way that may be statistically significant but not related to an exposure.

C. Assess the nature of the concern from the evidence collected from the concerned resident(s) and evaluate the need for further action.

1. If necessary, convene and discuss with a team of epidemiologists, health educators, environmental scientists, and other key stakeholders. Consider inviting ODH subject matter experts (e.g., epidemiologists, staff from the Bureau of Environmental Health and Radiation Protection) to assist in the initial assessment.
2. Assess and determine if, with the preliminary evidence collected, any of the following criteria are met:
 - a. Multiple cases of one site/type of cancer or related cancers (similar sites/types, common risk factors) have been identified.
 - b. Unusual sites/types of cancer in a particular population or age group have been identified.
 - c. An unusual spatial (geographic) or temporal (time) pattern is suggested.
 - d. An exposure pathway to a cancer-causing agent is plausible.
 - e. A biologically plausible explanation for an increase in cancer cases has been determined.
3. Evaluate the need for further action.
 - a. If one or more criteria in **Step 1.C.2. (a)-(e)** have not been met, provide a response (**See Step 1.D**) and end the assessment.
 - b. If one or more criteria in **Step 1.C.2. (a)-(e)** have been met, provide an initial response to the resident(s) (**See Step 1.D**) then proceed to **Step 2**.

D. Response Documentation

1. Document the concern, including a written summary of the response, and retain a copy. Sample response letters are included in the Community Cancer Communications Toolkit (ODH, 2014).
2. Provide a written response to the concerned resident(s) that includes the following:
 - a. A summary of the community cancer and/or environmental concern
 - b. Information on the cancer sites/types and exposures of concern and relevant cancer risk factors.
 - c. Reasons for no further action; OR,
 - d. Reasons for further action. If further action is warranted, provide a summary of further action and proposed timeline for completion, where applicable (Note: Following the initial response, status reports should be provided to the concerned resident(s) throughout the assessment to update current activities and timelines, if applicable).

- e. Relevant data and published materials (e.g., county rates, “Cancer” fact sheet, “Cancer Clusters” fact sheet and “Exposure to Toxic Chemicals and Cancer” fact sheet).
 - f. Resources with contact information to appropriate cancer prevention and control organizations such as:
 - 1) ODH Comprehensive Cancer Control Program (<http://www.healthy.ohio.gov/cancer/compcancer/cancerprog.aspx>)
 - 2) American Cancer Society (<http://www.cancer.org>)
 - 3) Local cancer organizations
 - 4) Hospital oncology centers
 - g. For concerns regarding potential environmental exposures, referrals to appropriate environmental agencies and programs such as:
 - 1) For air, water, waste disposal, and hazardous waste site concerns: Ohio EPA (<http://www.epa.state.oh.us>)
 - 2) For work related health concerns: National Institute for Occupational Safety and Health (www.cdc.gov/niosh/hhe)
 - 3) For chemical related concerns: ODH Bureau of Environmental Health, Health Assessment Section (www.odh.ohio.gov/odhprograms/eh/hlth_as/HAS.aspx)
 - 4) For radiation concerns: ODH Bureau of Radiation Protection (www.odh.ohio.gov/odhporgrams/rp/radprot/radprot1.aspx)
 - h. Invitation for resident(s) to contact TLCHD with additional questions or concerns.
3. Provide a summary of the response (and subsequent status reports, where applicable) that does not contain protected health information that may identify individuals to relevant health department officials, environmental agencies, and other stakeholders.

Step 2. Verify Reported Cancer Cases

Verify cancer cases and associated information provided by the concerned resident(s) by reviewing existing databases, medical records and/or contacting reporting facilities if the case is too recent to be reported to the Ohio Cancer Incidence Surveillance System (OCISS).

A. Verify reported cases:

- 1. Review relevant data (e.g., OCISS, vital statistics) to verify the reported cancer cases and associated information (e.g., name, cancer site/type, year of diagnosis, address, demographics).
 - a. OCISS can be contacted directly for assistance in case verification at (614)-752-2689 or OCISS@odh.ohio.gov.

