

International Institute of Information Technology, Bangalore

Consent Management System for Distributed Electronic Health Records
(Under the Guidance of Professor T.K Srikanth and Swapnil Shrivastava)

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Objective

Our main objective is to build a Consent Management System for Distributed Electronic Health Records.

Electronic Health Records are an electronic version of a patient's medical history that is maintained by the provider over time, and may include all of the key administrative clinical data relevant to that person's care under a particular provider, including demographics, progress notes, problems, medications. Ease of access, improved clarity and reduction of redundancy are some of the advantages of EHRs. Health Data is extremely sensitive personal data thus we must ensure that they are used appropriately i.e., only by authorized parties and for the intended purpose.

A consent management system is an attempt to manage this sharing of E- Health Records (EHRs) by giving patients (data principal acc. to Indian PDP Draft) more control in choosing who is using their records, for what purpose and for how long. It also helps eliminate the power asymmetry existing in current data sharing scenarios by giving patients ample choice from rejecting consent to access EHRs to abstracting information that they are unwilling to reveal (Scoping).

Our project intends to be a demonstration of consent-driven data sharing in Healthcare keeping in mind the aforementioned points.

Requirements and Use cases

Hospital App

S no.	Use Case	Description	Participants	Status
1	Adding hospital	Hospitals will be added manually.	Done manually	Done
2	Add doctor	Doctor has to be added by hospital admin first before his registration for security purposes	Hospital Admin	Done
3	Register the doctor	Doctor registers himself. OTP verification is done	Doctor	Done
4	Doctor's login	Doctor needs to login before he can access every hospital.	Doctor	Done
5	Doctor requests consent to access patient EHR	Doctor requests the patient for EHR access according to his requirements and consent request will be sent as a notification	Doctor	Done
6	Doctor adds EHR record	Doctor can add EHR after getting patient's consent	Doctor	Done
7	Doctor Create Login	Doctor can create his/her login credentials in the hospital app after first time registration. If the doctor is already registered, the doctor can create login credentials directly. OTP verification is done.	Doctor	Done
8	Displaying consented EHR	The patient EHR (only data that has been provided approved by patient) and consent details - date & time of consent, validity etc	Doctor	Done
9	Consent delegation	When the doctor gets access to any EHR, he is allowed to transfer or forward the consent to other doctors if the patient has given access to the doctor to delegate the consent. But the delegated doctor cannot delegate the consent further.	Doctor	Done

10	Approve/Reject Create Login	Admin can approve/reject the create login request submitted by doctor. If approved, the	Admin	Done
	request	doctor can log in to the system		

Patient App

S no.	Use Case	Description	Participants	Status
1	Registration	Patient fills a registration form. OTP verification is done.	Patient	Done
2	Adding Nominee	Patients can add nominee's according to their will.	Patient	Done
3	Patient Login	Patients can login using his/her credentials.	Patient	Done
4	Display all EHR records	Display all of the patient's records	Patient	Done
5	Create consent	Patients will be provided options to create and revoke consent.	Patient	Done
6	Display EHR access logs	Patients can view the access logs for his/her EHR accessed by various doctors across different hospitals.	Patient	Done
7	Consent request notification	View consent requests received.	Patient	Done
8	Display Patient Consent History	Will display all the history of consent given by the patient. Here the patient has options to revoke consent, view consent details.	Patient	Done

Consent Repository

S no.	Use Case	Description	Status
1	Consent Creation	Consent creation shown in the patient app. When a patient grants consent a unique consent id is generated and the consent artifact is stored in the consent repository.	Done
2	Granted Consents	Retrieve all the valid consents associated with a doctor id from the consent repository.	Done
3	Consent Validation	Consent validation request received from doctor app. The request is validated against consent stored in the consent repository.	Done
4	Consent Retrieval	Retrieve all the consents associated with a patient id from consent repository	Done
5	Consent Revocation	Consent is revoked by the patient. The consent is marked as invalid in the consent repository.	Done

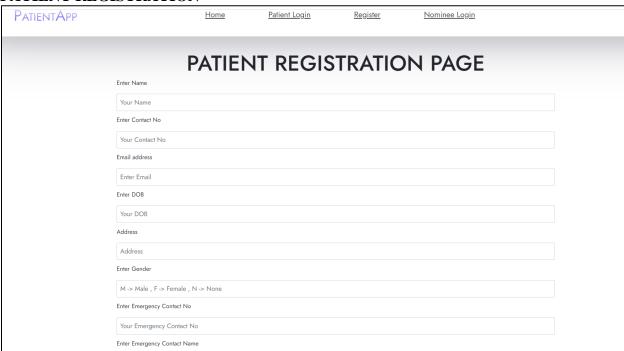
Non Functional Requirements

S no.	Requirement Description	Applicable Use Cases	Status
NFR - 1	Password Encryption	UC – 1,3	Done
NFR - 2	Performance		Done
NFR - 3	Compatibility		Done
NFR - 4	Usability	UC - 2,4,5,8 (patient app)	Done

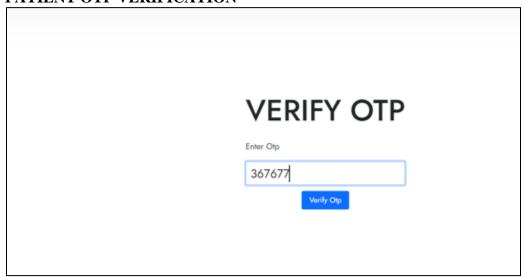
UI structure/flow

PATIENT APP

PATIENT REGISTRATION



PATIENT OTP VERIFICATION

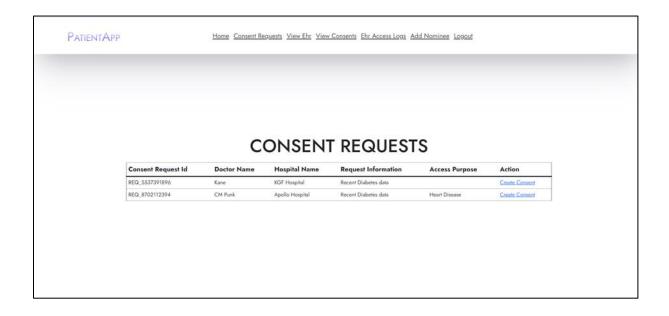


HOME PAGE(after login)



