

# Education Course for External Clinical research associate

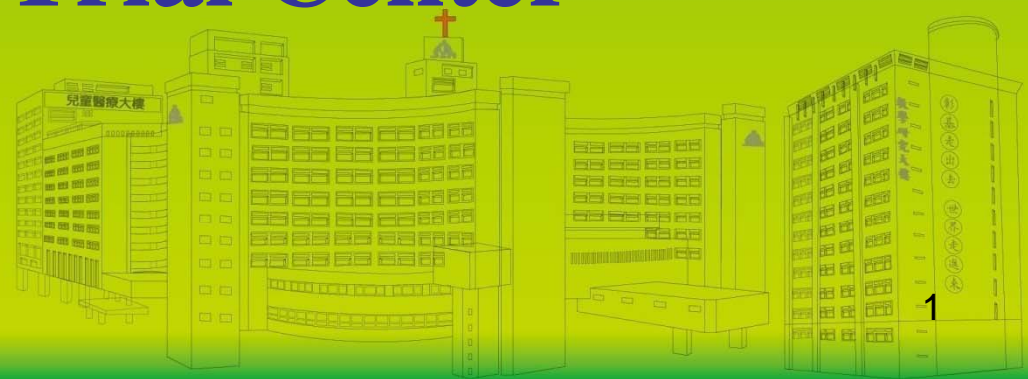
## Clinical Trial Center



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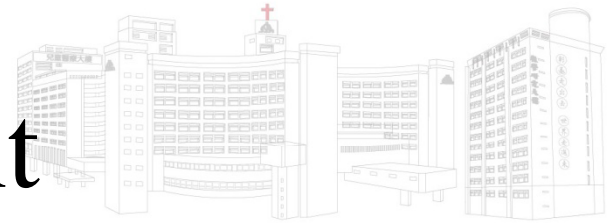
彰化基督教醫院  
CHANGHUA CHRISTIAN HOSPITAL

醫療 · 傳道 · 服務 · 教育 · 研究





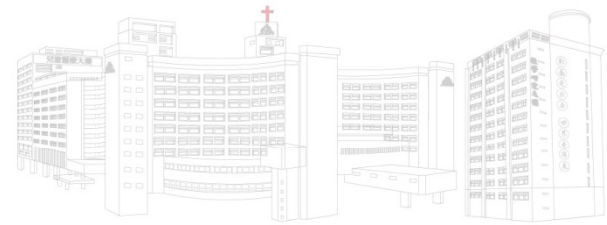
# Course Content



- **Medical Record Maintenance and Regulations of Confidentiality**
  - **Monitoring/Auditing Rules for CCH**
  - **Legal basis for monitoring/auditing**
  - **Legislatures on confidentiality**
  - **CCH's rules on confidentiality**
- **Infection Control and Prevention**
  - **CCH's rules on infection control and prevention**
  - **CCH's isolation measures**
  - **Measures for infection prevention**

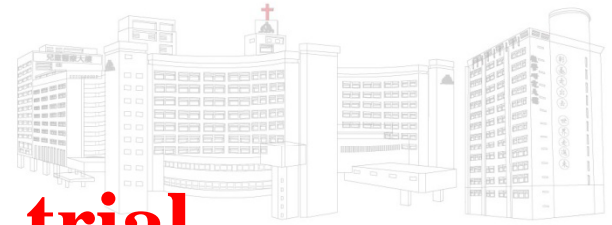


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# Medical Record Maintenance and Rules of Confidentiality





## **Monitoring/Auditing clinical trial research associate for CCH:**

- ✓ **Must have authorization from the trial sponsor**
- ✓ **Trial sponsor/institution must verify the GCP education training certification of the monitoring/auditing personnel**
- ✓ **Must obey all related legislatures**
- ✓ **Must observe CCH's rules on confidentiality**
- ✓ **Must follow CCH's rules on infection control and prevention**