- b. For Vital Statistics data, contact the Office of Vital Statistics, ODH, at (614) 466-2531 or VitalStat@odh.ohio.gov.
 - c. Epidemiologists from the ODH Chronic Disease and Behavioral Epidemiology Section can provide epidemiologic guidance, as needed.
- B. For cases not yet reported to OCISS, contact reporting facilities or review medical records to verify unreported cases, when appropriate.
- C. Review relevant information regarding reported environmental exposures:
 - 1. Contact appropriate environmental agencies to review published records regarding reported environmental exposures.
 - a. For Ohio EPA, contact Laura Factor, Assistant Director, Ohio EPA, (614) 644-2782, web.requests@epa.state.oh.us
 - b. For NIOSH, contact the Health Hazard Evaluation Program, 1-800-CDC-INFO (1-800-466-4636)
 - c. For ODH Bureau of Environmental Health and Radiation Protection, contact (614) 466-1390, BEH@odh.ohio.gov
 - d. For ODH Bureau of Radiation Protection, contact (614) 644-2727, BRadiation@odh.ohio.gov
 - 2. Review literature to determine if the suspected environmental agent(s) are known to be associated with the cancer(s) of concern.
- D. Evaluate the need for further action:
 - 1. If necessary, convene and discuss the request with a team of epidemiologists, health educators, environmental scientists, physicians, and other key stakeholders. TLCHD may wish to invite ODH subject matter experts (e.g., epidemiologists, staff from Bureau of Environmental Health and Radiation Protection) to participate, as well.
 - 2. Assess the confirmed cases and environmental information to determine if an unusual spatial (geographic), temporal (time) or other pattern is suggested and if any of the following criteria exist:
 - a. Multiple cases of one site (e.g., lung)/type (e.g., leukemia) of cancer or related cancers (similar sites/types, common risk factors) have been verified.
 - b. Unusual sites/types of cancer in a particular population or age group have been verified by comparing the number expected based on a comparison population.
 - c. An exposure pathway to cancer-causing agent exists.
 - d. Verified cancer sites/types have known environmental risk factors.
 - 3. Determine if one or more of the criteria in **Step 2.C.2** have been met:

- a. If **NO**, provide a written response to the concerned resident(s) and ODH, (see **Step 1.D**) and end the assessment.
- b. If **YES**, proceed to **Step 3**.

Step 3. Determine TLCHD Resource Availability for Cancer Assessment

Determine TLCHD resource availability and the key decision points for determining whether a cancer assessment should be conducted. Conducting a cancer assessment requires significant resources, including access to relevant data, staff time and funding. If resources are lacking at TLCHD, TLCHD may wish to partner with other local health departments, academic institutions, or public health organizations to assist in the assessment. In almost every instance, an investigation may not be warranted if support from stakeholders is lacking or if the study is not plausible with respect to methodology or scientific contribution.

A. Determine availability of relevant data:

1. Case data
 - a. Ohio Cancer Incidence Surveillance System (OCISS)
 - 1) OCISS data is usually only available up to 2 years prior to present date.
 - 2) Cancer cases must be reported to the OCISS within 6 months of date of diagnosis and/or first contact with medical facility.
 - b. Vital statistics
 - c. Other databases or records
2. Population denominator for the geographic area and the time period (U.S. Census Bureau).
3. Enhanced surveillance data (i.e., recent cancer cases that have not yet been reported to OCISS). (Note: It is often difficult to determine if all recent cases have been identified through enhanced surveillance; use high-quality and complete data whenever possible.)
4. Supplemental data (e.g., Behavioral Risk Factor Surveillance System [BRFSS], medical records).
5. Reference population with comparable demographics (e.g., nation, state, peer community).

B. Determine available resources prior to beginning a cancer assessment:

1. Funding for staff, travel, software, equipment.
2. Amount of time that will be devoted to the investigation in relation to other priorities at TLCHD.
3. Human resources for conducting the assessment and interpreting the results:
 - a. If human resources are not available at TLCHD, consider contacting neighboring local health departments, academic institutions, researchers, physicians, other state or

federal agencies, ODH, and other public health organizations to identify available resources to assist with the investigation.