CONSENT REQUESTS

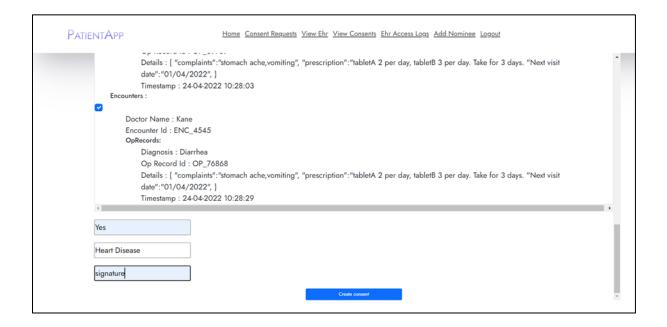
After logging in the patient can see the consent requests made by the doctor.

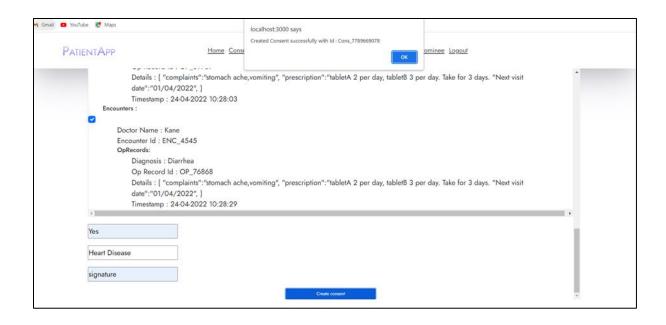


CREATE CONSENT

The patient can create consent and give access to his/her records to the doctor who requested.







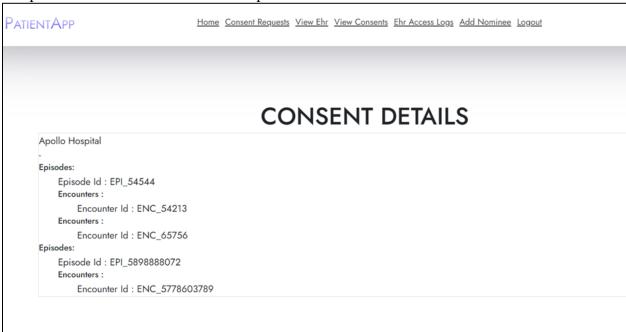
VIEW CONSENTS

The patient can view the consents given by him/her to the doctor and can also revoke them.



VIEW CONSENT DETAILS

The patient can see the details of the respective consented record



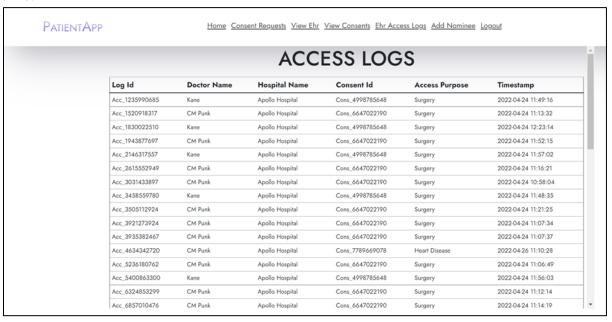
VIEW EHR

The patient can see all his/her health records

```
PATIENTAPP
                                         Home Consent Requests View Ehr View Consents Ehr Access Logs Add Nominee Logout
                                                                VIEW EHR
       Apollo Hospital
           Episode Id: EPI_54544
           Episode Name : General
           Encounters :
               Doctor Name : CM Punk
               Encounter Id: ENC_54213
               OpRecords:
                   Diagnosis : Diarrhea
                   Op Record Id: OP_89789
                   Details: { "complaints": "stomach ache, vomiting", "prescription": "tabletA 2 per day, tabletB 3 per day. Take for 3 days. "Next visit
                   date":"01/04/2022", }
                   Timestamp: 24-04-2022 09:57:36
               Doctor Name : CM Punk
               Encounter Id: ENC_65756
                   Diagnosis : Diarrhea
                   Op Record Id: OP_67868
```

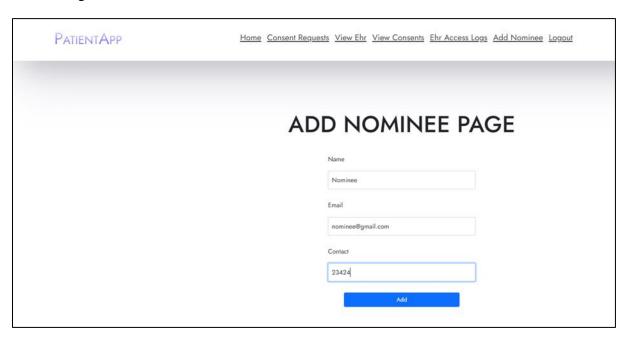
ACCESS LOGS

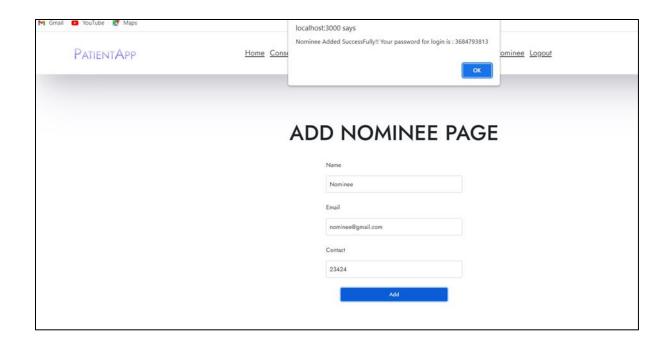
The patient can view the access logs, that is which record is accessed by which doctor at what time.