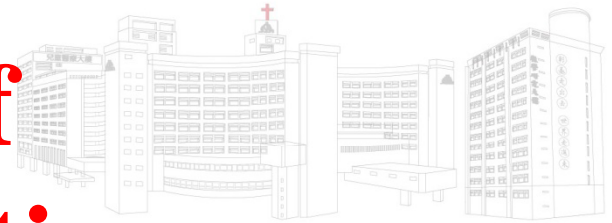
# Scope of Monitoring/Auditing



- Must apply beforehand to the CCH's Clinical Trial Center.
- Application for viewing of information of other trial protocols on the day is not accepted.
- May only apply for viewing of information limited to within the scope of the designated clinical trial protocol.
- Viewing is only limited to the information required by the clinical trial protocol.
- Viewing of medical record is only limited to the MR of the test subjects of the clinical trial protocol.
- Monitor/auditor who uses electronic medical record should sign a non-disclosure agreement.



# Legal basis of monitoring/auditing



## Guideline on Good Clinical Practice

- Article 50: the sponsor is responsible to obtain permission from the institution(s) to ensure direct access to all trial related sites, raw data, documents and reports for monitoring and auditing by the sponsor, and inspection by the competent authorities.
- Article 75: the monitors should be appointed by the sponsor.
- Article 81: the sponsor should appoint individuals, who are independent from the clinical trial and data collection system to conduct audits.



# Legal basis of monitoring/auditing

## Guideline on Good Clinical Practice

- Article 103: The monitor, auditor, Ethics Committee or the competent authorities may request to review any trial-related information. However, the subject's consent is required prior to the access to the subject's personal data.

## CCH Informed Consent Form Example

- By signing the informed consent, you agree that your original medical record can be reviewed by the **monitor**, **auditor**, IRB, and the competent authority to assure the process and the data of the clinical trial pursuant to the requirement of the related laws and regulations. Your identity will be kept in confidential.



# Legislatures on confidentiality



## Guideline on Good Clinical Practice:

- Article 11: All subject's identities and records related to the clinical trial should be kept confidential.
- Article 22: To the extent permitted by the applicable laws and regulations, the records identifying the subject will be kept confidential and not be made publicly available. If the results of the trial are published, the subject's identity will still remain confidential.





# Legislatures on confidentiality



## Personal Information Protection Act:

- Article 5: The rights and interests of the Party should be respected in collecting, processing or using personal information and the information should be handled in accordance with the principle of bona fide. It should not go beyond the purpose of collection and should be reasonable and fair.
- Article 41: A violation of §6, §15, §16, §19, §20 and §21; a person who intends to commit the crime in the preceding Paragraphs to make unlawful profits for himself or for a third party, should be imposed of a sentence of no more than 5 years and a fine of no more than NT\$1,000,000.



# Legislatures on confidentiality

## Personal Information Protection Act:

- Article 42: A person who intends to make unlawful profits for himself or for a third party, or intends to infringe upon the interests of others by illegally changing or deleting personal information files, or by other illegal means and has impeded the accuracy of other people's personal information files and caused damages to others should be imposed of an imprisonment or custody of no more than 5 years.

## Enforcement Rules of the Personal Information Protection Act

- Article 8: When commissioning others to collect, process or use personal information, the commissioning agency shall properly supervise the commissioned agency. The supervision prescribed in the preceding paragraph shall contain at least the followings...



# Legislatures on confidentiality

## Criminal Code

- Article 316: A medical doctor, pharmacist, pharmaceutical company, midwife, mental therapist, clergyman, lawyer, defender, notary public, accountant, one of their business assistants, or one who has previously engaged in such occupation, who without reason discloses the secrets of another which he knows or possesses because of his occupation, shall be sentenced to imprisonment for not more than one year, short-term imprisonment, or a fine of not more than 50,000 NTD.
- Article 318-1: A person without reason discloses the secrets of another which he knows or possesses through the use of a computer or other relating equipment shall be sentenced to imprisonment of not more than two years, short-term imprisonment, or a fine not more than 5,000 NTD.



