

# INVESTIGATIONAL DRUG SERVICE MANUAL

RAMATHIBODI CLINICAL RESEARCH CENTER

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## WHAT WE DO

The Investigational Drug Service (IDS) at Ramathibodi Clinical Research Center (RAMACC) provide pharmacy support and guidance ensuring patient safety and data integrity of clinical research studies matched with international standards. We are one of the core functions for the faculty of Medicine, Ramathibodi hospital providing services to investigators of Mahidol University. RAMACC IDS is capable of providing services to support studies of investigational products, natural products, biologics, supplement and medical devices. Our inventory management system is state-of-the-art and our facilities are continuously monitored and highly secured. RAMACC IDS ensures the delivery of high-quality pharmaceutical care by adhering to guidelines and institutional policies for investigational drug control.

RAMACC IDS pharmacists are dedicated to pharmacy support enrolled in clinical research studies defined in protocols and guidelines. Services include medication counseling, medication reconciliation in patient screening, and relevant clinical services.

RAMACC IDS maintains documents required in clinical studies and total management of investigational drug. This includes but not limited to stock tracking, ordering, receiving, destruction, returns, storage and dispensing. We maintain appropriate alignment in all relevant parties including principle investigators and sponsors to ensure proper conduct of clinical studies.

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## EQUIPMENT

- Refrigerators (2-8 c)
- -20 c freezer
- -80 c freezer
- Controlled room temperature cabinets (15-25 c)
- Drug return from patient cabinet
- Temperature monitor devices during shipment

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## **FULL-SERVICE**

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- Medication reconciliation for study eligibility
- Medication review for possible interactions with study drug
- Patient counseling
- All aspect of investigational management
  - Accountability
  - Ordering investigational drug
  - Receiving study drug
  - Destruction/destroying study drug
  - Returning drug to sponsor
  - Dispensing study drug
- Labeling and packaging of investigational products
- Monitoring expiration date of investigational drug
- Inventory control and maintenance
  - Secured drug storage area that are monitored and alarmed to ensure proper storage conditions
- Satellite transfer for investigational drug

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## **PARTIAL-SERVICE**

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- Inventory control and maintenance
  - Secured drug storage area that are monitored and alarmed to ensure proper storage conditions
- Monitoring expiration date of investigational drug

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## **REQUEST FOR INVESTIGATIONAL DRUG SERVICE**

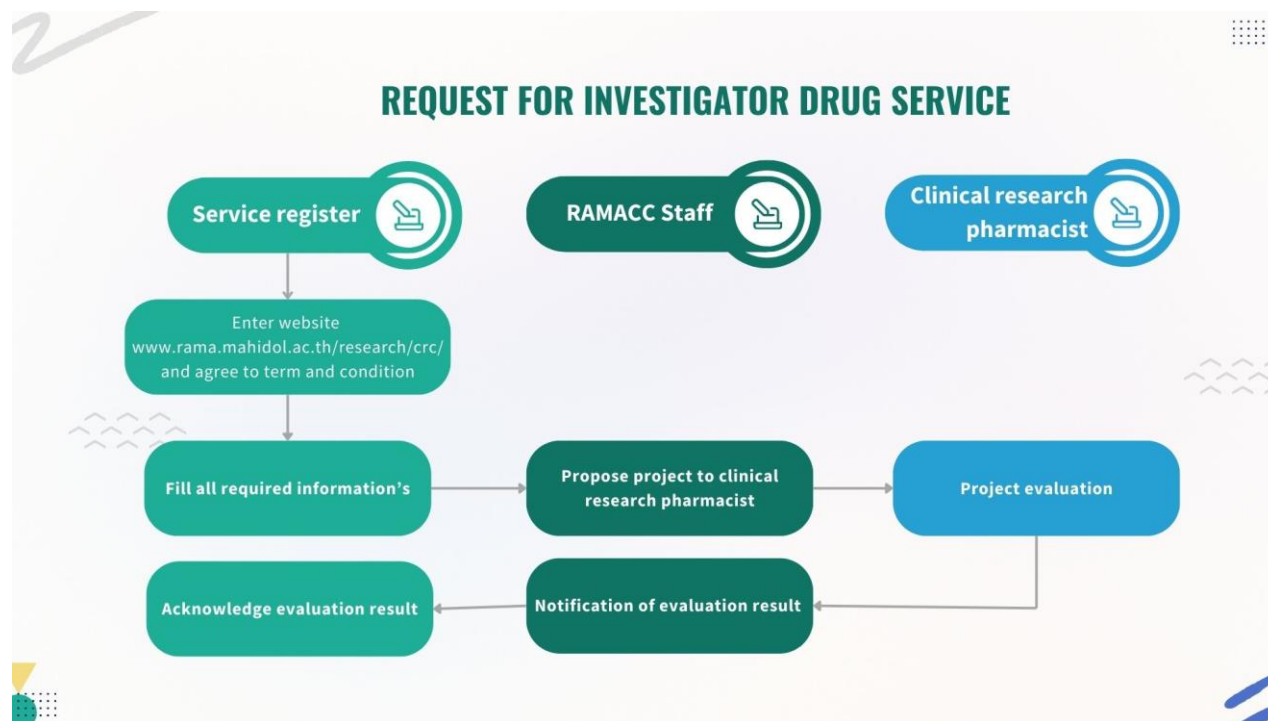
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- Full service
- Partial service

