**PROTOCOL TITLE:** Racial and Ethnic Disparities in the Timeliness of Nephrology Care for Patients with Chronic Kidney Disease

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|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |

**Table of Contents**

[1.0 Study Summary 3](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162129)

[2.0 Objectives\* 4](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162130)

[3.0 Background\* 4](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162131)

[4.0 Study Endpoints\* 4](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162132)

[5.0 Study Intervention/Investigational Agent 4](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162133)

[6.0 Procedures Involved\* 5](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162134)

[7.0 Data and Specimen Banking\* 5](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162135)

[8.0 Sharing of Results with Subjects\* 6](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162136)

[9.0 Study Timelines\* 6](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162137)

[10.0 Inclusion and Exclusion Criteria\* 6](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162138)

[11.0 Vulnerable Populations\* 6](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162139)

[12.0 Local Number of Subjects 7](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162140)

[13.0 Recruitment Methods 7](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162141)

[14.0 Withdrawal of Subjects\* 7](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162142)

[15.0 Risks to Subjects\* 7](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162143)

[16.0 Potential Benefits to Subjects\* 8](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162144)

[17.0 Data Management\* and Confidentiality 8](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162145)

[18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects\* 8](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162146)

[19.0 Provisions to Protect the Privacy Interests of Subjects 9](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162147)

[20.0 Compensation for Research-Related Injury 9](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162148)

[21.0 Economic Burden to Subjects 9](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162149)

[22.0 Consent Process 9](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162150)

[23.0 Process to Document Consent in Writing 12](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162151)

[24.0 Setting 13](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162152)

[25.0 Resources Available 13](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162153)

[26.0 Multi-Site Research\* 13](https://usc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en%2DUS&rs=en%2DUS&wopisrc=https%3A%2F%2Fmedstarcloud-my.sharepoint.com%2Fpersonal%2Fdelisia_l_wicks_medstar_net%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F58ccad7e417a4a05b8d2721d0029361a&wdenableroaming=1&mscc=1&wdodb=1&hid=08F447A0-20EC-D000-0ABD-501C82E79242&wdorigin=ItemsView&wdhostclicktime=1655392417188&jsapi=1&jsapiver=v1&newsession=1&corrid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&usid=2a204ac7-4293-4dbf-b6f7-b761d2e81c7f&sftc=1&cac=1&mtf=1&sfp=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush&rct=Medium&ctp=LeastProtected#_Toc496162154)

# **GHUCCTS Questions**

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# GHUCCTS is the Georgetown-Howard Universities Center for Clinical and Translational Science.

# **Is this study a GHUCCTS Study?**  \_\_\_\_Yes X\_\_\_\_No

#

# **Is the project being sponsored or funded by GHUCCTS?** \_\_\_\_Yes X\_\_\_\_No

#

# **Does the project utilize GHUCCTS services or facilities?** \_\_\_\_Yes X\_\_\_\_No

**(**e.g., is the study conducted on the Clinical Research Unit (CRU), is the study supported by a GHUCCTS biostatistician, etc.)

# **1.0 Study Summary**

|  |  |
| --- | --- |
| **Study Title** | Racial and Ethnic Disparities in the Timeliness of Nephrology Care for Chronic Kidney Disease  |
| **Study Design** | Retrospective analysis |
| **Primary Objective** | To evaluate racial and/or ethnic disparities in the timeliness of nephrology care amongst patients with newly diagnosed CKD |
| **Secondary Objective(s)** | To identify factors associated with observed racial and/or ethnic disparities in timely nephrology care |
| **Research Intervention(s)/ Investigational Agent(s)**  | NA |
| **IND/IDE #**  | NA |
| **Study Population** | Includes all newly diagnosed CKD Stage 3 and CKD Stage 4 patients with an eGFR between 15 and 59 ml/min/173m2 who follow with MedStar primary care |
| **Sample Size** | Estimated sample of 200,000 subjects with newly diagnosed Stage 3 CKD or Stage 4 CKD  |
| **Study Duration for individual participants** | NA, retrospective analysis of OHDSI data from January 1, 2017 to May 31, 2022 |
| **Study Specific Abbreviations/ Definitions**  | CKD = Chronic Kidney DiseaseOHDSI = Observational Health Data Sciences and Informatics eGFR = estimated Glomerular Filtration Rate |

# **2.0 Objectives\***

* 1. The goal of this project is to evaluate racial and/or ethnic disparities in the timeliness of first nephrology outpatient encounter, for patients with newly diagnosed chronic kidney disease.
	2. Our secondary objective is to identify the factors associated with observed racial and/or ethnic disparities in the first nephrology visit.