# Legislatures on confidentiality

## Civil Code

- Article 195: If a person has wrongfully damaged to the body, health, reputation, liberty, credit, privacy or chastity of another, or to another's personality in a severe way, the injured person may claim a reasonable compensation in money even if such injury is not a purely pecuniary loss. If it was reputation that has been damaged, the injured person may also claim the taking of proper measures for the rehabilitation of his reputation.
- Article 188: The employer shall be jointly liable to make compensation for any injury which the employee has wrongfully caused to the rights of another in the performance of his duties.



# CCH's rules on confidentiality



## CCH's clinical trial agreement example

- The identity of the test subjects and all medical records must not be disclosed without proper cause by both parties and the trial investigator. Violator of the non-disclosure agreement shall bear all related legal responsibilities and damage compensations.



# CCH's rules on confidentiality



## Non-disclosure agreement

- Monitor/auditor is responsible for the protection of confidentiality of any privacy information during the monitoring period, including items, documents, diskettes, optical disks, information, message, charts and graphs, analysis reports, electronic file transmissions and confidential operations.
- When using the electronic medical record system, the system will track all records of computer usage. The monitor/auditor is required to cooperate with investigation by the hospital in suspicion of violation of personal information protection act.



# CCH's rules on confidentiality



## Non-disclosure agreement

- The confidential information may not be disclosed, assisted, informed, submitted, copied, cited or through any methods to be taken out of the hospital, transfer or refer to third parties.
- May not in any ways make alterations to the original information (notations, revisions, circling, damage, replace, extract, disassemble, reassemble, steal or make markings of any other kind)
- Bear permanent responsibility to the confidentiality of the contents, which shall not terminate even after cessation of monitor/auditor duties.



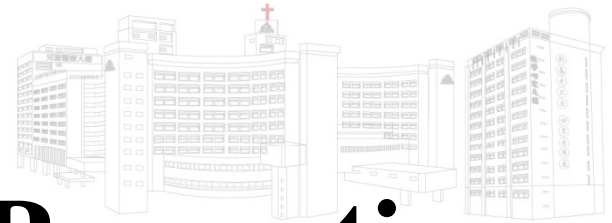
# CCH's rules on confidentiality



## Non-disclosure agreement

- In the event of my violation of the matters denoted in this agreement or other related legislatures which lead to the damage to third parties or the rights of your hospital, and have been validated and proven to be caused by my behaviors, I hereby agree to accept the processing of your hospital, and will bear any civil, criminal and administrative responsibilities. If my behaviors have led to any damages to the third parties or your hospital, I agree to be responsible for any damage compensations incurred.





# Infection Control and Prevention



From: CDC, Taiwan



## CCH's rules on infection control and prevention

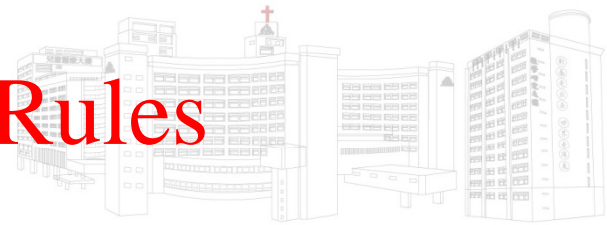


### Monitoring of body temperature, diarrhea and coughing

- **Purpose:** to understand the health condition of visitors and to detect any abnormal fever, diarrhea and coughing to prevent population infection.
- **Subjects:**
  1. Employees
  2. Hospitalized patients and family members
  3. Contract workers
  4. Other individuals who frequent hospital
- **If you have a fever above 38 degrees or experiencing diarrhea or coughing, please notify the center immediately.**