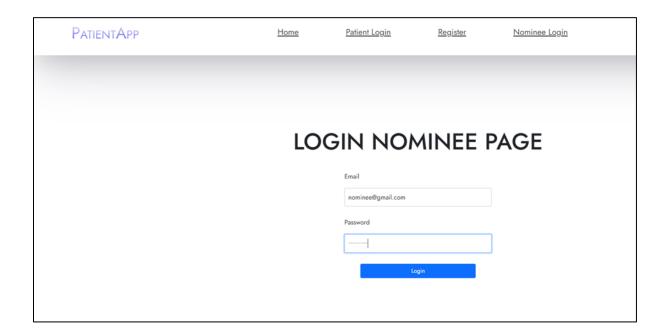
ADD NOMINEE

The patient can add a nominee, who can make the important decisions on his/her behalf other than adding another nominee.





LOGIN NOMINEE



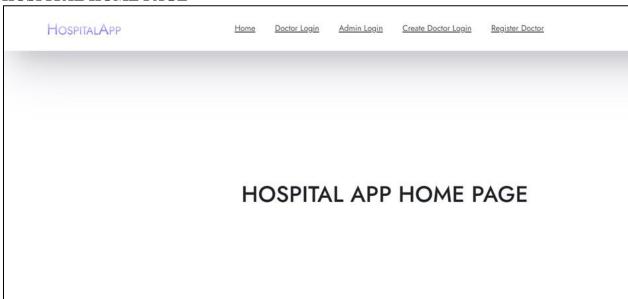
HOME PAGE AFTER NOMINEE LOGIN

After logging in as a nominee, all the other functionality remains the same but the add nominee functionality is not available anymore since only the patient can add the nominee.

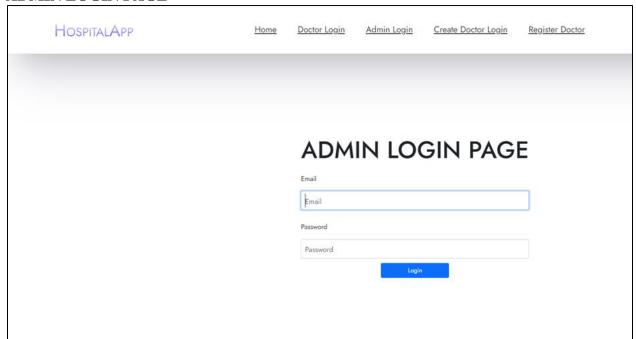


HOSPITAL APP

HOSPITAL HOME PAGE

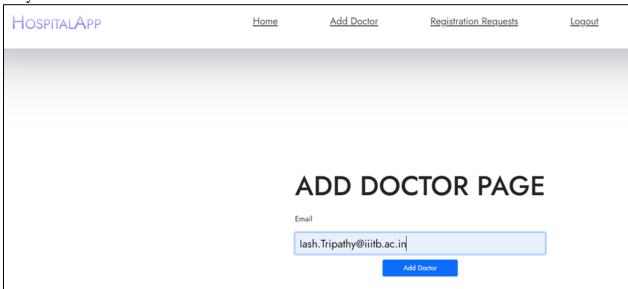


ADMIN LOGIN PAGE



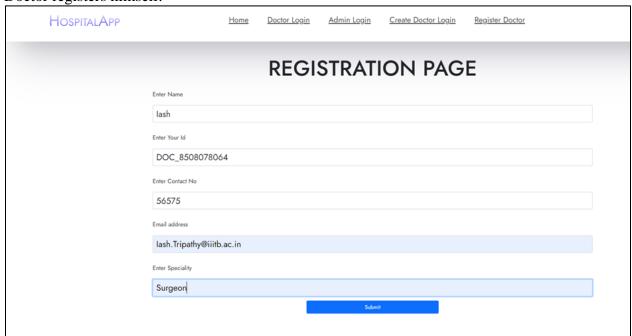
ADD DOCTOR

Only admin can add a doctor.



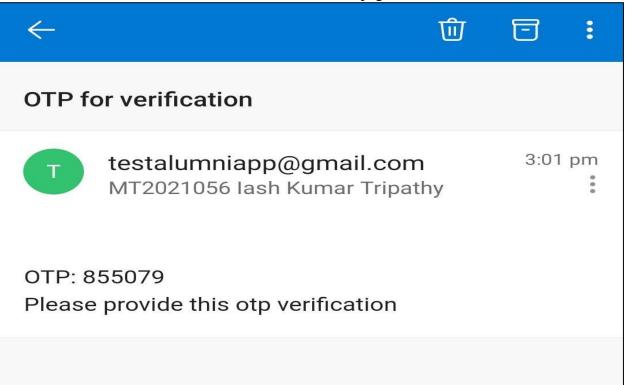
DOCTOR REGISTRATION

Doctor registers himself.

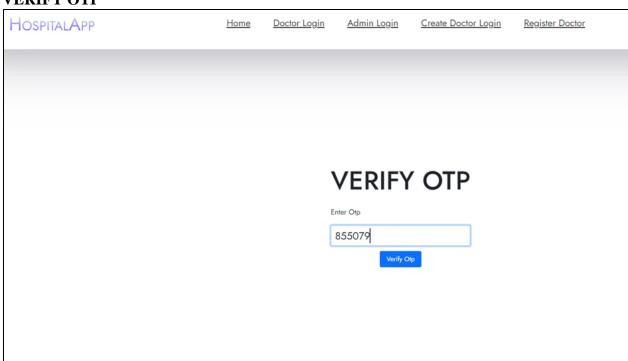


OTP VERIFICATION

In the registration page after clicking the submit button an OTP Will be sent to the doctor's email id and the Doctor will be redirected to OTP verification page.