4. Epidemiologic and statistical capacity.
5. Staff to verify cases, gather additional information, conduct follow-up.

C. Determine level of support from stakeholders:

1. ODH and other local health departments, if applicable.
2. Environmental agencies.
3. Local governance (e.g., mayor, legislators, county commissioners).
4. Local hospitals, physicians.
5. Media, public relations.
6. Concerned citizens.

D. Evaluate study plausibility:

1. Ability to demonstrate a higher than expected cancer burden.
2. Ability to contribute to the existing body of knowledge about cancer prevention and control.

E. Evaluate results:

1. If the resources/factors described in **Step 3.A-D** are not available, provide a response (see **Step 1.D**) and end the assessment. Refer to the Community Cancer Communications Toolkit (ODH, 2014) for strategies on providing this information to the community and ending the assessment. (Note: If it is determined that an investigation will be feasible at a later date, e.g. new data will be available, or staffing will increase, include the anticipated timeline for conducting the assessment in the response).
2. If the resources/factors described in **Step 3.A-D** are available, then proceed to **Step 4**.

Step 4. Establish Case Definition and Study Population

Determine a case definition and study population for the proposed cancer assessment. TLCHD may contact ODH epidemiologists in the Chronic Disease and Behavioral Epidemiology Section for assistance if local resources are not available.

A. Determine criteria for defining a case based on the information collected in Step 1 and Step 2:

1. Cancer site/types.
2. Vital status – alive (incidence) or deceased (mortality).
3. Appropriate ICD Oncology (ICD-0-3) codes (incidence) and/or ICD and Related Health Problems, Tenth Revision (ICD-10) codes (mortality).
4. Demographics – age, gender, race.

B. Define the study population:

1. Geographic area (e.g., county, city, township, zip code, place of employment, etc.).
(Note: Population data are available from the U.S. Census Bureau FactFinder, <http://factfinder2.census.gov>).
2. Time period, i.e., years of diagnosis and/or death

C. Evaluate whether the case definition and study population will serve to answer the concern.

1. If **NO**, provide a written response (see **Step 1.D**) and end assessment. Refer to Community Cancer Communications Toolkit for sample letters and strategies on providing this information to the community, media, and other stakeholders.
2. If **YES**, proceed to **Step 5**.

Step 5. Conduct Cancer Assessment

If resources are not available at TLCHD to conduct the cancer epidemiologic assessment, human resources identified in Step **3.B.3** may assist with **Step 5**. If epidemiology support resources are not available, TLCHD should request assistance from ODH. ODH can analyze data and information regarding the cancer burden and associated risk factors. TLCHD should request for ODH to provide the results in a summary report to TLCHD. TLCHD should provide verbal and/or written status reports to stakeholders, administration, and community members throughout the assessment, including a revised timeline if necessary.

- A. Identify one or more defined objectives
- B. Generate a line listing of relevant cases and/or deaths for the defined study population that includes OCISS, Vital Statistics, and/or non-reported cases verified in **Step 2.A**. Mapping to ensure that cases reside within the defined geographic area may be necessary (i.e., do not rely on mailing address alone).
- C. Determine a plan of analysis and statistical methods (e.g., frequencies, age-specific rates, age-adjusted rates, Standardized Incidence Ratios [SIR], confidence intervals, etc.).
- D. Conduct analyses and create tables/figures of results.
- E. Collect relevant risk factor information for the cancer sites/types of interest and/or those with a higher than expected number of cases, focusing particularly on factors that can be modified through behavioral changes to decrease cancer risk.
- F. Collect relevant information regarding environmental exposures. This information may be obtained by contacting an appropriate environmental agency or person (see **Step 1.D.2.g**)
- G. Prepare a draft summary report. The report may include background (summary of concerns), objectives, data sources, methodology, results, relevant risk factors, assumptions, limitations, implications, and recommendations for further action, if applicable. If ODH is conducting the analyses, TLCHD should send a written request to ODH for a summary report of the analyses.