# Hospital Entry/Exit Rules



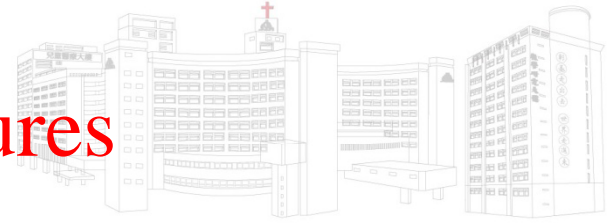
Recommendations for family members and visitors:

- (1) Due to the possible contact of the patient's family members to the common source of exposure and living environment, please check whether they display respiratory symptoms exist. If yes, please treat it as possible disease cases and conduct disease assessment.
- (2) Visitor access should be strictly limited to only those required for patient care, and inform them of possible risks of infection.
- (3) Provide personal protection gears to visitors and instruct them in the proper usage and hand washing procedure.

Source: hospital admission information



## CCH's Isolation Measures



### Standard isolation:

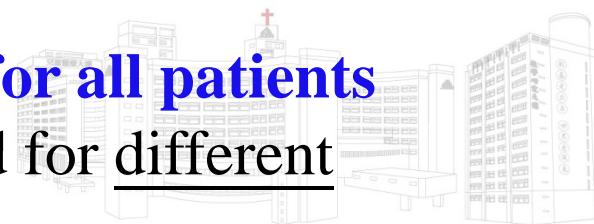
Protective measures are provided regardless of confirmed or suspected infected patients. Must wash hands before and after contacting patients.

- Wear gloves when there is possibility to come into contact with body fluids, blood, body secretions and excretions.
- Wear masks, eye masks or face masks when there is possibility to come into contact with splatters of body fluids, blood, body secretions and excretions.

Source: manual for infection control and prevention



**Standard** isolation measures: applicable **for all patients**  
Additional isolation measures are required for different contamination pathways



Disease	Isolation measures	Protective gears
<b>Tuberculosis, Chicken Pox, Measles</b>	Standard+ <b>Airborne</b> isolation	N-95 mask
<b>Influenza</b>	Standard+ <b>Droplet</b> isolation	Surgical mask
<b>MDRO, Scabies</b>	Standard+ <b>Contact</b> isolation	Gloves + gown

Source: manual for infection control and prevention



## Preventive measures for infection



- Alcohol based hand sanitizers are installed in clinics and elevator exits.
- For hand wash, press the nozzle once or twice to dispense sanitizer, and rub your hands for 20~30 seconds to kill the microbes on your hands.
- Please wash your hands before leaving the hospital or after touching the clinical environments (desks, chairs, door handles) to eliminate unseen microbes. Protect yourself and prevent transmitting microbes back to your homes.



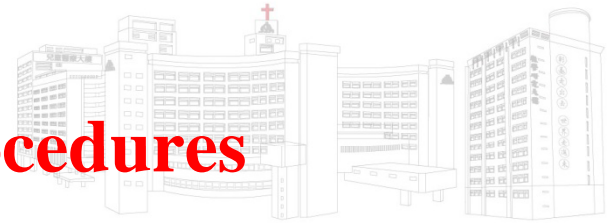
# Proper Hand Sanitation Procedures



<p>1a 1b</p>   <p>拱起的手掌中放入一手掌的洗手液，並抹勻全手。</p>	<p>2 內</p>  <p>掌對掌搓洗</p>
<p>3 外</p>  <p>右手掌對左手背，手指交叉搓洗，反之亦然</p>	<p>4 夾</p>  <p>掌對掌，手指交叉搓洗。</p>
<p>5 弓</p>  <p>手指的指背對著另一手的掌面，兩手交扣搓洗。</p>	<p>6 大</p>  <p>右手掌包住左手指，旋轉式搓洗，反之亦然</p>
<p>7 立</p>  <p>左手掌包住右手指，前前後後旋轉式地搓洗，反之亦然。</p>	<p>完 20-30 sec</p>  <p>約20-30秒，待手乾後，你的手就是清潔乾淨的了。</p>