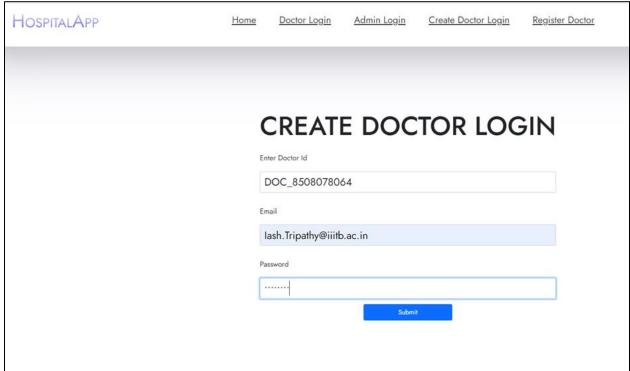


VERIFY OTP



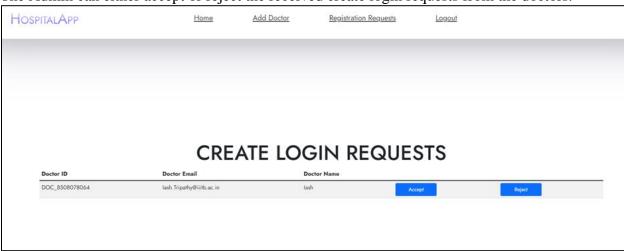
CREATE DOCTOR LOGIN

The doctor creates his login credentials before logging in which is specific to the hospital.

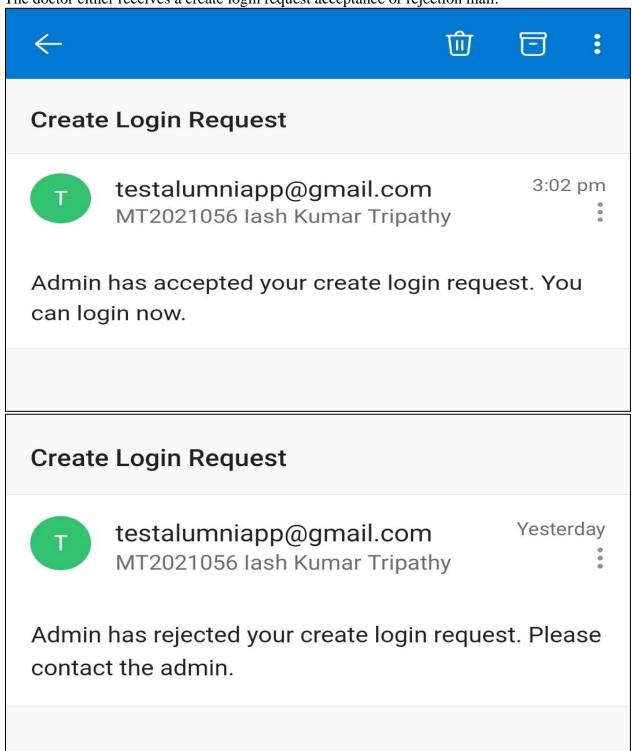


CREATE LOGIN REQUESTS

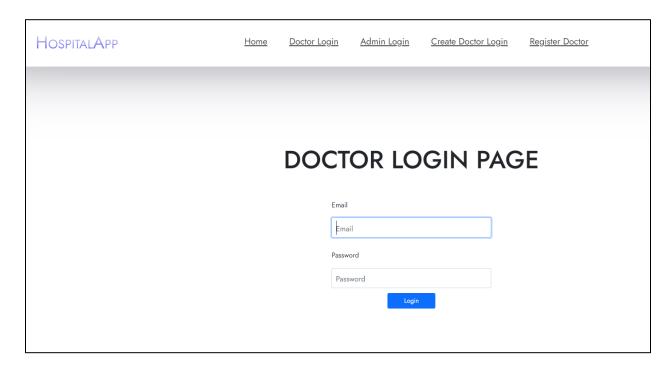
The Admin can either accept or reject the received create login requests from the doctors.



The doctor either receives a create login request acceptance or rejection mail.

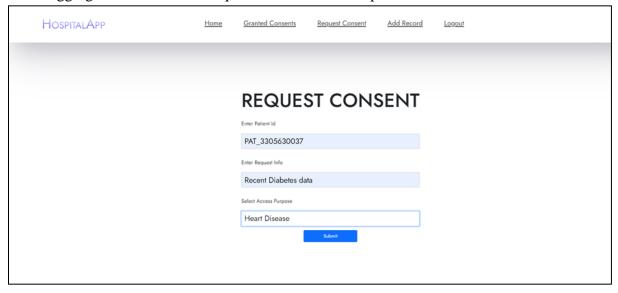


DOCTOR LOGS IN



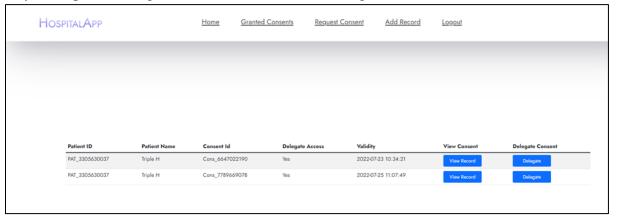
REQUEST CONSENT

After logging in the doctor can request consent from the patient.



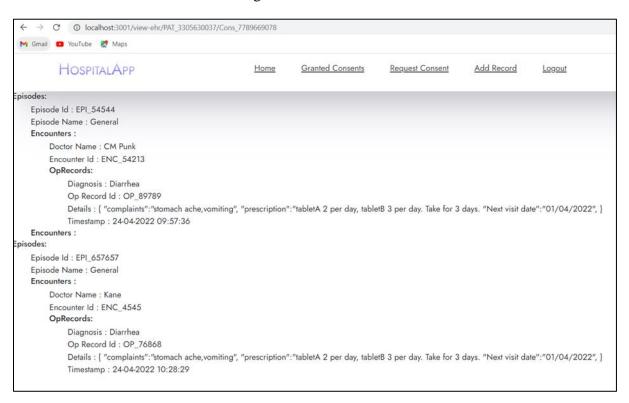
GRANTED CONSENT

The doctor can view all the consents granted to him/her. The delegate consent button will appear only if the patient has given access to the doctor to delegate the consent.