- H. Provide verbal and/or written status report(s) to stakeholders, appropriate administration and community members throughout the assessment. A sample progress letter is included in the Community Cancer Communications Toolkit: Sample Letters (NPHIC, 2013).
1. Present progress to date.
 2. Provide estimated timelines for completion without committing to specific dates and revise the timeline as necessary.
 3. In all cases, proceed to **Step 6**.

Step 6. Release Assessment Findings

Coordinate the release of the cancer assessment findings with administration and the public information officer.

- A. Obtain approval from appropriate administration, public information officer, and other key officials prior to releasing the findings.
- B. Develop a plan for releasing the findings in coordination with stakeholders.
1. Date and time
 2. Distribution method, e.g. mail, internet, public meeting
 3. If a public meeting, identify:
 - a. Location (i.e., health department, community building)
 - b. Attendees (e.g., LHD personnel, elected officials, community members, news media)
 - c. Tool for sharing information (e.g., presentation, handouts, oral report, written report)
- C. Release the findings in accordance with the plan developed in **Step 6.B**.
- D. Discuss recommendations for further action with stakeholders, where applicable.
- E. Evaluate the process – Determine what worked, what did not work, and what could be done to improve the process.
- F. Evaluate the need to conduct a cancer cluster investigation.
1. If the findings do not warrant further investigation into possible risk factors or potential causes of an identified cancer cluster, end the assessment. Refer to the *Community Cancer Communications Toolkit* (ODH, 2014) for strategies on providing this information to your community and ending the assessment.
 2. If the findings warrant further investigation into the possible risk factors or potential causes of an identified cancer cluster, proceed to **Step 7**.

Step 7. Conduct Cancer Cluster Investigation

Identify persons and/or organizations that can assist in conducting a cancer cluster investigation. These may include TLCHD staff, neighboring LHD staff, academic institutions, researchers,

physicians, state/federal agencies, and other public health organizations. ODH may provide assistance if extraordinary circumstances warrant consideration; for example, the study that found an association between perinatal exposure to trichloroethylene and subsequent development of childhood leukemia in Wilburn, MA. Due to the variety of methods and procedures for conducting cancer cluster investigations, a stepwise approach is not provided here. However, procedures similar to those outlined in **Steps 5 and 6** above for conducting a cancer assessment and releasing the findings may serve as a framework.

VII. Cancer Incidence Data Anomaly in Lucas County

John Kollman from ODH observed an anomaly in Lucas County cancer incidence rates while creating the *Lucas County Cancer Profile* in 2015. Kollman observed that cancer incidence rates decreased dramatically in 2009 through 2012 in Lucas County, while mortality rates remained steady during that time period. The cause of this decrease for those years is likely due to delayed or incomplete reporting of cancer cases, as Lucas County showed the lowest estimated percent (72%) of OCISS case completeness for all cancer sites/types combined in Ohio for 2008-2012. Incidence data for 2013 indicate a marked increase in total cases in Lucas County to previous levels. This anomaly could impact any community cancer assessments conducted with data from 2009-2012.

VIII. Maintenance

A. Review

1. The *Community Cancer Concern* standard operating procedure is to be reviewed annually to ensure compliance with both agency and accreditation standards.

B. Revision

1. All changes made to this SOP are to be noted on the **Record of Change**. Substantial changes will require renewed signatures from all applicable parties. This includes changes to the intent, scope, procedures, or policy statement.
2. Changes in style, format, grammar or minor error correction will not require renewed signatures but must be indicated on the Record of Change.