## Proper Hand Sanitation Procedures



- 1a and 1b: arch one palm and dispense the hand sanitizer into the palm. Spread it all over the hand.
- Palm to palm rubbing (**Inner**內).
- Rub you right palm over left dorsum, and left palm over right dorsum (**Outer**外)
- Palm to palm fingers interlaced (**cross** 夾).
- Backs of fingers to opposing palms with fingers interlocked (**arch** 弓).
- Rotational rubbing of right thumb clasped in left palm and vice versa (**thumb**大).
- Rotational rubbing backwards and forwards with clasped fingers of right hand in left palm and vice versa (**upright** 立).
- Wait 20~30 seconds for the hands to dry and complete the hand washing procedures (**complete** 完).



## 防疫「十招」從洗手做起，「手」當其衝，潔「手」為上

### 第一招：勤洗手

1. 勤洗手保健康，洗手五時機：

(1) 吃東西前 (2) 看病前後 (3) 照顧小孩前 (4) 上廁所後 (5) 擦鼻涕後

2. 當雙手有明顯髒污時，請用洗手皂搓揉至少15秒後用水沖淨；若雙手沒有明顯髒污時，則可使用酒精乾洗手液搓揉至少20秒。

3. 洗手搓揉步驟七字訣：內、外、夾、弓、大、力、完，動作如圖示。



### 第二招：咳嗽戴口罩

1. 有咳嗽、打噴嚏等呼吸道症狀時應戴口罩，若沾到口鼻分泌物就立即更換。
2. 打噴嚏時，應用面紙或手帕遮住口鼻，或用衣袖代替。
3. 有呼吸道症狀，與他人交談時，盡可能保持1公尺以上。



### 第三招：提高警覺性

如果有發燒、咳嗽、嘔吐、腹瀉、骨頭肌肉疼痛、發疹等症狀，有可能是傳染病的徵狀，請盡速就醫，並向醫師說明旅遊史、職業別、接觸史、其他人是否有相同症狀。

### 第四招：生病在家休息

生病時在家休息，不上班不上課，並且避免出入公眾場所。



### 第五招：吃熟食、喝開水

這是預防A型肝炎、痢疾等腸胃道傳染病最好的方法。



避免吃生食

### 第六招：咳三週、快驗痰

1. 長期咳嗽是結核病主要症狀之一，咳3週就應該驗痰，可早診斷、早治療，且能避免傳染給其他人。
2. 可利用結核病「七分篩檢法」進行自我檢測：咳嗽兩週(2分)，有痰(2分)，胸痛(1分)，沒有食慾(1分)，體重減輕(1分)，而當上述症狀達5分以上，請即早就醫。





# The ten strategies of contamination control: start by washing your hands in the proper way



## Strategy 1: wash your hands regularly

- Wash your hands for better health at the following five occasions: 1) before eating, 2) before and after clinical visit, 3) before taking care of children, 4) after using bathroom, and 5) after sneezing.
- When there are visible stains on the hands, please wash with hand soap for at least 15 seconds and rinse clean with water; if there are no visible stains, rub the hands with alcohol based hand sanitizer for at least 20 seconds.
- The seven tips of hand washing: inner -> outer -> cross -> arch -> thumb -> upright -> completion. The motions are shown in the figure.



## The ten strategies of contamination control: start by washing your hands in the proper way



### Strategy 2: wear masks when coughing

- Please wear masks when experiencing respiratory symptoms such as coughing and sneezing. Replace the masks when in contact with oral and nasal secretions.
- Please cover your mouth and nose with tissue paper, handkerchief or sleeves of your clothes during sneezing.
- When experiencing respiratory symptoms, please maintain at least 1 meter distance when talking with other people.