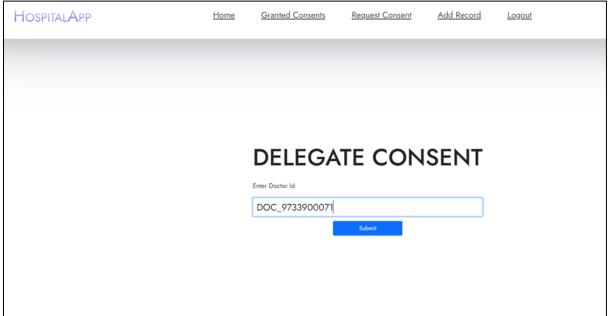
VIEW CONSENT

The doctor can view the EHRs of the granted consents.



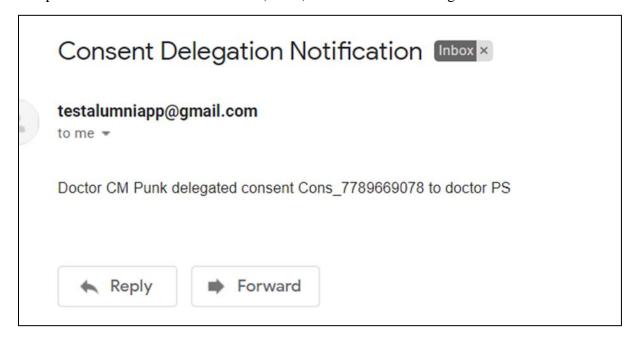
DELEGATE CONSENT

The doctor can delegate the consent to another doctor by entering his doctor id.



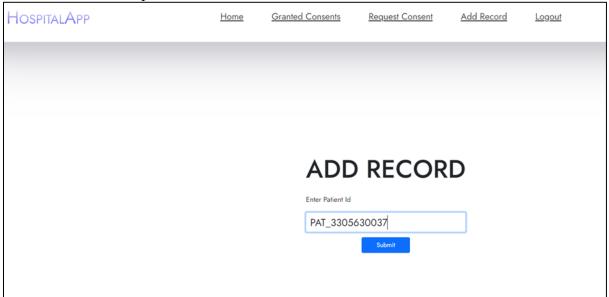
CONSENT DELEGATION NOTIFICATION

The patient will receive a notification (email) after the consent delegation.



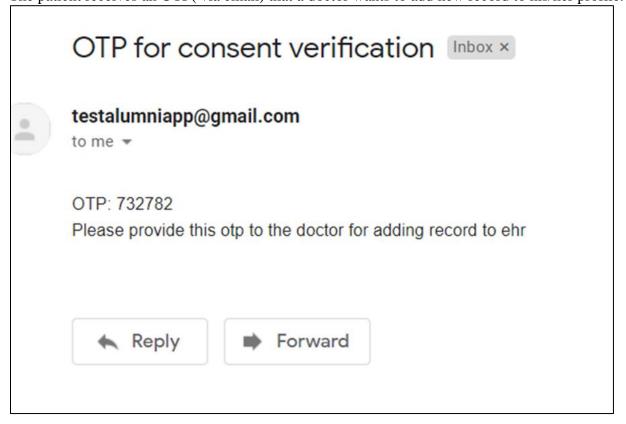
ADD RECORD

The doctor enters the patient id for whom he/she wants to add a new record.



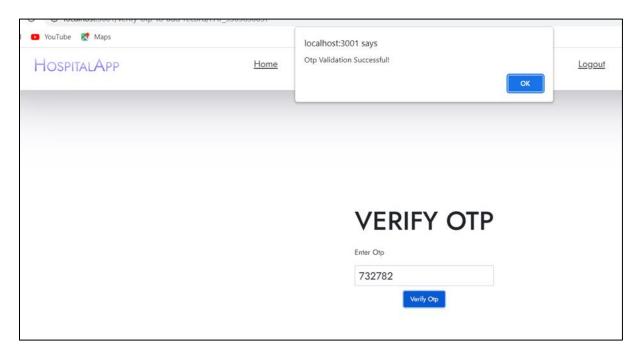
RECORD ADDING NOTIFICATION

The patient receives an OTP(via email) that a doctor wants to add new record to his/her profile.



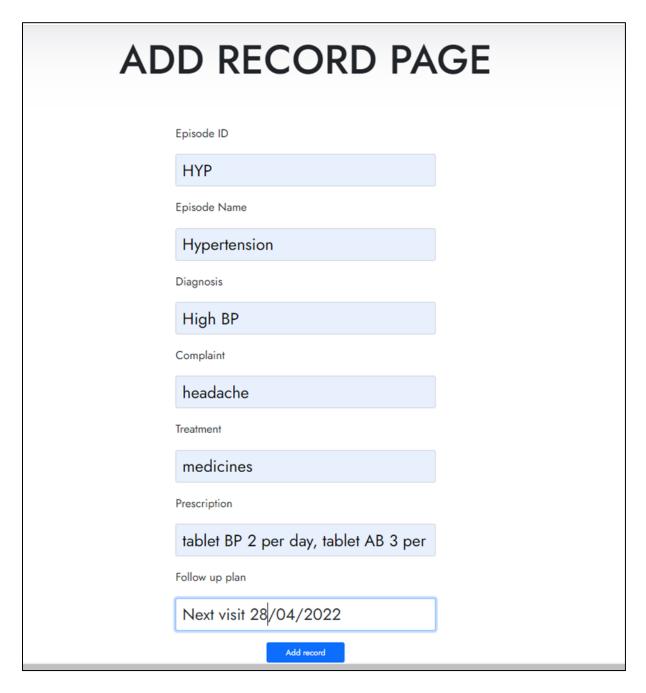
OTP VERIFICATION FOR ADD RECORD

The patient shares the OTP with the doctor and the doctor verifies the OTP.

