**APPROVAL SIGNATURES:**

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| *The REDCap Project Specification document has been reviewed and approved. I understand that this document may change over the course of the project. This is the original project team approval for this document.* | | | |
| **Name** | **Signature** | **Title** | **Date** |
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| *The REDCap Project Specification document has been reviewed and approved. I understand that this document may change over the course of the project. This is the original sponsor approval for this document.* | | | |
| **Name** | **Signature** | **Title** | **Date** |
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**DOCUMENT HISTORY:**

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| --- | --- | --- | --- | --- |
| **Revision** | **Author** | **Date reviewed/revised** | **Changes** | **Reason for changes** |
|  |  |  |  |  |

1. **Main Project Settings**

|  |  |
| --- | --- |
|  |  |
| Enabled | Use surveys in this project |
| Enabled | Use longitudinal data collection with defined events? |

1. **Event/Instrument Table (longitudinal projects only)**

|  |  |  |  |
| --- | --- | --- | --- |
| Data Collection Instrument | Baseline | 1 Month | Study End |
| Demographics | X |  |  |
| Medical History (survey) | X | X | X |
| Adverse Events (survey) | X | X | X |

1. **Survey Settings**

|  |  |
| --- | --- |
| Demographics |  |
| Survey Access: |  |
| Response Limit (optional) | 150 |
| Time Limit for Survey Completion (optional) |  |
| Survey Expiration (optional) |  |
| Allow “Save & Return Later” option for respondents? | Yes |
| * Allow respondents to return without needing a return code | X |
| * Allow respondents to return and modify completed responses | X |

1. **Optional Modules and Customizations**

|  |  |
| --- | --- |
|  |  |
| Enabled | Repeatable instruments and events |
| Enabled | Auto-numbering for records |
| Disabled | Scheduling module (longitudinal only) |
| Enabled | Randomization module |
| Disabled | Designate an email field for sending survey invitations |

*Note: Document any options selected on the “Additional customizations” page here.*

1. **User Rights and Roles**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Basic Rights | CRC | PI | Sponsor | Project Owner |
| Highest level privileges: |  |  |  |  |
| Project Design and Setup |  |  |  | X |
| User Rights |  |  |  | X |
| Data Access Groups |  |  |  | X |
| Privileges for data exports (including PDFs and API exports), reports and stats: |  |  |  |  |
| Data Exports | X | X |  | X |
| Add/Edit Reports | X | X |  | X |
| Stats & Charts | X | X |  | X |
| Other privileges: |  |  |  |  |
| Manage Survey Participants | X | X |  | X |
| Calendar | X | X |  | X |
| Data Import Tool | X | X |  | X |
| Data Comparison Tool | X | X |  | X |
| Logging | X | X |  | X |
| File Repository | X | X |  | X |
| Randomization |  |  |  | X |
| Data Quality | X | X |  | X |
| API |  |  |  | X |
| Settings pertaining to the REDCap Mobile App: |  |  |  |  |
| REDCap Mobile App |  |  |  |  |
| Allow users to download data for all records to the app? |  |  |  |  |
| Settings pertaining to project records: |  |  |  |  |
| Create Records | X | X |  | X |
| Rename Records | X | X |  | X |
| Delete Records | X | X |  | X |
| Settings pertaining to record locking and E-signatures: |  |  |  |  |
| Record Locking Customization |  | X |  | X |
| Lock/Unlock Records |  | X |  |  |
| Allow locking of all forms at once for a given record? |  | X |  |  |

1. **Data Entry Rights**

*Note: The data entry rights only pertain to a user’s ability to view or edit data on a web page in REDCap (e.g., data entry forms, reports). It has no effect on data imports or data exports.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| CRC: |  |  |  |  |
| Instrument Name | No Access | Read Only | View & Edit | Edit survey responses |
| Demographics |  |  | X |  |
| Medical History (survey) |  |  | X | X |
| Adverse Events (survey) |  |  | X | X |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| PI: |  |  |  |  |
| Instrument Name | No Access | Read Only | View & Edit | Edit survey responses |
| Demographics |  |  | X |  |
| Medical History (survey) |  |  | X |  |
| Adverse Events (survey) |  |  | X |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sponsor: |  |  |  |  |
| Instrument Name | No Access | Read Only | View & Edit | Edit survey responses |
| Demographics |  | X |  |  |
| Medical History (survey) |  | X |  |  |
| Adverse Events (survey) |  | X |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Project Owner: |  |  |  |  |
| Instrument Name | No Access | Read Only | View & Edit | Edit survey responses |
| Demographics |  |  | X | X |
| Medical History (survey) |  |  | X | X |
| Adverse Events (survey) |  |  | X | X |

1. **Data Access Groups**

*Access to certain project records may be limited by using Data Access Groups, in which only users within a given Data Access Group can access records created by users within that group. This may be useful in the case of a multi-site or multi-group project that requires that groups not be able to access another group’s data.*

Data Access Groups:

* MGH
* BWH

1. **Randomization**

Subjects are randomized <insert how subject are randomized> (e.g. by provider, by site). The randomization schema is provided by a blinded statistician and incorporated into the database design so that randomization can occur through REDCap. A sample randomization table is also provided and the randomization process is tested using sample data.

1. **Record Locking Customization**

|  |  |  |  |
| --- | --- | --- | --- |
| Display the Lock option for this instrument? | Data Collection Instrument | Also display E-signature option on instrument? | Lock Record Custom Text |
| X | Demographics | X | My dated signature below confirms that I have personally examined all of the available data recorded for this electronic case report form.   This is to certify that I, <PI Name>, Principal Investigator of the <ProjectName> project, and following all applicable regulatory guidelines, intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.   To this I do attest by supplying my REDCap username and password and clicking the button marked "Save". |
| X | Medical History |  |  |
| X | Adverse Events |  |  |