# The ten strategies of contamination control: start by washing your hands in the proper way



## Strategy 3: raise awareness

- If you are experiencing symptoms such as fever, coughing, vomiting, diarrhea, muscular and skeleton pain or rashes, they may be signs of infectious disease. Please seek medical attention immediately and explain to your doctor your travel history, occupation, contact history, and whether other people are experiencing similar symptoms.

## Strategy 4: rest at home when sick

- When sick, please rest at home, do not go to class or work, and avoid going to public places.



## The ten strategies of contamination control: start by washing your hands in the proper way



### Strategy 5: eat well-cooked foods and drink boiled water

- This is the best method to prevent gastrointestinal contagious diseases such as hepatitis A and dysentery.

### Strategy 6: Have your phlegm examined when you have coughed for more than 3 weeks

- Long term coughing is one of the main symptoms of tuberculosis. Please have your phlegm examined when you have coughed for more than 3 weeks. Early detection leads to early treatment and can prevent spreading the contamination to other people.
- Use the 7 point screening method for tuberculosis to test yourself: coughing for two weeks (2 points), phlegm/sputum present (2 points), chest pain (1 point), loss of appetite (1 point), weight reduction (1 point). Seek immediate medical attention when you score 5 points or more.

### 第七招：打流感疫苗

預防流感，符合「疾病管制署」公告施打流感疫苗對象者，請每年配合政府之通知施打流感疫苗。



### 第八招：清除孳生源，做好防蚊措施

1. 預防登革熱最好每週「清除戶外及室內蚊蟲孳生源」。
2. 正確使用防蚊液、穿長袖衣褲、避免蚊蟲叮咬，是預防蟲媒傳染病最好的方法。



### 第九招：安全性行為

全程正確使用保險套，可免於性傳染病的侵襲。



### 第十招：不共用針具、不共用餐具、不共用牙刷

養成「每人1套」的良好個人衛生習慣，是預防腸胃道傳染病與血液傳染病最好的方法。



參考資料：  
衛生福利部疾病管制署 <http://www.cdc.gov.tw/>

制定日期：2014年3月  
編碼：5736-單張-中文-386-01

# 防疫衛生 教育宣導



感染管制委員會、護理部 製作

諮詢專線：(04)7256652  
諮詢專線服務時間：  
週一到週六 上午8：00-12：00  
週一到週五 下午1：30- 5：30  
讚美專線：(04)7238595轉3920  
抱怨專線：(04)7238595轉3925  
網址：[www.cch.org.tw/knowledge/knowledge.aspx](http://www.cch.org.tw/knowledge/knowledge.aspx)



彰化基督教醫院  
CHANGHUA CHRISTIAN HOSPITAL

給予「防疫衛生教育宣導」 護理指導及單張 編碼：5736-單張-中文-386-01	家屬/病人簽名
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# The ten strategies of contamination control: start by washing your hands in the proper way



## Strategy 7: influenza vaccination shots

- Populations targeted by the annual CDC announcement for influenza vaccinations should receive annual influenza vaccination shots as directed by the government announcement.

## Strategy 8: clear the source of mosquito breeding and practice anti-mosquito measures

- To prevent Dengue fever, please clear all indoor and outdoor mosquito habitats weekly.
- The best methods to prevent mosquito bites and insect-borne contagious diseases are using anti-mosquito spray and wear long sleeved clothing and pants.



## The ten strategies of contamination control: start by washing your hands in the proper way



### Strategy 9: practice safe sex

- Use condoms correctly to prevent sexually transmitted diseases

### Strategy 10: do not share needles, eating utensils and toothbrushes

- Please have your own set of personal sanitation items to prevent blood borne and gastrointestinal contagious diseases.