**3.0 Background\***

CKD is a global public health challenge that places a significant economic burden on patients and health systems throughout the United States.1 Prior research has demonstrated that early nephrology referral in patients with newly diagnosed CKD results in lower mortality, lower hospitalization rates, and improved outcomes.2-3 Timely nephrology care can prevent delayed initiation of renal replacement therapy and delayed referral for transplantation. These results signify the importance of timely follow-up for patients with newly diagnosed Chronic Kidney Disease.

Despite an almost equal prevalence of Chronic Kidney Disease among Non-Hispanic Black and Non-Hispanic White populations,4-6 there are known disparities in the progression and treatment of Chronic Kidney Disease between Non-Hispanic Black and Hispanic/Latinx populations compared to non-Hispanic White populations.7 Prior research that has examined timeliness of nephrology care has shown a lower odds of early nephrology care in Black populations than in White populations.8-11 However, research in this area has been limited with defining timeliness of care based on months before onset of dialysis, which may be confounded by the rate of progression of disease and other factors. Thus, there is a need to establish whether or not racial and/or ethnic disparities exist in the timeliness of nephrology care based on criteria using laboratory values indicating the presence of newly diagnosed CKD and need for nephrology care.

This analytic approach will leverage access to EHR data and advance our understanding of disparities in timely nephrology care, including an evaluation of factors associated with observed disparities. If there are observed racial and/or ethnic disparities in the timeliness of nephrology care, this insight will not only guide national strategies designed to target timely identification and management, but also will increase awareness among health care providers to optimize integrated care for historically marginalized patients with CKD.

# **4.0 Study Endpoints\***

4.1 Primary outcomes:

* Stage 3 CKD Analysis
	+ Disparity in odds of first nephrology visit within 3 months of newly diagnosed Stage 3 CKD, defined as two consecutive eGFR values 30-59 ml/min/173m2 at least 90 days apart.
	+ Number of days until first nephrology visit among newly diagnosed Stage 3 CKD patients.
* Stage 4 CKD Analysis
	+ Disparity in odds of first nephrology visit within 3 months of newly diagnosed Stage 4 CKD, defined as two consecutive eGFR values 15-29 ml/min/173m2 at least 90 days apart.
	+ Number of days until first nephrology visit among newly diagnosed Stage 4 CKD patients.

4.2 Secondary outcomes:

# Disparity in number of days for nephrology referral by Primary Care Physician of newly diagnosed Stage 3 or Stage 4 CKD

# Disparity in interval between first eGFR value less than 60 ml/min/173m2 and second eGFR value

* Disparity in proportion of individuals with an initial abnormal outpatient eGFR value between 15-59 ml/min/173m2 without a second eGFR value checked within 5 months12

# **5.0 Study Intervention/Investigational Agent**

*NA*

# **6.0 Procedures Involved\***

The study’s dataset will include retrospectively collected data from OHDSI, which contains data routinely mapped from the Cerner electronic health record used across MedStar facilities and has been standardized and validated. OHDSI visit-level data will be used to create a limited dataset for analysis containing the variables outlined in Table 1 below. The limited dataset will be restricted to our study population outlined under Inclusion Criteria in Table 3. This dataset will be maintained on MedStar’s secure, password protected server throughout the course of the study, with access limited to study personnel.

|  |
| --- |
| **Table 1. Planned Study Variables**  |
| ***Encounter Characteristics*** |
| Number of days between newly diagnosed CKD and first nephrology visit |
| Number of days between the first abnormal eGFR and second eGFR lab test |
| Second eGFR value checked within 5 months after first abnormal eGFR (yes/no) |
| Nephrology Referral (yes/no) |
| ***Patient Demographic Characteristics*** |
| Age (continuous) |
| Sex (male, female, other) |
| Race & Ethnicity (non-Hispanic white, non-Hispanic Black, Hispanic/Latino, non-Hispanic Asian/Pacific Islander, other) |
| Payer type (Medicare, Medicaid, Dual-Eligible, Private, Self-Pay/Medicaid Pending) |
| Residential Address (to link ACS data) |
| ***Patient Comorbidities*** |
| Elixhauser Comorbidity Index13 |
| Body Mass Index |
| Diabetes |
| Hypertension |
| Congestive Heart Failure |
| ***Patient Behavioral Factors*** |
| Smoking history (former smoker, current smoker, non-smoker) |
| ***Labs*** |
| eGFR level |
| Urine albumin-to-creatinine ratio |
| Serum albumin |
| Serum bicarbonate |
| Serum phosphorous |
| Serum calcium |
| ***Neighborhood Social Drivers of Health*** (from the American Community Survey (ACS)) |
| Area Deprivation Index (categorical: high, medium, low based on quartiles of distribution) |
| Population aged ≥ 25 with <9 years of education (%) |
| Population aged ≥25 with at least a high school diploma (%) |
| Median household income ($) |
| Median home value ($) |
| Median gross rent ($) |
| Median monthly mortgage ($) |
| Income disparity ($) |
| Employed persons aged ≥16 in white-collar occupations (%) |
| Civilian labor force population aged ≥16 unemployed (%) |
| Families below the federal poverty level (%) |
| Population below 150% of the federal poverty level (%) |
| Owner-occupied housing units (%) |
| Occupied housing units without complete plumbing (%) |
| Occupied housing units without a telephone (%) |
| Occupied housing units without a motor vehicle (%) |
| Occupied housing units with >1 person per room (%) |
| Single-parent households with children aged <18 (%) |