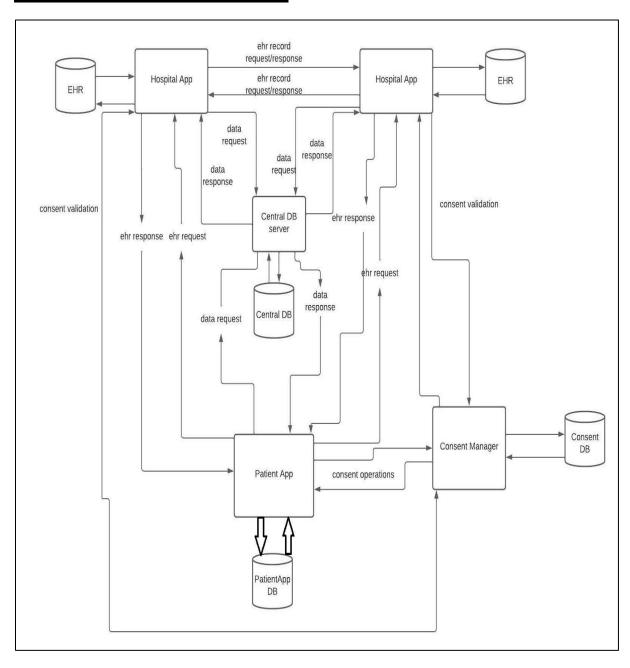


ADD RECORD

The doctor can now add the record after OTP verification.



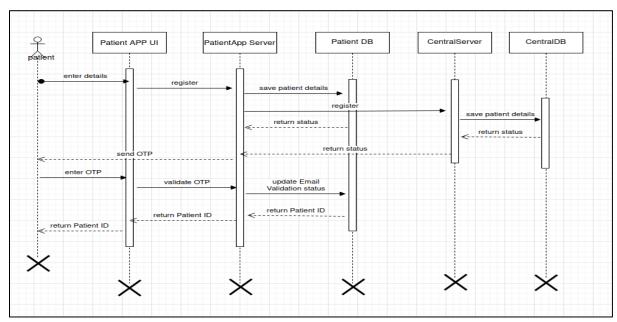
Architecture and key modules



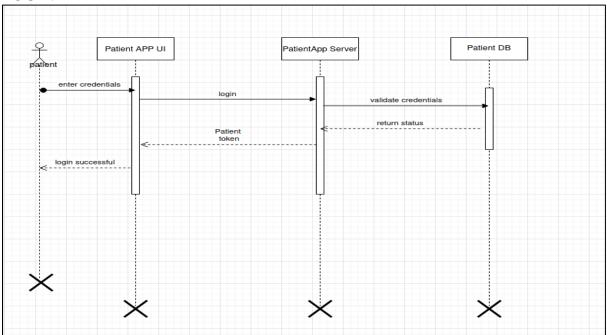
Sequence diagrams for representative flows