IX. Cancer Assessment Decision Tree

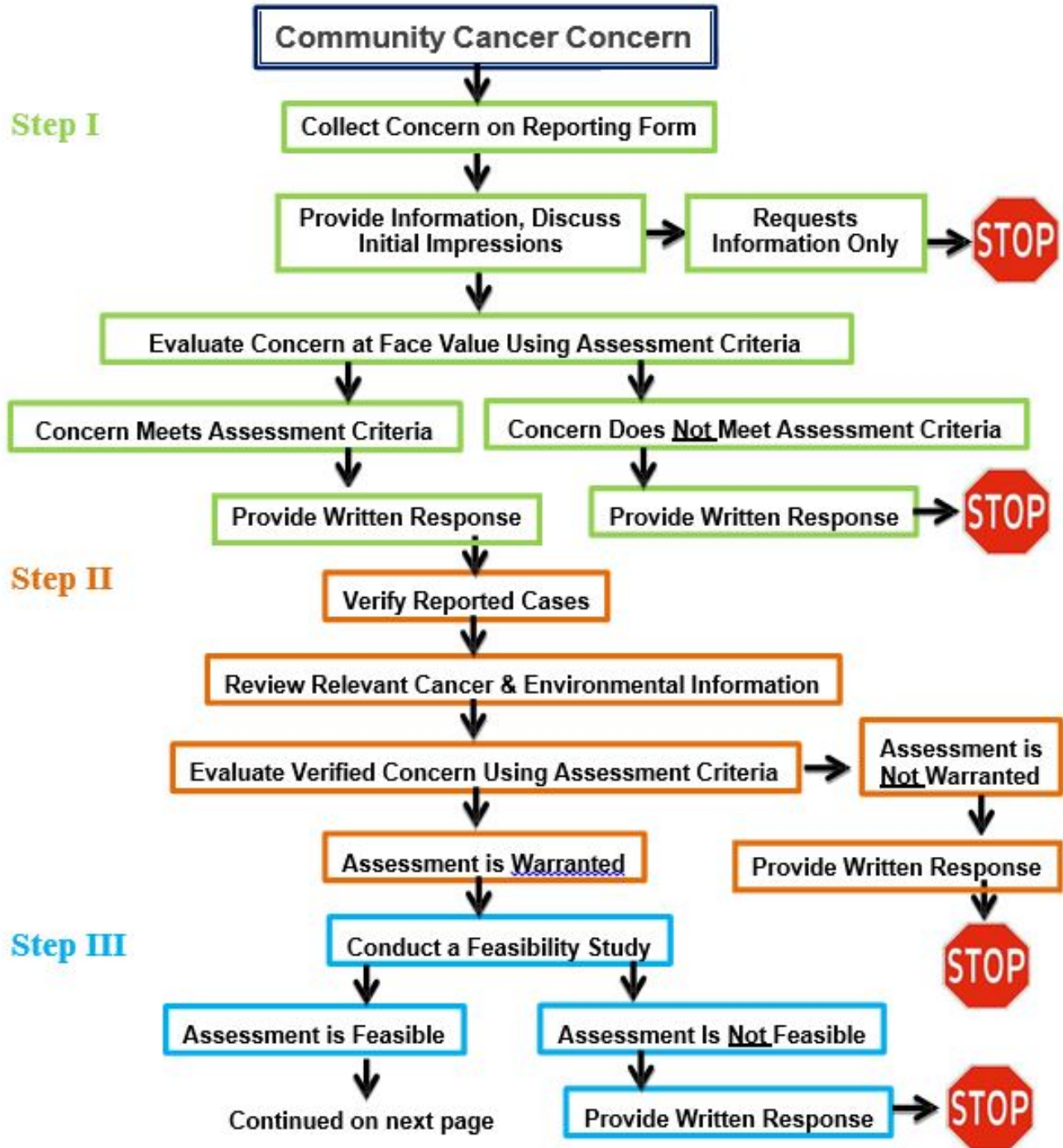
ODH created the following two-page decision tree graphic to assist with the *Community Cancer Concern* procedure (see following two pages):

Cancer Assessment Decision Tree

(page 1 of 2)



Step I Collect information, evaluate, and respond to the concern.
Step II Verify reported cancer cases and evaluate the need for further action.
Step III Determine resources available at the LHD to conduct a cancer assessment.