Neighborhood social drivers of health will be examined using the area deprivation index (ADI) based on the patient’s residential address by census block and linked to the dataset from the publicly available American Community Survey (ACS). ADI is an index of seventeen socioeconomic indicators from the ACS 5-year sample. We will test use of the composite ADI versus its individual components in the study’s analysis. The individual components of ADI are outlined in Table 1.

After the composition of the study dataset, we will perform the following analytic procedures:

(1) Descriptive Statistics

We will perform descriptive statistics comparing patient demographics, comorbidities, and behavioral factors, lab findings, and neighborhood characteristics between the reference group and the comparison groups (outlined in Table 2). We will use Chi-Square tests for categorical variables and two-sample t-tests for continuous variables.

(2) Logistic Regression Analysis

We will perform univariate logistic regression to describe the relationship between variables in the data set with (a) disparity in the odds of first nephrology visit within 3 months of newly diagnosed Stage 3 CKD and (b) newly diagnosed Stage 4 CKD. We will then perform multivariate logistic regressions for these same outcome measures to risk-adjust for covariates associated with the outcome.

(3) Linear Regression Analysis

We will use multivariate linear regression analysis to examine disparities in (a) the number of days for nephrology referral by the primary care physician, (b) the number of days until the first nephrology visit among newly diagnosed Stage 3 and Stage 4 CKD patients and (c) the number of days from the first eGFR value < 60 ml/min/173m2 and the second eGFR test.

|  |
| --- |
| **Table 2: Subgroups for Disparity Analysis**  |
|   | **Comparison Groups** | **Reference Groups** |
| Aggregate Analysis | Non-White | Non-Hispanic White |
| Subgroup Analysis | Non-Hispanic BlackHispanic/LatinxOther | Non-Hispanic White |

# **7.0 Data and Specimen Banking\***

*NA*

# **8.0 Sharing of Results with Subjects\***

*NA*, all data in the study’s analytic dataset will be de-identified.

# **9.0 Study Timelines\***

3 month project period, with 1 month for dataset construction, 1 month for statistical analysis, and 1 month for iterative updates to the analysis and composition of the final study reports (e.g. non-technical research briefs, abstract, and manuscript)

# **10.0 Inclusion and Exclusion Criteria\***

|  |
| --- |
| Table 3. Inclusion and Exclusion Criteria |
| Inclusion Criteria:The inclusion criteria for all iterations of data analysis will follow the same structure with the study population consisting of all available patients who meet the following criteria |
| 1. Individuals with a newly diagnosed eGFR between 15-59 ml/min/173m2, with two consecutive outpatient eGFR values between 15-59 ml/min/173m2 at least 90 days apart.
 |
| 1. MedStar patient for at least one year.
 |
| 1. Has a MedStar Primary Care Physician
 |
| Exclusion Criteria: |
| 1. Procedures or treatments indicative of existing CKD (i.e. prior fistula placement, dialysis, or kidney transplant)
 |
| 1. Prior history of solid organ transplant
 |
| 1. Ages less than 18
 |

# **11.0 Vulnerable Populations\***

*NA*

# **12.0 Local Number of Subjects**

We estimated a total of 200,000 subjects with newly diagnosed stage 3 or stage 4 CKD in our study cohort.

# **13.0 Recruitment Methods**

*NA*

# **14.0 Withdrawal of Subjects\***

*NA*

# **15.0 Risks to Subjects\***

There are no direct risks to patients. Indirect risks consist primarily of breach of confidentiality which will be minimized by having data de-identified prior to statistical analyses, using the OHDSI data source for which data extraction from the electronic health record is automated, and following strict data confidentiality procedures as outlined below.