To request for Investigational Drug Service, please click

<https://www.rama.mahidol.ac.th/research/crc/th/content/08102024-1514#>

## Steps to request for investigational drug service:



## FEE

- Study drug storage: 100 baht/shelf/day
  - Area of shelf for refrigerator: 36 x 25 x 12 centimeter
  - Area for shelf for room temperature storage: 44 x 32 x 16 centimeter

## LOCATION AND HOURS

- The IDS core is located in Zone G 2<sup>nd</sup> floor Somdejphrathep Building Ramathibodi hospital
- Investigational drug service staff are available from 8 a.m. to 4 p.m., Monday through Friday

## CONTACT

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Investigation drug service	Full Service	Partial Service
<b><i>Preparation of Investigational Drug Storage</i></b>		
<ul style="list-style-type: none"> <li>Preparation of investigational drug storage for dispensing</li> </ul>	✓	
<ul style="list-style-type: none"> <li>Preparation of investigational drug storage for returned drug from patient (As required by the study)</li> </ul>	✓	
<ul style="list-style-type: none"> <li>Preparation of investigational drug storage for expired drug, end of study investigational drug</li> </ul>	✓	
<ul style="list-style-type: none"> <li>Preparation of shared digital worksheet for record</li> </ul>	✓	
<b><i>Investigational Drug Receipt</i></b>		
<div style="border: 1px solid green; padding: 10px; margin-bottom: 10px; text-align: center;">Schedule to receive drug with sponsor</div> <div style="text-align: center;">↓</div>	✓	
<div style="border: 1px solid green; padding: 10px; margin-bottom: 10px; text-align: center;">Receive drug delivery from sponsor</div> <div style="text-align: center;">↓</div>	✓	
<div style="border: 1px solid green; padding: 10px; margin-bottom: 10px; text-align: center;">Organize into basket and record date of investigational drug received, quantity, expiry date and sign into digital worksheet</div> <div style="text-align: center;">↓</div>	✓	
<div style="border: 1px solid green; padding: 10px; margin-bottom: 10px; text-align: center;">Store basket with properly recorded investigational drug into storage</div> <div style="text-align: center;">↓</div>	✓	✓
<div style="border: 1px solid green; padding: 10px; margin-bottom: 10px; text-align: center;">Create drug log for study</div> <div style="text-align: center;">↓</div>	✓	
<div style="border: 1px solid green; padding: 10px; text-align: center;">Confirm investigational drug receipt in IVRS</div>	✓	

Investigation drug service	Full Service	Partial Service
<p><b><i>Investigational Drug Dispensing</i></b></p> <div> <div>Call investigational drug in IVRS to obtain code</div> <div>↓</div> <div>Contact RAMACC staff to bring investigational drug basket out of storage</div> <div>↓</div> <div>Pick investigational drug according to the given code and verify</div> <div>↓</div> <div>Record date, quantity, next vисти and sign in digital worksheet</div> <div>↓</div> <div>Labeling to be prepared for dispensing</div> <div>↓</div> <div>Medication review for possible drug interaction with study drug</div> <div>↓</div> <div>Patient counseling</div> <div>↓</div> <div>Record in drug accountability form</div> <div>↓</div> <div>Record in Administration drug form</div> <div>↓</div> <div>Record in IVRS</div> </div>	<div>✓</div> <div></div> <div>✓</div> <div>✓</div> <div>✓</div> <div>✓</div> <div>✓</div> <div>✓</div> <div>✓</div> <div>✓</div>	<div></div> <div>✓</div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div>

Investigation drug service	Full Service	Partial Service
<p><b><i>Destruction of Expired Investigational Drug and Drug in Completed Studies</i></b></p> <div> <div>Store expired investigational drugs or drugs in completed studies in prepared storage, and record date, quantity, and sign in digital worksheet</div> <div>↓</div> <div>Contact CRA for destruction of investigational drug within 30 days, counting from expiration or completion of studies</div> <div>↓</div> <div>Send for destruction in case of destruction on site, or return to sponsor, record date of destruction, quantity, and sign in digital worksheet by both study coordinator and RAMACC staff</div> </div>	<p>✓</p> <p>✓</p> <p>✓</p>	<p>✓ (verify and sign)</p>
<p><b><i>Monitoring of Expired Investigational Drug</i></b></p> <div> <div>Check for expired investigational drugs every 1 month</div> <div>↓</div> <div>Move expired drug items from dispensing area to store in expired investigational drug storage and record date, quantity, and sign in digital worksheet</div> </div>	<p>✓</p> <p>✓</p>	<p>✓</p> <p>✓</p>