# The ten strategies of contamination control: start by washing your hands in the proper way

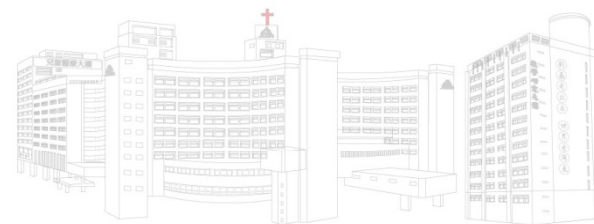


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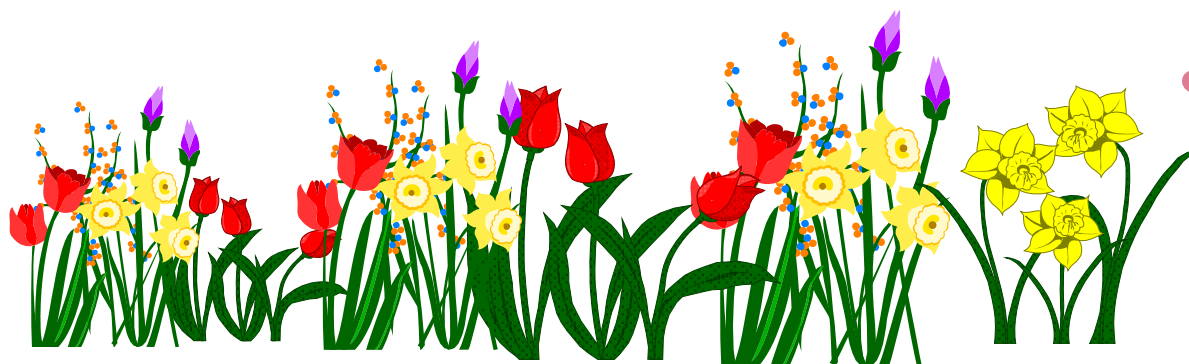
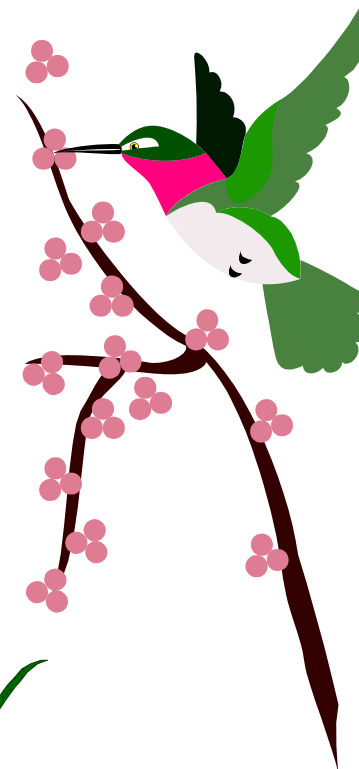
- Centers for Disease Control, Ministry of Health and Welfare <http://www.cdc.gov.tw/>
- Date: March 2014
- Code: 5736-brochure-Chinese-386-01

## Health Education for Infection Prevention and Sanitation

- Produced by the Committee of Infection Control and the Department of Nursing
- Consultation hotline: (04)7256652
- Consultation hotline service hours:
  - Monday to Saturday: morning 8:00-12:00
  - Monday to Friday: afternoon 1:30-5:30
- Hotline for praising: (04)7238595 ext 3920
- Hotline for complaint: (04)7238595 ext 3925
- Website: <http://www.cch.org.tw/knowledge/knowledge.aspx>
- Conducted nursing care direction and brochure on Health Education for Infection Prevention and Sanitation
- Signature by family member/patient



# Thank you for listening



~Please remember to take the test after the course, thank you very much~  
Webpage for online test:

[https://docs.google.com/forms/d/1A8pLTZBaW0jL-GCGKSyo44ilZ4kfxUPfzOYQTre4ux4/viewform?usp=send\\_form](https://docs.google.com/forms/d/1A8pLTZBaW0jL-GCGKSyo44ilZ4kfxUPfzOYQTre4ux4/viewform?usp=send_form)