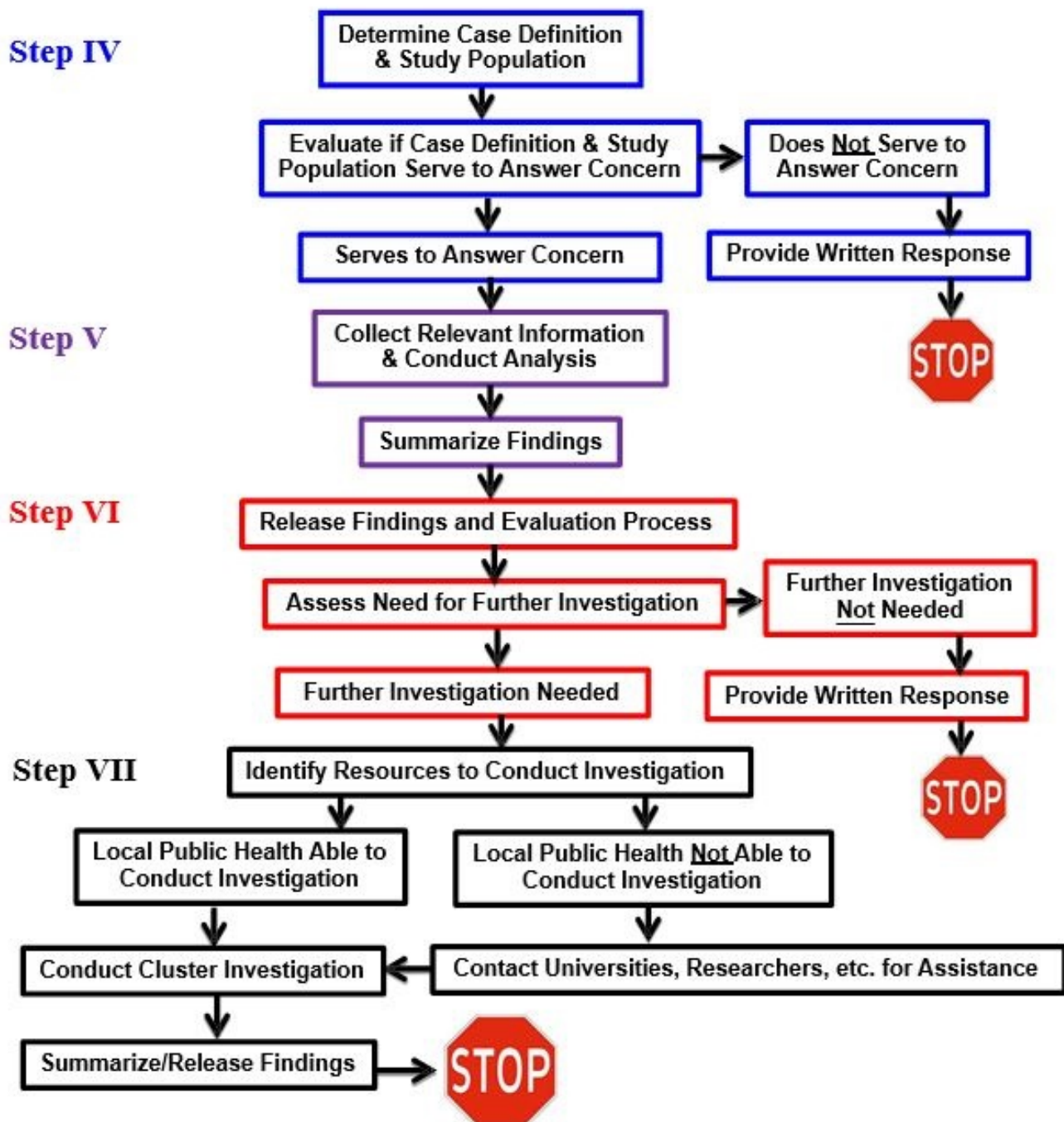


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Cancer Assessment Decision Tree (page 2 of 2)



Step IV Establish a case definition and study population.
Step V Conduct the cancer assessment.
Step VI Release the assessment findings and evaluate the process.
Step VII Conduct a cancer cluster investigation.



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X. Glossary

- A. Cancer assessment:** The collection, analysis, and evaluation of cancer data and related information among a group of people in a geographic area over a defined period of time.
- B. Cancer cluster:** A greater than expected number of cancer cases that occurs within a group of people in a geographic area over a defined period of time
- C. Cancer cluster investigation:** A study to determine possible risk factors or potential causes of a greater than expected number of cancer cases occurring among a group of people in a geographic area over a defined period of time.