PATIENT APP

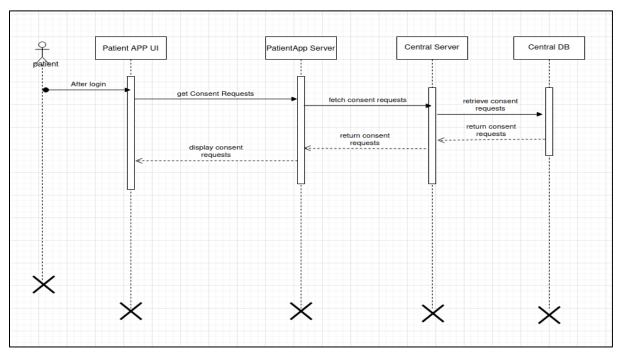
REGISTER



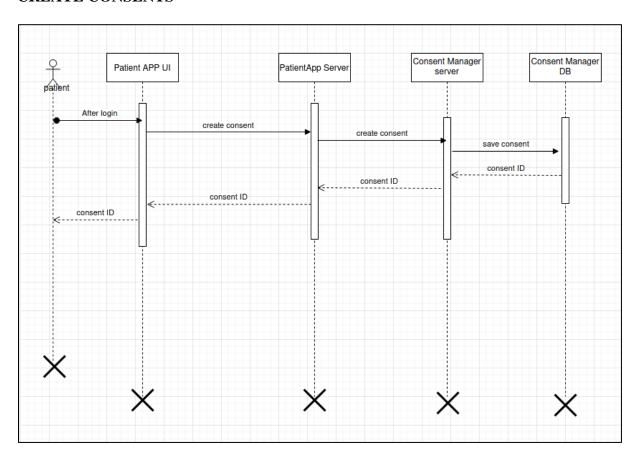
LOGIN



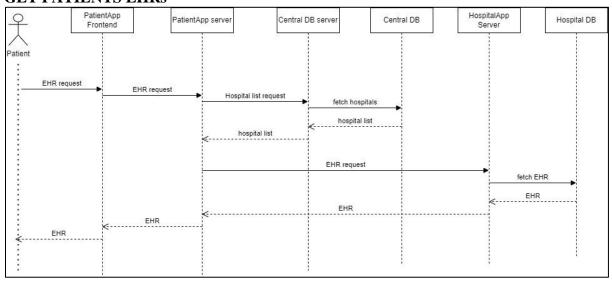
CONSENT REQUESTS



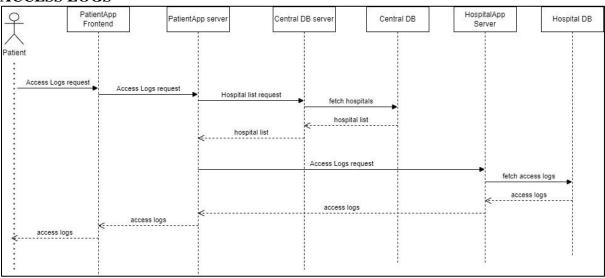
CREATE CONSENTS



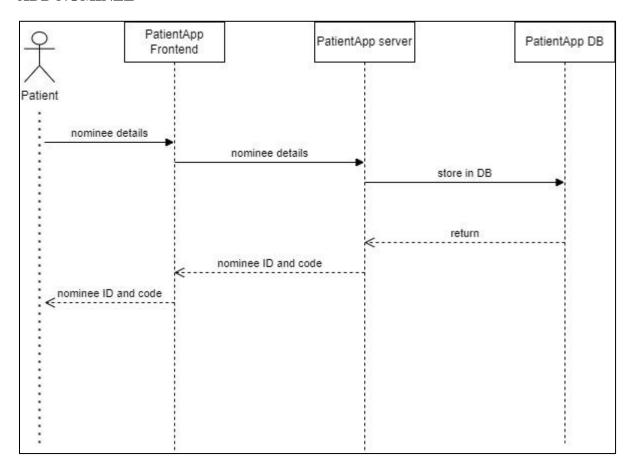
GET PATIENTS EHRs



ACCESS LOGS

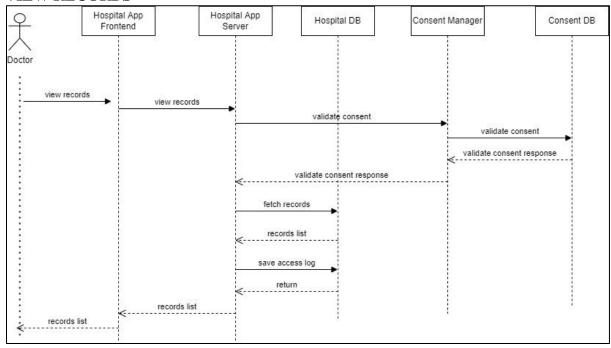


ADD NOMINEE

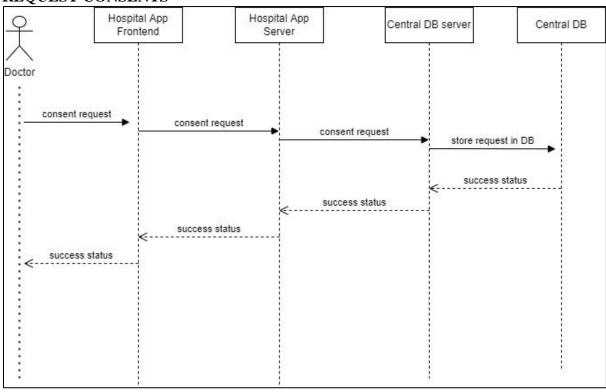


HOSPITAL APP

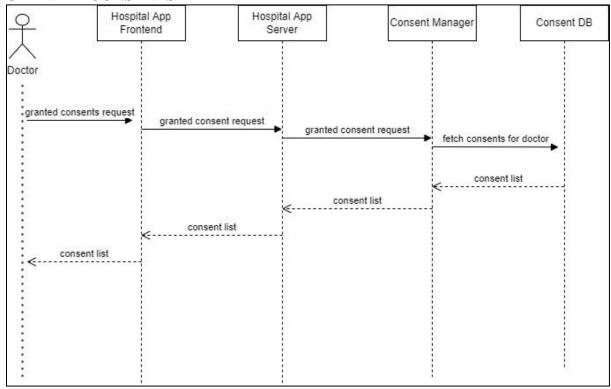
VIEW RECORDS



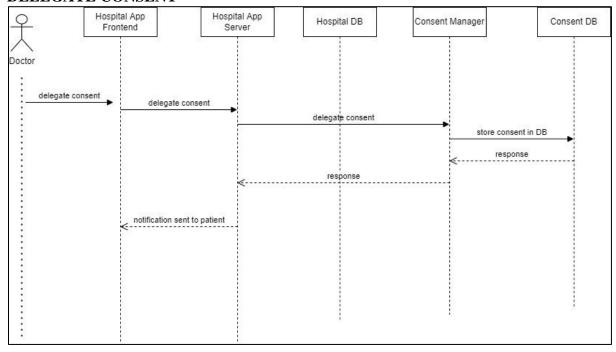
REQUEST CONSENTS



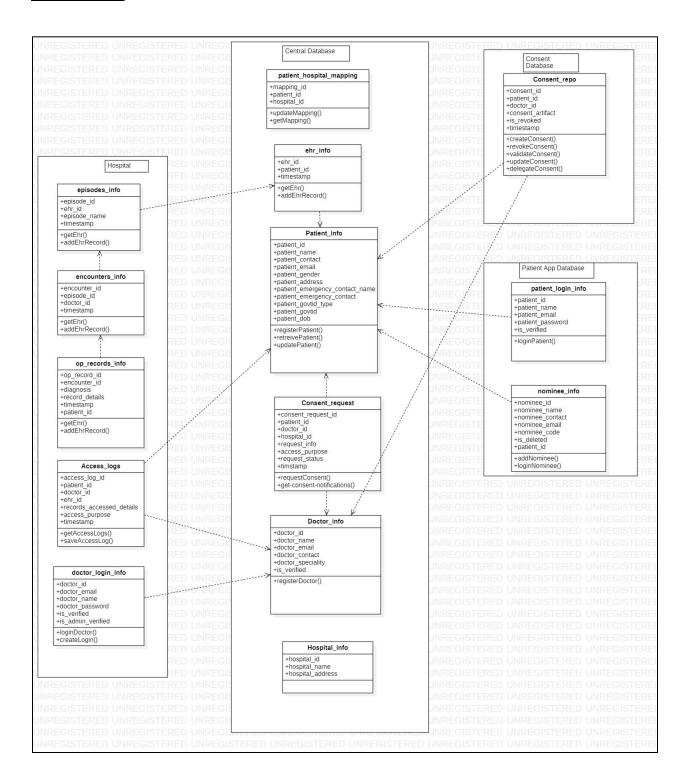
GRANTED CONSENTS



DELEGATE CONSENT



DB design



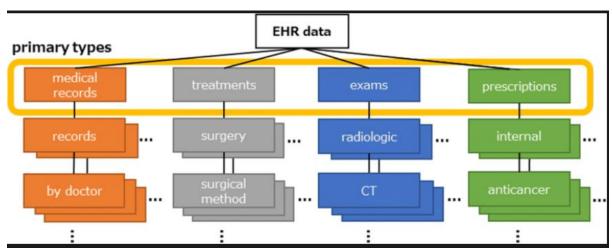
Frameworks libraries used

Tech Stack

Front End Framework	React JS
Backend Framework	Java with Spring Boot
Databases	MySQL

Key technical challenges

1. Designing and displaying the EHR Tree



Source: The Improvement of the Electronic Health Record User Experience by Screen Design Principles - Scientific Figure on ResearchGate. Available from: https://www.researchgate.net/figure/The-example-tree-structure-of-EHR-data-types-and-primary-types_fig1_337879439 [accessed 27 Apr, 2022]

An EHR Tree provides a division of how the EHR data is represented. For our project we have merged the location (hospital where the record originated) and the data present in the EHR i.e..

Hospital

Episode 1
Record 1
Episode 2
Record 2

Designing the EHR tree structure and displaying it posed a challenge for us. Initial designs include - Cascading List i.e, Hospital > Episodes > Records in the form of drop downs. This proved to be hurtful for the UI.

After many iterations we decided on creating an according design for the EHR with a multi select operation as shown below.



2. Implementing and Storing Consent according to MeitY Specifications
We followed a report issued by MeitY on creating and storing Consent Artifact. Our
main technical hurdle was storing the artifact. Initially we chose to store across columns
field wise. But for our final implementation the consent is stored as a JSON string.
Below is a sample consent artifact stored in the consent repository

```
"patientId": "PAT_3305630037",
"beneficiaryId": "DOC_9858151117",
"ehrDetails":{
 "ehrId": "EHR_78768",
 "dataCustodians":[
     "dataCustodianId": "HOSP_123",
     "episodes":[
        "episodeId": "EPI_54544",
        "time_limit_records":"",
        "encounterDetails":[
            "encounterId": "ENC_54213"
            "encounterId": "ENC_65756"
         "episodeId": "EPI_5898888072",
        "time_limit_records":"",
         "encounterDetails":[
            "encounterId": "ENC_5778603789"
"purpose": "Surgery",
"delegateAccess": "Yes",
"creationDate": "2022-04-28 10:46:48",
"validityDate": "2022-07-27 10:46:48",
"signature": "signature",
"systemId": "consent manager"
```

Open/incomplete issues

- 1. Nurse registration