# **16.0 Potential Benefits to Subjects\***

There is no direct benefit to study subjects, however this study will help determine if racial and/or ethnic disparities exist in the timeliness of nephrology care and identify factors associated with potential disparities. If disparities are identified, this study will help inform the development of local, state, and national health strategies aimed at reducing disparities in the timeliness of nephrology care.

# **17.0 Data Management and Confidentiality\***

This research study will utilize de-identified encounter-level data from the Observational Health Data Sciences and Informatics (OHDSI), which automates data extraction from hospital EHRs. Patient information will be assigned a unique, random identifier for the study’s dataset after database linkage procedures are completed. For this study, the databases used will be stored on MHRI’s password protected secure server with only authorized users gaining access. Multiple safeguards are in place to protect the integrity of the MedStar network and include firewalls, secure remote access, intrusion detection, virus prevention and detection, spam filtering, website filtering, server and network monitoring and incident reporting. Through routine data security procedures at MHRI, usage of computers servers and network equipment is continually monitored and modified as needed.

We will maintain strict confidentiality and data storage procedures to protect against indirect identification of individuals and healthcare facilities. The purpose of using OHDSI data is to identify disparities in the timeliness of the first nephrology encounter in patients with newly diagnosed CKD and potential factors associated with disparities. The OHDSI dataset contains information related to patient demographics, diagnoses, encounter characteristics, with the study variables outlined in Table 1. Only the members of the research team will be given access. The study’s dataset will be supplemented with information from the publicly available American Community Survey (ACS), which provides neighborhood characteristics and will be used to link socioeconomic data based on patient’s residential address. After linkage of ACS data, residential address information will be removed from the study’s limited dataset.

We will ensure that all reports of the research findings provided outside of the research group are presented in the aggregate to protect against indirect identification of individuals or healthcare facilities. The PHI data elements included in Table 1, i.e. residential address and encounter dates, will be used to compose variables necessary for the study’s analysis and then deleted from the dataset prior to analyses. Additionally, the patient age variable will be categorized such that rare ages (>89) are grouped into a 90+ age category.

Protected health information (PHI) will be destroyed at the earliest opportunity, consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. The protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512.

# **18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects\***

*NA*

# **19.0 Provisions to Protect the Privacy Interests of Subjects**

*NA*

# **20.0 Compensation for Research-Related Injury**

*NA*

# **21.0 Economic Burden to Subjects**

*NA*

# **22.0 Consent Process and HIPAA Authorization**

This is a retrospective analysis of a large database of electronic health record data, and so the project does not involve the recruitment of participants.

This study meets criteria for a full waiver of authorization as follows:

1. **The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:**

This study involves no more than minimal risk to the subjects. The EHR data that will be used in this study exists prior to its inclusion for analysis, and subjects will not be exposed to a study intervention. Therefore, the risks of this study involve only a risk of a confidentiality breach. Strict data management and confidentiality procedures will be followed, as described in 17.0, to safeguard subjects.

1. **The research could not practicably be conducted without the waiver or alteration; and**

This study relies upon a large database of EHR encounter-level data to evaluate racial and/or ethnic disparities in the timeliness of the first outpatient encounter in patients with newly diagnosed CKD. The estimated dataset size is 200,000 MedStar ambulatory Stage 3 or Stage 4 CKD patients from January 1, 2017 to May 31, 2022 and so it would be impractical to obtain consent for each subject included in the study dataset. Additionally, the study dataset will not include any patient contact information, with PHI limited to FIN/MRN account numbers to support data linkage for database construction, patient residential address to support linkage of area deprivation index data from the publicly available American Community Survey, and encounter dates to compose the timeliness of nephrology care variables. All PHI data elements will be destroyed from the study dataset at the earliest opportunity after linkage procedures have been completed.

1. **The research could not practicably be conducted without access to and use of the protected health information.**

Patient-level residential addresses will be needed to link area deprivation index and other neighbourhood characteristics that represent socioeconomic factors that may be associated with observed disparities and are required elements for the statistical analysis. Additionally, FIN and MRN will be needed to link data elements on the encounter and patient level, respectively, across data sources to create the analytic dataset. Encounter dates will be needed to calculate the timeliness of nephrology care measure.

# **23.0 Process to Document Consent in Writing**

*NA*

# **24.0 Setting**

*MedStar Health Research Institute and MedStar Health Quality & Safety*

# **25.0 Resources Available**

*NA*

# **26.0 Multi-Site Research\***

*NA*

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