 - a. Other roles which help to demonstrate administrative hierarchy have not been included such as nurse, resident doctor etc. these have been avoided because of the increased complexity it would present when granting consent and sharing EHRs.
- 2. Update consent time, records
 - a. We have not implemented update consent due to its increased level of complexity.
- 3. Change password/forgot password
- 4. View patient profile, Update patient profile.
- 5. During consent creation, instead of selecting records one by one under an episode, the patient can give a time period. All the records that fall in this time period will be part of the consent.
- 6. View nominees
- 7. Consent logs: the patient or the nominee can view the list of consent granted by him/her to every doctor.

Key learnings

Non - Technical Learnings

- From classroom lectures we have learnt about various initiatives of IIITBangalore EHRC in helping digitize Healthcare. The regulatory perspective of
 designing healthcare applications and the massive amount of user experience
 issues that come along with it. In our project we could experience the same
 difficulties while implementing the EHR Tree structure.
- The considerable gap between techies and doctors and their process (eg.
 Handwritten prescriptions are easier for doctors instead of typing or selecting from various dropdowns)
- Role of Consent in Healthcare and how complex it is to abstract data according to patient privacy choices.

Technical Learnings

- Spring Boot and Micro services
- APIs
- React

Experience

- Designing an application has taught us the brainstorming of ideas, team spirit and
 most of all the importance of a well formed design. Initially our struggles
 revolved around understanding the requirements of healthcare applications and
 the concept of 'Consent'.
- Through multiple brainstorming sessions we were able to come up with a foundational design that we would carry on throughout our project.

References

- The Improvement of the Electronic Health Record User Experience by Screen Design Principles - Scientific Figure on ResearchGate. Available from: https://www.researchgate.net/figure/The-example-tree-structure-of-EHR-data-types-and-primary-types_fig1_337879439 [accessed 27 Apr, 2022]
- 2. https://reactjs.org/docs/getting-started.html
- 3. https://docs.spring.io/spring-boot/docs/current/reference/htmlsingle/
- Rantos, K., Drosatos, G., Demertzis, K., Ilioudis, C., Papanikolaou, A., Kritsas, A. (2019). ADvoCATE: A Consent Management Platform for Personal Data Processing in the IoT Using Blockchain Technology. In: Lanet, JL., Toma, C. (eds) Innovative Security Solutions for Information Technology and Communications. SECITC 2018. Lecture Notes in Computer Science(), vol 11359. Springer, Cham. https://doi.org/10.1007/978-3-030-12942-2_23
- 5. https://www.youtube.com/channel/UC29ju8bIPH5as8OGnQzwJyA
- 6. https://www.figma.com/
- 7. MeitY Consent Framework